S. HRG. 110–400

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Before the Committee on Appropriations

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations

Fiscal Year 2008

110*th* CONGRESS, FIRST SESSION

H.R. 3043/S. 1710

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENT OF LABOR
NONDEPARTMENTAL WITNESSES

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations, 2008 (H.R. 3043/S. 1710)

S. HRG. 110–400

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

H.R. 3043/S. 1710

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2008, AND FOR OTHER PURPOSES

Department of Health and Human Services
Department of Labor
Nondepartmental witnesses

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

MONDAY, MARCH 19, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 1 p.m., in room SH–216, Hart Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF HON. ELIAS A. ZERHOUNI, M.D., DIRECTOR

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will come to order. I welcome you today to the hearing on the fiscal year 2008 budget for the National Institutes of Health.

Whenever I talk about NIH, it is always a pleasure to sit with my good friend Senator Specter, who will join us very shortly. Maybe I should wait till he gets here so he can hear all the good things I've got to say about him.

But I'll just say that no one has fought harder to improve biomedical research in this country. He and I worked in lockstep to double funding for NIH between fiscal years 1998 and 2003, covering two different administrations. I always say it's one of my proudest accomplishments in my entire career in the Senate. I know he shares my disappointment that the NIH has fallen on tougher budgetary times since then.

The fiscal year 2007 joint funding resolution that Congress passed a few weeks ago brought some good news. We increased NIH funding by $637 million, enough to launch the National Children's Study. We added another 500 research grants and provided additional funding for high-risk grants and young investigators.

Even with that increase, however, fiscal year 2007 marked the fourth year in a row that NIH funding failed to keep up with the cost of inflation. In fact, since the end of the doubling period in fiscal year 2003, NIH funding has dropped by about 8 percent in real terms. That cut threatens to squander our Nation's investment in

biomedical research, delay new cures and treatments, and discourage the next generation of young investigators from entering the field.

The President's fiscal year 2008 budget would make matters even worse. On paper, it would seem to cut NIH funding by $328 million. But the actual reduction is about $200 million more, so a total of about $529 million, because, under this budget, NIH would pick up the entire tab for the Global AIDS Fund, rather than sharing it with the State Department.

So, as a result of this, comparable funding for the National Cancer Institute would drop by $79 million, funding for the National Heart, Lung, and Blood institute, by $36 million, and the National Children's Study, which we just launched, would be stopped cold. I'm not ever in the habit of ever speaking for my good friend Senator Specter, but I think I can say we will not allow those cuts to take place.

This is the first of six budget hearings on NIH that this subcommittee will hold this spring. At today's hearing, we'll hear first from Dr. Elias Zerhouni, the Director of NIH. Our second panel today will consist of four leading scientists who have received NIH grants. They will discuss the impact of Federal funding on their areas of research, and why it's so important to increase our investment in NIH. All four of these scientists helped produce a new report on NIH, which I got last week, and it's entitled, "Within Our Grasp—or Slipping Away? Assuring a New Era of Scientific and Medical Progress." So, we're going to be discussing that in our second panel. This report will be released at a press conference immediately following this hearing.

Next Monday, we'll hold a hearing with the directors of five NIH institutes: NINDS, NIDA, NIAAA, NIMH, and NIDCD. Before the spring is over, the subcommittee will hear from the directors of each institute and center at NIH.

So, that's the agenda. Before I introduce Dr. Zerhouni, I'll yield to my good friend Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you very much, Mr. Chairman.

This is a very important hearing by this subcommittee to hear from the director of the National Institutes of Health, our premier health agency in the United States, and he's the number-one administrator. Health is our most important capital asset. Without health, there is nothing any of us can do. I can attest to that, personally, from the medical problems that I have worked through.

In 1970, President Nixon declared war on cancer, and, had that war been pursued with the intensity of our other wars, my chief of staff, a beautiful young woman, 48 years old, Carie Lachman, wouldn't have died of breast cancer. One of my best friends, a very distinguished Federal judge, Judge Edward Becker, wouldn't have died last year from prostate cancer. We all know, within our immediate circle of friends and family, of fatalities which have occurred because of the maladies of one sort or another. It is within reach to cure cancer, to find ways on a breakthrough on Parkinson's and Alzheimer's and heart disease and juvenile diabetes, and the other maladies, with sufficient funding.

Senator Harkin and I, who have transferred this gavel with seamless efficiency from time to time, have worked on this matter together for decades, and we've taken the lead to increase in funding, sometimes on an annual basis in excess of $3 billion, to do the job. Well, it is simply unacceptable to have a $500+ million cut in NIH funding, as proposed by the administration this year. When you have a Federal budget of $2.9 trillion, an enormous sum of money, this large hearing room insufficient to stuff $10,000 bills into it to make, to make that kind of funding, to have an allocation of less than $30 billion, candidly, is scandalous. In an era when we are beset in the Congress all the time on how to reduce healthcare costs from the smallest of businesses to individual families to the biggest corporations, and the best way to reduce healthcare costs is to eliminate these major maladies, to prevent illness. We are blind, really, to this very, very, important objective.

Earlier today I called Dr. Zerhouni and asked that he focus on the issue of cost savings. That seems to be an item which has special appeal on Capitol Hill. Elimination of disease, and the suffering that goes with it, ought to be our primary concern, but somehow if it saves dollars, it attracts more attention.

We also have the issue of stem cell research which we've been fighting. We found out about stem cells, and their potential, in November 1998, and, within 10 days, this subcommittee held a hearing, and we've since had 20 hearings. Stem cells have the potential to be a veritable fountain of youth. We, regrettably, cannot use Federal funding on stem cell research, except for a few lines, which were available back on August 9, 2001. But if these embryotic stem cells were to be used to create life, no one would want to use them for research, but there are 400,000 available, and they're going to be discarded unless they're used to save lives.

Here again, Senator Harkin and I took the lead to appropriate $2 million for adoption, and a few have been adopted, but a very few, in the range of 100, contrasted with 400,000, which will be thrown away. So, our work is cut out for us.

You have two strong allies in Senator Harkin and myself, Dr. Zerhouni, and you have the potential to have 533 more if there's sufficient political pressure brought to bear on Washington, DC. I've talked about a million-person march on the Mall. A million people could be heard in the living quarters of the White House. Attitudes are changed in Washington, with political pressure. With 110 million people affected, directly or indirectly by disease, that group of public opinion could write its own ticket. Senator Harkin and I want to be the scriveners.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Specter.

Dr. Elias Zerhouni has served as Director of the National Institutes of Health since May 2002. Prior to that, Dr. Zerhouni was the executive vice dean of Johns Hopkins University School of Medicine, chair of the Department of Radiology and Radiological Science, and Martin Donner professor of radiology and professor of biomedical engineering. Dr. Zerhouni received his medical degree from the University of Algiers School of Medicine, completed his residency in diagnostic radiology at Johns Hopkins.

I might just add that since May 2002, every report that we've gotten, every indication, all the people that we've talked to, both in NIH and out in the countryside, have basically reported that Dr. Zerhouni has done an outstanding job of leading NIH since he's been there.

With that we welcome you back to the committee, Dr. Zerhouni. Your statement will be made a part of the record in its entirety. They had set it for 5 minutes; I said boost it up to 10, and, if you need more than that, we'll give you more than that.

So, please proceed as you so desire.

SUMMARY STATEMENT OF HON. ELIAS A. ZERHOUNI

Dr. ZERHOUNI. Thank you very much.

It's my pleasure to appear before you, Mr. Chairman and Senator Specter. There couldn't be more passionate supporters of science and research than both of you. As I've worked with you over the past 5 years, I have to be, also, a witness to not only your passionate support, but also your profound understanding of what makes science, and what makes medical research, work, and why it is so important to the Nation.

I also would like to thank you and the committee for your personal support for the increased funding for NIH in 2007 and the focus that you have brought towards supporting the next generation of scientists, and making sure that we do not become stale in our research, that our momentum is kept, in terms of new breakthroughs.

What I'd like to do is attract your attention to the slide and give you a very short summary of the essence of where we think NIH as a whole is going and why we're directing our efforts into what we would call a new era in medicine.

VISION FOR THE FUTURE

We need to have a vision for the future as a country. I think it is absolutely clear that the 21st century will be for the life sciences what the 20th century has been for the physical sciences. Mastery of the biological world will impact not just health, but also our ability to develop sensitive solutions to our environmental and energy challenges, and will be, in my opinion, a key determinant of national competitiveness for the 100 years in front of us. It is important to sustain our momentum in that regard.

I'd like to, first, point out to you that NIH has been, and continues to be, a very, very productive investment for the American people. We are living longer and healthier. Let me give you some specifics.

For the second consecutive year, annual cancer deaths in the United States have fallen. This is an unprecedented event. This has not occurred in any other country. It has not occurred for the time that we've had records. The absolute number of deaths decreasing is happening at the same time that our population is increasing in number and aging, at the same time.

What has been the investment that each one of us has made in that regard, in the war on cancer? On average, each American has spent about $9 per year, from 1974 to 2004, to accomplish these re-

sults, which are still insufficient. The complexity of cancer is such that we need to accelerate our research, not slow it down.

If you look at heart disease, there's been a remarkable drop in mortality from heart disease and stroke. In 2004, for example, a drop in death for women with heart disease has dropped from 1 in 3 to 1 in 4. More importantly, as Senator Specter was pointing out, the economic value of this drop in mortality and morbidity is estimated at $1.5 trillion to $2.5 trillion per year. This is the kind of result that I think we can foresee for the future. What has been the investment? About per year per American for each year over the past 30 years.

More importantly, I think it is clear that disability is decreasing among older Americans. It has dropped by 30 percent in the past two decades. Life expectancy has risen to 78 years, up 6 years since 1974. What has been the average total investment per American per year at NIH? Only $44 per year for medical research.

I think we can say that NIH has been a good investment, and continues to see itself as the vanguard for changing—changing, not just how we cure disease once the disease has struck us, but how we really advance our research to make a profound difference in what I think is our concern today, and that is the challenge of rising U.S. health expenditures. Biomedical research must deliver, and NIH is poised to deliver.

If you look at the percent of GDP consumed by healthcare costs, and its upward curve, it is clear that this will be one of the greatest challenges facing our society, because this growth rate of healthcare expenditures is not sustainable in the long run.

Historically, medicine has been reactive, and patients did not seek attention until an acute event required them to seek a doctor's cure. But our system of care has been based on managing these late events on an episodic basis. Is there a better vision? Is there a way science can help the country tackle this problem? I think there is. When you look at the projection of doubling of our costs in 10 years, to $4.1 trillion a year, I think one cannot but feel that there is a real race against time to discover new ways of practicing medicine.

Let me be clear. If we practice medicine in 25 years the way we practice it today, we will have lost the game of the century. It is very important that we understand that. Is there a paradigm in the future that will change that? The answer is yes. We need to advance the science that will allow us to pre-empt disease.

PARADIGM FOR THE FUTURE

I think if you look at this chart, you can divide any disease into three stages. One is what we call the preclinical stage, the bottom yellow band, where people do not know that they have a disease. We may not know that someone has a disease, because chronic diseases, which are the dominant factor in our healthcare cost, can begin 20–25 years before they become clinically obvious. Then symptoms start to appear, and we can intervene at that time. This is what we call the tolerable or compensated phase of a disease. Last, but not least, is the uncompensated phase, where, typically, curative treatment tends to occur.

What we've done over the past 30 years is try to move back in time to try to address diseases before the critical phase. But, in the future, what we see with the advances we've made in the past 10 years is, that for the first time—the complexity of biology and the advances we've made in science tell us that we could start to understand disease years before it strikes by understanding the first molecular events that lead to disease and intervening at that time. The potential cost savings are enormous, because, as the white curve shows, costs increase exponentially with the typically late interventions that we today practice. It is much more expensive to take care of heart disease in the late stages than to try to prevent it with an intervention very early in the life cycle of the disease.

That is, in my view, the vision of the future. This is how NIH research can potentially provide new insights, which we do not have today. But it is clear that the opportunities are there. Our scientists are doing an enormous amount of work in discovering, every day, new targets to understand the complex diseases that harm our people. We need to maintain the momentum of that research.

Let me just show you an example here of a disease called rheumatoid arthritis. This is a patient's hands at early stage, middle stage, and late stage. How are we going to improve costs? How are we going to make a change in the natural history of this disease? Obviously, in the late stage, not much can be recovered, and managing that late stage is quite expensive. We've made progress over the past 10 years. There's a new class of antirheumatic drugs that dramatically slows disease progression by focusing on a factor called tumor necrosis factor and reducing the impact of that factor. But that is not enough. We really need to go earlier in the disease process. That's why, in 2006, for example, genetic discoveries have revealed new genes, which we didn't know about 3 years ago, before the—at the end of the doubling of the NIH budget. The completion of the human genome in 2003 has allowed us to accelerate this kind of discovery. But every time we find a gene, that means more research has to be done on that gene, because the gene is only the code of what may be wrong in that disease. Much more research lies ahead of the discovery of a gene. Therefore, it is important for us to see that this research continues so that, in the future, we will pre-empt by intervening on the very fundamental factors that lead to that disease, and hopefully eliminate the costs of that disease.

4 P'S—PREDICTIVE, PRE-EMPTIVE, PREVENTIVE, AND PARTICIPATORY

So, the future paradigm, if you will, if I can summarize it, is what we call the 4 P's.

One, using the new technologies we've developed, the new insights we've developed over the past 10 years, there is potential for us to be much more predictive about to whom, how, when a disease will occur. By using gene-chip technology, we can, today, do that in several diseases.

Second, treatments are going to have to be personalized. Every one of us is different, and we react differently to different therapies. That's the second P.

Third, we have—through that knowledge, we have to become preemptive. But this will also require a revolution in the way we conceive of healthcare. Instead of a disease-based healthcare system, or healthcare system driven by disease, we should focus on a healthcare system drive by health, where patients are not sick, patients are healthy when they come in contact with us. That will mean people will have to participate a lot more in their care than ever before. That means transformation of the healthcare system, driven by new science. This is what I call the Era of Precision Medicine. This is what we're working for. This is what NIH's vision has been, and continues to be. More importantly, we feel that we are at the edge of being able to do that.

PREPARED STATEMENT

NIH and its scientists deeply believe that we are in the transformative phase of the biomedical and behavioral sciences, where opportunities for discoveries and their translations—translation have never been greater. We believe that we're on the path to do that. We want to encourage not only the current generation of scientists, but the future generation of scientists, to come unhampered, and to be supported, because this is the race of the century. In the 21st century, no nation will prevail unless it prevails in the life sciences.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. ELIAS A. ZERHOUNI

Good afternoon, Mr. Chairman and distinguished members of the subcommittee. It is an honor and a privilege to appear before you today to present the National Institutes of Health (NIH) budget request of $28.9 billion for fiscal year 2008, and to discuss the priorities of NIH for this year and beyond.

I would first like to thank the Committee for your longstanding support of NIH, including in the fiscal year 2007 Joint Resolution that provided additional support.

INTRODUCTION

The 21st century will be for the life sciences what the 20th century has been for the physical sciences. Mastery of the biological world will impact not just health, but also our ability to develop sensitive solutions to environmental and energy challenges and will be a key determinant of national competitiveness. One of the greatest challenges facing our society is the unsustainable growth rate of healthcare expenditures. NIH and its scientists deeply believe that we are in a transformative phase of the biomedical and behavioral sciences, where opportunities for discoveries and their translation have expanded considerably. We believe that we are on a path to transform medicine from the current practice of intervening often too late in a disease process, to a new era when medicine will be more predictive, personalized and preemptive, through a broader scientific understanding of the fundamental mechanisms that lead to disease years before it strikes the patient. In a relatively constant budget, we made the tough but necessary choices to ensure that the investment and momentum of biomedical research continues.

A more predictive, personalized and preemptive form of medicine is no longer just a dream but a vision to strive for, because it can reduce disease burden and its costs while improving individual quality of life.

Last year, I discussed the return on the Nation's investment in biomedical research. Today, I will highlight some of the progress we've made in the last 12 months and where we must be in the future to create a sustainable environment for the discoveries needed to transform people's health.

THE IMPACT OF PAST NIH RESEARCH

NIH-supported research of the past several decades has contributed to dramatically improved health outcomes across many diseases and conditions. For instance,

we have made remarkable advances in coronary heart disease, the leading cause of death in the United States for the past 80 years. Were it not for ground-breaking research on the causes and treatment of heart disease, supported in large part by NIH, heart attacks would still account for an estimated 1.6 million deaths per year instead of the actual 452,000 deaths experienced in 2004. Our Nation has had particular success in reducing fatal heart disease in women. In February of this year, NIH's National Heart, Lung and Blood Institute announced that the number of women who died from heart disease decreased by nearly 18,500 deaths from 2003 to 2004. Part of this success is attributed to NIH's efforts to increase awareness among women that heart disease is their number one killer.

The mortality rates of cancer, the second-leading cause of death in the United States, have been steadily falling. This year, for the second year in a row, the absolute number of cancer deaths in the United States has declined despite the growth and aging of our population—a truly unprecedented event in medical history. More effective therapies have also led to improved outcomes for more than 10 million American cancer survivors. In 2006, new clinical guidelines were announced for the treatment of advanced ovarian cancer. And for another of our most deadly cancers, melanoma, a new gene therapy approach resulted in sustained regression of advanced disease in a study of 17 patients, whose own white blood cells were genetically engineered to recognize and attack cancer cells.

Nearly 21 million Americans have diabetes, a disease that can damage multiple organs and lead to death. Without NIH research, the improvements of the past two decades in the therapies for diabetes would not have occurred, and we would have many more cases of the dreaded complications of diabetes, including blindness and end-stage kidney disease. Our research has shown the enormous benefits to be gained by tightly controlling blood glucose levels in diabetes. The NIH-funded Diabetes Control and Complications Trial confirmed that individuals with diabetes can cut their risk for nerve disease by 60 percent, and half their risk for kidney disease and cardiovascular disease by intensively controlling their blood glucose levels. Our diabetes research has also shown that tight glucose control can slash the risk for eye disease by more than 75 percent—a critical finding for the estimated 24,000 Americans who lose their sight to diabetes each year. In fact, diabetic retinopathy is the leading cause of blindness in adults under age 65.

The treatment of cognitive decline and mental disorders continues to improve at an incredibly rapid pace. In 2006, NIH supported the development of new strategies that helped depressed patients become symptom-free and prevented disease recurrence in older adults with single-episode depression.

Other noteworthy advances from 2006 included the development of promising new drugs for tuberculosis, inflammatory disease and muscular dystrophy, as well as exciting experimental results of vaccines against increasingly dangerous staph infections and against the H5N1 avian flu virus. Last year we also launched a trial for a new and promising vaccine against HIV/AIDS, and just last month, our scientists' discovered a unique molecular weak spot in the armor of the HIV virus, which could have profound implications for vaccine development.

In brief, thanks to the Nation's investment in biomedical research, we have learned to diminish the harmful impact of many diseases and disabilities for all Americans. The estimated total cumulative investment at the NIH per American over the past 30 years—including the doubling period—is about $1,334, or about $44 per American per year over the entire period. Over the same time period, Americans have gained over 6 years of life expectancy and are aging healthier than ever before. New industries such as biotechnology, based on NIH-funded discoveries, have led to the creation of thousands of companies in the life sciences with impact beyond health. The American people's return on their investment in NIH is truly spectacular.

CURRENT CHALLENGES

In short, the many scientific advances achieved by NIH-funded researchers—over many decades—now allow our population to live longer and healthier lives. But as our population continues to age, a striking change becomes evident. The burden of our Nation's health problems has dramatically shifted from acute to chronic diseases. Chronic diseases now consume over 75 percent of healthcare costs and continue to grow at a rapid pace. Profound lifestyle changes have led to the emergence of non-communicable diseases such as obesity and attendant growth in the prevalence of associated conditions, such as diabetes and heart, kidney and musculoskeletal diseases. It is important to note that the burden of these chronic diseases is not uniformly distributed among our population; health disparities remain a critical health issue that requires new and continuing efforts.

Let me now present a sobering reality. Despite medical progress, healthcare costs in the United States have risen to more than $2 trillion, or about 16 percent of the Gross Domestic Product (GDP), and they grow at a rate greater than the GDP. The average amount spent on healthcare per person is about $7,100 today. The causes of healthcare inflation are varied and complex, but it is clear that this growth rate is unsustainable in the long term and will impose an enormous burden on our people and the competitiveness of our Nation. Biomedical research alone will not solve all of these problems, but it is an essential component toward a sustainable future. NIH and its scientists understand the need to reduce the impact of this great challenge through transformative discoveries and their rapid translation from laboratory to patients.

While seeking medical discoveries that will address ongoing concerns, we must also be prepared to confront new and unpredictable threats. Emerging and re-emerging infectious diseases are on the rise, as micro-organisms develop strategies for evading our best drugs. We face the rapid globalization of mass transportation and the staggering worldwide threat of HIV/AIDS and other familiar foes. We must stand ready for the threat of pandemic influenza and of man-made bioweapons for which we have greatly expanded our investments in the past several years. Addressing these many new threats will require sustained scientific efforts and further breakthroughs.

STRATEGIC VISION FOR THE FUTURE: FROM CURATIVE TO PREEMPTIVE MEDICINE

Historically, medicine has been reactive, and patients did not seek attention until an acute event required them to seek a doctor's cure. Our system of care is based on managing these late events on an episodic basis—an increasingly costly and unsustainable approach. What then is the scientific vision for change? Our goal at NIH is to usher in an era where medicine will be predictive, personalized and preemptive. This trend will also require a transformation in the fundamental relationship between healthcare providers and patients, necessitating continuous participation of individuals, communities and healthcare institutions as early as possible in the natural cycle of a disease process.

Based on NIH-supported research, we now know that many of the most prevalent diseases of our time begin silently, many years before they inflict their obvious damage to patients. Increasingly, we are able to identify biomarkers that are predictive of the likelihood of developing a serious condition later in life. Just in the past year, we have discovered genetic variations that help predict the development of age-related macular degeneration, a major cause of late-life blindness. We also discovered a new gene associated with Alzheimer's disease, a major control gene for diabetes and a marker of genetic susceptibility to prostate cancer. The genetic marker for prostate cancer risk came from the NIH-supported Cancer Genetic Markers of Susceptibility (CGEMS) study. Through the CGEMS database, genetic information about prostate cancer risk will be shared with cancer researchers across the country. The mining and sharing of genetic information will provide much-needed information to help us develop new strategies for the early detection and prevention of prostate cancers, which take the lives of nearly 27,000 American men each year and disproportionately affect African Americans.

Just consider, for a moment, how more predictive and personalized treatments could improve the safety and effectiveness of drugs. We know that drugs do not fall into the "one size fits all" category. The same drug can help one patient and harm another. Recent research shows that we will be increasingly able to know which patients will benefit from treatment and which patients might be harmed. This field of study is known as pharmacogenetics. Using the latest genomic data—acquired thanks to the doubling of the NIH budget—the NIH established a Pharmacogenetic Research Network, which is studying the interactions of drugs and molecules, as well as the biological processes that eliminate compounds from the body.

As an example of emerging personalized medicine, cancer researchers have developed a test that helps to determine the risk of recurrence for women who were treated for early-stage, estrogen-dependent breast cancer. This information can help a woman and her doctor decide whether she should receive chemotherapy, in addition to standard hormonal therapy. The test has the potential to change medical practice by identifying tens of thousands of women each year who are unlikely to benefit from chemotherapy, sparing them from unnecessary and costly treatments and their harmful side effects. Such a test is now being readied for FDA review and is being evaluated in a long-term clinical trial sponsored by the NIH's National Cancer Institute.

Ultimately, this individualized approach—completely different than how we treat patients today—will allow us to preempt disease before it occurs. We have already

benefited greatly from these insights. For example, we know that controlling blood pressure, cholesterol levels, weight and diet, and eliminating smoking, greatly reduce the risk of heart disease and lung cancer. Mortality from colon cancer has dropped because our scientists have shown that such cancers evolve from accumulated genetic mutations in initially benign colon polyps which, if removed, preempt the development of lethal cancers.

Because of a hundredfold reduction in the unit cost of genomic technology, we can now study, at affordable costs, the differences between patients who have a disease and their normal counterparts. These breakthroughs form the basis of our budget request for the continuation of the Genes, Environment and Health Initiative started in 2007 and strongly supported by Secretary of Health and Human Services Michael Leavitt, who is also championing the concept of personalized medicine across all of HHS. With this new initiative, we expect to uncover—within three years—the potential molecular causes of the 10 most common diseases afflicting the U.S. population. As part of this initiative, we will also launch a technology development effort that will enable scientists to measure many types of environmental exposures at the individual level.

Taken together, these studies will lead to better understanding of the environmental and genetic factors that affect the development of many diseases. Imagine that your heart rhythm, brain activity, blood pressure and many other variables could be remotely monitored through a device like your cell phone and sent to a secure web-based analyzer with direct access to experts and a modern health information system. Suppose, for example, that these technologies could identify dangerous patterns in your heart rhythms or key biomarkers and warn you of an impending heart event or stroke or other complications. Imagine your doctor could tell—based on your genes—whether you need to take preemptive action to thwart a costly or painful disease, or whether you can avoid taking expensive medications for life because you are not at risk. This is not some science fiction. NIH is supporting the development of that future today.

MAINTAINING MOMENTUM TOWARD 21ST CENTURY MEDICINE AND HEALTH

Building toward the future involves innovations in multiple areas, including technology, research and training paradigms, information interoperability, and greater knowledge and resource management. We have seen an explosion of new discoveries and novel opportunities for progress across all areas of science—from the most basic discoveries to the sequencing of the human genome, to the development of fields that simply did not exist a few years ago. These emerging fields include proteomics, computational biology, or more recently the discovery of RNA interference, for which two NIH-funded scientists—Drs. Craig Mello and Andrew Fire—received the 2006 Nobel Prize in Physiology or Medicine.

The greatly expanded scope of research and new health challenges have necessitated a dramatic expansion of the Nation's research capacity, which was a primary outcome of the doubling of the NIH budget. This remarkable growth in research capacity was accomplished by leveraging NIH resources with private sector resources to nurture more investigators, develop new technologies and build infrastructure.

The United States is now the preeminent force in biomedical research, and continues to lead the highly competitive biotech and pharmaceutical sectors, but it is also the focus of increasing challenges from government-supported research in Europe and Asia. NIH basic research and training programs produce steady streams of novel discoveries and innovative people that flow into our industries, making them more competitive. Multi-national corporations often choose to set up facilities here, to tap into the American pool of talent and research nexus, both largely developed through NIH funding.

NIH-funded research leads to patents and spin-off companies across the Nation. Through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, NIH helps to support entrepreneurs, as they bring to the international market products that improve health and help to maintain American economic leadership. Thus, NIH research and training dollars leverage state and private investment, resulting in powerful academic research centers and entire geographic regions for greater creativity and productivity.

The American health research enterprise now has the capacity to achieve extraordinary medical advances and economic benefits for the Nation, and we must continue this momentum. We must sustain the capacity we have worked so hard to build and harness its potential.

The talented scientists and institutions we have nurtured are stepping up to the challenge. For example, NIH now receives twice as many applications for grants than before the doubling of its budget. Due to the marked competition for funds

across so many novel areas of research and health challenges, competition for grants and the quality of projects submitted to NIH is better than ever. We anticipate that the fiscal year 2008 budget will again support about one-fifth of applications submitted, as opposed to one-third in fiscal year 2003. We focused our budget request on maximizing the number of competing grants for new and established scientists. To encourage innovation and sustain the next generation of scientists to the greatest extent possible, we have also developed programs for new investigators and for pioneering high-risk/high-impact investigator-initiated research, the mainstay of fundamental discoveries.

To achieve our vision of modern medicine, we also need research scientists with broad expertise, from widely varied disciplines, coming together in highly cooperative and efficient teams to answer ever-more complex questions. To this end, NIH recently changed a long-held policy of having only a single principal investigator on any NIH grant to a new policy that allows, when appropriate to the science, multiple principal researchers to apply for a grant together. This new policy is encouraging collaboration across disciplines and enabling academic scientists to exercise creative leadership in a project while bringing more of the best and brightest from physical, biological and behavioral sciences to the task of solving the multifaceted and complex health-related problems.

As biomedical research becomes more comprehensive, and we recognize that complex diseases come under the purview of more than one or a few NIH Institutes and Centers, we have been stimulating collaborative endeavors through multiple trans-NIH activities, such as the NIH Roadmap for Biomedical Research. These trans-NIH activities focus on providing the impetus and support for high-risk/high-impact research through Pioneer Grants; developing tools and new scientific teams for furthering our understanding of the complexity of biological systems; and stimulating a large effort to re-engineer the Nation's clinical and translational research enterprise to support more effective interactions between laboratory research and its clinical translation.

In 2006, we launched the Clinical and Translational Science Awards (CTSA) Program, which is the first in-depth redesign of our system of applied research in 50 years. The CTSA Program is stimulating research institutions to foster more productive collaboration among investigators in different fields. The program also encourages creative organizational models and programs for training the next generation of clinician scientists, without whom much basic research cannot be applied to human populations. Ultimately, patients will be better served because new prevention strategies and treatments will be developed, tested and brought into medical practice more rapidly.

In addition, the NIH Intramural Research Program is launching several initiatives to make even more effective use of the highly talented scientists and state-of-the-art resources in our federal laboratories.

We have made every effort to generate greater synergies between NIH Institutes and Centers. For example, the NIH Strategic Plan for Obesity Research was launched in 2003 and involves 19 Institutes. The Neuroscience Blueprint brings together 15 NIH Institutes and Centers and the Office of the Director, pooling resources and expertise to confront challenges in neuroscience research that transcend any single Institute or Center.

NIH is also taking advantage of emerging information technologies and is making management changes in response to public health needs. We are working to modernize our governance and improve efficiency. For example, the Office of Portfolio Analysis and Strategic Initiatives (OPASI) is developing a new knowledge management-based system, which performs text mining on NIH projects for more efficient research portfolio analysis. This tool will provide our Institutes and Centers with the information needed to more effectively manage their large and complex scientific portfolios, identify important emerging scientific opportunities and public health challenges, and target investments to those areas. OPASI will be invaluable for supporting key trans-NIH initiatives being incubated through the NIH Common Fund, which is a central feature of the NIH Reform Act of 2006.

We would like to take this opportunity to thank Congress for passing this landmark legislation, which will enable NIH to modernize its organization; incubate innovative ideas and potentially ground-breaking research; address emerging areas of scientific opportunities; stimulate support of cross-cutting science; and encourage collaborative efforts while preserving the ability of Institutes and Centers to continue their outstanding record in fulfilling their specific missions. We are diligently working to implement this legislation.

BUDGET PRIORITIES: NURTURING A NEW GENERATION OF SCIENTISTS AND SUSTAINING INNOVATION

New visions require new talent. One of NIH's highest priorities will be to preserve the ability of new and junior scientists with fresh ideas to enter the competitive world of NIH funding. We plan to use the additional funding provided to NIH in the fiscal year 2007 Joint Resolution on these valuable initiatives. In fiscal year 2007 and 2008, we will make every effort to maintain an average yearly number of approximately 1,500 new investigators receiving their first NIH R01-equivalent grants to create the vital next generation of scientific leaders.

Also in fiscal year 2008, the NIH budget proposes to continue to grow fresh talent through the new "Pathway to Independence" program and to support 175 recently trained scientists in their quest to become independent researchers at an earlier point in their careers. These efforts, however, cannot come at the expense of the need to provide continuing support to our most productive and already established scientists. History shows that no one can predict from whom and from where the next great discovery or life-saving breakthrough will occur. It is therefore critical that NIH maintain a large variety of approaches to science and continue to work hard to encourage diversity among its scientists across all strata of our society.

We also strive to maintain the historical balance between the critically important investigator-initiated research portfolio and agency-driven priorities. Our successful model of research is based on creative and unconstrained scientists who propose their best ideas, so we can subject those ideas to rigorous and independent peer review, and then support the most promising and high-quality projects. Our budget targets resources to providing as large a number of competing Research Project Grants for individual scientists as possible. To support our vision and initiatives in the current budget environment, we made difficult but strategic decisions, like maintaining the average cost for competing grants at the fiscal year 2007 level and not providing inflationary increases for direct reoccurring costs in non-competing grants. Our budget also proposes to reduce intramural research expenses.

Our basic science projected percentage in fiscal year 2008 is 54.1 percent, and applied science is projected at 42.1 percent. The percent of NIH's budget designated for infrastructure support will increase slightly in fiscal year 2008, to 3.2 percent. In total, the budget provides $144 million to enhance our infrastructure stewardship to provide robust, modern, energy-efficient, and environmentally safe and secure facilities to conduct basic and clinical research.

SUMMARY

In closing, let me emphasize—we are at a critical point in biomedical research and must maintain the momentum to reach our vision. The opportunities for significant advances exist on virtually every front. We must not let these opportunities slip away. We do not want to lose the scientific capacity that we have developed in the recent past across the entire country. The transformation of health and medicine from the curative paradigm of the past to the preemptive paradigm of the future is within our grasp. As an example, in the past year alone, we realized a huge victory against cervical cancer, a disease that affects hundreds of thousands of women worldwide—a victory that we only dreamed about 10 or 15 years ago. The discoveries of Drs. Doug Lowy and John Schiller of NIH's National Cancer Institute on the human papilloma virus and the hard work of our private-industry partners have led to the development of the first FDA-approved vaccine against cancer. This is the kind of preventive intervention that will help us transform medicine in this century. The development of this vaccine represents just a small example of the NIH contribution to biotechnology and its transfer to the bedside—in this case before the "bedside" is ever needed.

We are also working to preempt disease through evidence-based education that draws on the best behavioral and social science research. Let me give you just one of the many examples of how NIH translates research results into practical health interventions for the public. In 2005, NIH launched the WE CAN (Ways to Enhance Children's Activity & Nutrition) program. WE CAN is a behavioral intervention at the level of communities aimed at preventing childhood obesity. The overwhelming response from around the country has been gratifying. In less than two years, individuals and groups—ranging from schools and youth organizations to community and recreation centers—have joined with NIH and our partners in 36 states to energize WE CAN. This is what I mean when we talk about the necessary participation of communities and individuals in their own health in a future redesigned healthcare system.

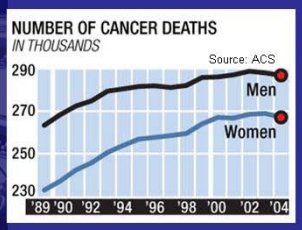
NIH also continues to expand its outreach and participatory efforts through its website, one of the most-visited in the word. The NIH website averages about 47 million visits each month, with more than 330 million page views.

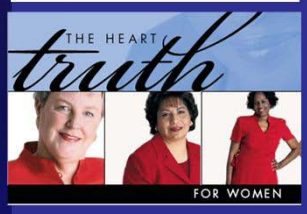
I ask you to consider the challenges and the opportunities before us today in medicine and health, and the essential role of biomedical research. We have the key elements in place for overcoming a host of diseases and conditions and their societal burden, and momentum is on our side. Our research efforts have ushered in revolutionary changes in the diagnosis, treatment and prevention of disease. Sustaining the pace of biomedical discovery is essential to realizing a true and necessary transformation of medicine and health in our country.

I will be happy to answer any questions you may have. Thank you.

Due to Advances of Past 30 Years

Americans are Living Longer and Healthier



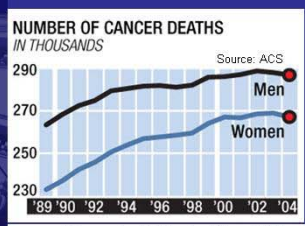


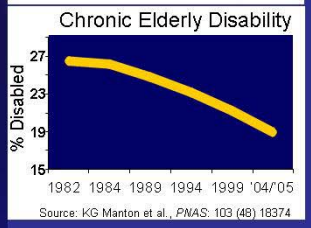
- For the second consecutive year, annual cancer deaths in the United States have fallen
- Over 60% drop in mortality for heart disease and stroke – in 2004, drop in deaths of women from Heart Disease from 1/3 to 1/4 reported

Heart disease investment per American
~$4/yr
1974-2004

Due to Advances of Past 30 Years

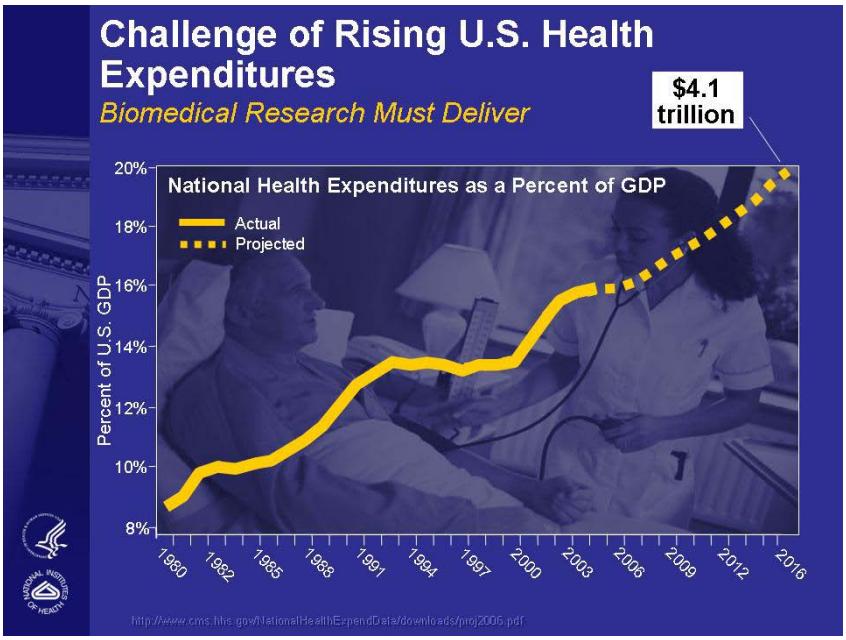
Americans are Living Longer and Healthier

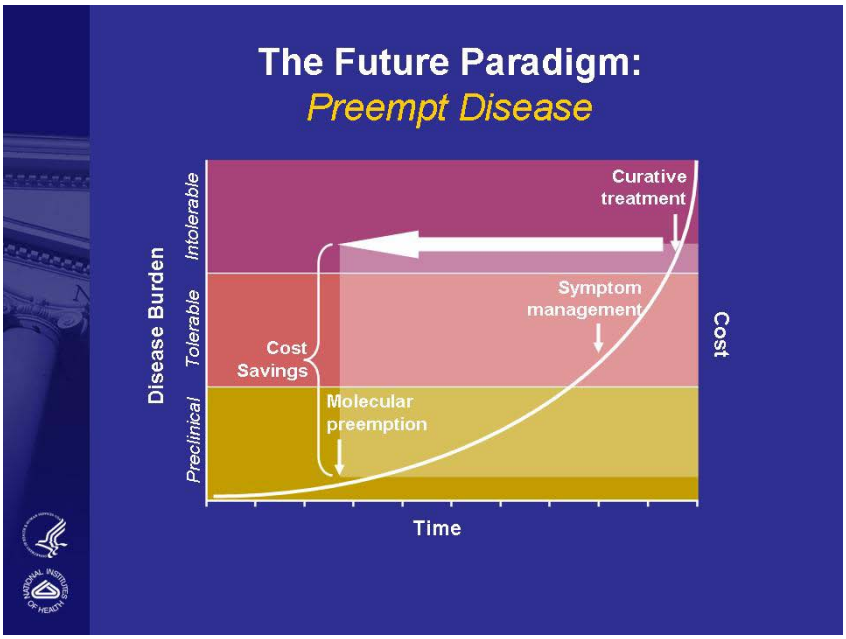


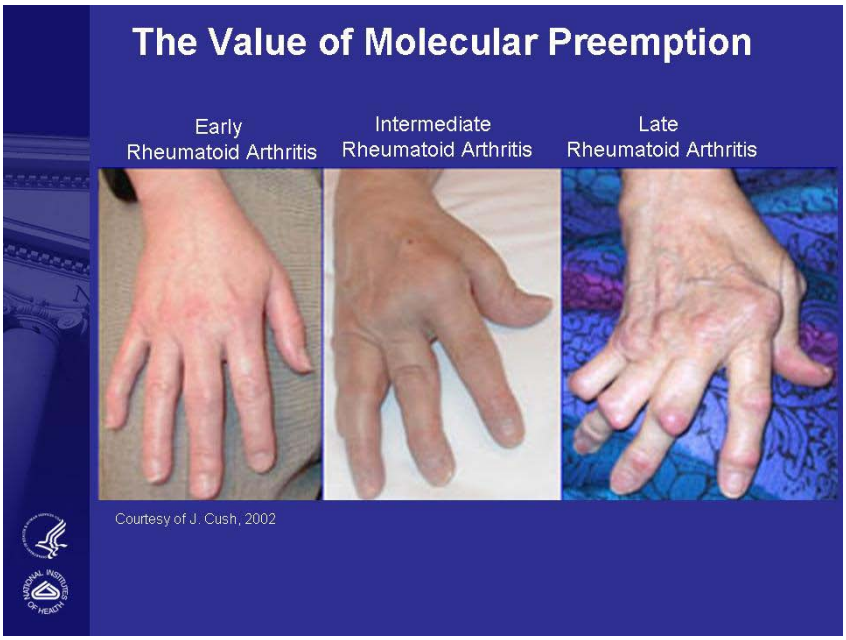


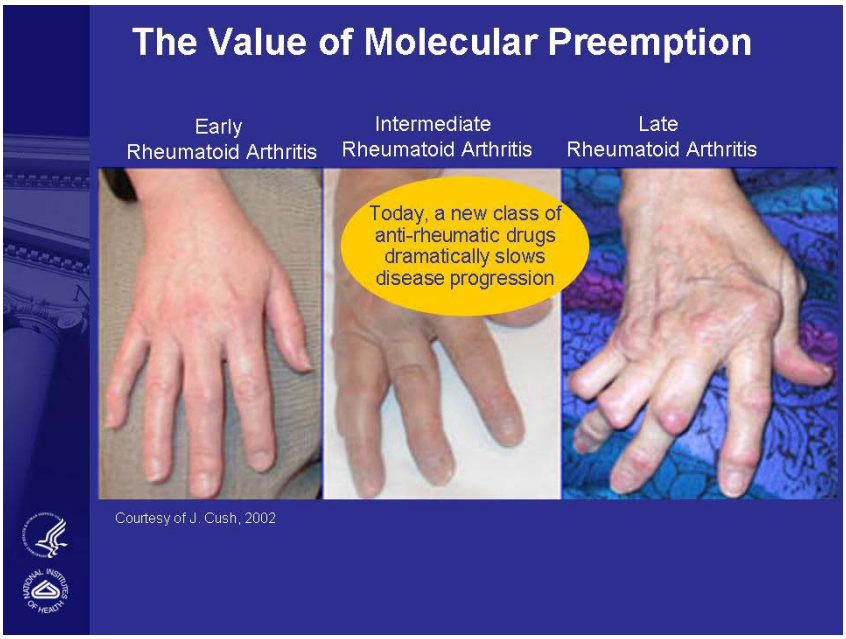
- For the second consecutive year, annual cancer deaths in the United States
- Over lity for heart ke – in 2004, drop in deaths of women from Heart Disease from 1/3 to 1/4 reported
- Chronic disability among older Americans has dropped by 30% in the past 2 decades, and the rate of decline is accelerating
- Life expectancy rises to 78 years, up 6 years since 1974

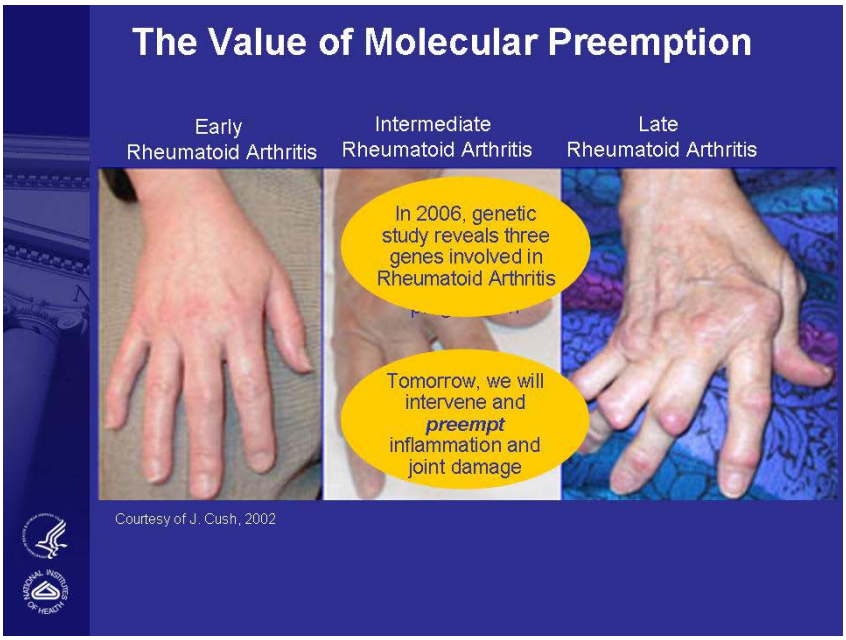
Total NIH Investment per American
~$44/yr
1974-2004

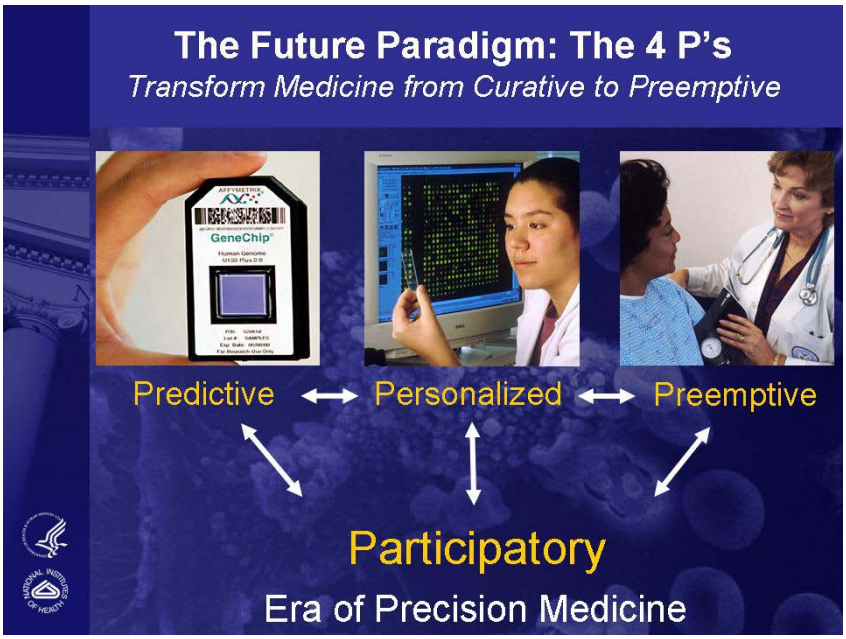

Challenge of Rising U.S. Health Expenditures
Biomedical Research Must Deliver
$4.1 trillion
National Health Expenditures as a Percent of GDP
Actual
Projected
Percent of U.S. GDP
20%
18%
16%
14%
12%
10%
8%
1980
1982
1985
1988
1991
1994
1997
2000
2003
2006
2009
2012
2016
http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf


The Future Paradigm:
Preempt Disease
Disease Burden
Intolerable
Tolerable
Preclinical
Curative treatment
Symptom management
Cost Savings
Molecular preemption
Cost
Time


The Value of Molecular Preemption
Early Rheumatoid Arthritis
Intermediate Rheumatoid Arthritis
Late Rheumatoid Arthritis
Courtesy of J. Cush, 2002


The Value of Molecular Preemption
Early Rheumatoid Arthritis
Intermediate Rheumatoid Arthritis
Late Rheumatoid Arthritis
Today, a new class of anti-rheumatic drugs dramatically slows disease progression
Courtesy of J. Cush, 2002


The Value of Molecular Preemption
Early Rheumatoid Arthritis
Intermediate Rheumatoid Arthritis
Late Rheumatoid Arthritis
In 2006, genetic study reveals three genes involved in Rheumatoid Arthritis
Tomorrow, we will intervene and preempt inflammation and joint damage
Courtesy of J. Cush, 2002


The Future Paradigm: The 4 P's
Transform Medicine from Curative to Preemptive
GeneChip
Predictive
Personalized
Preemptive
Participatory
Era of Precision Medicine

Senator HARKIN. Dr. Zerhouni, thank you very much for a very enlightening and succinct presentation.

I've been fond of saying a lot in the past that in America we don't have a healthcare system, we have a sickcare system. When you get sick, you get care. There's not much up front to help keep you from getting sick. A statistic I saw recently was that 75 percent of all medical cost in Medicare is due to the treatment of chronic illnesses which have reached their later stages. So, a lot of these are preventable, if you get to them early on. That's what you're showing here, to get to a true healthcare system, where you keep people healthy in the first place.

So, I really appreciate that presentation. I think that's a good note on which to begin our questioning.

STEM CELL RESEARCH

Dr. Zerhouni, I have a series of questions, and then I'll yield to Senator Specter. We may go back and forth here for a while. But the first thing I want to get into is something that Senator Specter brought up. Both of us worked together on this, very hard. Senator Specter had the chairmanship during all those years when we first isolated embryonic stem cells, in Wisconsin, at the University of Wisconsin. Senator Specter had the first hearings on that. As he said, we've had 20 since then. He and I have worked together harmoniously on this to try to push the frontiers of this and to get around the restrictions.

But when you were appointed to your position 5 years ago, a lot of people were anxious about what we were going to do about embryonic stem cell research and about the restrictions that were placed on August 9, 2001, at 9 p.m. At that time, you know, there

was a limit of how many stem cell lines could be financed through Federal funds for research. We were told, at that time, there were 78. But then, we've found out a lot since then.

Now, again, when you first came before this committee, you said you wanted to let science take its course. Well, over the last 5 years, science has taken its course. I thought that was profound on your part to do so, to say that, because what we've discovered is that those 78 lines are not 78, they're really about 21. At least that's the latest I've been told. Only a handful are used on a regular basis, limiting their genetic diversity. We know, also, that all of them have been contaminated, because they were grown on mouse feeder cells. So, the likelihood that they would ever be used for any human intervention is unlikely. We now know that there are much better ways of deriving and growing stem cells than what we knew in 2001. However, the lines derived from these new methods are not eligible for Federal funding.

So, given all that's happened in the last 5 years, I'd just like to revisit this issue with you. With everything you've told us about the vision for the future and getting in front of this, would scientists have a better chance of finding these new cures, new interventions for diseases, if the current restrictions on embryonic stem cell research were lifted?

Dr. ZERHOUNI. I think the answer is yes. My experience has been this. In 2001, I think the policy that was put in place was the first one to fund embryonic stem cell research. I think NIH has done a great job in the first 3 years of that in establishing infrastructure, funding new scientists, which weren't fundable before. Since 2004, I think it's very clear, from the point of view of science and what I have overseen, that these cell lines will not be sufficient to do all the research we need to do, for the reasons that you mentioned, but the most important one is that these cell lines have exhibited instability, from the genetic standpoint, and it's not possible for me to see how we can continue the momentum of science in stem cell research with the cell lines that we have currently at NIH that can be funded. So, from my standpoint, it is clear today that American science is—would be better served, and the Nation would be better served, if we let our scientists have access to more cell lines, because they can study with the different methods that have emerged since 2001, the different strategies that we now understand, underlie the fundamental issue, which is nuclear programming, or DNA programming, or reprogramming.

So, the answer is yes.

Senator HARKIN. Well, Dr. Zerhouni, let me ask you to comment on two things, then.

We're hearing a lot now in the popular press, not so much in the scientific journals, that we don't have to do this, that adult stem cells can take care of it all, then we have amniotic stem cells, and then we have umbilical cord stem cells, and that we don't need embryonic stem cells, that all these others will handle it, will take care of it.

Second, on the issue of stem cell research itself, why is it so important that NIH do this? Already, California is doing it. I think Missouri just passed a constitutional amendment on it. In Iowa, my own State, the legislature just voted, and the Governor signed a

law lifting the ban, in Iowa. Wisconsin, of course, New York. So, different States are doing different things. A lot of times when I talk about this, people say, "Well, if the States are doing it, there's no real reason for NIH to be involved in this." So, if you could address both—why is it important for NIH? What about adult stem cells and all these others being sufficient?

Dr. ZERHOUNI. Well, let me give you my point of view, and, I think, the scientific point of view here. Again, my statement that I—as I made 5 years ago, is that I will always stick to the scientific truth, and disease knows no politics. So, let me say this. The presentations about adult stem cells having as much, or more, potential than embryonic stem cells, in my view, do not hold scientific water, if you will. I think they are overstated. I think we do not know, at this point, where the breakthroughs will come from. I think scientists who work in adult stem cells, themselves, will tell you that we need to pursue, as vigorously, embryonic stem cells.

My point of view is that all angles in stem cell research should be pursued. I think people sometimes misunderstand what the fundamental challenge is in stem cell research. It's not solely to use it to replace things, like in adult stem cell transplantation, but it's to really understand, for the first time in the history of mankind, how DNA is programmed and reprogrammed. Well, to do that, you need to have copies of cells that have been programmed—adult stem cells—but also copies of cells that have never been programmed forward—embryonic stem cells. The key thing here is that the nation that understands that will be as—in the stronger position, as we were in the 20th century for the information revolution, for computers. It's basically the software of life that we're talking about. So, from my standpoint as NIH Director, it is in the best interests of our scientists and our science, our country, that we find ways, that the Nation finds a way, to allow the science to go full speed across adult and embryonic stem cells equally.

Senator HARKIN. Why is it so important for NIH?

Dr. ZERHOUNI. Right. So, why is it important? As the NIH Director, I can tell you that the role that NIH has played in this country over the years has been second to none. There is no State that can really provide the depth of oversight and stimulation of this research over the long run. This is not a 1-mile race; this may be a marathon. It is important, I think, for NIH to play its historical role. I think that we have done that. We can do this, with appropriate oversight, a lot of safeguards, to make sure that this research is not misused.

NIH'S LEADERSHIP IN STEM CELL RESEARCH

Senator HARKIN. Ethical guidelines.

Dr. ZERHOUNI. Ethical guidelines. You know, Senator, we've done this. We've done this with the Recombinant DNA Advisory Committee in 1976, 1977, 1978. At that time, as you know, genetic engineering came on the scene. There was a huge question about both the safety and the ethics of using genetic engineering. Well, NIH took the lead, and set up a Committee called the Recombinant DNA Advisory Committee. We've been probably the most successful country in biotechnology. We've created a completely new industry. I think that this is the kind of role NIH can play. If you have a

patchwork of policies, a patchwork of different approaches, you may not have the same standards. It will be very difficult for our country to muster its strength unless we have some sort of moving—of move forward in this area. We cannot, I think, be second-best in this area. I think it is important for us not to fight with one hand tied behind our back here.

Senator HARKIN. I also——

Dr. ZERHOUNI. NIH is key to that.

Senator HARKIN. I also see what's happening out there now in California, where they're in a bidding warfare to get scientists to come there. Missouri's now going to do some bidding. Wisconsin. I suppose Iowa will probably get in the game now that we've lifted the law. So, it just seems that—to me, anyway—by providing NIH with this authority, which—you have the experience, the oversight, you are the world's leader. Everyone recognizes NIH as being the gold standard of unbiased research—that if you put NIH's blanket over the thing, I think it would reduce, a lot, this kind of bidding warfare between States, and then we'd have a national kind of an approach on this. Plus, NIH could reach out to other countries and coordinate other countries in doing this research, also. Is that, sort of, the kind of process would take place?

Dr. ZERHOUNI. My view is that I think it's time to move forward on—in this area. It's time for the Nation's policymakers to find common ground to make sure that NIH does not lose its historical leadership. I think we've maintained that leadership all the way to 2004–2005. But, as we've discovered, the lines that we have are less viable than we would have liked them to be—as these lines are older, I think it's important to realize that we need to move forward here, and NIH needs to continue its historical role as the leader of biomedical research in the world. To sideline NIH on an issue of such importance, in my view, is shortsighted. I think it wouldn't serve the Nation well in the long run. We'd need to find a way to move forward. I look at—obviously——

Senator HARKIN. Yeah.

Dr. ZERHOUNI [continuing]. It's more than science that is involved here, but I hope that we can find that way forward soon.

Senator HARKIN. Well, Dr. Zerhouni, let me thank you for a very profound and courageous statement that you've made here today.

Dr. ZERHOUNI. Thank you.

Senator HARKIN. Thank you.

DECLINE IN CANCER DEATH RATE

Senator Specter.

Senator SPECTER. Dr. Zerhouni, as you have testified, the deaths due to cancer have declined in the last 2 years. To what extent would you attribute that to research done by NIH?

Dr. ZERHOUNI. It's difficult to figure out exactly what is contributing to what, but I can be somewhat specific. Most scientists look at this decrease and feel that the main cause has been the decrease in smoking, that behavioral changes—social and behavioral sciences have contributed to epidemiology and prevention a great amount. The second cause has been early screening. If you look, for example, at colon cancer, the rates of colon cancer, and the death rates, have come down. Why? Because we have promoted the early

detection of polyps. Now, how does NIH play into that? Well, it turns out that the discovery that told us that polyps are really the pre-emptable, the preventable cause of the cancer, was that the genetic changes that lead to cancer start with a polyp. So, it's a——

Senator SPECTER. So, it is the NIH research which has identified a way for early screening to treat cancer at an early stage.

Dr. ZERHOUNI. But the basic research——

Senator SPECTER. Is that correct?

Dr. ZERHOUNI. That is correct, Senator. The most important is the NIH basic research, the study—the findings of Dr. Vogelstein, for example, who discovered that cancer of the colon does not happen overnight, but happens through a cascade of genetic changes that start with a polyp. That's what then led to the development of screening, and its impact on the reduction of cancer rates.

Senator SPECTER. NIH has researched and found treatments for various strains of cancer, isn't that correct?

Dr. ZERHOUNI. Absolutely.

UNDERSTANDING CANCER

Senator SPECTER. How many strains of cancer are there? We talk about cancer as one generalized term, but approximately how many different strains of cancer are there?

Dr. ZERHOUNI. That's an excellent question, Senator. Most people will say 200 types of cancer are known. But my view is that, as I've followed this field very closely—is even within breast cancer, for example, there are many subtypes of breast cancer. So, if you look at cancer, it's not one disease, it's 200 separate diseases, and the molecular changes that occur in each one of them may actually be different from one to the other. This is why we need to do more research, to understand what's different between a cancer that kills and a cancer that doesn't, and how do you treat this one versus that one?

Senator SPECTER. We have had estimates, on prior hearings by this subcommittee, on how long it would take to cure Parkinson's. Would you say that it would be realistic to give an approximation as to what it would cost to cure cancer, and how long it would take?

Dr. ZERHOUNI. Very difficult to do that, as you know.

Senator SPECTER. Well, that's why I'm asking you, Dr. Zerhouni.

Dr. ZERHOUNI. I appreciate that, Senator. I think it's clear that if you look at the advances that we're making today, that the—the challenge in front of us is to understand the complexity of cancer treatments relative to the complexity of the biology of cancer. Most people would say that in the area of Parkinson's disease, for example, that there are—we need to make progress at the basic level to understand what are the—what is the first mechanism of disease. We have several mechanisms of disease that we are working on. As long as you don't know that, it's very hard to predict when you're going to cure Parkinson's disease. But we're already studying—knowing, for example, which genes are involved in Parkinson's disease. We've made discoveries that tell us that Parkinson's disease relates to abnormalities in the neurons. Some people think it's because there's accumulation of abnormal protein mechanisms. But

here is the answer. The answer is, I can assure you that with less research, the cure will take much longer than with more research.

Senator SPECTER. Well, that's a pretty obvious conclusion, Dr. Zerhouni——

Dr. ZERHOUNI. I know. Well, it's like the question——

Senator SPECTER [continuing]. But——

Dr. ZERHOUNI [continuing]. You posed, Senator.

QUANTIFY FUNDING DECISIONS

Senator SPECTER [continuing]. But what we are looking for, within reason, is finding some way to quantify it. Now, I've had some experience with Hodgkins, and I have been informed of a variety of advances in the treatment of Hodgkins. Different—they call it a cocktail—that wasn't my idea of a cocktail before I had Hodgkins—and they told me a complex categorization and various substances. I've talked to others, and the field has progressed tremendously. All for the better. What would be very meaningful, as we approach your budget, would be to try to get some way to quantify, as best you can—now, I know this is not going to work out to be a mathematical formula, but, when we talk about the various strains of cancer, it is important to know how many research projects are undertaken, and how many you are turning away.

We moved, on this committee, to appropriate very substantial sums over a 4-year period of time. From fiscal year 1999, we increased the budget to slightly under $2 billion—$1.950 billion. The next year, we appropriated the increase was $2.190 billion. The year following a $2.630 billion increase. The year following, an increase of $2.830 billion. The year following, an increase of $3.770 billion. So that we are able to increase funding over a 5-year period, some $13 billion.

Now, how did we do that? We took a budget in the range of $140 billion, which the subcommittee has, which funds three very important departments, Health and Human Services, Education and Labor and we pruned through the budget, found, with very sharp pencils, where we could establish priorities to increase the funding for NIH.

Now, you've testified, in the past, that increase in funding enabled you to grant many, many more applications for funding. More recently, we have seen a decrease. Senator Harkin and I had to fight like tigers last year to add a little over $600 million to stop a $50 million cut in the National Cancer Institute. Now, what catches the attention of our colleagues would be specifics. So, my request to you—and I've made similar requests in the past—is to go back and make an analysis, and give us your best judgment as to what is happening with the decrease in the funding. The President's budget now is more than $500 million below last year, without considering an inflationary increase. We would like to know what effect that's going to have on research, so that—tell us, number one, your best judgment as to what it would cost to cure cancer, or as close as you can to that analysis, taking the strains of cancer and how many research projects you need, and over what period of time; and then, second, what's going to happen to NIH if the budget is cut by more than $500 million. If you take an inflationary factor of 2 percent, it's several billion dollars that it's being cut.

Then, the third factor that would be very helpful would be to tell us what would be done by way of prevention. It's very expensive to treat somebody with Hodgkins. I can tell you that personally. Your statistics are also impressive when you say that the second year in a row there's been a 60-percent drop in mortality for heart disease and strokes. That means 60 percent fewer people have died. The drop in deaths of women from heart disease, from one-third to one-fourth, reported.

[The information follows:]

PROFESSIONAL JUDGMENT COST TO CURE CANCER

If I may: "What will it cost if we do not cure cancer?". The National Institutes of Health estimate overall costs for cancer in 2006 as $206.3 billion: $78.2 billion for direct medical costs (total of all health expenditures); $17.9 billion for indirect morbidity costs (cost of lost productivity due to illness); and $110.2 billion for indirect mortality costs (cost of lost productivity due to premature death).[1] Between 1974 and 2004, on average, each American has spent about $9.00 per year on cancer.[2] Moreover, economists at the University of Chicago, Graduate School of Business have estimated that a 1 percent reduction in cancer mortality would be worth $500 billion to current and future Americans. A "war on cancer" that would spend an additional $100 billion on cancer research and treatment would be worthwhile if it has a 1-in-5 chance of reducing mortality by 1 percent and a 4-in-5 chance of doing nothing at all.[3]

The primary focus of the NCI is on research and developing prevention and treatment options; it is necessary for others in the cancer community to ensure that the results of our efforts are disseminated and applied.

COST TO CURE CANCER

It is probably unrealistic to predict when cancer will be cured. Cancer is not one disease, but represents over 200 diseases and as a result is an exceptionally complex health care problem. Eliminating cancer as a significant burden will require stepwise gains in scientific knowledge and innovative ways for translation of this knowledge to the clinic. Progress is made by building upon pre-existing discovery, and the pace of scientific advances is, of course, driven by the amount of resources available for laboratory research and clinical translation. The NCI has never been at a more exciting place in terms of understanding the molecular mechanisms causing cancer and determining its progression. We have made tremendous progress over the last decade that has resulted in a measurable decline in cancer deaths for both men and women. Three decades ago there were 3 million caner survivors; today there are over 10 million.

What can also be said with certainty is that we are rapidly moving toward an era when cancer treatment will involve a molecular diagnosis of each tumor followed by highly personalized recipes of therapy. We are identifying the underlying genetic changes identified with the risk of developing cancer, we are increasingly able to detect cancer before clinical symptoms, we are learning how to use the immune system to keep cancer from progressing, and we are developing therapies that specifically target cancer cells. Using these combinations of approaches to prevention, diagnosis and treatment, we are beginning to see some cancers as manageable chronic diseases.

Of great concern is the knowledge that cancer incidence is 10 times greater for those 65 and older than for those under 65, and the death rate is 16 times higher. By 2030, 20 percent of the U.S. population will be over age 65 compared with 12 percent in 2004. Therefore, it is imperative that we maintain, if not accelerate, the momentum of scientific discovery.

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[1] American Cancer Society, Cancer Facts and Figures 2007.

[2] Congressional Transcripts, Congressional Hearings, March 19, 2007, page 5: Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies Holds Hearing on the Fiscal year 2008 Budget for the National Institutes of Health.

[3] Murphy KM, Topel RH: The value of health and longevity, J Political Economics: vol. 114, no. 5, pages 871–904.

BUDGET CUT BY MORE THAN $500 MILLION

The following examples illustrate what NIH can't do with the fiscal year 2008 President's Budget, relative to the fiscal year 2007 enacted level:

National Cancer Institute

Despite many fruitful studies on prostate cancer initiation and progression, the prostate cancer cell of origin has not been conclusively identified. **NCI will not be able to fund an R01 on the "Study of the Cell-of-Origin and Cancer Stem Cells in Prostate Adenocarcinoma" which seeks to identify the prostate cancer cell of origin—an understudied area in cancer biology.** In this highly focused application, the investigator would test the hypothesis that, in the prostate, there is a specific progenitor cell population that is sensitive to oncogenic transformation, and that this cell population is also responsible for hormone resistant prostate cancer formation. The application is innovative, timely, and likely to yield significant meaningful data that will drive the future of the field. Because most current therapeutics target what may be a more differentiated cell type, the success of this proposal could lead to novel strategies for treating prostate cancer. There are very few applications currently funded to identify cancer stem cells in prostate cancer.

National Institute on Alcohol Abuse and Alcoholism

The most serious adverse consequence of prenatal alcohol exposure is fetal alcohol syndrome (FAS), a devastating developmental disorder characterized by craniofacial abnormalities, growth retardation, and nervous system impairments that may include mental retardation. Preliminary data suggests that pharmacological and nutritional interventions may prevent deficits in alcohol-exposed fetuses even when administered following the exposure to alcohol. Recently studies in animal models have shown that choline is capable of preventing deficits due to alcohol exposure in utero. **The fiscal year 2008 President's budget does not provide sufficient funds to proceed with larger scale studies to determine the effectiveness of choline in preventing deficits in humans due to in utero alcohol exposure.**

National Institute of Child Health and Human Development

There will be no expansion of research efforts to translate NICHD-supported basic scientific findings into a new class of antimicrobial agents that could prevent bacterial or viral infections in the gastrointestinal tract, overcoming a major and growing public health problem of bacterial and viral drug resistance. Researchers found that oligosaccharides, non-nutritive components of human milk, inhibit the toxic effects of Escherichia coli and other gastrointestinal pathogens. These pathogens infect thousands of adults, and children, annually, causing extreme discomfort and even death. In the U.S., infections due to C. jejuni, E. coli, and five other food borne pathogens have been estimated to cost $6.5 billion to $34.9 billion annually. The critical advantages of developing these amazing antimicrobial products are that they: a) can prevent both viral and bacterial infections, and b) do not interfere with protein synthesis and bacterial/viral replication. Instead, these compounds prevent the pathogens from binding to intestinal walls, thus overcoming a major and growing public health problem of bacterial and viral drug resistance.

National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK can provide only very limited funding to solicit applications investigating the effect of maternal obesity on mechanisms that could potentially contribute to obesity, diabetes, cancer, cardiovascular or metabolic disease in the offspring.

NIDDK has not been able to initiate an Autoimmune Hepatitis Clinical Research Network which would focus upon elucidating the pathogenesis and developing means of prevention, treatment and control.

National Institute of Neurological Diseases and Stroke

The NINDS developed the Spinal Muscular Atrophy (SMA) Project as a pilot of how to speed the translation of basic science advances to therapies that are ready for clinical testing. The project is implementing a systematic drug development plan via a "virtual pharma organization," which develops and applies the resources for drug development through subcontracts to companies that serve the pharmaceutical industry. **The project is making encouraging progress, enough so to warrant application for a provisional patent on promising compounds that have been developed. Although there are other neurological disorders that might be ripe for a similar targeted therapy development program, NINDS**

would not be able to undertake such an activity under the President's budget.

National Institute on Aging

Specific examples of the potential impact of budget constraints on the momentum of the federally-supported Alzheimer's disease research agenda include:

—**NIA may be unable to maximize data collection efforts or to capitalize on the data being generated through studies under its two recently-released Program Announcements aimed at the discovery, development, and preclinical testing of novel compounds for the prevention and treatment of Alzheimer's disease.**

—**NIA will fund fewer studies under the Alzheimer's disease Neuroimaging Initiative, a public-private partnership that tests whether imaging techniques, other biological markers, and clinical and neuropsychological assessment can be combined to measure with greater sensitivity the progression of mild cognitive impairment (MCI) and early Alzheimer's disease.**

—**Constrained budgets could slow the process of studying and identifying genes through the ongoing Alzheimer's disease Genetics Initiative, which is designed to develop the resources necessary for identifying late-onset Alzheimer's disease risk factor genes, associated environmental factors, and the interactions of genes and the environment. Identification of informative subjects, genetic typing, and data analysis would all be slowed, delaying the identification of genetic and environmental factors that could provide new approaches for the prevention and treatment for Alzheimer's disease.**

National Institute of Allergy and Infectious Diseases

There is an intensified need for the development of a safe, effective and acceptable topically applied chemical and /or biologic barrier to prevent sexually transmitted HIV infection. Topical microbicides hold great promise as a strategy for preventing future HIV infections and AIDS-related complications and are designed to allow women to protect themselves against HIV and other sexually transmitted infections. The NIH supports several research programs and initiatives to help develop and advance candidates into human clinical trials, including the Integrated Preclinical/Clinical Program for HIV Topical Microbicides, Microbicide Innovation Program, and the Microbicide Design and Development Teams. **There are 38 lead microbicide candidates, of which seven are advancing to clinical trials in the next few years, and over 100 proposed candidates in the microbicide development pipeline. Additional funds would allow NIAID to ensure a vibrant pipeline and advance five additional compounds into early clinical studies.**

PREVENTION RESEARCH

The following examples of prevention research should lead us toward the era of personalized medicine, where we will be able to preempt the disease early in its process or even before it starts.

National Institute of Mental Health

NIMH is supporting a prospectively designed research network to predict, characterize, and preemptively treat schizophrenia:

—Schizophrenia is generally diagnosed between ages 18 and 21 when a young person has a psychotic episode that requires hospitalization and intensive treatment.

—However, most people with schizophrenia are ill for at least 18 months before their first psychotic episode—this period is known as the prodromal phase of the illness.

—The goal of this research network will be to determine whether treating schizophrenia during the prodromal phase can prevent psychosis and functional disability. Researchers will identify genomic and imaging biomarkers to define risk and to develop interventions.

National Institute on Alcohol Abuse and Alcoholism

NIAAA is supporting research to identify "trait" biomarkers which are inborn characteristics of increased vulnerability for specific types of alcohol-use disorders including alcohol dependence (alcoholism).

Through the identification of trait biomarkers for the specific subtypes, early preemptive interventions would be feasible in individuals at high risk for future alcohol

dependence, as would interventions in early stages of the disease itself with personalized treatment based on subtype.

National Institute of General Medical Sciences

Part of the difference in how people respond to drugs is due to genetic variations, particularly in the pathways that control drug metabolism. Such variations can render some drugs ineffective in certain individuals or, in other cases, increase the likelihood of dangerous adverse drug reactions. Since 2000, NIGMS has led the Pharmacogenetics Research Network, a trans-NIH effort to elucidate the genetic basis of differences in drug responses and guide the implementation of this knowledge into clinical practice. In several cases, findings by network scientists have already impacted practice, such as by providing genetic tests to support the use (or avoidance) of a given drug. Pharmacogenetics is a leading example of how investments in the Human Genome Project will broadly affect medical treatment, in this case by personalizing drug therapy.

National Eye Institute

The Age-related Eye Disease Study2:

—The Age-Related Eye Disease Study (AREDS), a multi-center study of cataract and age-relate macular degeneration (AMD) originally launched in 1992, demonstrated that high-dose antioxidant supplements (beta-carotene, vitamins C and E, and zinc) can slow the progression of AMD. Additional studies have suggested that the nutritional supplements lutein/zeaxanthin and omega–3 long chain polyunsaturated fatty acids might have benefit in preventing or slowing the progression of AMD and the formation of cataract. Leveraging these findings, the NEI began the Age-Related Eye Disease Study2 (AREDS 2), a multicenter study that will include up to 100 clinical sites.

—It is hoped that data from ARESD2 will improve therapeutic regimens that can prevent or slow the progression of AMD and cataract. It is further hoped that additional study data from AREDS2 will help create prognostic criteria to determine who will likely benefit from these nutrient supplements.

National Human Genome Research Institute

To speed research on the causes of common diseases such as asthma, arthritis, the common cancers, diabetes, and Alzheimer's disease, the Department of Health and Human Services announced in February 2006 two related groundbreaking initiatives in which NHGRI will play a leading role. Using the newly derived HapMap, both of these initiatives will search for the specific DNA variations that are associated with increased risk for common illnesses. Finding the DNA variants that predispose a person to common disease is one of the highest priorities of current biomedical research, since it will enable the identification of new drug targets and the development of personalized medicine.

The Genes, Environment and Health Initiative (GEI) is a trans-NIH research effort to combine comprehensive genetic analysis and environmental technology development to understand the causes of common diseases. GEI will support more than a dozen studies, beginning in fiscal year 2007.

The Genetic Association Information Network (GAIN) is a related public-private partnership between the NIH, the Foundation for the NIH, and private sponsors including Pfizer and Affymetrix. In 2006, GAIN selected six research studies for support: psoriasis, ADHD, schizophrenia, bipolar disorder, major depression and diabetic nephropathy. Results will begin to appear in June 2007.

National Institute of Neurological Diseases and Stroke

Research funded by NINDS has identified specific variants of a gene called phosphodiesterase 4D (PDE4D) that significantly increase the risk of stroke in women aged 15–49. The risk is magnified in women who smoke cigarettes. The study is the first to identify a possible interaction between this gene and an environmental factor in triggering stroke.

This study is part of a larger effort called the Stroke Prevention in Young Women Study2, which is designed to identify genetic and environmental risk factors for ischemic stroke (stroke that results from blockage in artery) in young women. The NINDS-funded investigators are now carrying out a study of risk factors for early-onset stroke in young men to help further clarify the role of the PDE4D gene and characterize the genetic basis for ischemic stroke. This research could help identify those at risk for stroke so that they may modify their behavior and eliminate certain environmental influences (e.g., smoking) to pre-empt the occurrence of a stroke. The research may also help in the development of new types of interventions to prevent stroke in those high risk individuals.

National Institute of Dental and Craniofacial Research

Salivary Diagnostics.—The day is approaching when a tiny computer chip glued to a tooth will allow early, personalized diagnosis and treatment by closely monitoring levels of proteins associated with specific diseases, as well as the medications prescribed to treat them.

—NIDCR support helped develop the current generation of rapid HIV antibody testing that uses intraoral fluid. The OraQuick™ HIV test reportedly has a 99.8 percent accuracy rate, compared to 99.9 percent for a blood test.

—Current grantees recently fabricated the first disposable, low-cost miniaturized diagnostic platform to process small amounts of saliva to detect the levels of DNA sequences of interest. The work is proceeding to ultimately create a fully functional hand-held instrument for salivary diagnostic tests that is about the size of a BlackBerry™.

—In the future, miniaturization of the technology will allow salivary diagnostic chips to be attached to a tooth for continual personalized monitoring of biomarkers for specific diseases.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The NIAMS places a high-priority on studies to identify risk factors and biomarkers of disease. To this end, the Institute will continue its commitment to a novel public-private partnership to improve prevention of osteoarthritis (OA), or degenerative joint disease. The Osteoarthritis Initiative (OAI) is a long-term effort, developed with support from numerous NIH components, private sector sponsors, and with the participation of the Food and Drug Administration, to create a publicly-available research resource to identify and evaluate biomarkers of OA for use in clinical research. The study has 4,800 participants who are at high risk for knee OA and, as of early fiscal year 2007, clinical data from approximately 2,000 of them were available for research projects. Over the next 5 years, the OAI will provide an unparalleled, state-of-the-art longitudinal database of images and clinical outcome information available to researchers worldwide to facilitate the discovery of biomarkers for development and progression of OA. In this effort, a biomarker would be a physical sign or biological substance that indicates changes in bone or cartilage. Today, 35 million people—13 percent of the U.S. population—are 65 and older, and more than half of them have radiological evidence of OA in at least one joint. By 2030, an estimated 20 percent of Americans—about 70 million people—will have passed their 65th birthday and will be at increased risk for OA.

National Institute of Diabetes and Digestive and Kidney Diseases

Preempting Risk Factors for Type 2 Diabetes in Children:

—Previously considered a disease of adults, type 2 diabetes is now increasingly observed in children, particularly minority youth. Identifying new strategies to preempt risk factors for diabetes is extremely important because recent data estimate that 1 in 14 children in the U.S. between 12 and 19 years of age has pre-diabetes—and many of the children with pre-diabetes have risk factors for cardiovascular disease (CVD).

—In August 2006, the NIDDK launched a multicenter clinical trial, called HEALTHY, which is aimed at preempting risk factors for type 2 diabetes in middle-school children.

—Half of the 42 enrolled schools are receiving the intervention, which consists of: environmental changes to school food service and physical education class activities; behavior change activities; and communications and promotional campaigns.

—Children are being enrolled in the sixth grade and followed for 3 years. Importantly, the schools have large (50 percent or more) minority or under-served populations.

NIH OFFICE OF WOMEN'S HEALTH

Senator SPECTER. Now, we go back to before your time, Dr. Zerhouni. It was about 1991, wasn't it, Senator Harkin, when the woman's branch of NIH was established? Is that correct?

Dr. ZERHOUNI. That's correct. The Office of Women's Health.

Senator SPECTER. There wasn't an Office of Women's Health before this subcommittee picked it up and found the money for it. My wife pointed out to me the difference in heart disease for women, and we took the lead, here in this subcommittee, to establish a

women's unit. So, it's very gratifying to see your statistics this year, that heart disease of women dropped from one-third to one-fourth.

Well, you get my point. I'd like to have it in a concrete form so that we could tell our colleagues, on the budget resolution. As I told you earlier today, Senator Harkin and I are going to be going to the floor and asking for an increase in the budget resolution on NIH. I'm not sure how much it's going to be. We're going to ask for the most we think we can get—that is realistic—that we can get adopted, maybe a little more than that in terms of bargaining. Last year, we increased the budget for the subcommittee by $7 billion. But that's confederate money on the budget resolution. Doesn't turn into real cash until you have an allocation.

I had a disagreement with Senator Byrd, back in 1988, on the allocation for the budget, and I did the unheard of thing for a Senator my age compared to a Senator of his standing, to disagree with a chairman's mark. I got three votes. It was 25 to 3. You may think three votes out of 28's not many, but it's a lot. Senator Byrd told me, at that time, "Someday you'll be chairman of the Appropriations Committee." It didn't seem possible. But now I'm right behind Senator Cochran. With term limits and a change in party, I'm getting pretty close to that, Dr. Zerhouni. If, and when that happens, you won't have to provide all these fancy statistics. But, in the interim, we need them—something really concrete that we can point to—to show our colleagues, as a way of elevating the status of health and how much NIH means to promoting health, our greatest capital asset, and how much it means in reducing costs by preventing disease.

SUSTAINING OUR PRESENT RESEARCH CAPITAL

What do you think, Dr. Zerhouni?

Dr. ZERHOUNI. Let me just give you the three points that I think are essential, in terms of policy, and then also take the opportunity to supplement that answer with specifics for the record.

First and foremost, you asked the question about: What is the optimal way for us to accelerate our research to get to cures as optimally as possible? It's hard to give an answer for any one disease, but I can show you, from my standpoint as a science administrator, what I think the optimal point is in our ability to sustain research.

Let me show you, if you don't mind, a slide, here, of what has happened to NIH success rates. Historically, we've funded about 3 grants in 10 applications. Today, we fund 2 in 10. Our experience, as—myself, as a scientist, when I ran my lab; as a dean for research at a major institution; and now as NIH Director, is that 3 in 10 is the historical percentage where NIH has always sustained its success rate, and where we've gotten the return that we wanted. I'm concerned that 20 percent is too low. I think you will hear, from our scientists, that this is straining the enterprise, and it is also discouraging new generations.

So, if you ask me, "What is the wisdom of science administrators worldwide as to: 'How do you sustain areas of research in cancer,'" or whatever, I think people would say that success rates in the 25- or 30-percent range are a minimum that you need to sustain re-

search over time so that you can, in fact, have a healthy environment.

Now, in this case—and I published these figures—I'm showing you here, in red, the success rate of NIH. If you look, historically, it was around 30 percent, if you follow the line. Then, in about 2002–2003, it dropped. Why did it drop? Not just because we had flat funding. Flat funding did lead to a loss of purchasing power. But here is the real story, Senator. More scientists are needed to study the complexity of the diseases we're dealing with. So, if you look at the curve, the blue curve, this is the number of applications we've received at NIH. You can see there are more scientists now—there are twice as many applications at NIH from twice as many scientists, almost, who want to do research. We can't sustain—not even one-third, not even 30 percent; we are at about 20 percent right now.

So, that's answer number one. If you don't want to lose momentum, that is an objective that you need to look at.

The second is what you said about: What is the greatest impact, and what do we need, to make sure we don't lose? Well, first, as you know, we've made some very tough decisions in not allowing inflationary increases and focusing, as you've helped us this year, on the next generation of scientists. Typically, NIH funds 1,500 new scientists a year who get their first major grant. Last year, we dropped to 1,400. I want to get back to 1,500, because if we don't, 10 years from now you won't have the researchers to implement the cures that will be discovered in the basic research laboratories. So, it's important to realize that we need to sustain that. But that cannot be done without some compromise or some decrease in other areas.

So, we have favored, over the past 2 years, what we call investigator-initiated research—research project grants to individual investigators. At the expense of what? Well, at the expense of clinical trials. If you look at our ability to conduct clinical trials on patients like yourself, you know we want to optimize a protocol for cancer, optimize a protocol for prevention of heart disease—prevention of stroke is another example—we've had to cut these programs, because they're extremely expensive.

I'll give you an example. Clinical trial costs grow faster than inflation, because it's like healthcare, most of the care in the clinical trial cost is healthcare. So, it grows at 7–8 percent. When you have a flat budget, you lose your ability to study as many patients. So, that's what we're seeing. This is what we're giving up. We're giving up the ability to do clinical trials to enable us to change the science and change the medicine that we do. So, that's the second answer that I think is important here, is that the impact is primarily in our ability to translate from the laboratory to the clinic to the bedside and to the community what we need to do to prevent diseases.

But I will be happy to provide you very specific answers, institute by institute, for the record, Senator.

[The information follows:]

REDUCTION IN SOCIETAL BURDEN & HEALTH CARE COSTS

The following examples illustrate how research funded by NIH institutes lead to reduced societal burden and/or healthcare costs:

National Cancer Institute

Tamoxifen.—A Preventative Agent for Breast Cancer

In 2006, breast cancer is estimated to have affected 214,640 Americans. Since 1978, when Tamoxifen was first approved in the treatment of breast cancer, the National Cancer Institute has pursued further research to exploit the utility of this hormone receptor-blocker as a cancer preventative agent. Several studies by NCI and others, using over 20,000 women, confirm that tamoxifen can be given to prevent Estrogen Receptor-positive (ER-positive) breast cancer, and the preventative benefits continue for many years after the women stop taking the drug. ER-positive breast cancer accounts for about 60 to 70 percent of breast cancers. This equates to approximately 128,000 to 150,000 cases of breast cancer that could be prevented annually. NCI previously conducted the STAR trial (Study of Tamoxifen and Raloxifene), with nearly 20,000 women, that showed the benefit for breast cancer prevention when taking either tamoxifen or raloxifene, and for the women taking raloxifene, a lower occurrence of blood clots or uterine cancer.

Cancer Survivorship.—Reducing the Societal Burden

NCI leads the nation in championing research on the health and quality of life of our growing population of cancer survivors, currently numbering more than 10 million, up from only 3 million in 1971. While the ultimate goal of eliminating cancer continues to be our long term commitment, the capacity to dramatically reduce the societal burden caused by cancer, by increasing survivorship rates, is within our immediate reach. Advances in out ability to detect, treat and support cancer patients have turned this disease into one that is chronic or readily managed for many and curable for increasing numbers.

HPV Vaccine.—Societal Benefits and Cost Savings

An important public health milestone was realized when the FDA approved a vaccine that prevents infection by HPV 16 and HPV 18, the two subtypes of the human papillomavirus responsible for up to 70 percent of cervical cancer cases worldwide. This approval is a watershed moment that highlights the very best of biomedical research: the translation of basic and population science into an intervention that will save lives.

Widespread vaccination has the potential to reduce cervical cancer deaths around the world by as much as two-thirds (about 250,000 women). In addition, the vaccine can reduce the need for medical care, biopsies, and invasive procedures associated with the follow-up from abnormal Pap tests, thus helping to reduce health care costs. This advance also allows NCI to stress the continued importance of cervical cancer screening and provides an opportunity to educate the public about HPV. By monitoring benefits and risks of HPV vaccination, we can optimize the use of HPV vaccines to achieve the greatest health benefit for women.

The National Heart, Lung and Blood Institute

During the past several years, American men and women have benefited greatly from continued reductions in morbidity and mortality due to cardiovascular disease. The following new findings from NHLBI-supported research have improved our ability to treat and prevent a range of cardiovascular conditions:

—The ALLHAT revealed that diuretic drugs are at least as effective as newer, more expensive medications in treating hypertension, a major risk factor for coronary heart disease, stroke, and congestive heart failure.

—The AFFIRM trial established the superiority of a heart-rate control approach to treat atrial fibrillation.

—An emergency-room-based study demonstrated the utility of magnetic resonance imaging in rapidly diagnosing acute myocardial infarction, thereby enabling timely intervention to restore blood flow to the heart muscle.

—The PREVENT trial established the efficacy and safety of long-term, low-dose warfarin therapy to prevent the recurrence of blood clots in patients with a history of deep-vein thrombosis and/or pulmonary embolism.

—A community-based trial found that public access defibrillation performed by trained volunteers increases survival for victims of cardiac arrest.

—The Sudden Cardiac Death in Heart Failure trial reported that an implanted cardiac defibrillator significantly reduces deaths among patients with moderate-to-severe heart failure.

—The Prevention of Events with Angiotensin-Converting Enzyme (ACE) Inhibition trial revealed that heart disease patients who are already receiving state-of-the-art therapy do not benefit from additional treatment with ACE inhibitors.

—The Women's Ischemia Syndrome Evaluation study reported a number of important findings regarding diagnosis and prognosis of chest pain in women.

—The SHOCK trial concluded that treating heart attack patients who develop life-threatening cardiogenic shock with emergency angioplasty or bypass surgery greatly improves the long-term survival.
—The first totally implantable permanent artificial heart—the culmination of many years of research efforts by the NHLBI and others—received FDA approval for implantation in certain patients with severe heart failure.
—The Occluded Artery Trial found that late angioplasty after a heart attack offers no advantage over standard drug therapy.

National Institute of Allergy and Infectious Diseases

Adult male circumcision reduces HIV transmission

The NIAID supported two clinical trials in Uganda and Kenya that found an approximately 50 percent lower risk of heterosexual transmission of HIV among adult men who received a medical circumcision compared to men who were not circumcised. These results were announced in December 2006.

The study results indicate that HIV transmission from women to men could be lowered, though not eradicated, by increased rates of male circumcision.

The impact of increased access to male circumcision would be most pronounced in those areas with low rates of male circumcision and high rates of heterosexually transmitted HIV.

Based on the results of these studies, an international expert consultation, convened by the World Health Organization (WHO) and the UNAIDS Secretariat, recommended that male circumcision now be recognized as an additional important intervention to reduce the risk of heterosexually-acquired HIV infection in men.

Modeling studies suggest that male circumcision in sub-Saharan Africa could prevent 5.7 million new cases of HIV infection and 3 million deaths over 20 years.

Survival benefits of AIDS treatment

The NIAID supported a study to quantify the cumulative survival benefits of AIDS care in the United States. The results were published online in The Journal of Infectious Diseases, in June 2006.

At least 3 million years of life have been saved in the United States as a direct result of care of patients with AIDS.

The study data demonstrate the dramatic impact that advances in anti-retroviral therapy have made on the long-term survival of the most vulnerable HIV-infected persons, those who develop AIDS.

The data also underscore the importance of the global implementation of HIV treatment in resource-limited countries and the potential for huge survival benefits in those countries.

National Institute of Diabetes and Digestive and Kidney Diseases

Reducing the Burden of Chronic Kidney Disease and Kidney Failure

Diabetes is the leading cause of chronic kidney disease and end-stage renal disease. Research has shown tight control of blood glucose levels can dramatically diminish the development of complications of diabetes. With good care, fewer than 10 percent of diabetes patients develop kidney failure.

Kidney disease can be detected earlier by standardized blood tests to estimate kidney function and monitoring of urine protein excretion. NIH research has shown that drugs (ACE inhibitors and ARBs) that better control blood pressure can slow the rate of kidney damage by about 50 percent. As a result of improved treatment, the number of new dialysis patients has stabilized, although troubling racial disparities persist.

The savings to Medicare for each patient who does not progress from chronic kidney disease to end-stage renal disease is estimated to be $250,000 per patient. Overall, estimated Federal savings from recent improvements in preventing kidney disease is approximately $1 billion per year.

National Institute on Deafness and Other Communication Disorders

Over the last three decades, the NIH's support has played a significant and important role in the development of cochlear implant (CI).

NIDCD-supported research demonstrates that the sooner a child with severe to profound hearing loss receives a CI, the greater the benefit showing age")appropriate speech perception and language production within six to nine months after the CI is turned on.

NIDCD-supported scientists have found that the benefits of the cochlear implant far outweigh its costs in children. A cochlear implant costs approximately $60,000 (including the surgery, adjustments, and training). In comparison, the services, spe-

cial education, and adaptation related to his or her deafness will cost more than $1 million if a child is born deaf or becomes deaf before the age of 3.

National Institute on Drug Abuse

Declining cancer deaths, in part due to decreases in cigarette smoking, have resulted from better treatment options for tobacco addiction and from effective prevention efforts—buttressed by NIDA-supported research. For the second year in a row, the CDC reported a decline in deaths due to cancer, a remarkable accomplishment stemming from research-backed treatments and public education campaigns.

—NIDA-supported research revealed nicotine as the main addictive component in tobacco, enabling the development of first-line therapies such as nicotine replacement, complemented by behavioral approaches.

—NIDA-supported education and prevention efforts targeting young people have paid off dramatically in falling rates of teen cigarette smoking, now at the lowest point since 1975, when our Monitoring the Future survey of drug use and attitudes among 8th, 10th, and 12th graders was initiated.

—Since most addiction begins in adolescence and even childhood, these declining smoking rates are likely to lead to continued public health dividends as young cohorts with lower smoking initiation rates age.

National Institute of Child Health and Human Development

Progesterone Injections Reduce Preterm Delivery.—Currently, 12 percent of all births are premature and two percent are "very preterm." Ten percent of the very premature babies will die and 15 percent will survive with major disabilities, such as cerebral palsy, deafness, blindness or mental retardation. The Institute of Medicine estimates that the annual societal economic burden associated with preterm birth in the United States was over $26.2 billion in 2005. The NICHD's dedication to advancing treatments for preterm birth has led to the first successful intervention, which has the potential to reduce the associated societal burdens and healthcare costs. Clinicians know that women who have previously experienced spontaneous premature labor are at greater risk than others to experience it again. Findings from a groundbreaking clinical trial showed that treating women, who had a previous preterm delivery, with 17 alpha-hydroxyprogesterone caproate (17P) reduced, by 34 percent, their risk of another preterm birth. The study—conducted within the NICHD's Maternal-Fetal Medicine Units Network—also showed that infants, who were born prematurely even though their mothers were treated with 17P, had significantly lower rates of severe complications. 17P holds tremendous promise for reducing preterm birth and life-threatening medical complications in infants of high-risk women. The therapy will have even greater public health impact when it is extended to other women who are at high risk of preterm delivery. Building on this significant public health advance, researchers are conducting a study to evaluate progesterone therapy in high risk women with twin or triplet pregnancies.

National Institute of Neurological Diseases and Stroke

One of the first systematic studies of the impact of a publicly funded research program on public health and health care costs evaluated the costs and benefits of all NINDS phase III clinical trials from 1977 to 2000. The total cost of the trials was $335 million. The study, published in The Lancet in April 2006, found that over 10 years, the trials provided economic benefits that exceeded $15 billion and were responsible for 470,000 additional healthy years of life. The benefits of the clinical trials program for the entire period covered by the study were estimated to be more than $50 billion, far greater than the total NINDS budget over that period ($29.5 billion). [Johnston et al., The Lancet, 2006, 367:1319–1327].

National Institute of Nursing Research

Program to Improve Knowledge and Coping Helps Improve Quality of Life for Parents of Premature Infants and Reduces Hospital Costs.—Parents of premature infants often endure high levels of stress, anxiety, and depression. NINR-supported investigators tested the ability of an educational intervention program for parents, implemented early in the Neonatal Intensive Care Unit (NICU), to reduce such psychological distress. In what is believed to be first randomized controlled trial of its kind, researchers found that parents in the program, called Creating Opportunities for Parent Empowerment (COPE), demonstrated improved parenting behaviors and reported decreased stress levels compared to parents in a control group. Infants of parents in the COPE program had a 3.8-day shorter NICU length of stay and a 3.9-day shorter total hospital length of stay than did comparison infants, resulting in decreased hospital costs of about $5,000 per infant.

Transitional Care Improves Outcomes for Elders After Leaving the Hospital.—In a randomized controlled trial, NINR-supported investigators evaluated the effective-

ness of a transitional care program in helping to maintain, after hospital discharge, the health and function of elders with heart failure. Elders received a three-month program managed by Advanced Practice Nurses (APNs) that was designed to assist the patients in managing their discharge planning. The APNs worked with the patients to identify goals, individualize care plans, coordinate care across the different settings from hospital to home, and implement a protocol to manage the multiple health issues of heart failure patients. A follow-up evaluation at one year showed that patients who had received the intervention had a longer time before first hospital readmission, along with fewer total rehospitalizations, hospital days, and deaths than a control group that continued in standard care. Improvements were also noted in patient satisfaction and quality of life. The total health care costs over the year-long study period were lower by almost $3,500 per patient for those in the APN intervention group, when compared to a control group.

Senator SPECTER. Thank you very much, Dr. Zerhouni.

Mr. Chairman, we have, on the floor at the moment, the legislation involving the U.S. attorneys who have been asked to resign. I am ranking on Judiciary, and I'm going to have to excuse myself for a few minutes to go to the floor. We are taking up the bill to change the authority of the Attorney General to replace U.S. attorneys on an indefinite basis, which has caused a lot of controversy. That is being debated right now, and I'm going to have to excuse myself to go down there to take care of other responsibilities. Senator Feinstein is on the floor now, and she was scheduled to speak. I'm scheduled to speak after her. But I will be back as soon as I can.

Thank you.

Dr. ZERHOUNI. Thank you, Senator.

Senator HARKIN. Thank you, Senator Specter.

IMPACT OF AN ADDITIONAL $1.9 BILLION

Dr. Zerhouni, just a couple of follow-up questions before we turn to our next panel.

As I said earlier, NIH has lost about 8 percent of its funding, in real terms, since the end of that doubling period, in 2003, which we saw on the screen also. The advocates from different disease groups have asked Congress to get NIH back on track by appropriating a 6.7-percent increase for the next 3 years. By fiscal year 2010, that would equal the amount NIH would have attained if it had simply received inflationary increases. So, this year, a 6.7-percent increase would equate to about $1.9 billion. Just what do you think you could accomplish with an increase of $1.9 billion? What would be different if we could obtain that $1.9 billion?

Dr. ZERHOUNI. Well, again, I think that is—it is key, from my standpoint, to understand that in flat budgets we have to make tradeoffs, and those tradeoffs tend to affect the ability to sustain scientists. So, the ability for us to stay at inflation translates directly into our ability to sustain the scientific workforce of the United States. For example, NIH supports, directly and indirectly, about 326,000 scientists in the United States. Every year that we fall behind, in terms of inflation, we have to make some difficult choices, which typically impact our ability to sustain scientists, who are really the key to scientific progress. So, the first thing that I think staying even with inflation will do is to allow laboratories the resources they need to recruit and retain the scientists that are needed to address the very complex issues that have come to light, from the scientific standpoint, over the past few years.

I think that the other important aspect of it is that we will recover our ability to conduct clinical trials at the rate that we need to conduct them. As I said, we've had a flat funding of clinical trials since 2003—we have not increased the dollars in clinical trials. But, because inflation in clinical trials is 6–7 percent, our purchasing power in clinical trials is 35 percent less than it was 4 years ago.

So, that would be probably be one of the priority areas that we would like to recover, after recovering what I call the optimal success rate. I don't think it's good to have success rates that are persistently low. I think we need to make sure that the opportunities for new scientists and established scientists are recovered.

So, those are the two things. First, maintaining a viable, vibrant workforce—a scientific talent pool of both established scientists and new scientists, so that the pipeline continues as strong as it has been. Second is to be able to do translation, especially when it comes to putting the bench discoveries to practice.

COMMON FUND

Senator HARKIN. The NIH Reform Act that we passed last year puts a big emphasis on the common fund——

Dr. ZERHOUNI. Yes, sir.

Senator HARKIN [continuing]. Again, to support trans-NIH initiatives that benefit all areas of disease research. A couple-three, things. One, again, can you just spend a couple minutes describing what you hope to attain—accomplish that fund, what are some of the examples of the kind of initiatives that would be funded through this effort. Last, how about initiatives for particular diseases? Some diseases cross many institutes and centers. Could they be funded through the common fund?

Dr. ZERHOUNI. Sir, the common fund is about 1.5 percent of the NIH budget today. It really came from the concept of having—as I said, institutes are extremely good at fulfilling their missions; however, science changes, and often there are areas that fall between the cracks, that you need to sustain, especially when it comes to high-risk, high-impact research. So, we want to sustain our ability, despite tight budget times, to fund innovative ideas and innovative scientists. That is a role that I see for the Common Fund.

Second, emerging areas of science that are not necessarily in the priority of any one institute. A good example is nanotechnology. When I became Director the total investment of NIH in nanotechnology was $50 million. There wasn't an institute that really focused on that. The new institute, the National Institute of Bioimaging and Bioengineering, was just created, and that's their mission, but they were too new, and clearly you needed to make a large advance across the board. That's when we use common fund monies, to sort of launch this area.

Another example is what we call molecular libraries. Scientists told us that they needed to have access to more molecules to see if they could understand better the diseases in their own assays. Well, that was not available to NIH-funded scientists. So, the—no institute really has either the mission or the interest or the scope to fund that. So, we funded it. But what is really important, Sen-

ator, is that the common fund is like a glue fund. In other words, it's the—you know, NIH is like 27 fingers; the common fund is the palm, is the coordination, the strategizing of the future of science, funding areas that wouldn't be funded otherwise. It is really to incubate novel ideas. For example, you could have seen the common fund being used in emerging areas of science, like stem cells, at the beginning, or RNA interference. RNA interference is a new mechanism that was discovered in 1998. The work received the Nobel Prize in 2006. When I became Director of the NIH, I was very keen on finding monies to support that area of research. It was emerging at the time. So, that's the kind of uses that you would want to see for the common fund, uses that are at the frontier of science, serve all institutes, that are not specifically for something that will last forever, but it's just like the kickoff fund, if you will. Five years of funding, 10 years of funding, to get a new area of science started.

Think of the human genome. In 1991—I think you were on the committee at the time——

Senator HARKIN. Chairman.

Dr. ZERHOUNI [continuing]. You were the chairman of the Committee—the then-Director of NIH came to you and asked you, as an exceptional measure, to fund the human genome. The human genome was going to be done at the Department of Energy, because they had an Opportunity Fund. NIH did not have that. So, when I talked to my predecessors, Dr. Varmus, Dr. Wyngaarden at that time, they all said the one thing that is needed at NIH is some sort of a common fund for common purposes that emerge unpredictably that we need to respond to. That could apply to a public health emergency, no doubt about it. But, again, it's a revolving venture fund to make the agency nimble, reactive, not to serve specific interests, but to serve the agency as a whole. I don't know if I'm making myself clear.

Senator HARKIN. Can particular diseases, then, be funded through this, or not?

Dr. ZERHOUNI. I would rather not. I would think that the particular diseases that need to be funded should be funded through the institutes that have the missions——

Senator HARKIN. But some of these——

Dr. ZERHOUNI [continuing]. To serve that.

Senator HARKIN [continuing]. Diseases cross a lot of different institutes. That's the problem.

Dr. ZERHOUNI. So, what we do in that case, when there are diseases that are relevant to the mission of multiple institutes, we have other mechanism, where we encourage institutes to work together. For example, we've had an obesity research plan. It's not funded through the common fund. It's the responsibility of different programs in the institutes, so that what we do there is, we encourage the institutes to work together. For example, the strategic plan for obesity research was published and involves over 19 institutes. The neuroscience blueprint is another example of addressing diseases that need to be served by the institutes whose mission is to serve those diseases in their various dimensions.

Unless it's an area that really requires across-the-board stimulus—remember, no initiative in the common fund stays for more than 5 to 10 years, max. That is the idea of the common fund. It's

not to replace, or a new source of funding for special diseases that don't find a home somewhere else. Very important, I think, to keep that in mind.

PUBLIC ACCESS

Senator HARKIN. I appreciate that.

One last thing, we have to move on to the next panel. It concerns public access to NIH-funded research. You have proposed that NIH-funded researchers should have to submit their final peer-reviewed papers to an NIH database after they're accepted by scientific journals, and that these papers should be made available through the database within 12 months after their publication in the journals. What's the scientific value of increasing public access to this research, as you propose? Why 12 months? Why not 6 months? You've asked Congress to require NIH-funded researchers to adhere to this policy; why do we have to do it? Can't you do that on—you know, can't you simply require that through NIH? Why do we have to do it?

Dr. ZERHOUNI. First of all, I think it's important, in the information age that we're in, to make sure that publicly funded research be available in a database that we can search and connect to all the many other databases that are available to us. It is also important not to damage peer review. But it is important to realize that NIH needs to have a—the ability to do that without damaging journals. That's why 12 months, that's why not 6 months. Because most journals will say that 6 month—for 78 percent of journals, 6 months might be okay, but for others that are not published as frequently, it's not—it will damage their ability to sustain themselves. So, I think we need to be more flexible.

What I think we can't be flexible on is the mandatory nature. We've tried voluntary. I have data about how this is working. I mean, you can see here, for example, that the publications that are being submitted represent less than 10–15 percent—the compliance is the red number, the red bar—the compliance is not as high as it should be. I think we should—we need to make this a condition of Federal grant funding, and that's why we need you to express the wish of Congress to do that, as easily as we can.

So, my position is, a mandatory policy seems to be the one that will be necessary for us to achieve our goals. We've tried voluntary. It doesn't seem to be working as well. I think we need to be flexible on the time. I don't think that we should force a date certain, because it would harm some journals and not others.

Senator HARKIN. That's really all the questions I have, Dr. Zerhouni. Is there any last thing that we didn't bring up that you'd want to get out before I——

Dr. ZERHOUNI. Again, I think that what I'd like to say is how appreciative of you and Senator Specter and the rest of the subcommittee I am. I think that it is key that we continue the momentum.

I have been in—I wanted to give you a perspective about international competition. I just came back from Europe. They have decided to focus on life sciences, and accelerate their investment in life sciences. They've just created a new NIH-like institution in Europe, $57 billion of funding in 5 years. I've been to China; there's

a tripling of the research budget. I've been to India; and there is also an increase in research. There are strong attempts to re-recruit back from the United States. I think we definitely need to understand the strategic importance of NIH. I think you do, but I just want to be on the record to say that nothing is more important than sustaining our investment in science and medical research.

Thank you.

Senator HARKIN. Well, Dr. Zerhouni, thank you very much for your leadership, and also, again, I want to thank you for your statement concerning embryonic stem cells. Hopefully, we're going to move ahead on that, this year, put it behind us, and get about funding this much-needed area of research in our society. So, I thank you for your statement today.

Well, Dr. Zerhouni, now, we're going to move to our next panel. Respectful of your time, if you'd like to stay, and maybe there might be some questions we might have afterward, but I——

Dr. ZERHOUNI. I'd be happy to stay.

Senator HARKIN [continuing]. It's not part of the deal, so if you can stay, we'd appreciate it; if not, then that's fine.

Dr. ZERHOUNI. Thank you, Mr. Chairman. I'll be happy to stay.

Senator HARKIN. Well, I appreciate that very much, Dr. Zerhouni.

Let's bring our next panel up: Dr. Iverson, Dr. Brugge, Dr. Siliciano, and Dr. Strittmatter.

Again, for all of you, welcome to the subcommittee. All of your statements will be made a part of the record in their entirety. I'd ask, if you could sum it up in 5 minutes, your major point, I'd appreciate that. We can elucidate more of it in our questions-and-answer period.

So, I'll go in the order in which I called you. Dr. Brent Iverson, distinguished teaching professor of organic chemistry and biochemistry at the University of Texas at Austin, received his bachelor's of science degree from Stanford and his Ph.D. from the California Institute of Technology.

Dr. Iverson, welcome to the committee, and please proceed.

STATEMENT OF BRENT IVERSON, Ph.D., UNIVERSITY DISTINGUISHED TEACHING PROFESSOR OF ORGANIC CHEMISTRY AND BIOCHEMISTRY, THE UNIVERSITY OF TEXAS AT AUSTIN, AUSTIN, TEXAS

Dr. IVERSON. Thank you, Mr. Harkin.

I am here representing NIH-funded scientists at research universities. I was an undergraduate business major at Stanford until I worked in Professor Jim Coleman's laboratory in chemistry research. It was an NIH-funded research laboratory. My undergraduate research experience charted the course that directly led to my scientific career.

My research spans the interface of organic chemistry and molecular biology on the basic science and of the biomedical research spectrum. I am an inventor on 20 patents, many of which are being used by companies right now.

I would like to make three points concerning the importance of growing the NIH budget.

The first point concerns being able to take full advantage of what the doubling allowed us to initiate. In my own lab, the increased

funding provided by the doubling allowed my collaborators and I to develop a powerful new method we call APEx that allows us to enhance the activity of antibodies. Antibodies are the hottest segment of the pharmaceutical industry today, with over 20 now approved, such as Avastin and Herceptin, for treating colon and breast cancer, and Remicade and Humira for treating rheumatoid arthritis and Crohn's disease.

Antibody drugs are so-called targeted therapies because they're capable of seeking out and attacking only their intended disease targets, with remarkable precision; sort of the smart-bomb approach for drugs. The result is a much more concentrated therapy, one that limits many of the serious side effects of traditional approaches.

Our APEx allows us to make existing antibodies more powerful by a factor of 10 or 100 or more. For example, we started with an antibody against anthrax that could delay, but not prevent death, in animals exposed to live anthrax spores. After making the original anthrax antibody about 20 times more potent, our engineered antibody prevented illness and cured animals treated with the same lethal dose of live anthrax spores. That antibody is being pursued commercially by Elusys, Incorporated, of New Jersey, and will hopefully become a stockpiled countermeasure that should be effective past the point at which Cipro alone works.

With APEx, we are starting—we are ready to start working on engineered antibodies that attack a variety of diseases, such as allergies, inflammatory diseases, and cancer. I believe there are many, many researchers like me poised to make a difference with all the tools now in place, but limited by a flat budget. This is not the time to pull back.

My second point concerns basic science breakthroughs. Flat funding, as we have now, has the effect of making grant funding decisions overly conservative. Let me bottom-line it for you. There is currently too little support for innovative, risk-taking, basic research without new money, because the money we are given largely goes to fund the many worthy older ideas. Less than 10 percent of the grants in my research area receive money each round of consideration. Less than 10 percent. There is simply not enough money left over for new ideas that are not yet proven.

In other words, there is not enough money right now for new ideas that could establish new paradigms or provide new opportunities for new therapies, exactly the kind of basic science research that cannot be done in the commercial sector.

For example, I want to draw your attention to the green panel in our report. This is a molecule from my lab that binds to DNA in an entirely new way. It was discovered in the context of an exploratory project designed to move in an entirely different direction, yet it could someday form the basis for a therapy of the target's DNA directly as a point of interaction.

Conservative funding decisions mean there is also not enough money to fund those scientists who have not yet had the opportunity to prove themselves; namely, new faculty members. Further, our current graduate students are being dissuaded from an academic research career by the difficulty young faculty are having in receiving funding right now.

I would like to finish by describing my concerns about science education. I hope all of you understand that the product of NIH funding is not only the research itself, but, additionally, the training of students. For the U.S. pharmaceutical and biotech industries, NIH is, by far, the most important sponsor of projects that result in scientist training. Talk about strategic economic leveraging.

I generally accept three to four new Ph.D. students in my laboratory every year. With the significantly reduced chance of getting a grant funded, I am forced to take proportionately fewer graduate students. In fact, I am not accepting a single new graduate student this year in my antibody engineering laboratory.

Tight funding impacts undergraduate research opportunities, as well. I have had over 100 undergraduates work in my lab. Across our campus, around 1,000 undergraduates will take part in cutting-edge scientific research, many in state-of-the-art labs with NIH funding. Fewer research grants means fewer opportunities for undergraduate researchers.

PREPARED STATEMENT

Together, I view this as a very ominous combination. Not enough money to take advantage of recent advances, a conservative research environment that discourages risk-taking, and not enough support for state-of-the-art science education. I am convinced that a lack of new money today will have a crippling effect on our global competitiveness, and will limit medical breakthroughs for decades.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. BRENT IVERSON

My name is Dr. Brent Iverson. I am a Distinguished Teaching Professor and the Raymer Professor of Chemistry and Biochemistry at the University of Texas at Austin. I am here representing NIH funded scientists at research universities, both public and private. I was an undergraduate business major at Stanford University until I worked in Professor Jim Collman's chemistry research laboratory. My undergraduate research experience in that NIH-funded lab charted the course that directly led to my scientific career.

Today, I want to tell you about NIH funding from my individual perspective, to help put a face on the budget numbers. My research spans the interface of organic chemistry and molecular biology, on the basic science end of the medical research spectrum. I have well over 100 publications, many in the most prestigious scientific journals. I hold 20 current or pending patents, most of which are licensed and are being used by companies across the country.

I would like to make three points concerning the importance of growing the NIH budget. The first point concerns being able to take full advantage of what the budget doubling allowed us to start. In my own lab, the increased funding provided by the doubling allowed the development of a powerful new method we call APEx that allows us to engineer better antibodies.

Antibodies are the hottest segment of the pharmaceutical industry today, with over 20 now approved for the treatment of diseases such as cancer (ex. Avastin and Herceptin, for treating colon and breast cancer, respectively) and rheumatoid arthritis (ex. Humira). Antibodies are even being pursued as a new approach to treating infectious diseases. Antibody drugs represent the new generation of so-called targeted therapies, because they are capable of seeking out and attacking only their intended disease targets with remarkable precision. The result is a much more concentrated therapy, one that avoids many of the serious side-effects of more traditional approaches such as the standard chemotherapeutic agents used to fight cancer.

Our APEx method allows us to take existing antibodies and make them more powerful by factors of 10 or even 100 or more. This can often make the difference

between an effective or ineffective antibody treatment. For example, we started with an antibody against anthrax that could delay but not prevent death in animals exposed to live anthrax spores. After making the original anthrax antibody about 20 times better, our engineered antibody prevented illness and even cured animals treated with the same dose of live anthrax spores. That antibody is being pursued commercially and may soon become a stockpiled countermeasure.

With APEx developed, we need continued strong funding to take full advantage of it. We are ready to start working on engineered antibodies that attack a variety of disorders such as allergies, inflammatory diseases, and cancer. I am very worried that in the current funding climate, our ability to pursue these diseases is going to be severely limited. You can only imagine my frustration at working so hard to develop the means of making a difference, then having limited support to apply it broadly.

I would like to make a second important point, this one concerning basic science breakthroughs. Tight funding as we currently have now has the effect of making grant funding decisions overly conservative. I have been on many NIH funding panels and have seen this phenomenon in action. Right now, only about 10 percent of the grants in my research area receive money, so the panels must choose the "can't miss, sure things" that represent the obvious next steps of research. It is not that the panels are overly conservative, it is just that no panel can reject these proposals because they will almost certainly lead to advances based on the strong scientific foundation upon which they are built. But what about new ideas that are not proven yet? In other words, the ideas that come out of nowhere, establish new paradigms and change the way we think. With such a limited number of grants supported, there is no money in the system for us to work on more speculative projects, ones closer to the leading edge of knowledge. There is also not enough money to fund those scientists who have not yet had the opportunity to generate extensive preliminary results, namely new faculty members.

Scientific breakthroughs rarely come from a research effort aimed at the "can't miss obvious next step". In my experience, our breakthroughs have come when we least expected it while we were exploring beyond the boundary of what we understood well. For example, I want to draw your attention to the cover of the brochure you have been given today. There is an outline of a complicated molecule in the green panel. It is actually a molecule from my laboratory that binds to a large, specific sequence of DNA using an entirely new type of interaction we have named threading polyintercalation. Our molecule is the first reported to bind to the DNA double helix with a topology that can be described as being similar to how a snake might climb a ladder.

This new approach came from a highly speculative project in my lab intended to make an artificial protein, but once we started analyzing the behavior of our molecules, we realized that what we were doing was also applicable to targeting DNA. Although not yet ready for commercial application, imagine a new class of drugs of the future that target the DNA sequences of viruses, bacteria, or cancer cells directly. Talk about getting to the heart of the matter!

Without increased funding, our ability to explore boundaries such as these and make startling breakthroughs is going to be severely limited. True breakthroughs that move science in new directions often take years to turn into a practical new therapy and only occur when scientists are given the freedom to take scientific risks. I am deeply concerned that a lack of money today to explore beyond conservative boundaries will have a crippling effect on medical breakthroughs that will be felt for decades.

As a corollary to this, I am also concerned that the current lack of funding support will take a heavy toll on young scientists in two ways. The most direct is that they will not receive enough funding to launch their careers because there is only enough for the established scientists. As a more indirect effect, I am worried that the bleak funding picture will dissuade the best and brightest from even pursuing a career in academic scientific research.

I would like to finish by describing my concern about science education. I hope all of you understand that the product of NIH research funding to University researchers is not only the research itself, but additionally, the training of students. It is a very simple equation. Limited funding for research now means fewer trained scientists for the future and consequently fewer research breakthroughs for years to come. As a result, I am very concerned that our place as the world leader in medical research is not secure.

I generally accept 3–4 new PhD students in my laboratory every year. My former students now work in academics as professors/researchers or in many companies around the country. With a significantly reduced chance of getting a grant funded, I am forced to take proportionately fewer graduate students. In fact, I am not ac-

cepting a single new graduate student this current year in the antibody engineering lab. The bottom line is that limited funding means we are also limiting the number of students being trained, and I believe our country needs more, not fewer, highly trained scientists to maintain a healthy technology-based economy.

Finally, being on the campus of one of the largest undergraduate institutions in the country, I am acutely aware that NIH research funding has a tremendous impact on large numbers of undergraduates. I have had over 100 undergraduates work in my lab. Across our campus, around 1000 undergraduates will take part in state-of-the-art scientific research, most of it in state-of-the-art labs with NIH funding. The positive impact of this is almost incalculable. Most of these individuals will not go on to become scientists like I did, but they will be able to articulate to the rest of society what science is, and what research means for our country. With every study pointing to the frightening inadequacy of scientific education across our population, a rare piece of good news is undergraduate research. We need leaders in all segments of society who understand science and can make appropriate choices as we chart the increasingly technological future of our country and our world. Again, it is a simple equation. Not enough money for the labs means proportionally fewer undergraduate as well as graduate student research opportunities across the country.

As a University researcher in the prime of my career, I need to see enough money in the NIH budget so that I can take full advantage of what the doubling allowed me to create. There needs to be enough money in the system to help provide an environment that allows risk taking, thus making scientific breakthroughs more likely and allowing young scientists the opportunity to launch their careers. We also need budget growth to continue the essential scientific training of students ranging from undergraduates to PhD's. All of this is essential if the United States is to remain the world leader in both academic and commercial medical research.

Senator HARKIN. Dr. Iverson, thank you very much for that statement.

Now we turn to Dr. Joan. I hope I pronounce that right—Brugge?

Dr. BRUGGE. Perfect.

Senator HARKIN. The chair of the Department of Cell Biology at Harvard Medical School. She received her B.A. in biology from Northwestern, and her Ph.D. in virology from Baylor College of Medicine.

Dr. Brugge, please proceed.

STATEMENT OF JOAN S. BRUGGE, Ph.D., CHAIR, DEPARTMENT OF CELL BIOLOGY, HARVARD MEDICAL SCHOOL, BOSTON, MASSACHUSETTS

Dr. BRUGGE. So, first I'd like to thank Chairman Harkin and ranking member Specter and the members of the subcommittee for this opportunity to tell you about some of the real remarkable advances in biomedical research that have been made possible by your strong support for NIH.

I also hope to convey, as well, my personal excitement for the incredible potential that's still to be realized in my field of cancer research. Unfortunately, this enthusiasm is dampened by my profound concerns that the past 4 years of flat funding has significantly compromised our ability to fully realize this potential.

When I was a sophomore math major at Northwestern University, my sister was diagnosed with a malignant brain tumor. This event, and her subsequent death, redirected me towards a career in cancer research. Most of my career has been spent in universities and medical schools, but, before becoming a professor and then chair at Harvard, I served as the founding scientific director of a biotech company in Boston, and that—the industry experience has significantly shaped my understanding of the critical issues that are involved in translating basic discoveries into clinical therapies for patients.

So, as you're probably aware, in the early 1970s, when I entered cancer research, it was actually a very heady time for science. Many of us expected, on the basis of the success of the polio vaccine and the congressionally mandated war on cancer, that we would very soon have a cure for this horrible disease, but we very rapidly learned that cancer is not just caused by a single agent, and it's not just a single disease, as Mr.—or Senator Specter pointed out earlier. We now know that there are hundreds of different forms of cancer. In fact, each tumor from an individual patient contains a unique set of genetic changes. So, this unexpected complexity, which is really unique to cancer, presented a huge challenge in the development of effective treatments.

So, actually, over the last decade there has been an enormously rapid pace of discoveries on the causes of cancer, but it's really not until recently that I have felt real confidence that the year—the congressional investment in cancer research was going to pay off much more directly to patients.

So, at this time, our fundamental understanding of the causes of this disease, and the molecular underpinnings, have led to substantially new and revolutionary new approaches to treating cancer. So, as you're probably aware, most cancer therapies that are used today are—very nonspecifically target any kind of proliferating cell. So, that's why there are significant toxicities to blood cells and immune cells, to your hair, digestive system. But the recently developed cancer therapies are aimed very specifically at what we now understand to be the very—the unique vulnerabilities of tumors, the so-called Achilles' heel of tumor cells. This is leading to much more effective and less toxic therapies.

You're probably familiar with some of the many examples of effective drug treatments that are targeting these specific subsets of tumors with specific molecular defects. These successes are actually providing a blueprint for application to many more types of cancer.

So, I think what we now foresee that is in the near future, there—we'll have customized therapies for cancer, that will be based on the specific molecular diagnosis of a tumor. So, this is already being done in breast cancer, where each tumor tissue is evaluated for specific markers that will predict whether a specific drug will work or the specific drug will not work. Results are really dramatic, so these drugs are adding years to the lives of patients—and the most aggressive forms of blood cancer—sorry—breast cancer. So, it's an example of the precision medicine that Dr. Zerhouni introduced.

So, these successes are really just the tip of the iceberg. Underneath the surfaces, there's a real foundation for much more rapid pace of breakthroughs in cancer detection and treatment based on the research investment in the past.

So, this, then, brings me to my profound concerns regarding the state of NIH funding today. Four years of flat funding have had a very significant impact on the trajectory of cancer research. We are losing momentum and the dedicated careers that were fueled by the previous investments. We're damaging the research capacity, and this will certainly delay relief from the cancer burden.

So, you've seen the statistics indicating a 20-percent success rate of grant applications. Let me just give you appreciation for what

those mean—those numbers mean to the team of scientists in the research labs.

While the reported success rate is 20 percent, this number actually represents the success of either first, second, or third submission of a grant, or the eventual success. So, what—the actual first rate of—the success rate on first submissions is actually half of that, around 10 or 12 percent. So, basically, 90 percent of the scientists that apply for grants are not receiving them the first time around. So, what does that mean? That means there's at least a lapse in funding, and perhaps the loss of the grant. So, what happens when a lab director fails to get a grant? The—a lapse in funding forces the lab to cut back, they have to let staff go, and now your efforts are redirected on alternate funding and resubmission of the grant, instead of moving forward. So, this not only forestalls progress, but it also creates an atmosphere of insecurity and anxiety, and that actually precludes conduct of a creative, innovative exploration.

Once the scientist does secure funding after this lapse, this requires retrenching and retraining, and—basically, a loss of continuity is probably the most serious problems for a scientist.

Scientists at all levels are being affected, not just at the higher—not just at the lower echelons, but even at Harvard. There's two to four investigators in every department that I surveyed, that has had a significant lapse or loss of grants, that were rated as outstanding by the peer-review group.

The other thing I think it's important to understand is that even if one is successful in getting a grant over one of these three submissions, each grant is getting cut between 20 to 30 percent. So, at NCI in the last year, there was a cut of 24 to 29 percent. So, for instance, a grant that's $200,000 will now get $140,000. That will barely cover the salary of the principal investigator. So, we're now faced with funding labs at levels that are 7—at levels that we have 7 to 10 years ago, just—with—and that's not—and so, we have to deal with inflation at the same time, a 30-percent increase in mandated stipends, and also the much higher cost of new technologies for state-of-the-art research. So, as a result, every grant is severely underfunded and—for achieving the approved goals—and scientists are starving.

As Brent mentioned, the frustration and anxiety of lab directors is not get—is not going unnoticed by trainees. Young scientists are looking for other venues to exercise their talents where their long investment and training won't be jeopardized by the lottery, even at the highest—even for the most outstanding grants. This has profound implications for science of the future, since we won't be able to fill in the gaps of that lost generation.

Then, last, I'd just like to make the point that we really can't afford to stand still, because the demographics are against us. As you're fully aware, in 2030 there will be twice as many Americans over 65 compared to the number today. So, given that there's a 10-times higher incidence of cancer in individuals over 65, there's going to be a virtual tsunami of cancer. This is staggering not only with respect to the personal suffering, but also the cost consequences of the cancer burden on our economy.

So, I feel that investment now could have profound savings later. According to one report, a 1-percent decrease in cancer mortality is reported to be worth $500 billion to our economy.

So, as Geoff Wahl, who's president of American Association of Cancer Research, has pointed out, unlike a real tsunami, which we have no time to prepare for, we are well aware of the impending crisis, and congressional investment in research has positioned us to make much more rapid progress in translating basic discoveries into the diagnosis, treatment, and eventually prevention of cancer. We really owe it to the public to capitalize on these investments.

I'd just like to finish, then, by making the point that it's through your foresight, and those of other members of the committee, that the public has generously provided a start towards eradicating one of the scourges of human health. But now, just as these new therapies, based on our molecular and cellular understanding of cancer, is emerging, the opportunity to expand them to other types of cancer, to build on them, and to provide for a future of more discoveries, has idled. Dr. Neiderhuber shared with me some slides that he just presented to his Board of Scientific Advisors, and there's this long list—long set of—or numerous slides showing missed opportunities he's unable to fund. This included a list of very important projects, resource development, and clinical trials that were canceled because of this cutback. This is very distressing. These cutbacks are going to delay benefit to the public.

PREPARED STATEMENT

So, we can't retreat now that the—our infrastructure is in place, and we're really mobilized to launch a full attack on this disease. So, for the sake of the American people, please find a political route to keep progress against cancer at a sustainable pace. The research findings are clear, there is a path to major advances. Help us get these advances to the public and fulfill the promises of the best in scientific research.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. JOAN S. BRUGGE

First, let me thank Chairman Harkin, ranking member Specter, and members of the committee for this opportunity to report to you some remarkable advances that have occurred in biomedical research because of your strong support for NIH. I hope that I can convey as well my personal excitement for the incredible potential still to be realized in my own field of cancer research. Unfortunately, this enthusiasm is dampened by profound concerns that the four years of flat funding has compromised significantly our ability to fully realize this potential.

When I was a sophomore math major at Northwestern University, my sister was diagnosed with a malignant brain tumor. This event and her subsequent death redirected me towards a career in cancer research. Most of my career has been spent in universities and medical schools. However, for five years before I came to Harvard Medical School, I served as the Scientific Director of a biotechnology company focused on cancer and other diseases. My industry experience significantly shaped my understanding of issues critical to the translation of scientific discoveries into therapies for patients. It taught me among other things, that though the path to treatment can be arduous, today the path between basic discovery and successful drugsalso can be remarkably short.

The early 70's, when I entered cancer research, was a heady time in science. Many of us expected, based in part on the success of the polio vaccine and the Congressionally mandated War on Cancer, that we would soon have a cure for this horrible disease. However, it soon became evident that cancer, unlike polio, is not a sin-

gle disease with a single cause. There are hundreds of different forms and, indeed, tumors from individual cancer patients carry unique sets of genetic changes. This unexpected complexity—unique to cancer—precluded rapid development of a single vaccine or simple cure.

Though we certainly underestimated the complexity of cancer, the Congressional investment in cancer research is now beginning to pay off. We have made enormous progress in understanding the cause of this disease and its molecular underpinnings. This fundamental information has led to revolutionary approaches to treatment, aimed specifically at the unique vulnerabilities of specific tumors; we now know how to target a tumor's genetic or molecular Achilles' heel. In addition, new imaging modalities and biomarkers provide the potential to identify tumors at early stages when treatments are most effective.

Today, I feel a new confidence that we are poised to make rapid progress in developing effective and less toxic treatments for the myriad different cancers. This confidence is based on initial evidence of success. We now have multiple examples of effective treatments that target the molecular alterations of specific subsets of tumors (such as Tarceva for a subset of lung tumors, Gleevec for chronic myelogenous leukemia, and Tykerb, approved just a week ago for treatment of certain breast cancers). These successes provide a blueprint for the development of treatments for many more types of cancer.

Cancer treatment in the future will involve a molecular diagnosis of each tumor, followed by customized therapies. Already this is being done for breast cancer, in which tumor tissues are probed for several markers that predict which tumors will respond to specific drugs (like Tykerb, Herceptin, or estrogen antagonists) and which will not. The results are dramatic, adding years to the lives of many patients with the most aggressive forms of breast cancer, and sparing patients of treatments that offer no promise of efficacy. For the first time, we are seeing a decrease in deaths associated with cancer. The tip of the iceberg is visible, underneath lies the foundation for a rapid pace of breakthroughs in cancer detection and treatment based on the research investment in the past.

We cannot afford to stand still—the demographics are against us. There is an impending increase in cancer due to the baby boomers aging into their cancer-prone years, which has been referred to as an impending tsunami. You are all keenly aware of the ramifications for government of Medicare entitlements associated with this surge in cancer. But unlike a real tsunami, which comes unexpectedly with no time for preparation, we are well aware of this impending crisis. And We know that the Congressional investment in basic and cancer-focused research has positioned the cancer research community to make more rapid progress in translating basic discoveries into the diagnosis, treatment, and eventually, prevention of cancer. We owe it to the public to capitalize on these investments; failure to maintain the pace of advancement towards reducing the suffering of cancer is not an option the American people should support or will support. We are all in this together.

This brings me to my profound concerns regarding the state of NIH funding today. Four years of flat funding have had a devastating impact on the trajectory of cancer research. We are losing the momentum and the dedicated careers that were fueled by the previous federal investments. We are now damaging the research infrastructure, and this will certainly delay relief from the cancer burden.

While you have seen the statistics regarding grant awards presented by Dr. Zerhouni and others at NIH and are aware of the inflationary erosion of our buying power, the mere numbers mask the profound effects on the research community. I would like to give you an appreciation for what these numbers mean to the cancer research community, which is emblematic of the whole research enterprise. While the eventual success rate of grants is 20 percent, this number reflects success of either the first, second, or third submission of a grant. The success rate of the first submissions is now about half of this; thus the vast majority of scientists are subjected to a lapse in funding and the negative consequences of this. Not only can a lapse in funding force labs to cut back, let staff go, and redirect efforts to finding alternative funding and resubmission, it creates an environment of insecurity and anxiety that is anathema to the conduct of creative, innovative exploration. Recovery after a 6–12 month funding gap requires retrenching and retraining of new staff. Many leads will never be followed up. Loss of continuity is one of the most serious problems for a scientist. For new investigators, repeated failure to launch their research program is also demoralizing, and discourages taking original and risky paths.

Researchers at all levels are affected—those beginning their careers and senior investigators with long and sustained track records of major discoveries. For example, multiple colleagues at Harvard Medical School who are leaders in their field with outstanding accomplishments, are suffering lapses in funding or losing grants that

received priority scores in the 10–20 percentile range. Peer review is too imprecise to distinguish differences in the quality of the grants in this tight range.

Second, in order for the success rate of grants to hit the mandated target number of grants, NIH has resorted to cutting grant size dramatically—at NCI, 24–29 percent (2006). Aggravating this situation are reductions in buying power due to inflation and the 30 percent increase in mandated stipends for graduate students and postdoctoral fellows over the past seven years (an increase that we applaud). Lab directors are faced with carrying their labs at funding levels equivalent to those 7–10 year years ago, at a time when there is a significant increase in cost of the new technologies required for state-of-the-art research. As a result, almost every grant is severely under-funded for achieving the approved goals, and scientists are starving for resources.

The frustration and anxiety of lab directors is not going unnoticed by trainees, and many young scientists are looking for other venues to exercise their talents, ones where their long training investment will not be jeopardized by this lottery in NIH grant review. This has major implications for the science of tomorrow, since we will not be able to fill in the gaps of this lost generation.

I would like to reiterate the long-term implications of the current research budget shortfall on the economy. Cancer incidence for those 65 and older is 10 times greater than for those under 65, and the death rate is 16 times higher. By 2030, 20 percent of the U.S. population will be over age 65 compared with 12 percent in 2004. The cost consequences of this tsunami of baby boomers hitting their cancer-prone years could devastate our economy.

A one percent decrease in cancer mortality is reported to be worth $500 billion to our economy according to an NCI report. Getting these potential new therapies I have outlined to patients will take a significant new investment in translational and clinical research, the cost of which can dwarf the cost of basic research. But without the most promising basic discoveries, we will not be able to improve early stage therapies and more and more translational and clinical endeavors will result in dead ends. We can't be shortsighted.

We recognize the challenges each member of Congress faces in balancing worthy priorities, but I can assure you that from a scientific perspective there is justification for fully supporting basic, translational, and clinical pursuits. Basic science now more than ever fuels the success of effective disease diagnosis, treatment, and prevention in the future.

Through the foresight of the members of this committee and others, the public has generously provided a start toward eradicating one of the scourges of human health. We are in fact in a better place to detect, treat, and potentially, prevent cancer. But just as new therapies based on our cellular and molecular understanding are emerging from our labs, the opportunity to expand them to other types of cancer, to build on them, and to provide for a future of more discoveries has idled. We can't retreat now that the infrastructure is in place and we are mobilized to launch a full force attack on a disease that we now understand. For the sake of the American people, please find a political route to keep progress against cancer at a sustainable pace. The research findings are clear. There is a path to major advances in cancer detection, diagnosis, therapy, and prevention. Help us get those advances to the public and fulfill the promises of the best in scientific research.

Thank you for your time,

Senator HARKIN. Thank you, Dr. Brugge.

I now will turn to Dr. Robert Siliciano, professor of medicine and molecular biology and genetics at the Johns Hopkins University School of Medicine. He received his A.B. degree in chemistry from Princeton, his M.D. and Ph.D. from the Johns Hopkins University School of Medicine.

Dr. Siliciano, welcome, and please proceed.

STATEMENT OF ROBERT SILICIANO, M.D., Ph.D., PROFESSOR OF MEDICINE AND PRINCIPAL INVESTIGATOR, HOWARD HUGHES MEDICAL INSTITUTE, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE, BALTIMORE, MARYLAND

Dr. SILICIANO. Mr. Chairman, thank you for inviting me to testify at this important hearing.

Let me begin by commending you and Senator Specter for your foresight and efforts to double the NIH budget between 1998 and

2003. As Dr. Zerhouni pointed out, we are on the cusp of a dramatic transformation in healthcare, which is the direct result of the Nation's investment in health science. I'm pleased to share with you my own experiences about this transformation and the vital role of funding basic research.

When AIDS first appeared, in 1981, we had no idea what we were dealing with. Between 1981 and the present time, scientists have identified the virus responsible, deciphered its generic code, elucidated its lifestyle, developed a blood test, licensed 22 antiviral drugs, and learned a great deal about human immunology. A uniformly fatal disease has been transformed into one that can now be managed effectively with antiretroviral drugs. A recent study suggests that at least 3 million years of life have been saved in the United States alone as a result of these treatments.

These remarkable advances have come directly from basic science research. Many of the big advances came in the last decade. Many were funded by the NIH. The doubling in funding was central to much of that work. Yet we do not have a vaccine or a cure, and we're now struggling to cope with an epidemic of drug-resistant HIV.

My laboratory, and Tony Fauci's lab at the NIH, have discovered how HIV hides in the body and escapes from the drugs that are being used to combat the infection. We've found that HIV can persist indefinitely in a latent state in long-lived cells of the immune system. In these cells, the HIV genome, is embedded into the host-cell DNA. As a result, the infection can never be cured by antiretroviral therapy alone. This discovery has changed the overall treatment paradigm from a hit-early-hit-hard approach aimed at eradication to a more conservative approach aimed at maintaining lifelong control of viral replication.

In addition to serving as a barrier to cure, this latent reservoir, as we call it, can also store drug-resistant HIV, so that if a patient develops resistance, they will always have that resistance.

Right now, drug resistance is the dominant problem in treating HIV. At our clinic in Baltimore, half of the 3,000 patients have multidrug-resistant HIV, and 10 percent of the new infections are with drug-resistant HIV. In developing countries, the problem of resistance is likely to become even more serious.

Now, many laboratories would like to pursue studies on how to eliminate this latent reservoir and how to control drug-resistant HIV, but, due to flat NIH budgets, research efforts are being scaled back. In my own lab, we're having difficulty taking on new student, and beginning new projects. In the past, I spent about 30 percent of my time applying for grants. Now it's up to 60 percent. Prominent investigators that I know in the field are getting out of research altogether. Fewer scientists want to tackle high-risk problems like this, because they know this kind of research will be difficult to fund.

A colleague of mine has made a major discovery on a unique group of patients who control HIV without medication, has been unable to get funding.

Although we have drugs that can control viral replication, we don't even know when therapies should be initiated. The definitive study of when therapy should be started may not be funded. Why?

Because of insufficient funds for vaccine and treatment trials due to competition for diminishing NIH dollars.

This is particularly unfortunate, because the return on NIH investment can be fantastic. For example, the discoveries made by AIDS researchers extend well beyond HIV. The discovery of how to evaluate levels of virus in the blood has revolutionized the treatment of patients with hepatitis B and hepatitis C infection, and will eventually be applied to all viral infections, including influenza.

At Johns Hopkins, we've seen a marked decline in the level of research grants awarded. Fewer projects are being funded, and NIH support for ongoing projects is being cut. In 2002, the average funding per grant was approximately $142,000 for the School of Medicine; by 2006, it had dropped to $92,000, a decline of 34.8 percent.

America's young researchers are being hit the hardest. I fear that we may lose a generation of inquisitive, enthusiastic scientists if they conclude that NIH funding is out of reach. According to the NIH, 8 out of 10 grant applications are turned down. This is a recipe for disaster.

The situation extends well beyond healthcare. Federal investment in biomedical research is also critical to U.S. competitiveness.

The United States has long been regarded as the world leader in scientific discovery, thanks, in large measure, to policies that encourage innovation. But today we face serious threats to this preeminence, as Dr. Zerhouni has mentioned. Other nations bring strong educational systems, focused government policy, and low-cost workers. Asia and Europe are committing unprecedented resources to scientific—to science and engineering.

PREPARED STATEMENT

Basic science research is essential to America's ability to meet this challenge. In the United States, funding for basic research has long been a Government function. Why? Because basic research much be sustained for years, and even decades, sometimes with no discernible immediate return on the investment. No other entity, other than Government, can take on this role. Aggressive, stable, and sustained Federal spending on NIH and on biomedical research much be understood and embraced as a critical component to America's competitiveness.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. ROBERT SILICIANO

INTRODUCTION

Mr. Chairman and members of the Committee, thank you very much for inviting me to testify today at this important hearing. I am Robert Siliciano, and I am a member of the Department of Molecular Biology and Genetics at the Johns Hopkins University School of Medicine.

Let me start by commending you, Mr. Chairman and Senator Specter, for your efforts and foresight in doubling the National Institutes of Health (NIH) research budget between 1998 and 2003. Many of the amazing advances in health care treatment today are the result of federal investment in research identifying early indicators and causes of diseases. I am convinced we are on the cusp of a dramatic transformation in health care, which is a direct result of the nation's investments in

health science discovery and cures. My fellow researchers on the panel and I are pleased to be here today to tell you about this transformation.

On behalf of myself and all my colleagues at Johns Hopkins, I would like to recognize the persistence of many on this committee for your ceaseless support of NIH's work. I would also take this opportunity to invite you to visit our campus in Baltimore to see for yourselves the exciting work that my colleagues and I—not to mention our students—engage in every day. You will find no more persuasive argument for the value of investing in research than witnessing innovation firsthand.

NIH SUPPORT FOR MY WORK ON HIV/AIDS

Early in the AIDS epidemic, an AIDS patient could expect to enter hospice care within a few years after the diagnosis. However, significant research developments in the area of "Highly Active Anti-Retroviral Therapy," or HAART—that combination of drugs commonly referred to as the "AIDS cocktail" has lead to increasing the survival rate of those diagnosed with HIV. This therapy involves a variety of drugs that attack the virus at different stages of its life cycle, thus reducing its ability to replicate itself in healthy cells. HAART combines drugs that were developed during some of the first stages of AIDS research. By 1990, monotherapy—treatment using one nucleoside analog—was showing some promise, but debate persisted in the research community as to which of this class of drugs were the most useful. In 1995, studies showed that treatment with simultaneous use of two nucleoside analogs would prove more effective in prolonging life. By 1997, combination therapy had expanded to include protease inhibitors and non-nucleoside reverse transcriptase inhibitors, both classes of drugs that attack HIV as it attempts to insinuate itself into healthy cells.

The result of HAART has been the transformation of AIDS from a disease that meant rapid and certain death to a chronic condition that can now be managed over a patient's lifetime. When widespread use of HAART began in the mid 1990s, U.S. mortality rates immediately plummeted—from nearly 41,000 in 1995 to 17,000 in 1997. HAART even proved effective for patients who had already reached the terminal stages of the disease; many were able to leave hospice care and return to relatively normal lives.

For the more than 40 million people infected with HIV, the best current hope for avoiding the fatal consequences of the infection lies in treatment with HAART. The benefits of HAART in reducing mortality are clear, but major questions remain about how best to use HAART and how to make it available to all who need it.

Our work has shown that current HAART regimens cannot cure the infection in most patients because the virus persists in a very stable latent reservoir in resting memory CD4+ T cells (cells that control the activities of all of the other cells). Because HAART is not curative, treatment of HIV infection is a lifelong challenge. Most infected individuals will ultimately have to depend upon HAART to avoid fatal immunodeficiency. Problems of drug resistance and drug toxicity make this an alarming prospect.

My lab is interested in understanding viral persistence and in applying basic studies of viral dynamics in HIV infection to optimizing antiretroviral therapy. Our work on viral persistence began in 1994, with the idea that the capacity of HIV to establish a state of silent or latent infection at the level of individual cells might provide a mechanism for viral persistence in the face of immune responses and antiretroviral therapy. We hypothesized that HIV might capitalize on an extremely fundamental aspect of the immune system, immunologic memory, to ensure its persistence in the host.

At any given time, most of the lymphocytes in the body are in a resting state. When a lymphocyte encounters a bacterial or viral protein that it is programmed to recognize, it becomes activated and begins to proliferate, generating effector cells that eliminate the invading microorganism. Most of these effector cells die, but some survive and return to a resting state as memory cells. These cells persist indefinitely, allowing effective responses to future challenges with the relevant microorganism.

HIV preferentially infects activated CD4+ T lymphocytes, inserting its genetic information into the genome of the host cells and directing the production of new virus particles in a process that usually leads to the death of the infected cells. However, a small subset of the activated CD4+ T cells that are infected with HIV survive long enough to revert back to a resting memory state. Because the expression of HIV genes depends on host transcription factors induced in activated T cells, viral gene expression is automatically extinguished when these cells return to a quiescent state. The result is a stably integrated but transcriptionally silent form of the HIV genome in a memory T cell, a cell whose function it is to survive for years in a qui-

escent state. Upon subsequent re-exposure to the relevant microorganism, the latently infected cell is reactivated and becomes competent for HIV gene expression and virus production. Over the past several years, we have been able to demonstrate the presence and persistence of latently infected resting memory CD4+ T cells with integrated HIV DNA in infected individuals. The cells are present only at low frequencies, reflecting the fact that most productively infected CD4+ T cells die before they can revert back to a resting memory state. Particularly important is whether this small reservoir of latent virus persists in patients on HAART. In the years following the advent of HAART, which began in the mid-1990s, there was considerable optimism that virus eradication might be possible with prolonged treatment, based on analysis of the rapid decay of plasma virus to undetectable levels following the initiation of HAART.

We have shown, however, that the frequency of latently infected cells does not decrease even in patients on HAART who have had suppression of viremia to undetectable levels for as long as seven years. As a result of this discovery in 1999, the overall approach to the treatment of HIV infection has significantly changed. In particular, it became more conservative. Patients were no longer started on therapy as soon as they were diagnosed. Initiation of therapy was delayed until later stages of disease, since there was no hope of eradication. This work raised the possibility that the virus could persist indefinitely in all patients on HAART, leading many investigators to question the wisdom of beginning aggressive therapy with the goal of eradicating the infection, particularly in light of the substantial long-term toxicities of HAART regimens.

Several additional findings add to the seriousness of the problem presented by the latent reservoir. We have shown that this reservoir is a permanent archive for drug-resistant viruses that are generated by inadequate treatment. Once drug-resistant viruses have entered the reservoir, they persist there indefinitely, permanently restricting the patient's therapeutic options. The problem of stored drug-resistance mutations is particularly severe in the case of perinatally infected children, who face a lifetime of treatment.

In 2000, we demonstrated the presence and persistence of this latent reservoir in these children. In addition, we have demonstrated that latency operates at the transcriptional level. Latently infected cells carry integrated HIV DNA but contain little translatable HIV RNA. Unfortunately, the last hope for detecting and targeting latently infected cells was that the cells might be expressing low levels of particular viral proteins, allowing recognition by immune effector mechanisms. It now appears that we may be dealing with a completely silent form of latent infection that will be difficult to target with antiretroviral drugs or HIV-specific immune responses. These findings apply not only to children but to all HIV patients.

In 2001, we became interested in understanding the nature of the low-level virus production that continues in patients on HAART whose plasma virus levels are below the limit of detection of standard assays. We have developed methods for cloning and characterizing the extremely low levels of plasma virus that are present in such patients. We have shown that this virus is generally archival in nature, is devoid of new drug-resistance mutations, and may be derived from the activation of latently infected cells. Most importantly, we do not see evidence for the continued evolution of drug resistance in most patients on suppressive HAART regimens. This provides a counterpoint to our disheartening findings on the stability of the latent reservoir. Although current HAART regimens cannot produce eradication because of the extraordinary stability of the latent reservoir, they can largely halt virus evolution, affording patients the possibility of lifelong suppression of viremia if the problem of drug toxicity can be overcome.

It is important to point out that despite the spectacular advances that have been made in anti-retroviral therapy—at least 3 million years of life have been saved in United States alone—the definitive study that would allow us to determine when exactly treatments should commence may not be funded because of insufficient funds for vaccine and treatment trials. An unfortunate tension exists due to this competition for diminishing NIH dollars.

It is also worth pointing out that the discoveries our community of researchers have made extend well beyond HIV. What we have learned from studies of HIV can be applied to other viruses. For example, we have learned how to measure the amount of virus in the blood. This knowledge, which has provided us with a real-time measure of the amount of viral replication in a patient, along with the importance of utilizing it to treat viruses such as influenza and Hepatitis B and C, has revolutionized the success of these treatments.

In the future, we hope to address several critical questions related to the molecular mechanism of HIV latency and the clinical implications of this form of viral persistence. We are interested in whether it will ever be possible to eliminate this

reservoir. Furthermore, we hope to translate our findings on mechanisms of viral persistence into new approaches for optimizing antiretroviral therapy. The correct choice of a HAART regimen is literally a matter of life and death for many patients, and we feel basic studies of viral persistence can be applied to improving decisions about how and when antiretroviral therapy should be given. Over the years, this research has received nearly $7 million in support from the NIH.

I want to emphasize that many labs would like to pursue the problem of how to eliminate the latent reservoir, but everyone I know has had to scale back research efforts because of flat NIH budgets. In my own lab we are now finding it difficult to take on new staff and begin new projects. Typically, in the past, I would spend about 30 percent of my time applying for grants; now about 60 percent of my time is spent preparing applications. Furthermore, some prominent investigators are getting out of research. Few scientists want to tackle high-risk problems like this because research of this type is more difficult to fund. In fact, a very good colleague of mine has made a major discovery on a unique group of patients who control HIV without medication. He has not been able to get funding even though the potential savings is more than $14,000 annually per patient. Additionally, a mentor of mine, and one of the most respected people in the field, is thinking of getting out of research because he has no funding.

FEDERAL INVESTMENT IN RESEARCH IS A CRITICAL COMPONENT OF OUR NATION'S COMPETITIVENESS

The United States has long been the world leader in scientific discovery, thanks largely to government policies that encourage innovation, improve education, and facilitate the transfer of knowledge from the laboratory to the marketplace. Today we face serious threats to this preeminence. Other nations bring to the table strong educational systems, focused government policies, and low-cost workers.

Basic research is essential to our ability to meet this challenge. William R. Brody, president of The Johns Hopkins University and co-chair of a national committee on competitiveness, puts it this way: "Knowledge drives innovation. Innovation drives productivity. Productivity drives economic growth." Our ability to compete in the global economy depends, first and foremost, on our ability to continue making new discoveries. The more we learn about how things work—the principles of basic biology, chemistry, physics, and mathematics—the more opportunity we have to put that knowledge to work. When we know more, we can use that knowledge to make our world better, to build new businesses, devise new products, and to improve our standard of living.

America's most innovative industries are built on decades of basic research, research that had no discernable practical application at the time it was undertaken. For example, the highly theoretical world of quantum mechanics spawned the semiconductor industry and the information revolution. Johns Hopkins scientists thinking about the principle of physics, called the Doppler effect, used it to invent what became today's Global Positioning System. Two Johns Hopkins biologists shared a Nobel Prize in 1978 for using restriction enzymes to cut DNA into fragments that created today's thriving biotechnology industry, which is based on genetics.

In the United States, funding basic research has long been a governmental function. Why? Because it takes a long time to do it, because there is always a risk that any single project will come to nothing, and because it is difficult to capture an immediate return on investment for an idea that has not yet been developed to the stage of a marketable invention.

Despite a societal consensus that basic research is a government responsibility, U.S. Federal research and development spending, as a percentage of Gross Domestic Product (GDP), peaked 40 years ago in 1965, at just below 2 percent of GDP. In the past 40 years, that percentage has diminished by more than half, to about 0.8 percent of GDP. Overall R&D spending, especially in basic sciences, continues to decline. We must reverse this trend now, by strengthening the Nation's commitment to science related federal agencies and departments.

The investments in biomedical research being made by rising economic powers such as China are increasing. While China lacks a central institution like the NIH to oversee its national investment in biomedical research, its National Science and Technology Plan for 2006–2020 emphasizes a long-range strategy to raise its biomedical research to world-class standards. This is being supported by a pledge to raise R&D spending from 1.3 percent of GDP in 2005 to 2.5 percent by 2020 (Science 9 March, 2007: Vol. 315. no. 5817).

If we look to one promising field of the future—that of nanotech—overall government spending globally grew by 10 percent to $6.4 billion in 2006. According to a report released by Lux Research, the United States came out on top, with $1.78 bil-

lion, followed by Japan and Germany. But China actually ranks second when purchasing power parity is considered. China's funding is the equivalent of $906 million. (UPI 9 March, 2007). In this sector, like so many others, China will compete.

The life sciences research funded by the NIH is a key component of our overall national science agenda. For example, Johns Hopkins University is the nation's leading recipient of federal research grants. In fiscal year 2005, our researchers attracted nearly $1.3 billion in federal R&D funding and $1.4 billion in overall R&D funding, a category in which Johns Hopkins has led all U.S. institutions for 27 consecutive years. This support enables us to improve medical care worldwide, advance human knowledge, and train new generations of innovative researchers.

Investment in research universities like Johns Hopkins yields tangible economic benefits as well. In 2006, Johns Hopkins researchers filed more than 420 U.S. patent applications, received 79 U.S. patents, and licensed 72 technologies for commercial development. Some of these inventions will be commercialized by Maryland companies. Already, there are at least 19 existing Maryland-based start-ups bringing Johns Hopkins technology to market. That is a tremendous amount of knowledge made available to American business and the American public for an incalculable range of benefits.

While the President and Congress have embraced the notion that funding for basic research in the physical sciences is essential to strengthening America's competitive standing in the world, and Johns Hopkins certainly recognizes and appreciates the significant investments included in the fiscal year 2007 Continuing Resolution, we remain concerned that funding for biomedical research has not kept pace with this commitment. Aggressive, stable, and sustained federal spending on the NIH and biomedical research must be understood and embraced as a critical component of America's competitiveness.

JUSTIFICATION OF NIH FUNDING

On January 15, 2007, President Bush signed the National Institutes of Health Reform Act of 2006. While the law calls for a 6 percent increase for fiscal year 2007 and an 8 percent increase for fiscal year 2008, the reality is that this funding commitment has not fully materialized. For fiscal year 2006, the NIH budget was cut in both nominal and real terms. For fiscal year 2007, the NIH received a modest yet important increase of approximately $620 million. We are very grateful that this Congress chose to single out the NIH, along with several other science agencies, to be among the few areas of federal spending to receive increases. We recognize that budgets are tight and we see this as a critical statement of Congress' desire to strengthen and preserve the scientific enterprise in this country. Despite this increase, however, fiscal year 2007 marks the fourth year in a row, when adjusting for inflation, that NIH funding has been cut.

At Johns Hopkins, we have annually led the nation in NIH research dollars and we have seen a marked decline in grants awarded to our School of Medicine. Fewer projects are being funded and NIH support of on-going investigations is being cut. Recent figures suggest that the number of grants and overall funding levels have declined. In fiscal year 2002, the average funding level per grant was $142,210 for the School of Medicine. By fiscal year 2006, the funding level dropped nearly $50,000 per grant to $92,683, a decline of 34.8 percent. Hardest hit are America's young researchers. I fear that we may lose a generation of enthusiastic, inquisitive scientists if they conclude that NIH grants are out of reach.

FLAT FUNDING THREATENS OUR YOUNG INVESTIGATORS

One of the first and earliest victims of declining NIH funding has been the young investigator. You have heard today, and often over the past several years, from Dr. Zerhouni regarding NIH's concern that we are potentially sacrificing an entire generation of young scientists. The Director's concern is real and very serious.

Quite simply, we have to do more to support and encourage our young investigators. Most ideas that turn into Noble Prizes come from investigators before they reach the age of 40. As a country, then, shouldn't we be supporting these scientists when they are in their professional prime? Unfortunately, the statistics tell an entirely different story. In the case of initial R01/R29 awards, between 1970 and 2004, the average age by which an investigator with a Ph.D gains his or her first award has gone from 34.3 years of age to 41.7. In the case of MDs, during this same period, that age has gone from 36.7 years to 43.3 (AAMC 12 July, 2006). With diminished NIH funding, our young scientists are witnessing firsthand the decline in overall success rates for grant applications. In 1998, the first year of the doubling, overall success rates were about 31 percent for grant submissions. For 2007, the success rate is projected to drop to only about 19 percent. Left unaddressed, there

is no question that the current decline in NIH funding places an entire generation of young scientists at risk.

Even at my own institution, where we have many of the best and brightest among the current generation of young scientists, we are seeing many of these men and women unable to gain funding support. Without sustainable and predictable increases in NIH funding, this nation is at risk of losing an entire generation of scientists.

RESEARCH IMPACTS HEALTH CARE COSTS

When advocates for increasing biomedical research funding meet with members of Congress and their staff, they are often asked: "What have we to show for the money that NIH has received in the past?" As we think about this question, it is important to recognize that the pace of biomedical research and science in general is often slow and unpredictable. It may be years before we can point to specific therapies or new medical devices that can trace their origins to recently funded efforts. But the simple answer is: We have a great deal to show!

Here are three powerful examples—there are, of course, many more—of what Johns Hopkins scientists have accomplished in terms of improving healthcare and reducing costs, thanks to NIH support.

Detection of Vision Problems of Diabetics

Diabetes is the leading cause of blindness in adults, with 12,000 to 24,000 new cases each year. Early identification of retina disease is critical to stave off vision loss, especially for the 10 million diabetics who are 60 years or older, most of them on Medicare or Medicaid. Yet more than half of all diabetics fail to get an annual eye exam as recommended by the American Diabetes Association. To address this dilemma, Dr. Ran Zeimer, director of the Ophthalmic Physics Laboratory at the Johns Hopkins Wilmer Eye Institute, came up with a novel solution after more than a decade of research: Why not develop an easy-to-use digital camera that tests for retinopathy when diabetics visit their primary care physicians for check-ups?

Thanks to NIH support, Dr. Zeimer perfected an instrument called the DigiScope. The DigiScope takes images of the retina in just minutes as patients sit in front of an automated camera and look at a series of blinking lights. These images are then transmitted via the Internet to a reading center for expert interpretation. More than 20,000 individuals not under the care of an ophthalmologist have been screened to date in the offices of primary care physicians. Those with vision-threatening disease have been identified and referred to eye specialists. In most cases, diabetics without complications are spared visits to an ophthalmologist, while Medicare and Medicaid are spared an expense.

Advances in Treatment for Sickle Cell Patients.

Thanks to continuous NIH grants extending back to 1982, Drs. George Dover and Samuel Charache of Johns Hopkins spent their careers fighting sickle cell disease—a miserable, inherited illness in which sickle-shaped red blood cells get stuck in narrow channels and block blood flow to tissue and vital organs. Patients with sickle cell disease—72,000 in the United States—suffer frequent bouts of fatigue and shortness of breath, joint and body organ pains that turn excruciating and lead to frequent hospitalizations. The pneumonia-like conditions, chest pains, and fever can be life-threatening. Until fairly recently, early death was the norm, with life expectancy for a sickle cell patient projected to be only 20 to 30 years.

In the 1990s, Drs. Dover, Charache, and their Hopkins research team found that a cancer drug (hydroxyurea) did remarkable things for sickle cell sufferers. A 1995 NIH-supported multi-center study proved that hydroxyurea therapy dramatically reduces the frequency and severity of painful episodes, hospitalizations and transfusions. In a 2003 study, daily doses led to 30 percent fewer hospital days, 58 percent fewer transfusions, and a 40 percent reduction in deaths. Today, hydroxyurea therapy is recommended for adults and adolescents with moderate-to-severe recurrent pain. As a result, the life expectancy for sickle cell patients has doubled.

There have been financial benefits, too. According to another NIH-sponsored study, hydroxyurea therapy saves the U.S. health care system $5,210 per sickle cell patient per year. With 72,000 Americans suffering from sickle cell disease, the potential annual savings is more than $375 million annually.

Faster Diagnoses in Emergency Rooms

With the existing threat of bioterrorism, it is crucial to find ways to swiftly identify patients in hospital emergency rooms who have biochemical pathogens or life-threatening infectious diseases, such as meningitis, sepsis, and bacterial endocarditis (an infection of the inner lining of the heart or heart valves). Current test-

ing methods are time-consuming and usually lead to delays in diagnosing and treating these diseases. The current blood and culture tests for some diseases can take 24 hours or more.

Dr. Richard E. Rothman of the Johns Hopkins Department of Emergency Medicine is working on novel ways to identify quickly multiple blood-borne and pulmonary infectious diseases and bioterrorism pathogens. His patented molecular diagnostic tests involve both exhaled breath and body fluids. Early experiments have shown that these new diagnostic tools can detect 25 common bacterial infections and five categories of bioterrorism agents in fewer than 4 hours. Faster response times are expected as the diagnostic tools are fine-tuned.

CONCLUSION

Thank you for your efforts to strengthen America's biomedical research community. Johns Hopkins stands ready to support you in this important endeavor. I invite you and your staff to visit our campuses, explore our facilities, and meet our researchers who are taking the lead in these vital fields.

Senator HARKIN. Dr. Siliciano, thank you very much. I'll have some questions about the drop in GDP, also.

Now we'll turn to Dr. Stephen Strittmatter, professor of neurology and neurobiology at Yale University School of Medicine. Dr. Strittmatter earned his undergraduate degree from Harvard and his M.D. and Ph.D. degrees at Johns Hopkins.

Dr. Strittmatter?

STATEMENT OF STEPHEN M. STRITTMATTER, M.D., Ph.D., PROFESSOR OF NEUROLOGY AND NEUROBIOLOGY, YALE UNIVERSITY SCHOOL OF MEDICINE, NEW HAVEN, CONNECTICUT

Dr. STRITTMATTER. Chairman Harkin, I thank you for the opportunity to share some of my thoughts on NIH-supported science and the NIH budget.

To be frank, my three decades in clinical neurology and basic neuroscience have convinced me that the recently flat NIH budget is stifling creative high-risk research. On the one hand, the doubling of the NIH budget that was provided by Congress and championed by you and the rest of this subcommittee has laid the foundation for fantastic advances, revolutionizing the care of patients with nervous-system diseases; however, for most types of neurologic and psychiatric diseases, we still face a crucial hurdle: the translation of basic molecular analysis of brain function into effective treatments. To leap over this translational hurdle requires the most creative and risk-taking experiments, including those that may lead to an experimental dead-end before achieving a critical insight towards a new therapy.

Regrettably, the decline of inflation-adjusted NIH spending in recent years has produced a marked chilling effect specifically on this type of research. If that's not reversed, we're going to fail to reap the full benefits of the expansion that occurred from 1998 to 2003 in research in the United States.

My own field in neuroscience relates to nerve-fiber growth and provides one example of how high-risk research can succeed when the environment is appropriate. In humans, single nerve cells extend fine threads, called axons, for very long distances, up to 3 feet. You can imagine, if the cell body were blown up to the size of a baseball, the axon would be the width of a pencil and extend for half a mile. When all these nerve fibers are correctly connected, this provides the wiring of the brain, and the function of the brain is critically dependent on all this being connected correctly.

During the 1990s, molecular insights into the basis of axon guidance advanced very rapidly. We identified dozens of axon guidance molecules and genes that help put the brain together. These molecular insights were fascinating, but they didn't immediately improve human health. So, the next step was to apply this knowledge to settings of neurologic injury, where axonal disconnection occurs. The clearest example of this, one—a field that I work in—is traumatic spinal cord injury. Despite the profound, and the persistent, neurologic deficits that occur after spinal cord injury, such as the inability to move or feel below the level of the injury, nearly all of the nerve cells remain intact. The primary cause of disability is the disconnection of one nerve cell from another, not the loss of cells. Very little axon regrowth occurs after injury, and this is why there's very little recovery in adults.

So, here's the translational problem, the hurdle, to overcome. How do we use basic knowledge about axon growth to restart—during development—how do we use that to restart adult axon growth, repair function, and recover ability of people to live a productive life? It's certainly a problem that I wanted to take on as a neurologist caring for patients while running a basic developmental laboratory. However, without the sort of environment that was created by the budget doubling through the NIH funding, I wouldn't have tackled this problem myself. But when I did take it up, in that time period, we discovered, in my laboratory, a molecule, termed Nogo, that prevents nerve fiber growth. By analyzing the mechanism of action of this Nogo molecule, we identified genetic, and then pharmacologic means to prevent its function; thereby, stimulating nerve fiber growth. Remarkably, therapy with a Nogo receptor antagonist allows rats to walk after spinal cord injury or to recover better paw use after a stroke. Today, a closely related approach using an antibody against Nogo is in clinical trials.

So, I think this illustrates how high-risk research can occur. But I'm convinced that similar challenges in Alzheimer's or in schizophrenia research are not being tackled today, because of the limitations that have occurred in the NIH budget. The reason I say that is that when researchers and peer-review panels are faced with the idea that junior investigators can't be funded at all, or that senior investigators are losing funding, everyone shifts towards what I'd call "safe science." Scientists pursue those experiments that have the highest probability of success in the short term, incremental gains. They shy away from the paradigm-shifting discoveries that will really move science into the clinic, where it will solve the major health problems that we have caring for this country.

Researchers essentially become worriers focused on how to maintain their laboratories, rather than explorers seeking to solve the crucial issues. High-risk, high-payoff studies are what we need most, but they have the most volatile dependence on the NIH funding level.

PREPARED STATEMENT

Of course, Dr. Zerhouni and the NIH have recognized the need for this kind of research, and they've taken steps to achieve it within the confines of the NIH budget. This is certainly important and commendable, but it's not a substitute for the kind of investment

of Federal funds that will encourage creativity and reward risk. Specialized programs or set-asides, by definition, can only affect a small percentage of all the research that's going on. Moreover, creativity cannot be dictated by policy alone. Only a reversal of the inflation-adjusted decline in the NIH budget can reset the community's outlook. By establishing an NIH funding level that, at a minimum, restores recent net losses to inflation and keeps pace with costs in the future, Congress, this committee, can achieve the research environment required to promote the health of all of our citizens.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. STEPHEN M. STRITTMATTER

Chairman Harkin, and Members of the committee, I thank you for the opportunity to offer my insights on the NIH budget. To be frank, my three decades in clinical Neurology and basic Neuroscience research at Yale, Harvard and Johns Hopkins have convinced me that the recently flat NIH budget is stifling creative, high-risk research endeavors.

The doubling of the NIH budget provided by Congress, and championed by many of you on this committee, laid the foundation to revolutionize the care of those suffering with nervous system diseases. However, for most types of neurological and psychiatric disease, we still face the crucial hurdle: the translation of basic molecular analysis of brain function and dysfunction into effective treatments. To leap over this translational hurdle requires the most creative and the riskiest experiments, including those that may lead to an experimental dead-end or multiple failures before achieving the one critical insight that will establish a new therapy. Regrettably, the decrease of inflation-adjusted NIH spending in recent years has produced a marked chilling effect on precisely the type of research that is most needed. If this chilling effect is not alleviated, we will fail to reap the full benefits of the research expansion that occurred from 1998–2003—and we will push better treatments farther into the future.

My own field in Neuroscience relates to nerve fiber growth, and provides an example of how high-risk research can succeed in the appropriate environment. In humans, single nerve cells extend fine threads, called axons, for distances as long as a meter. If the cell were magnified to the size of a baseball, the axon would be the width of a pencil and extend for half of a mile. These axons conduct electricity and provide the "wiring" of the brain. There can be no useful brain function unless these fibers are correctly connected, and failure to connect—or reconnect—contributes to many diseases, from strokes, Alzheimer's and Parkinson's to Multiple Sclerosis and Lou Gehrig's disease.

Twenty years ago when I started in this field, little, if anything, was clear about how the cells of the developing brain become connected over long distances. However, molecular insights into the basis of axonal guidance began in the early 1990's and the pace of discovery accelerated rapidly during the NIH budget doubling. Basic studies led to the identification of dozens of axon guidance molecules and genes with defined roles in the developing brain.

These molecular insights were fascinating from the scientific perspective, but did not immediately improve human health. The next step was to apply this knowledge to settings of brain injury where axonal disconnection occurs. The clearest example is traumatic spinal cord injury. Despite the profound and persistent neurological deficits after spinal cord injury, such as the inability to move or feel, nearly all of the neurons that initiate arm and leg movements and provide skin sensation survive injury. The primary cause of disability is the interruption of nerve fibers—not the loss of cells. This, we learned, has important implications for treatment.

Inside the brain and spinal cord, very little axon regrowth occurs after injury, explaining the poor recovery of adults. Here the translational hurdle emerged: how do we use basic knowledge of embryonic fiber growth to restart axonal growth and restore proper function after injury or disease. As a Neurologist caring for patients while directing a brain development laboratory, I was particularly keen to attack this hurdle. Despite my interest, I would not have pursued this goal in 2000 without the risk-taking climate created by the NIH budget doubling.

We discovered the existence of a molecule, termed Nogo, which prevents nerve fiber growth, and mice lacking the gene for Nogo or its partner NogoReceptor exhib-

ited significant axonal regeneration. Moreover, such animals recover substantial walking after spinal cord injury, or improved paw use after stroke. By analyzing the action of the Nogo molecule, we identified methods to prevent its function. Remarkably, therapy with a NogoReceptor antagonist allowed rats to walk after spinal cord injury and those with strokes recovered greater paw use. Today, a closely related approach using an antibody directed against Nogo is in clinical trials.

While this story illustrates past progress in high-risk research, I am convinced that similar challenges are not being tackled today because of the NIH budget situation. When researchers and peer review panels are faced with many junior investigators failing to achieve NIH research support and established investigators losing support, the first change is a retrenchment to "safe" science. Scientists pursue those experiments that have the highest probability of achieving an incremental short-term goal, rather than a chance of generating a paradigm-shifting long-term discovery. Researchers have become "worriers" focused on how to maintain their laboratories and jobs, rather than "explorers" seeking to solve the most crucial translational issues. High-risk, high-payoff studies have the most volatile dependence on NIH funding levels. Nonetheless, we require high-risk endeavors now more than ever to take advantage of basic science and research tools developed during the doubling of the NIH budget.

Dr. Zerhouni and the NIH have recognized the need for high-risk, high-payoff research and have taken steps to foster such work within the confines of restricted NIH budgets. This is important and commendable but it is not a substitute for an investment of federal funds that encourage creativity and reward risk. Specialized programs and set-asides can only affect a small percentage of biomedical research by their very nature. Furthermore, creativity cannot easily be dictated by policy. Only a reversal of the inflation-adjusted decline in the NIH budget can reset the biomedical community's outlook.

Future health care can be dramatically improved if researchers explore the highest risk research areas, allowing researchers to clear the translational hurdle and bring the benefits of expanding basic science to the public. By setting an NIH funding level that, at a minimum, restores recent net loses to inflation and keeps pace with costs in the future, Congress can achieve the research environment required to improve health for all of our citizens. I would be pleased to answer any questions.

Senator HARKIN. Thank you very much, Dr. Strittmatter

Just some general questions for the panel. We've all heard about the drop in the success rates, from 1 in 3 to about 1 in 5 right now. Some institutes are rated even lower. I'm concerned that when you get that low, some scientists, especially the young investigators, will just say, "Why bother?" You've all kind of spoken to that, in one way or the other. But what's the minimum success rate that makes sense? What should we be aiming for? Is there something we should be aiming for? What's the minimum? I just open it up.

Dr. STRITTMATTER. Well, I don't know if there's one minimum. There's not one answer to the question. I think Dr. Zerhouni put forth the notion that, historically, the success rate of grants had been around 30 percent. That's one where the culture of research in the United States is comfortable with the idea that we choose the best grants, we move forward with the best ideas. The problem now is that that funding rate has gone down, so we not only—the feeling that scientists have is not that creativity or risk-taking is rewarding, but that we should shut down. We're going backwards, not forward. So, perhaps reaching back to that historical level, not 100-percent funding, but——

Senator HARKIN. Yeah.

Dr. STRITTMATTER [continuing]. 30-percent success rate in grants, will restore the kind of driving forward of the research, moving science into changing healthcare that we need.

Senator HARKIN. That's——

Dr. STRITTMATTER. That's one answer. I don't know——

Senator HARKIN [continuing]. Sort of, overall. Should there be some areas where it should be higher than 30 percent?

Dr. STRITTMATTER. Well, I think one way to judge that would be whether there's—what you'd really want to know is whether, on the margin, the grants that are funded discover something useful, advance healthcare. If funding levels were at 30 percent, do the worst 1 percent or 2 percent of the grants help the American public? I think you could easily argue that the enormous cost of healthcare—they're so large that looking for cures, or preventive, pre-emptive medicine, has such a huge financial benefit—I think that's what Dr. Zerhouni alluded to with his figure of $44 per person in the United States for all of the NIH budget. You could easily argue that we should be at a higher level, and we would still save immense amounts of money compared to the amount that we spend on healthcare and insurance otherwise. That's one answer.

Dr. IVERSON. If I could answer that specifically—excuse me—I would say that, from my perspective, I think 30 percent is a great number. I would also like to see an allocation for a common fund that can be targeted at particularly exciting opportunities that should not fight each other.

Senator HARKIN. Uh-huh. Anything else?

All right. The other thing—Dr. Siliciano, you pointed out in your statement—you didn't state it, but I read it—and it said that—when was it? In 1965, we peaked at the percent of our GDP that went for—was that all R&D—I guess, just all R&D lumped together? Now it's about eight-tenths of 1 percent.

Dr. SILICIANO. Yes, I believe so.

Senator HARKIN. Then you pointed out that China had just recently committed going from 1.3 percent, where they are now—so, they're even higher than we are as a percent of GDP—to 2.5 percent of GDP by 2020. I'm going to have my staff find out what it would be if we were at 2 percent right now? I just wonder what the figure might be. I didn't see it there, but we can find that out. I just didn't know if you knew it, off the top of your head.

Dr. SILICIANO. I don't—not off the top of my head.

Senator HARKIN. Well, obviously it would, what, at least 2.5 times where we are right now.

The other thing that I—you talked about these—about 30-percent approval rates and what should the right number be, what should we aim for. I still don't know if I got a good handle on that. But I also wonder about the whole peer-review process—and I have brought this up for the last 20 years that I've been on this Committee—on the one hand, you want good peer reviews, because you want good, legitimate science being done. So, you want those that are knowledgeable in those areas to look at it and give their evaluation as whether or not it's legitimate, sound, and should go forward or not. It's a good system. On the other hand—on the other hand, peer reviewers tend to be those that have been in that area of scientific research for some length of time, they have all pursued certain interests. You know, maybe they're looking for the safer things, the things that they're comfortable with, that they have more understanding of. I'm often wondering, do these sort of off-the-wall kinds of things that—the new-paradigm types of research that some of you spoke about, do they—what's your comfort level

that some of these actually get through that peer-review process, these kind of really new things that maybe a peer-reviewer had never, ever been involved in before—how do they get through that?

Dr. SILICIANO. Mr. Chairman, I've had quite a bit of experience on these type of review panels, and my overall impression is that they do a really excellent job of finding the good science. There has been a mandate on these panels, for many years, to look for what's called high-risk/high-yield types of projects. My own experience is that those types of projects do get funding. The biggest—and I think the overall system works extremely well. I'd be anxious to hear what my colleagues think. But I think the problem is that the amount of funding that the system has at its disposal right now is just too low to allow the system to work effectively. When you go down from 30 percent grants being funded to——

Senator HARKIN. So, the lower the funding level, the——

Dr. SILICIANO. The whole system——

Senator HARKIN [continuing]. The increase in the safety factor tends to go up.

Dr. SILICIANO. Yes. So, I don't really think it's a problem with the mechanism, I think it's a problem with the funding.

Senator HARKIN. Yeah.

Yes, Dr. Brugge.

Dr. BRUGGE. I completely agree, but I think that, in addition, we need visionary leaders, like Dr. Zerhouni was pointing out, in terms of the nanotechnology investment. We need leaders to be aware of and make opportunities available to those individuals that are at the forefront. Because often, as you mentioned, they're—these people are—can't really be evaluated appropriately by the standing committees. So, for instance, if there's technology that is at the interface between biology and engineering, there's not really a great place—I mean, there is now, but there—initially, there wasn't a place for those grants to be reviewed. So, I think it—we do have to have extraordinary opportunity kind of funds available for the leadership at NIH and the other institutes to have RFAs in those areas so that they—we will be able to bring new ideas and new—or kind of force new—considering new options.

Senator HARKIN. Well, we had said, when we added that money, that $647 million in the continuing resolution, that some of that would be used for high-risk, high-impact research. Dr. Zerhouni has already announced those awards. New Innovators Awards. So, he's already taken that step—Dr. Zerhouni's already taken that step, and I just—but I—you know, we've often wrestled with this, over a long period of time.

Dr. BRUGGE. In our department of Cell Biology, our chairman felt very strongly that we needed better technology expertise in the Department, and so, he actually encouraged recruitment of technology experts that weren't really cell biologists. They would never have been recruited if there was a consensus vote on those individuals. But, because a slot was made for those individuals both are someone who's doing mass spectroscopy and cryoelectron microscopy, they've had more impact in our Department in our school than any other investigator. They have more collaborative papers with other individuals, and their papers are all being published in the very top journals. So, again, you need visionary leaders to be able to

highlight those types of individuals and that type of science, and bring them in, because—because of the issues that you raised, in terms of people being just comfortable where they are.

Senator HARKIN. Dr. Brugge, your statement was something I had not focused on, sort of went by me. When we're talking about the 20 percent that, for the first submission, it's about 10 percent. Is that factual now, that about——

Dr. BRUGGE. So, if you look at the chart over here—this was a chart that was just provided to me by Dr. Neiderhuber, the director of the National Cancer Institute. If you look at the yellow curve, which might be difficult to see—I asked him to specifically give me data on first submission, so all that data is on first submission—and then, to break it down into competing renewals versus new applications from either new investigators or established investigators. If you look at the yellow line, those are for competing renewals. Those are for teams that are already in place.

Senator HARKIN. Okay.

Dr. BRUGGE. Over the long haul, they've been in the range of 45 to 50 percent, but, as you can see, since 2003, there's just a precipitous drop. So, that shows that 80 percent of established investigators that are asking for renewing their team's efforts are being turned down on the first submission.

Senator HARKIN. So, that's down——

Dr. BRUGGE. And——

Senator HARKIN. But that's 20 percent.

Dr. BRUGGE. Twenty percent are being funded, 80——

Senator HARKIN. Right.

Dr. BRUGGE [continuing]. Percent are being rejected.

Senator HARKIN. Rejected. But you said for first submissions, though, it's 90/10.

Dr. BRUGGE. Okay. So, 90/10 is the overall success rate for any one cycle. So, that's a combination of the established investigators and the new investigators. So, as you can see, the new investigators are down to around 5 percent. So, the—overall 10 percent. So, for instance, NCI is funding new—or first awards from competing renewals at some—wait a minute. Okay. Maybe somebody from NCI can help with this, because it's a little complicated.

Senator HARKIN. Let me see if I can—ask it this way. Okay. So, if you take all of the first, second, third submissions and all that—so, what's the success rate? Approximately.

Dr. BRUGGE. Success rate——

Senator HARKIN. Add'em all up, and then——

Dr. BRUGGE. 20 percent.

Senator HARKIN. That's 20 percent. Take out second, third—you want first submissions. This is the first time they've submitted it.

Dr. BRUGGE. Yes. Submitted, but it could be a competitive renewal.

Senator HARKIN. Competitive renewal.

Dr. BRUGGE. It's a—you know, every 5—every 4 or 5 years, you have to——

Senator HARKIN. You have to get it renewed, right.

Dr. BRUGGE [continuing]. Get renewed. So, it could be the first submission of a competitive renewal.

Senator HARKIN. Does anyone know, or maybe Dr. Zerhouni could provide it for us—what would the success rate be just for first submissions? I don't mean renewals. I mean just for the first.

NIH SUCCESS RATE

Dr. BRUGGE. Oh. That's 5 percent.

Senator HARKIN. Oh, it's 5 percent.

Dr. ZERHOUNI. The success rate on first submissions, whether you're established or new——

Senator HARKIN. I'm going to ask Dr. Zerhouni to take a microphone.

Dr. ZERHOUNI. Dr. Brugge is right. If you come in with a new grant, the average success rate on the first submission is 10 percent. But if you are an established investigator, it's more like 17 percent.

Senator HARKIN. Yes.

Dr. ZERHOUNI. If you're a completely new investigator, it's more like 5 percent. So, on average, it's 10 percent; but it's much worse for a new investigator versus a new application from an established investigator. But, on the average, 90 percent at the first submission will have to go back and resubmit again and work on finding—on reapplying.

Senator HARKIN. I always thought that it was higher than that. I don't know why I thought——

Dr. ZERHOUNI. Right. What it is, is this, is that Dr. Brugge's talking about the first time that you submit a request——

Senator HARKIN. Right.

Dr. ZERHOUNI [continuing]. Your chances of being funded, if you're a new investigator—and this is why we really thank you for the support of new investigators—is between 5 and 7 percent.

Senator HARKIN. Now, has that been true for a long time?

Dr. ZERHOUNI. No, it has been true for the past 2–3 years.

Senator HARKIN. Okay. Good. What was it, back in the 1980s—late 1980s, early 1990s, in those areas? What happened when we doubled the funding?

Dr. ZERHOUNI. So, when you doubled the funding, the average success rate overall was about 30 percent. If you look at the statistics, you can see that the success rate for a new investigator was around 15 percent, and the success rate for an established investigator was around 40 percent. The two, together, made about 30 percent.

Senator HARKIN. So, can I—is this a correct statement I'm about to make, that—when we finished the doubling, or during that doubling, that first submissions of—first submissions—not renewals, first submissions—the approval rate would have been three times higher than it is right now—15 versus 5?

Dr. ZERHOUNI. It would have been three times higher for a new investigator.

Senator HARKIN. Yes.

Dr. ZERHOUNI. About twice as high for an established investigator.

Senator HARKIN. That's it. That—now I understand it. Hmm. Three times.

Dr. BRUGGE. That's why there's——

Senator HARKIN. Now, see——

Dr. BRUGGE [continuing]. A lot of distress.

Senator HARKIN. Now, here's another problem we get into. See, that—so, we double the funding, we get more grants out there, but obviously these grants are longer than just 3 or 4 or 5 years. They come in to get renewed. So, all the new ones that we got during the bump-up are now in the system, and they get renewed, and the new ones can't get in.

Dr. ZERHOUNI. Yes, sir, that's why we——

Senator HARKIN. I'll have to think about this one. I mean—and how we crack that. I mean, that doesn't seem to me to be the right course that we ought to be on. Obviously, the correct answer that—we talked about this doubling for a long time before we started. One of the reasons was, we had seen, over the years, how the number of peer-reviewed applications, the approval rate had gone down and down and down. We looked at each institute. Some were better than others. Some really got bad, way down, 1 in 7, 1 in 8, that kind of thing—1 in 10. The idea was to get it back up to the level so that the peer-reviewed grants would be about where we were, I don't know, 25–30 years ago. That happened. But we also wanted to make room and to encourage this new—what was that word I used? High-risk/high-impact kind of research to be done. Are we now at the point where we did the high-risk/high-impact research maybe on a one-shot basis or for a couple of years, but now we're not doing it? I mean——

Dr. STRITTMATTER. I think that's the point that I was trying to make. I think there is that influence, that, during the doubling, there was an atmosphere created where people took high risks, where things advanced rapidly. We made great strides. But the retrenchment, a backward progress in the rate of grant funding——

Senator HARKIN. Yeah.

Dr. STRITTMATTER [continuing]. Has an enormous—the biggest influence is on high-risk research and creativity in science, more——

Senator HARKIN. Sure.

Dr. STRITTMATTER [continuing]. Than steady advance.

Senator HARKIN. Sure.

Dr. STRITTMATTER. Even though—whether it's a 9-percent or 13-percent net decline in total dollars, the effect on high-risk research might be much, much greater—5, 10 times decline in these kind of crucial experiments.

Senator HARKIN. Yeah, I can understand that.

Well, I just think, Dr. Zerhouni, we're going to have to continue to work on that. On the one hand—I mean, it's both valuable. I mean, you don't want to cut off people that are in the midst of their research project. I mean, you want to continue it on, and you want to let new researchers know that, if they do get it, they're not going to be cut off at the knees once they just get established. On the other hand, you do want to encourage new people coming into the system.

Well, I think the obvious thing that strikes me is that we're simply not on a growth pattern like we ought to be on. We have to be on a growth pattern on this, and we're just not. I get the sense that a lot of people thought, "Well, we doubled it. Now we don't have

to do anything for a long time. We can just sort of sit there." I have to tell you, I hear that around here, you know, "Well, we gave you all that money once. You got all that you've got up there, so quit squawking all the time." But I don't think they realize that we were just making up for lost time, that we needed to keep that line going up.

Well, I've got a lot of questions I could ask. I don't know if Senator Specter is coming back or not right now.

One other question. You're the correct panel to ask this question to. One other thing that I want to get a better handle on is undergraduate researchers and training scientists. Now, we heard a lot during the doubling that this was going to have a ripple effect downward, even—maybe down even into high schools, getting more high school students taking science if they knew they could really become a scientist and have a career as a scientist. So, since I think most of you are all—you're all college-based, one way or the other—tell me about undergraduate researchers and scientists, and how does it look to you for the future in actually appealing to these young people to take up research and be a research scientist as a career? Because these are long-term things. That's another thing that people ask me about, "Well, you know, you don't need to do all that. I mean, if you"—it's like you can just get a researcher—just get someone to take a little time off of their practice, and they can be a researcher for a few months, and then they can go back to practice again. So, what's happening with undergraduate researchers and budding young scientists out there? You're in contact with them all the time. On the one hand, is there a desire? Do you find young people interested in the life sciences that Dr. Zerhouni talked about, this new century of life sciences? Is that interest there? Are we responding to that? Just an open—just how you feel about it.

Dr. IVERSON. Well, thank you. I'm going to take this one.

It turns out that there's nothing more transformative in science education than undergraduate research. The reason is that, in an NIH-funded laboratory doing current state-of-the-art research, an undergraduate is immersed in an environment where they finally understand what's really happening. There's no way to convey that in the lecture hall. I try my best. You can't.

Senator HARKIN. Interesting.

Dr. IVERSON. I'm here today—as I said, I'm here today because of a transformative experience. I was on my way to business school, and that event changed my thinking—not immediately, but it was because I was doing state-of-the-art research, or, you know, I was being exposed to it.

The way it generally operates is that you have laboratories that are set up, you have postdocs and graduate students, and undergraduates will come in, and they'll be working along with a graduate student or a postdoctoral fellow, be brought along slowly. What we hope is that, by the end of their second or third year, if they're excited about it, they're going to be really doing, with their own hands, research that may have an impact.

Senator HARKIN. Yeah.

Dr. IVERSON. There is nothing more transformative than this. If we don't take graduate students, we don't have those opportunities

for undergraduates. I wasn't kidding, we put 1,000 undergraduates in research opportunities at our university. We don't attempt to make 1,000 new scientists out of them. Whatever they end up doing, if they go to medical school, if they go to law school, if they do anything, they will finally understand what we have difficulty conveying in the classroom or in the media, and that is: what research is all about—the excitement, the difficulties, the real ramifications of cutting-edge research. I think that when you discuss what happens with grant funding pay lines, you have to realize that there's a very simple equation that says: fewer research opportunities for investigators translates directly into fewer research opportunities for undergraduates, as well as graduate students.

Dr. SILICIANO. I think there's another dimension to that, and that is that the undergraduates are very perceptive, and they see the environment, and they see that no matter how exciting the science is and how much fun the research is, if the principal investigator spends all of their time applying for grants and worrying about funding, that it's not an appealing sort of career choice. That's my major worry.

Senator HARKIN. Didn't you have something in your statement about how much time it took—or may time—how long it takes to—for these application processes?

Dr. SILICIANO. Yeah, I mean, traditionally it took me 30 percent, and now it's 60 percent.

Senator HARKIN. Yeah. That's a lot of time to take out just for filling out paperwork and stuff.

Dr. SILICIANO. Yeah, that's right. There's a lot less time to interact with undergraduate students, too——

Senator HARKIN. That's right.

Dr. SILICIANO [continuing]. Which is true—it is very true in my case.

Senator HARKIN. Any last things before I call a halt to this panel? Anything else that you want to bring up? Senator Specter just got the floor, I'm told, so he won't be coming back.

Dr. IVERSON. Very briefly. I would like to make one comment, and that is——

Senator HARKIN. Yes, sir.

Dr. IVERSON [continuing]. We talk about the increased grant pressure almost as a burden, and, in fact, I see it as the opposite, it's the success of the doubling that allowed us to create so many good ideas, collectively, as a scientific community that they just demand to be funded. That's what's pushing out the new ideas.

Senator HARKIN. That's good.

Dr. IVERSON. This is not a negative thing, it's a very positive thing for American science, and we just need to keep up the momentum that we've established now, as well as look toward the future with new ideas that are, right now, being pushed out.

Senator HARKIN. That was good. I like that a lot.

Well, listen, we'll close this panel down.

But now we're going to be having a press conference, with some of you, to release this study that was done, "In Our Grasp—Or Slipping Away?" So, we're going to have a press conference here. We'll close this down, and we're going to move to a press conference within just a couple of minutes.

ADDITIONAL COMMITTEE QUESTIONS

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

VULVODYNIA

Question. In fiscal year 2006, the Committee called upon the Office of Research on Women's Health to implement a national education program for primary care health professionals, patients and the general public on vulvodynia's symptoms, diagnosis and treatment options. I commend ORWH, under the leadership of Dr. Vivian Pinn, for its work so far to develop the campaign. Please provide an update on its current status, including a brief summary of its components, expected launch date and the resources that have been and will be allocated for this effort. Information on the resources should include the amount of funds that will be used to publicize the campaign and disseminate materials to the lay and professional communities. OD/ORWH

Answer. The Office of Research on Women's Health (ORWH), National Institutes of Health (NIH), Department of Health and Human Services (HHS), is developing a national education program for primary care health professionals, patients and the general public on vulvodynia's symptoms, diagnosis and treatment options. The first step was to initiate collaborations with relevant HHS/NIH Institutes and Centers (ICs) and key consumer and health care professional organizations through several planning meetings convened by the ORWH. Participants in on-going discussions include representatives from the National Institute of Child Health and Human Development (NICHD) and the National Institute of Neurological Disorders and Stroke (NINDS) as well as other stakeholders such as the National Vulvodynia Association (NVA), the National Women's Health Resource Center (NWHRC), the American College of Obstetricians and Gynecologists (ACOG) and interested researchers. Other Offices of Women's Health across HHS will be invited to become partners in this effort as plans for distribution of materials and additional educational efforts are developed.

A tentative launch date of this educational campaign is planned for October 2007. An initial list of documents under development includes a new ORWH Vulvodynia Fact Sheet with Questions and Answers (Q&As); a vulvodynia resource guide with relevant web site information, such as the ORWH web site for vulvodynia at http://orwh.od.nih.gov/health/vulvodynia.html; reprints of current scientific journal articles on vulvodynia, such as Vulvodynia—A State-of-the-Art Consensus on Definitions, Diagnosis and Management; and the ACOG Vulvodynia Guidelines—A Literature Review. Plans are underway to develop additional public outreach materials.

Parallel with the print material campaign will be the expansion and enhancement of the current ORWH vulvodynia web page. NICHD, the Institute that provides the majority of NIH funding for vulvodynia research, will contribute to the development and implementation of this educational effort especially through contributions of the NICHD Information Resource Center (IRC), where the materials developed will be stored and distributed for target audiences. Additionally, NICHD has offered the services of the IRC Information Specialists to answer questions in English and Spanish related to vulvodynia both online and through a 1–800 telephone line. NICHD also plans to track the labor, material, and postage for NIH vulvodynia material so that these costs can be documented.

Focus group testing will occur prior to the launch of the education campaign, including creating questions related to the materials for focus group testing, locating participants, preparing the group logistics, conducting small focus groups, and reviewing and sharing the results with the group collaborating in this effort.

Concurrent with the launch of this educational campaign, ORWH will dedicate its monthly podcast, Pinn Point on Women's Health Research, to vulvodynia, including an announcement of available materials. The podcast will also include interviews and Q&As with vulvodynia research experts and appropriate web site references for further information. The podcast will be the first step in disseminating the educational campaign. Additional plans and activities are under development. ORWH and its partners will also send html e-mail announcements to targeted organizations announcing the start of the campaign to various listserves and other internet out-

lets, as well as to women's magazine editors and other similar consumer oriented media outlets. Radio spots, produced by the NIH and widely distributed across the nation's airwaves, will also be used to focus on vulvodynia.

ORWH is developing these materials, resources, and educational plans utilizing both budgetary expenditures and in-kind contributions. For example, the contributions of the NICHD IRC will be in-kind but would ordinarily represent a significant budgetary expenditure for this project. In addition, ORWH staff time spent in development of the plan, materials and implementation of the project are not included in cost estimates.

Note: This estimate does not include dedicated ORWH staff time, NICHD staff time, or other in-kind contributions.

	Amount
ORWH Preliminary cost estimate:	
Vulvodynia Information Packet and Materials Development	$6,000
Reproduction of the vulvodynia information packet and materials (5000 copies)	115,000
Development of additional consumer information materials	30,000
Medical journal reprints	25,000
Logistical support for focus groups and direct distribution of materials	10,000
Total Estimated Cost	186,000

BEHAVIORAL RESEARCH

Question. Behavior and the environment cause more than 70 percent of avoidable deaths, suggesting that many instances of disease can be prevented. Furthermore, a recent IOM report called for the conduct of transdisciplinary research on the interactions across the genetic, behavioral, and social environments. While NIH has made great advances in understanding the genomic side of health, are there plans now to enhance research on the impact of the behavioral, social, and physical environment on health?

Answer. Building on over 50 years of behavioral and social science findings, together with recent advances in understanding genetics, NIH is poised to more fully examine the complex interactions between genetic mechanisms and environmental factors that lead to disease and disability. As noted, the recent Institute of Medicine Report, Genes, Behavior, and the Social Environment: Moving Beyond the Nature/Nurture Debate, recommends a number of ways to foster the necessary transdisciplinary research teams to accomplish this. The NIH's Office of Behavioral and Social Sciences Research (OBSSR), located in the Office of the Director, is leading the implementation of the recommendations produced by this report. Working with several NIH Institutes and Centers (ICs), OBSSR is currently developing an initiative to supplement ongoing research to allow for the addition of social environmental information to genetic studies and/or the addition of genomic information to behavioral and social science research projects. OBSSR has set aside $3 million in fiscal year 2008 for the funding of this initiative and is requesting funding contributions from the participating ICs.

OBSSR also is planning an annual genomics training institute for behavioral and social scientists. This course will cover basic concepts and methods of genomics research to better enable these investigators to integrate behavioral, social, and physical environmental factors into genomics research and thereby work more effectively with their genomics and biomedical colleagues.

In February 2006, Secretary Mike Leavitt announced the trans-NIH Genes, Environment and Health Initiative (GEI), designed to combine genetic analysis and environmental technology development to better understand the causes of common diseases. As a first step toward implementing large scale gene and environment interaction studies, a need was identified to invest in the development and improvement of tools to assess individual exposures to environmental factors and to identify biomarkers which characterize the response of these exposures on key biological pathways. OBSSR and other IC staff have been leading the effort to include social and behavioral research in this effort, resulting in research funding announcements calling for the development of measures of diet and physical activity (RFA–CA–07–032) and psychosocial stress and addictive substances (RFA–DA–07–005).

These activities are examples of recent efforts to stimulate research at the interface of genetics and the behavioral/social sciences that will ultimately allow us to examine how interactions between our genes and our environments, broadly defined to include the physical, chemical, behavioral and social environments, influence health. Nearly all ICs support investigator-initiated behavioral and social science re-

search; they also issue funding opportunity announcements to solicit research applications on particular topics, often in partnership with each other and with OBSSR. Total NIH funding for behavioral and social science research is estimated at approximately $3 billion annually since fiscal year 2004, roughly 10 percent of the entire NIH budget.

TRANSLATIONAL RESEARCH

Question. It takes years for research discoveries to reach the population at large, suggesting a significant gap in translational research. Translation of research takes place across two phases: from bench to bedside and from bedside to the population at large. What percentage of the NIH budget supports translational research overall, and how much is spent on each of the two phases?

Answer. Presently, NIH does not collect funding levels for translational research. However, we do report funding levels for clinical research, and for the current year (fiscal year 2007) and the budget year (fiscal year 2008), we estimate $8.8 billion will be spent on this research category.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

REVISED MECHANISM TABLE

Question. The fiscal year 2007 enacted level provided NIH with increased funding that was not envisioned in the fiscal year 2008 Budget submission. It also requires NIH to submit a revised fiscal year 2007 operating plan. We realize increase funding in one year can impact the following year's distribution of competing grants and mechanisms. Therefore, please submit for the record a revised mechanism table that shows the impact of the fiscal year 2007 enacted level on the fiscal year 2008 President's Budget request. Also, please revise and submit any of the data in the "Tabular Data" section of NIH's Volume I Overview section of the CJ that changes to reflect the adjustments to fiscal year 2007 enacted level and its impact on the fiscal year 2008 Budget Request.

Answer. The requested revised "Tabular Data" section follows, which includes the NIH total mechanism display.

FISCAL YEAR 2006 APPROPRIATION ADJUSTMENTS

[In thousands of dollars]

IC	Cong. action		Subtotal cong. action	Real transfers					Subtotal, Pres. budget appendix
	Fiscal year			Global AIDS transfer	HHS transfer	Adv. dev. transfer	NIH RM transfer	Director's 1 percent transfer	
	2006 conference	2006 1 percent rescission							
NCI	4,841,774	−48,418	4,793,356	.....	−3,293	.....	−42,834	.....	4,747,229
NHLBI	2,951,270	−29,513	2,921,757	.....	−2,007	.....	−26,109	.....	2,893,641
NIDCR	393,269	−3,933	389,336	.....	−267	.....	−3,479	.....	385,590
NIDDK	1,722,146	−17,221	1,704,925	.....	−1,172	.....	−15,236	.....	1,688,517
NINDS	1,550,260	−15,503	1,534,757	.....	−1,054	.....	−13,715	.....	1,519,988
NIAID	4,459,395	−44,594	4,414,801	−99,000	−3,033	−49,500	−38,567	.....	4,224,701
NIGMS	1,955,170	−19,552	1,935,618	.....	−1,330	.....	−17,297	.....	1,916,991
NICHD	1,277,544	−12,775	1,264,769	.....	−869	.....	−11,302	.....	1,252,598
NEI	673,491	−6,735	666,756	.....	−458	.....	−5,958	.....	660,340
NIEHS	647,608	−6,476	641,132	.....	−440	.....	−5,729	−4,480	630,483
NIA	1,057,203	−10,572	1,046,631	.....	−719	.....	−9,353	.....	1,036,559
NIAMS	513,063	−5,131	507,932	.....	−349	.....	−4,539	.....	503,044
NIDCD	397,432	−3,974	393,458	.....	−270	.....	−3,516	.....	389,672
NIMH	1,417,692	−14,177	1,403,515	.....	−964	.....	−12,542	.....	1,390,009
NIDA	1,010,130	−10,101	1,000,029	.....	−687	.....	−8,937	.....	990,405
NIAAA	440,333	−4,403	435,930	.....	−300	.....	−3,896	.....	431,734
NINR	138,729	−1,387	137,342	.....	−94	.....	−1,227	.....	136,021
NHGRI	490,959	−4,910	486,049	.....	−334	.....	−4,343	.....	481,372
NIBIB	299,808	−2,998	296,810	.....	−204	.....	−2,652	.....	293,954
NCRR	1,110,203	−11,102	1,099,101	.....	−755	.....	−9,822	.....	1,088,524
NCCAM	122,692	−1,227	121,465	.....	−83	.....	−1,086	.....	120,296
NCMHD	197,379	−1,974	195,405	.....	−134	.....	−1,746	.....	193,525
FIC	67,048	−670	66,378	.....	−46	.....	−593	.....	65,739
NLM	318,091	−3,181	314,910	.....	−216	.....	−2,814	.....	311,880
OD	482,895	−4,829	478,066	.....	−328	.....	247,292	.....	725,030
B&F	81,900	−819	81,081	.....	−56	.....	.....	4,480	85,505
Total NIH	28,617,484	−286,175	28,331,309	−99,000	−19,462	−49,500	.....	.....	28,163,347
Superfund	80,289	−1,181	79,108	.....	.....	.....	.....	.....	79,108

FISCAL YEAR 2006 APPROPRIATION ADJUSTMENTS—Continued

[In thousands of dollars]

IC	Cong. action		Subtotal cong. action	Real transfers					Subtotal, Pres. budget appendix
	Fiscal year			Global AIDS transfer	HHS transfer	Adv. dev. transfer	NIH RM transfer	Director's 1 percent transfer	
	2006 conference	2006 1 percent rescission							
Ttl,w/Supfnd	28,697,773	−287,356	28,410,417	−99,000	−19,462	−49,500			28,242,455

IC	HHS comp. transfers		NIH comp. transfers		Other global AIDS	Subtotal HHS budg. auth.	Prog. level		Subtotal HHS table prog. level	Other NIH oblig. adjust.	Subtotal NIH CJ table
	PHSSEF pan. flu	Other HHS transfers	Roadmap comparable	Other NIH transfers			Type 1 diabetes	NLM PHS eval.			
NCI		−14	42,834	−1,872		4,788,177			4,788,177	6,896	4,795,073
NHLBI		−3	26,109	−3,824		2,915,923			2,915,923		2,915,923
NIDCR		−1	3,479	−404		388,664			388,664		388,664
NIDDK		−3	15,236	−601		1,703,149	150,000		1,853,149		1,853,149
NINDS		−3	13,715	−655		1,533,045			1,533,045		1,533,045
NIAID	18,000	−9	38,567	−1,060	99,000	4,379,199			4,379,199		4,379,199
NIGMS		−1	17,297	−244		1,934,043			1,934,043		1,934,043
NICHD		−4	11,302	−375		1,263,521			1,263,521		1,263,521
NEI		−1	5,958	−529		665,768			665,768		665,768
NIEHS		−4	5,729	−213		635,995			635,995		635,995
NIA		−3	9,353	−708		1,045,201			1,045,201		1,045,201
NIAMS		−1	4,539	−166		507,416			507,416		507,416
NIDCD		−1	3,516	−76		393,111			393,111		393,111
NIMH		−3	12,542	−735		1,401,813			1,401,813		1,401,813
NIDA		−2	8,937	−482		998,858			998,858		998,858
NIAAA		−1	3,896	−150		435,479			435,479		435,479
NINR			1,227	−98		137,150			137,150		137,150
NHGRI		−2	4,343	−58		485,655			485,655		485,655
NIBIB			2,652	1,482		298,088			298,088		298,088
NCRR			9,822	10,601		1,108,947			1,108,947		1,108,947
NCCAM			1,086	−248		121,134			121,134		121,134
NCMHD			1,746	−8		195,263			195,263		195,263
FIC			593	−15		66,317			66,317		66,317
NLM		−484	2,814	−133		314,077		8,200	322,277	1	322,278

OD	.....	−2	−247,292	571	.....	478,307	.....	.....	478,307	.....	478,307
B&F	.....	.....	.....	.....	.....	85,505	.....	.....	85,505	.....	85,505
Total NIH	18,000	−542	.....	.....	99,000	28,279,805	150,000	8,200	28,438,005	6,897	28,444,902
Superfund	.....	.....	.....	.....	.....	79,108	.....	.....	79,108	.....	79,108
Ttl,w/Supfnd	18,000	−542	.....	.....	99,000	28,358,913	150,000	8,200	28,517,113	6,897	28,524,010

FISCAL YEAR 2007 ADJUSTMENTS—JOINT RESOLUTION LEVEL

[In thousands of dollars]

IC	Joint resolution	Comp. trnsf. advanced dev.	Subtotal, Pres. budget appendix	Other HHS transfers	NIH comp. transfers	Subtotal, HHS budg. auth.	Prog. level		Subtotal, HHS prog. level
							Type I diabetes	NLM PHS Eval.	
NCI	$4,797,639	.....	$4,797,639	−$14	−$2,134	$4,795,491	.....	.....	$4,795,491
NHLBI	2,922,929	.....	2,922,929	−3	−2,946	2,919,980	.....	.....	2,919,980
NIDCR	389,703	.....	389,703	−1	−332	389,370	.....	.....	389,370
NIDDK	1,705,868	.....	1,705,868	−3	−639	1,705,226	$150,000	.....	1,855,226
NINDS	1,535,545	.....	1,535,545	−3	−638	1,534,904	.....	.....	1,534,904
NIAID	4,417,208	−$49,500	4,367,708	−9	−1,254	4,366,445	.....	.....	4,366,445
NIGMS	1,935,808	.....	1,935,808	−1	−182	1,935,625	.....	.....	1,935,625
NICHD	1,254,707	.....	1,254,707	−4	−559	1,254,144	.....	.....	1,254,144
NEI	667,116	.....	667,116	−1	−440	666,675	.....	.....	666,675
NIEHS	642,002	.....	642,002	−4	−225	641,773	.....	.....	641,773
NIA	1,047,260	.....	1,047,260	−3	−757	1,046,500	.....	.....	1,046,500
NIAMS	508,240	.....	508,240	−1	−179	508,060	.....	.....	508,060
NIDCD	393,668	.....	393,668	−1	−127	393,540	.....	.....	393,540
NIMH	1,404,494	.....	1,404,494	−3	−921	1,403,570	.....	.....	1,403,570
NIDA	1,000,621	.....	1,000,621	−2	−605	1,000,014	.....	.....	1,000,014
NIAAA	436,259	.....	436,259	−1	−201	436,057	.....	.....	436,057
NINR	137,404	.....	137,404	.....	−117	137,287	.....	.....	137,287
NHGRI	486,491	.....	486,491	−2	−62	486,427	.....	.....	486,427
NIBIB	296,887	.....	296,887	.....	1,504	298,391	.....	.....	298,391
NCRR	1,133,240	.....	1,133,240	.....	10,601	1,143,841	.....	.....	1,143,841
NCCAM	121,576	.....	121,576	.....	−197	121,379	.....	.....	121,379
NCMHD	199,444	.....	199,444	.....	−15	199,429	.....	.....	199,429
FIC	66,446	.....	66,446	.....	−24	66,422	.....	.....	66,422
NLM	320,850	.....	320,850	−484	−137	320,229	.....	$8,200	328,429

FISCAL YEAR 2007 ADJUSTMENTS—JOINT RESOLUTION LEVEL—Continued

[In thousands of dollars]

IC	Joint resolution	Comp. trnsf. advanced dev.	Subtotal, Pres. budget appendix	Other HHS transfers	NIH comp. transfers	Subtotal, HHS budg. auth.	Prog. level		Subtotal, HHS prog. level
							Type I diabetes	NLM PHS Eval.	
OD	1,096,401	.....	1,096,401	−2	586	1,096,985	.....	.....	1,096,985
B&F	81,081	.....	81,081	.....	.....	81,081	.....	.....	81,081
Total NIH	28,998,887	−49,500	28,949,387	−542	.....	28,948,845	150,000	8,200	29,107,045
Superfund	79,117	.....	79,117	.....	.....	79,117	.....	.....	79,117
Total, w/Supfnd	29,078,004	−49,500	29,028,504	−542	.....	29,027,962	150,000	8,200	29,186,162

FISCAL YEAR 2008 PRESIDET'S BUDGET REQUEST

Appropriation	Fiscal year				
	2006 actual [1 2 3 4 5 6]	2007 Presidet's budget [1 3 4 5 6]	2007 joint resolution [1 3 4 5 6]	2008 Presidet's budget [1]	2008 Est. +/− 2007 joint resolution
NCI	$4,795,073,000	$4,751,461,000	$4,795,491,000	$4,782,114,000	−$13,377,000
NHLBI	2,915,923,000	2,898,063,000	2,919,980,000	2,925,413,000	+5,433,000
NIDCR	388,664,000	385,762,000	389,370,000	389,722,000	+352,000
NIDDK [7]	1,853,149,000	1,843,656,000	1,855,226,000	1,858,045,000	+2,819,000
NINDS	1,533,045,000	1,524,109,000	1,534,904,000	1,537,019,000	+2,115,000
NIAID	[8 9] 4,379,199,000	4,394,233,000	[9] 4,366,445,000	4,592,482,000	+226,037,000
NIGMS	1,934,043,000	1,923,298,000	1,935,625,000	1,941,462,000	+5,837,000
NICHD	1,263,521,000	1,256,855,000	1,254,144,000	1,264,946,000	+10,802,000
NEI	665,768,000	660,917,000	666,675,000	667,820,000	+1,145,000
NIEHS	[10] 635,995,000	637,094,000	641,773,000	637,406,000	−4,367,000
NIA	1,045,201,000	1,039,068,000	1,046,500,000	1,047,148,000	+648,000
NIAMS	507,416,000	504,353,000	508,060,000	508,082,000	+22,000
NIDCD	393,111,000	391,428,000	393,540,000	393,682,000	+142,000
NIMH	1,401,813,000	1,393,882,000	1,403,570,000	1,405,421,000	+1,851,000
NIDA	998,858,000	994,222,000	1,000,014,000	1,000,365,000	+351,000
NIAAA	435,479,000	433,116,000	436,057,000	436,505,000	+448,000
NINR	137,150,000	136,433,000	137,287,000	137,800,000	+513,000
NHGRI	485,655,000	482,878,000	486,427,000	484,436,000	−1,991,000

NIBIB	298,088,000	296,354,000	298,391,000	300,463,000	+2,072,000
NCRR	1,108,947,000	1,108,843,000	1,143,841,000	1,112,498,000	−31,343,000
NCCAM	121,134,000	120,357,000	121,379,000	121,699,000	+320,000
NCMHD	195,263,000	194,284,000	199,429,000	194,495,000	−4,934,000
FIC	66,317,000	66,657,000	66,422,000	66,594,000	+172,000
NLM [12]	314,078,000	312,648,000	320,229,000	312,562,000	−7,667,000
OD [13]	478,307,000	[11] 508,909,000	1,096,985,000	517,062,000	−579,923,000
B&F	[10] 85,505,000	81,081,000	81,081,000	136,000,000	+54,919,000
Type 1 Diabetes	−150,000,000	−150,000,000	−150,000,000	−150,000,000	.....
Subtotal, Labor/HHS	28,286,702,000	28,189,961,000	28,948,845,000	28,621,241,000	−327,604,000
Interior/Superfund Research Program	79,108,000	78,414,000	79,117,000	78,434,000	−683,000
Total, NIH Discretioary B.A	28,365,810,000	28,268,375,000	29,027,962,000	28,699,675,000	−328,287,000
Type 1 Diabetes [7]	150,000,000	150,000,000	150,000,000	150,000,000	.....
Total, NIH Budget Authority	28,515,810,000	28,418,375,000	29,177,962,000	28,849,675,000	−328,287,000
NLM Program Evaluation	8,200,000	8,200,000	8,200,000	8,200,000	.....
Total, Prog. Level	28,524,010,000	28,426,575,000	29,186,162,000	28,857,875,000	−328,287,000

[1] Includes funds to be transferred to the Global Fund for HIV/AIDS, Malaria, and Tuberculosis (fiscal year 2006—$99,000,000; fiscal year 2007 PB—$100,000,000; fiscal year 2007 Annualized—$99,000,000; fiscal year 2008—$300,000,000).
[2] Includes Government-wide 1 percent rescission and HHS 1 percent transfer.
[3] Comparable for ASAM and ASPA transfer—$62,000.
[4] Comparable for DBEPS program transfer to NIBIB (fiscal year 2006—$1,496,000; fiscal year 2007—$1,528,000).
[5] Comparable for CIO transfer to OD (fiscal year 2006—$641,000; fiscal year 2007—$669,000).
[6] Comparable for K–30 transfer to NCRR ($10,613,000).
[7] Includes funds for the Type 1 Diabetes Initiative.
[8] NIAID includes $18,000,000 for Pandemic Influenza from PHSSEF.
[9] Comparable for transfer of Advance Development Fund to ASPR (−$49,500,000).
[10] Directors 1 percent transfer NIEHS to B&F ($4,480,000).
[11] OD comparable (−$159,500,000) to ASPR for Advance Development Fund.
[12] Comparable for transfer to DHHS for PHS Historian ($480,000).
[13] Total OD includes Roadmap funds for fiscal year 2006 of $82,170,000; fiscal year 2007 PB of $110,700,000; fiscal year 2007 Annualized Current Rate of $82,170; fiscal year 2008 of $121,540,000.

BUDGET MECHANISM—TOTAL

[Dollars in thousands]

MECHANISM	Fiscal year								Change		Percent change amount
	2006 actual [1]		2007 revised Pres. budget		2007 joint resolution		2008 estimate		No	Amount	
	No	Amount	No	Amount	No	Amount	No	Amount			
Research Grants											
Research Projects:											
Noncompeting	27,366	$11,070,308	26,669	$11,063,137	26,668	$10,896,993	26,573	$10,975,609	−95	$78,616	0.7
Administrative supplements	(1,678)	284,083	(1,254)	145,687	(1,463)	177,707	(1,543)	204,463	(80)	26,756	15.1
Competing	9,129	3,361,827	9,290	3,384,714	10,154	3,731,558	9,404	3,293,817	(750)	−437,741	−11.7
Subtotal, RPGs	36,495	14,716,218	35,959	14,593,538	36,822	14,806,258	35,977	14,473,889	−845	−332,369	2.2
SBIR/STTR	1,822	616,779	1,829	605,284	1,807	610,998	1,793	606,930	−14	−4,068	−0.7
Subtotal, RPGs	38,317	15,332,997	37,788	15,198,822	38,629	15,417,256	37,770	15,080,819	−859	−336,437	2.2
Research Centers:											
Specialized/comprehensive	1,190	2,144,310	1,104	2,147,862	1,114	2,196,970	1,108	2,198,277	−6	1,307	0.1
Clinical research	93	348,476	295	375,986	95	386,898	89	419,123	−6	32,225	8.3
Biotechnology	103	134,862	113	133,797	113	134,345	111	130,550	−2	−3,795	−2.8
Comparative medicine	51	123,032	49	122,294	49	123,019	47	117,735	−2	−5,284	−4.3
Research Centers in Minority Institutions	28	54,213	28	53,289	28	53,819	27	51,727	−1	−2,092	−3.9
Subtotal, Centers	1,465	2,804,893	1,589	2,833,228	1,399	2,895,051	1,382	2,917,412	−17	22,361	0.8
Other Research:											
Research careers	4,192	644,693	4,322	674,060	4,425	693,226	4,540	700,715	115	7,489	1.1
Cancer education	99	34,561	99	34,406	102	35,406	103	35,806	1	400	1.1
Cooperative clinical research	353	344,503	351	344,249	368	353,445	364	354,580	−4	1,135	0.3
Biomedical research support	140	65,518	139	64,312	212	98,312	139	61,745	−73	−36,567	−37.25
Minority biomedical research support	155	115,032	151	114,470	149	113,810	158	112,630	9	−1,180	−1.0
Other	1,685	465,044	1,648	469,711	1,722	473,598	1,708	481,691	−14	8,093	1.7

Subtotal, Other Research	6,624	1,669,351	6,710	1,701,208	6,978	1,767,797	7,012	1,747,167	34	−20,630	−1.2
Total Research Grants	46,406	19,807,241	46,087	19,733,258	47,006	20,080,104	46,164	19,745,398	−842	−334,706	−1.7
Ruth L. Kirschstein Training Awards:											
Individual awards	[2] 2,976	122,758	[2] 2,995	124,192	[2] 3,081	127,983	[2] 3,078	127,728	−3	−255	−0.2
Institutional awards	[2] 14,349	625,883	[2] 14,461	631,604	[2] 14,663	643,617	[2] 14,583	641,685	−80	−1,932	−0.3
Total, Training	[2] 17,325	748,641	[2] 17,456	755,796	[2] 17,744	771,600	[2] 17,661	769,413	−83	−2,187	−0.3
Research & development contracts	3,423	2,667,066	3,460	2,652,882	3,529	2,783,528	3,552	2,975,285	23	191,757	6.9
(SBIR/STTR)	(92)	(23,809)	(98)	(24,504)	(110)	(30,027)	(110)	(29,996)	.....	(−31)	−0.1
Intramural research	.....	2,772,036	.....	2,751,751	.....	2,791,706	.....	2,774,311	.....	−17,395	−0.6
Research management and support	.....	1,108,615	.....	1,122,498	.....	1,132,127	.....	1,142,492	.....	10,365	0.9
Cancer prevention & control	.....	505,705	.....	502,700	.....	516,565	.....	516,565	.....	.....	.....
Extramural Construction	.....	29,700	.....	25,000	.....	.....	.....	.....	.....	.....	.....
Library of Medicine	.....	311,264	.....	308,866	.....	320,229	.....	308,415	.....	−11,814	−3.7
(Appropriation)	.....	(314,078)	.....	(312,648)	.....	(320,229)	.....	(312,562)	.....	(−7,667)	−2.4
Office of the Director	.....	393,009	.....	398,209	.....	613,985	.....	395,522	.....	−218,463	−35.6
(Appropriation)	.....	(478,307)	.....	(508,909)	.....	(1,096,985)	.....	(517,062)	.....	(−579,923)	−52.9
Buildings and Facilities [3]	.....	93,425	.....	89,001	.....	89,001	.....	143,840	.....	54,839	61.6
(Appropriation)	.....	(85,505)	.....	(81,081)	.....	(81,081)	.....	(136,000)	.....	(54,919)	67.7
NIH Roadmap for Medical Research [4]	.....	(332,590)	.....	(442,673)	.....	(483,000)	.....	(486,153)	.....	(3,153)	0.7
Type 1 Diabetes [5]	.....	−150,000	.....	−150,000	.....	−150,000	.....	−150,000	.....	.....	.....
Subtotal, Labor/HHS Budget Authority	.....	28,286,702	.....	28,189,961	.....	28,948,845	.....	28,621,241	.....	−327,604	−1.1
Interior Appropriation for Superfund Res	.....	79,108	.....	78,414	.....	79,117	.....	78,434	.....	−683	−0.9
Total, NIH Discretionary B.A	.....	28,365,810	.....	28,268,375	.....	29,027,962	.....	28,699,675	.....	−328,287	−1.1
Type 1 Diabetes [5]	.....	150,000	.....	150,000	.....	150,000	.....	150,000	.....	.....	.....
Total, NIH Budget Authority	.....	28,515,810	.....	28,418,375	.....	29,177,962	.....	28,849,675	.....	−328,287	−1.1

BUDGET MECHANISM—TOTAL—Continued

[Dollars in thousands]

MECHANISM	Fiscal year								Change		Percent change amount
	2006 actual [1]		2007 revised Pres. budget		2007 joint resolution		2008 estimate		No	Amount	
	No	Amount	No	Amount	No	Amount	No	Amount			
NLM Program Evaluation	.....	8,200	.....	8,200	.....	8,200	.....	8,200	.....	.....	.....
Total, Program Level	.....	28,524,010	.....	28,426,575	.....	29,186,162	.....	28,857,875	.....	−328,287	−1.1

[1] Budget Authority 2006 total includes mechanism distribution of NCI breast cancer stamp funds of $6,896.

[2] FTTPs.

[3] Includes the B&F appropriation plus the following included in NCI—fiscal year 2006: $7,920; fiscal year 2007: $7,920; fiscal year 2008: $7,840.

[4] Included in above mechanisms. Roadmap contributions from the NLM and OD are reflected in the mechanisms of award.

[5] Included in NIDDK—fiscal year 2006: $150,000; fiscal year 2007: $150,000; fiscal year 2008: $150,000.

Numbers of grants identified in fiscal year 2007 and fiscal year 2008 are estimates, and WILL change as applications are received and selected for funding.

Fiscal year 2006 and fiscal year 2007 have been adjusted to display comparably proposed program changes in fiscal year 2008. The fiscal year 2008 President's Budget Appendix reflects an actual fiscal year 2006 budget authority total of $28,242 million, a difference of $282 million from the fiscal year 2006 program level reported above. fiscal year 2006 adjustments to the Budget Appendix include the addition of Special Statutory Type I Diabetes Funds +$150M); a transfer from the PHSSEF for Pandemic Influenza activities (+$18M); a comparable adjustment for the Global Fund for HIV/AIDS actual transfer (+$99M); revenue from the Breast Cancer Stamp (+$7M);and use of the Secretary's evaluation funds transfer authority for NLM (+$8M). The fiscal year 2007 budget authority in the fiscal year 2008 Budget Appendix is $28,450 million, a difference of $736 million from the fiscal year 2007 Joint Resolution program level reported above. In addition to increases provided by the fiscal year 2007 Joint Resolution, fiscal year 2007 program level adjustments include the addition of Special Statutory Type I Diabetes Funds (+$150M); and use of the Secretary's evaluation funds transfer authority for NLM (+$8M).

FISCAL YEAR 2008 SPECIAL INITIATIVES

[In thousands of dollars]

	Pathway to independence	CTSA
NCI	1,800	.....
NHLBI	1,980	.....
NIDCR	540	.....
NIDDK	1,080	.....
NINDS	1,170	.....
NIAID	540	.....
NIGMS	1,350	.....
NICHD	900	.....
NEI	360	.....
NIEHS	900	.....
NIA	630	.....
NIAMS	360	.....
NIDCD	360	.....
NIMH	900	.....
NIDA	540	.....
NIAAA	270	.....
NINR	180	.....
NHGRI	270	.....
NIBIB	450	.....
NCRR	90	10,000
NCCAM	180	.....
NCMHD	270	.....
FIC	180	.....
NLM	450	.....
Total	15,750	10,000

CTSA = Clinical Translational Science Awards

APPROPRIATION HISTORY

Fiscal year	Budget request to Congress	House allowance	Senate allowance	Appropriation [1]
1999	[2] $14,763,313,000	$14,862,023,000	$15,622,386,000	[3] $15,629,156,000
2000	[4] 15,932,786,000	16,964,547,000	17,613,470,000	[5] 17,820,587,000
2001	[6] 18,812,735,000	20,512,735,000	20,512,735,000	[7] [8] 20,458,130,000
2002	23,112,130,000	22,945,199,000	23,765,488,000	[9] [10] [11] 23,296,382,000
2003	[12] 27,343,417,000	27,351,717,000	27,369,000,000	[13] 27,066,782,000
2004	27,892,765,000	28,043,991,000	28,369,548,000	[14] 27,887,512,000
2005	28,757,357,000	28,657,357,000	28,901,185,000	[15] 28,495,157,000
2006	28,740,073,000	28,737,094,000	29,644,804,000	[16] 28,461,417,000
2007	28,578,417,000	[17] 28,479,417,000	[17] 28,779,081,000	[18] 29,228,004,000
2008	28,849,675,000	.....	.....	.....

[1] Reflects enacted supplementals, rescissions and reappropriations.
[2] Reflects a decrease of $34,530,000 for the budget amendment for bioterrorism. Includes $1,728,099,000 for HIV research in the NIH Office of AIDS Research.
[3] Includes $1,800,046,000 appropriated to the ICs for HIV research. Includes $10,230,000 for rescission.
[4] Includes $1,833,826,000 for HIV research in the NIH Office of AIDS Research. Includes $40 million appropriated in fiscal year 1999 for the Clinical Research Center.
[5] Includes $2,024,956,000 appropriated to the ICs for HIV research. Includes $99,883,000 for NIH share of across-the-board reduction and reflects $20,000,000 transferred to CDC. Includes $40,000,000 in forward funding appropriated in fiscal year 1999.
[6] Includes $2,111,224,000 for HIV research in the NIH Office of AIDS Research.
[7] Includes $2,244,987,000 appropriated to the ICs for HIV research. Reflects NIH share of across-the-board reduction ($8,666,000) and $5,800,000 transferred to the DHHS.
[8] In fiscal year 2001, NIH began receiving a separate appropriation for Superfund Research activities at NIEHS.
[9] Includes $2,535,672,000 appropriated to the ICs for HIV research. Reflects NIH share of across-the-board reduction ($9,273,000), Labor/HHS ($22,946,000) and government-wide ($34,243,000) rescissions, and transfer of $100M to the Global Fund for HIV/AIDS, malaria, and tuberculosis.
[10] Includes $10.5 million appropriated from the Emergency Relief Fund.
[11] Beginning with the fiscal year 2002 Appropriation, includes amounts authorized to the NIDDK for Type 1 diabetes research.
[12] Excludes $583,000 transferred to the Department of Homeland Security.
[13] Includes $2,747,463,000 appropriated to the ICs for HIV research. Reflects NIH share of the across-the-board reduction ($177,085,000), and transfers of $99,350,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis, and $583,000 to the Department of Homeland Security.
[14] Includes $2,850,581,000 appropriated to the ICs for HIV research. Reflects NIH share of across-the-board reduction ($165,459,000), Labor/HHS rescission ($17,492,000), and transfer of $149,115,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.
[15] Includes $2,920,551,000 appropriated to the ICs for HIV research. Reflects NIH share of across-the-board reduction ($229,390,000), Labor/HHS rescission ($6,787,000), and transfer of $99,200,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.
[16] Includes $2,903,664,000 appropriated to the ICs for HIV research. Reflects NIH share of the Government-wide rescission ($287,356,000), and transfer of $99,000,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.
[17] Reflects funding levels approved by the Appropriations Committees. Neither chamber had passed the Labor/HHS appropriations bill at the time this budget was prepared.
[18] Joint Resolution.

HISTORY OF CONGRESSIONAL APPROPRIATIONS, FISCAL YEARS 1998–2007

[In thousands of dollars]

Fiscal year	NCI	NHLBI	NIDCR	NIDDK	NINDS	NIAID	NIGMS	NICHD	NEI	NIEHS	NIA	NIAMS	NIDCD	NIMH
1998	2,547,314	1,531,061	209,415	900,860	780,713	1,351,655	1,065,947	674,766	355,691	330,108	519,279	274,760	200,695	750,241
1999	2,925,247	1,792,509	234,183	1,020,559	902,680	1,569,063	1,197,026	750,485	395,595	375,494	596,126	307,960	229,735	860,638

2000	3,314,554	2,029,424	268,811	1,168,476	1,029,376	1,778,038	1,354,420	858,291	450,300	442,449	686,479	349,968	263,771	973,146
2001	3,754,456	2,298,512	306,211	1,399,684	1,175,854	2,041,698	1,535,378	975,766	510,352	564,810	785,590	396,460	300,418	1,106,305
2002	4,181,233	2,572,667	342,664	1,562,144	1,326,666	2,342,313	1,724,799	1,111,674	580,713	645,422	892,267	448,248	341,675	1,246,640
2003	4,592,348	2,793,733	371,636	1,722,730	1,456,476	3,606,789	1,847,000	1,205,927	633,148	697,767	993,598	486,143	370,382	1,341,014
2004	4,739,255	2,878,691	383,282	1,821,803	1,501,207	4,155,447	1,904,838	1,242,361	653,052	710,701	1,024,754	501,066	382,053	1,381,774
2005	4,825,258	2,941,201	391,829	1,863,584	1,539,448	4,303,641	1,944,067	1,270,321	669,070	724,347	1,051,990	511,157	394,260	1,411,933
2006	4,793,356	2,921,757	389,336	1,854,925	1,534,757	4,315,801	1,935,618	1,264,769	666,756	720,240	1,046,631	507,932	393,458	1,403,515
2007	4,797,639	2,922,929	389,703	1,855,868	1,535,545	4,417,208	1,935,808	1,254,707	667,116	721,119	1,047,260	508,240	393,668	1,404,494

Fiscal year	NIDA	NIAAA	NINR	NHGRI	NIBIB	NCRR	NCCAM	NCMHD	FIC	NLM	OD	B&F	OAR	TOTAL
1998	527,175	227,175	63,597	217,704	.....	453,883	.....	.....	28,289	161,185	296,373	206,957	.....	[1] 13,674,843
1999	602,874	259,575	69,788	264,707	.....	554,446	.....	.....	35,402	181,189	306,356	197,519	.....	[2] 15,629,156
2000	685,781	292,369	89,522	335,527	.....	676,557	68,390	.....	43,494	214,068	282,000	165,376	.....	[3] 17,820,587
2001	780,833	340,453	104,328	382,112	.....	817,253	89,138	130,096	50,482	246,351	211,800	153,790	.....	[4] 20,458,130
2002	886,718	383,615	120,366	428,758	111,861	1,011,262	104,451	157,563	56,859	276,091	235,113	204,600	.....	[5] 23,296,382
2003	961,721	416,051	130,584	464,995	278,279	1,138,821	113,407	185,714	163,465	300,135	266,232	628,687	.....	[6] 27,066,782
2004	990,953	428,669	134,724	479,073	287,129	1,179,058	116,978	191,471	65,382	317,315	327,504	88,972	.....	[7] 27,887,512
2005	1,006,419	438,277	138,072	488,608	298,209	1,115,090	122,105	196,159	66,632	315,146	358,046	110,288	.....	[8] 28,495,157
2006	1,000,029	435,930	137,342	486,049	296,810	1,099,101	121,465	195,405	66,378	314,910	478,066	81,081	.....	[9] 28,461,417
2007	1,000,621	436,259	137,404	486,491	296,887	1,133,240	121,576	199,444	66,446	320,850	1,096,401	81,081	.....	[10] 29,228,004

[1] Funds for HIV research in the amount of $1,607,053,000 appropriated to the ICs. Beginning in fiscal year 1998, includes funds appropriated to NIDDK for Type 1 diabetes research.

[2] Funds for HIV research in the amount of $1,800,046,000 appropriated to the ICs. Reflects rescission of $10,230,000.

[3] Funds for HIV research in the amount of $2,024,956 appropriated to the ICs. Reflects NIH share of across-the-board reduction ($99,883,000) and transfer to CDC ($20,000,000). Includes $40,000,000 in forward funding appropriated in fiscal year 1999.

[4] Funds for HIV research in the amount of $2,244,987,000 appropriated to the ICs. Reflects NIH share of across-the-board reduction ($8,666,000) and transfer to DHHS ($5,800,000). In fiscal year 2001, NIH began receiving a separate appropriation for Superfund Research activities at NIEHS.

[5] Funds for HIV research in the amount of $2,535,672,000 appropriated to the ICs. Reflects NIH share of across-the-board reduction ($9,273,000), Labor/HHS ($22,946,000) and government-wide ($34,243,000) rescissions, and transfer of $100M to the Global Fund for HIV/AIDS, malaria, and tuberculosis.

[6] Funds for HIV research in the amount of $2,747,463,000 appropriated to the ICs. Reflects NIH share of across-the-board reduction ($177,085,000), and transfers of $99,350,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis, and $583,000 to the Department of Homeland Security.

[7] Funds for HIV research in the amount of $2,850,581,000 appropriated to the ICs. Reflects NIH share of across-the-board reduction ($165,459,000), Labor/HHS rescission ($17,492,000), and transfer of $149,115,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.

[8] Funds for HIV research in the amount of $2,920,551,000 appropriated to the ICs. Reflects NIH share of across-the-board reduction ($229,390,000), Labor/HHS rescission ($6,787,000), and transfer of $99,200,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.

[9] Funds for HIV research in the amount of $2,903,664,000 appropriated to the ICs. Reflects NIH share of the Government-wide rescission ($287,356,000), and transfer of $99,000,000 to the Global Fund for HIV/AIDS, malaria, and tuberculosis.

[10] Joint Resolution.

FULL-TIME EQUIVALENTS

Institutes and Centers	Fiscal year		
	2006 actual	2007 Joint resolution	2008 President's budget
NCI	2,777	2,835	2,875
NHLBI	797	806	817
NIDCR	245	252	256
NIDDK	638	646	655
NINDS	526	539	547
NIAID	1,589	1,617	1,639
NIGMS	125	126	129
NICHD	547	548	557
NEI	207	213	215
NIEHS	664	668	677
NIA	378	381	386
NIAMS	211	214	217
NIDCD	133	136	138
NIMH	616	641	651
NIDA	361	366	371
NIAAA	225	227	230
NINR	43	44	45
NHGRI	292	301	305
NIBIB	48	50	51
NCRR	99	108	109
NCCAM	74	76	77
NCMHD	25	29	31
FIC	52	54	55
Subtotals, ICs	10,672	10,877	11,033
NLM	656	662	671
OD	578	630	638
Central Services	4,966	5,037	5,107
Subtotal, NIH	16,872	17,206	17,449
Undistributed	.....	.....	.....
Ceiling exempt [1]	8	10	10
Total, NIH	16,880	17,216	17,459

[1] CRADA FTEs are supported by Cooperative Research and Development Agreements

BUDGET AUTHORITY BY OBJECT [1]

	Object Classes	Fiscal year		Increase or decrease
		2007 Joint Resolution	2008 estimate	
	Personnel Compensation:			
11.1	Full-Time Permanent	$838,033,000	$881,383,000	$43,350,000
11.3	Other than Full-Time Permanent	263,580,000	276,142,000	12,562,000
11.5	Other Personnel Compensation	29,783,000	31,112,000	1,329,000
11.7	Military Personnel	26,032,000	27,721,000	1,689,000
11.8	Special Personnel Services Payments	171,584,000	175,795,000	4,211,000
	Total, Personnel Compensation	1,329,012,000	1,392,153,000	63,141,000
12.1	Civilian Personnel Benefits	311,004,000	326,309,000	15,305,000
12.2	Military Personnel Benefits	17,255,000	18,026,000	771,000
13.0	Benefits for Former Personnel	.....	.....	.....
	Subtotal, Pay Costs	1,657,271,000	1,736,488,000	79,217,000
21.0	Travel & Transportation of Persons	55,429,000	52,639,000	(2,790,000)
22.0	Transportation of Things	5,174,000	4,938,000	(236,000)
23.1	Rental Payments to GSA	64,000	61,000	(3,000)
23.2	Rental Payments to Others	1,380,000	1,373,000	(7,000)

BUDGET AUTHORITY BY OBJECT [1]—Continued

	Object Classes	Fiscal year		Increase or decrease
		2007 Joint Resolution	2008 estimate	
23.3	Communications, Utilities & Miscellaneous Charges	29,949,000	29,770,000	(179,000)
24.0	Printing & Reproduction	14,418,000	14,093,000	(325,000)
25.1	Consulting Services	120,471,000	117,621,000	(2,850,000)
25.2	Other Services	515,643,000	485,772,000	(29,871,000)
25.3	Purchase of Goods & Services from Government Accounts	2,526,800,000	2,508,161,000	(18,639,000)
25.4	Operation & Maintenance of Facilities	297,892,000	263,545,000	(34,347,000)
25.5	Research & Development Contracts	2,140,434,000	2,315,525,000	175,091,000
25.6	Medical Care	16,482,000	16,110,000	(372,000)
25.7	Operation & Maintenance of Equipment	76,450,000	72,506,000	(3,944,000)
25.8	Subsistence & Support of Persons	.....	.....	.....
25.0	Subtotal, Other Contractual Services	5,694,172,000	5,779,240,000	85,068,000
26.0	Supplies & Materials	216,416,000	201,809,000	(14,607,000)
31.0	Equipment	126,456,000	119,236,000	(7,220,000)
32.0	Land and Structures	.....	.....	.....
33.0	Investments & Loans	.....	.....	.....
41.0	Grants, Subsidies & Contributions	21,297,989,000	20,831,478,000	(466,511,000)
42.0	Insurance Claims & Indemnities	10,000	10,000	.....
43.0	Interest & Dividends	117,000	106,000	(11,000)
44.0	Refunds	.....	.....	.....
	Subtotal, Non-Pay Costs	27,441,574,000	27,034,753,000	(406,821,000)
	Total Budget Authority by Object	29,098,845,000	28,771,241,000	(327,604,000)

[1] Reflects request to Labor/HHS/Education Subcommittee, and includes Type 1 Diabetes funds provided through Public Law 107–360.

BUDGET AUTHORITY BY OBJECT INCLUDING SERVICE AND SUPPLY FUND AND MANAGEMENT FUND [1]

	Object Classes	Fiscal year		Increase or Decrease
		2007 Joint Resolution	2008 Estimate	
	Personnel Compensation:			
11.1	Full-Time Permanent	$1,115,616,000	$1,168,343,000	$52,727,000
11.3	Other than Full-Time Permanent	339,113,000	353,676,000	14,563,000
11.5	Other Personnel Compensation	48,648,000	50,402,000	1,754,000
11.7	Military Personnel	35,988,000	37,905,000	1,917,000
11.8	Special Personnel Services Payments	175,535,000	179,832,000	4,297,000
	Total, Personnel Compensation	1,714,900,000	1,790,158,000	75,258,000
12.1	Civilian Personnel Benefits	416,629,000	434,651,000	18,022,000
12.2	Military Personnel Benefits	21,800,000	22,647,000	847,000
13.0	Benefits for Former Personnel	661,000	672,000	11,000
	Subtotal, Pay Costs	2,153,990,000	2,248,128,000	94,138,000
21.0	Travel & Transportation of Persons	58,562,000	56,236,000	(2,326,000)
22.0	Transportation of Things	6,602,000	6,369,000	(233,000)
23.1	Rental Payments to GSA	40,154,000	40,402,000	248,000
23.2	Rental Payments to Others	85,139,000	85,657,000	518,000
23.3	Communications, Utilities & Miscellaneous Charges	148,541,000	149,124,000	583,000
24.0	Printing & Reproduction	21,749,000	21,448,000	(301,000)
25.1	Consulting Services	136,456,000	133,654,000	(2,802,000)
25.2	Other Services	1,002,883,000	974,048,000	(28,835,000)
25.3	Purchase of Goods & Services from Government Accounts	858,478,000	821,161,000	(37,317,000)
25.4	Operation & Maintenance of Facilities	415,313,000	381,429,000	(33,884,000)
25.5	Research & Development Contracts	2,143,108,000	2,318,213,000	175,105,000

BUDGET AUTHORITY BY OBJECT INCLUDING SERVICE AND SUPPLY FUND AND MANAGEMENT FUND [1]—Continued

	Object Classes	Fiscal year		Increase or Decrease
		2007 Joint Resolution	2008 Estimate	
25.6	Medical Care	24,463,000	23,703,000	(760,000)
25.7	Operation & Maintenance of Equipment	173,642,000	170,147,000	(3,495,000)
25.8	Subsistence & Support of Persons	.....	.....	.....
25.0	Subtotal, Other Contractual Services	4,754,343,000	4,822,355,000	68,012,000
26.0	Supplies & Materials	336,691,000	321,810,000	(14,881,000)
31.0	Equipment	194,842,000	188,002,000	(6,840,000)
32.0	Land and Structures	77,000	77,000	.....
33.0	Investments & Loans	.....	.....	.....
41.0	Grants, Subsidies & Contributions	21,297,989,000	20,831,478,000	(466,511,000)
42.0	Insurance Claims & Indemnities	14,000	14,000	.....
43.0	Interest & Dividends	152,000	141,000	(11,000)
44.0	Refunds	.....	.....	.....
	Subtotal, Non-Pay Costs	26,944,855,000	26,523,113,000	(421,742,000)
	Total Budget Authority by Object	29,098,845,000	28,771,241,000	(327,604,000)

[1] Reflects request to Labor/HHS/Education Subcommittee, and includes Type I Diabetes funds provided through Public Law 107–360

SALARIES AND EXPENSES

Object Classes	Fiscal year		Increase or decrease
	2007 Joint resolution	2008 estimate	
Personnel Compensation:.			
Full-Time Permanent (11.1)	$838,033,000	$881,383,000	$43,350,000
Other Than Full-Time Permanent (11.3)	263,580,000	276,142,000	12,562,000
Other Personnel Compensation (11.5)	29,783,000	31,112,000	1,329,000
Military Personnel (11.7)	26,032,000	27,721,000	1,689,000
Special Personnel Services Payments (11.8)	171,584,000	175,795,000	4,211,000
Total Personnel Compensation (11.9)	1,329,012,000	1,392,153,000	63,141,000
Civilian Personnel Benefits (12.1)	311,004,000	326,309,000	15,305,000
Military Personnel Benefits (12.2)	17,255,000	18,026,000	771,000
Benefits to Former Personnel (13.0)	.....	.....	.....
Subtotal, Pay Costs	1,657,271,000	1,736,488,000	79,217,000
Travel (21.0)	55,429,000	52,639,000	(2,790,000)
Transportation of Things (22.0)	5,174,000	4,938,000	(236,000)
Rental Payments to Others (23.2)	1,380,000	1,373,000	(7,000)
Communications, Utilities and Miscellaneous Charges (23.3)	29,949,000	29,770,000	(179,000)
Printing and Reproduction (24.0)	14,418,000	14,093,000	(325,000)
Other Contractual Services:			
Advisory and Assistance Services (25.1)	103,157,000	100,069,000	(3,088,000)
Other Services (25.2)	515,643,000	485,772,000	(29,871,000)
Purchases from Govt. Accounts (25.3)	1,177,590,000	1,146,018,000	(31,572,000)
Operation & Maintenance of Facilities (25.4)	62,671,000	62,582,000	(89,000)
Operation & Maintenance of Equipment (25.7)	76,450,000	72,506,000	(3,944,000)
Subsistence & Support of Persons (25.8)	.....	.....	.....
Subtotal Other Contractual Services	1,935,511,000	1,866,947,000	(68,564,000)
Supplies and Materials (26.0)	216,416,000	201,809,000	(14,607,000)
Subtotal, Non-Pay Costs	2,258,277,000	2,171,569,000	(86,708,000)
Total, Administrative Costs	3,915,548,000	3,908,057,000	(7,491,000)

SALARIES AND EXPENSES—TOTAL—MODIFIED DEFINITION

Institutes and centers	Fiscal year		Percent change
	2007 Joint resolution	2008 President's budget	
NCI	$312,200,000	$315,226,000	1.0
NHLBI	107,364,000	108,390,000	1.0
NIDCR	20,949,000	21,151,000	1.0
NIDDK	60,867,000	61,450,000	1.0
NINDS	54,003,000	54,561,000	1.0
NIAID	229,065,000	231,142,000	0.9
NIGMS	47,317,000	48,300,000	2.1
NICHD	57,594,000	58,425,000	1.4
NEI	22,905,000	23,098,000	.8
NIEHS	22,141,000	22,313,000	.8
NIA	37,554,000	37,942,000	1.0
NIAMS	23,537,000	23,737,000	.8
NIDCD	18,434,000	18,624,000	1.0
NIMH	73,171,000	73,901,000	1.0
NIDA	57,628,000	58,205,000	1.0
NIAAA	26,946,000	27,179,000	.9
NINR	9,367,000	9,464,000	1.0
NHGRI	18,412,000	18,581,000	.9
NCRR	27,957,000	28,235,000	1.0
NCCAM	12,698,000	12,824,000	1.0
NCMHD	10,154,000	10,260,000	1.0
NIBIB	17,155,000	17,353,000	1.2
FIC	12,582,000	12,708,000	1.0
NLM	9,875,000	9,855,000	−0.2
OD	114,136,000	107,471,000	−5.8
Clinical Center	18,248,000	18,431,000	1.0
Total	1,422,259,000	1,428,826,000	0.5
Public Health Education Excluded from above	(28,384,000)	(28,779,000)	1.4

Note.—Section 408 of the PHS Act, as amended, defines administrative expenses as expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

In collaboration with staff of the General Accounting Office (GAO), a methodology was developed to account for administrative expenses as defined in Section 408. This methodology includes obligations in the RMS budget activity (except for Program Evaluation costs), obligations directly related to the administrative responsibilities of the Office of the Scientific Director in the Intramural budget activity, and administrative expenses in the Cancer Control program.

In addition, direct program costs in the Office of the Director (those for the Director's Discretionary Fund, AIDS research, the Office of Women's Health Research, the Office of Education, the Office of Behavioral and Social Science Research, the Office of Dietary Supplements, the Loan Repayment Programs, and the Office of Rare Diseases Research) have been excluded.

The definition of administrative expenses has been further modified to include those activities specifically excluded by the law (NINR, FIC, NLM, and the Clinical Center), and to exclude public health education activities. This is consistent with previous House Appropriations subcommittee requests on administrative costs using this definition.

Major cost categories excluded from this definition but included in the OMB/HHS definition of administrative costs: salaries and benefits for researchers; travel for patients undergoing treatment at the Clinical Center and travel to scientific workshops and conferences; costs associated with laboratory facilities; contractual support for R&D activities in the Intramural program; and scientific supplies.

STATISTICAL DATA—GRANTS, DIRECT AND INDIRECT COSTS AWARDED

[Dollars in millions]

Fiscal year	Direct costs awarded	Indirect costs awarded	Total dollars awarded	Percent to total in dollars		Percent growth in dollars	
				Direct	Indirect	Direct	Indirect
1996	$6,214	$2,627	$8,840	70.3	29.7	.....	.....
1998	7,246	3,038	10,284	70.5	29.5	.....	.....
1999	8,391	3,421	11,811	71.0	29.0	15.8	12.6
2000	9,787	3,881	13,668	71.6	28.4	16.6	13.5
2001	11,210	4,425	15,634	71.7	28.3	14.5	14.0
2002	12,721	4,937	17,658	72.0	28.0	13.5	11.6
2003	14,337	5,410	19,747	72.6	27.4	12.7	9.6
2004	14,780	5,760	20,540	72.0	28.0	3.1	6.5
2005	15,299	5,915	21,214	72.1	27.9	3.5	2.7
2006	15,095	5,905	21,000	71.9	28.1	−1.3	−0.2
2007 Joint Resolution	15,290	5,982	21,272	71.9	28.1	1.3	1.3
2008 President's Budget	15,049	5,887	20,936	71.9	28.1	−1.6	−1.6

Note.—Fiscal year 2007–2008 data is preliminary, and will change as actual data is received.

RESEARCH PROJECT GRANTS—TOTAL NUMBER OF AWARDS AND DOLLARS

[Dollars in thousands]

	Fiscal year													
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007 joint resolution	2008 revised President's budget
No. of Awards:														
Competing	6,759	6,653	7,390	7,578	8,566	8,765	9,101	9,396	10,411	10,020	9,599	9,129	10,154	9,404
Noncompeting	17,069	17,854	18,248	19,495	20,149	21,779	23,322	24,921	25,776	27,040	27,385	27,366	26,668	26,573
Subtotal (includes Non-comp)	23,828	24,507	25,638	27,073	28,715	30,544	32,423	34,317	36,187	37,060	36,984	36,495	36,822	35,977
SBIR	1,071	1,012	1,298	1,326	1,508	1,640	1,699	1,889	2,032	2,181	1,924	1,822	1,463	1,543

Total	24,899	25,519	26,936	28,399	30,223	32,184	34,122	36,206	38,219	39,241	38,908	38,317	38,285	37,520
Average Annual Cost:														
Competing	$231.2	$244.6	$245.9	$255.9	$293.6	$332.2	$333.1	$338.8	$337.8	$355.7	$354.8	$368.3	$367.5	$350.3
Total (includes noncomp)	$252.7	$262.1	$269.3	$277.7	$294.8	$319.4	$344.7	$365.5	$79.9	$392.9	$401.8	$403.2	$402.1	$402.3
Percent Change over prior year average costs:														
Competing RPGs	2.8	5.8	0.5	4.0	14.7	13.2	0.3	1.7	−0.3	5.3	−0.2	3.8	−0.2	−4.7
Total RPGs	3.8	3.7	2.7	3.1	6.2	8.4	7.9	6.0	3.9	3.4	2.3	0.4	−0.3	.....
Average Length of Award in Years	3.8	3.8	3.8	3.8	3.9	3.9	3.9	3.9	3.8	3.7	3.7	3.8	3.7	3.8

[1] As a policy, no inflationary increases were provided for competing RPGs. The apparent decrease in average cost in fiscal year 2008 is the result of an extremely large cohort of AIDS clinical trials cycling from competing into noncompeting status. (77 awards, average cost $1.8 million per award). While there will be no inflationary increases for direct, recurring costs in Noncompeting continuation RPGs, where the NIH has committed to a programmatic increase in an award, such increases will be provded.

Numbers of grants identified in fiscal year 2007 and fiscal year 2008 are estimates, and WILL change as applications are received and selected for funding.

RESEARCH PROJECT GRANTS—FISCAL YEARS 1999–2008

[Percent of success Rates]

Institutes and centers	Fiscal year									
	1999	2000	2001	2002	2003	2004	2005	2006	2007 joint resolution	2008 President's budget
NCI	32	26	27	28	27	24	20	19	19	17
NHLBI	36	35	36	33	34	29	24	20	19	18
NIDCR	24	27	34	29	27	30	24	19	20	15
NIDDK	33	28	29	34	33	27	24	21	19	17
NINDS	35	37	32	29	30	25	22	18	19	18
NIAID	34	36	38	36	35	24	25	21	22	21
NIGMS	39	37	37	39	38	30	27	26	31	25
NICHD	30	29	27	28	27	17	18	15	19	15
NEI	40	42	40	41	33	30	26	23	23	23
NIEHS	27	29	29	29	25	19	19	22	19	11
NIA	28	26	32	28	29	21	19	17	19	17
NIAMS	24	27	29	23	20	20	20	19	17	17
NIDCD	34	40	42	39	38	35	27	28	29	25
NIMH	27	29	31	28	27	24	21	20	22	19

RESEARCH PROJECT GRANTS—FISCAL YEARS 1999–2008—Continued

[Percent of success Rates]

Institutes and centers	Fiscal year									
	1999	2000	2001	2002	2003	2004	2005	2006	2007 joint resolution	2008 President's budget
NIDA	34	38	36	31	35	27	22	20	19	18
NIAAA	30	31	33	32	27	29	31	27	31	30
NINR	14	32	26	26	27	21	24	18	21	17
NHGRI	38	43	42	15	30	23	18	34	38	32
NIBIB	N/A	N/A	N/A	N/A	19	17	20	17	18	16
NCRR	34	18	29	30	28	21	14	13	21	17
NCCAM	57	29	17	14	14	17	17	14	17	21
NCMHD [1]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
FIC	39	23	30	28	19	22	24	19	20	18
ROADMAP	N/A	N/A	N/A	N/A	N/A	13	17	10	18	10
NIH	32	32	32	31	30	25	22	20	21	18

[1] NCMHD success rate is N/A due to co-funding agreements with other IC's.

Note.—Success rates identified in fiscal year 2007 and fiscal year 2008 are estimates, and WILL change as applications are received and selected for funding.

HISTORY OF OBLIGATIONS BY INSTITUTE OR CENTER [1]—FISCAL YEARS 1999–2008

[In thousands of dollars]

Institutes and centers	Fiscal year										
	1999	2000	2001	2002	2003	2004	2005	2006 actual	2006 comp.[1]	2007 revised joint resolution	2008 revised President's budget
NCI	2,918,050	3,314,580	3,758,566	4,177,830	4,595,477	4,727,365	4,797,731	4,754,121	4,795,073	4,795,491	4,782,114
NHLBI	1,788,008	2,027,286	2,298,035	2,569,794	2,793,681	2,882,601	2,922,573	2,893,527	2,915,923	2,919,980	2,925,413
NIDCR	233,605	268,521	306,152	342,292	371,630	382,013	389,346	385,589	388,664	389,370	389,722
NIDDK	1,018,063	1,167,110	1,399,184	1,560,013	1,712,959	1,829,473	1,852,592	1,838,511	1,853,149	1,855,226	1,858,045
NINDS	900,245	1,028,204	1,175,591	1,325,193	1,456,426	1,498,203	1,529,654	1,519,971	1,533,045	1,534,904	1,537,019
NIAID	1,565,201	1,777,154	2,041,311	2,339,779	3,606,789	4,141,769	4,276,433	4,274,201	4,379,199	4,366,445	4,592,482
NIGMS	1,203,079	1,366,994	1,535,056	1,722,890	1,846,917	1,915,130	1,931,690	1,916,927	1,934,043	1,935,625	1,941,462
NICHD	748,626	857,354	975,537	1,110,459	1,205,908	1,247,939	1,262,273	1,252,598	1,263,521	1,254,144	1,264,946

NEI	394,601	449,759	510,241	580,047	633,109	650,961	664,840	660,340	665,768	666,675	667,820
NIEHS	374,527	441,960	501,813	574,518	614,183	630,254	640,405	630,447	635,995	641,773	637,406
NIA	594,556	685,695	785,413	891,282	993,595	1,021,376	1,045,339	1,036,559	1,045,201	1,046,500	1,047,148
NIAMS	307,160	349,555	396,305	447,682	486,031	499,368	507,843	502,954	507,416	508,060	508,082
NIDCD	229,162	263,448	300,282	341,260	370,330	380,737	391,679	389,623	393,111	393,540	393,682
NIMH	858,520	972,127	1,106,095	1,245,292	1,341,014	1,379,225	1,403,007	1,390,009	1,401,813	1,403,570	1,405,421
NIDA	611,061	694,561	790,185	892,639	965,721	991,510	1,000,056	990,405	998,858	1,000,014	1,000,365
NIAAA	258,874	291,928	340,151	383,174	415,960	427,223	435,503	431,726	435,479	436,057	436,505
NINR	69,600	89,415	104,294	120,217	130,537	134,279	137,199	136,020	137,150	137,287	137,800
NHGRI	279,030	335,129	381,971	428,248	464,960	490,546	485,500	481,339	485,655	486,427	484,436
NIBIB	.....	.....	.....	111,740	278,279	286,684	296,324	293,954	298,088	298,391	300,463
NCRR	562,082	676,077	817,098	1,010,169	1,138,820	1,191,556	1,108,028	1,088,500	1,108,947	1,143,841	1,112,498
NCCAM	40,464	77,808	89,120	104,334	113,405	116,590	121,333	120,294	121,134	121,379	121,699
NCMHD	.....	.....	130,070	157,364	185,674	190,824	194,904	193,522	195,263	199,429	194,495
FIC	35,307	43,446	50,430	56,787	63,425	65,160	66,164	65,726	66,317	66,422	66,594
NLM	181,014	213,730	239,068	275,395	299,771	310,165	312,980	311,721	314,078	320,229	312,562
OD	255,584	281,587	212,482	234,784	266,161	327,267	533,673	724,831	478,307	1,096,985	517,062
Subtotal	15,426,419	17,673,428	20,244,450	23,003,182	26,350,762	27,718,218	28,307,069	28,283,415	28,351,197	29,017,764	28,635,241
B&F	216,856	140,311	205,756	114,839	305,628	303,254	239,246	170,456	85,505	81,081	136,000
TOTAL	15,643,275	17,813,739	20,450,206	23,118,021	26,656,390	28,021,472	28,546,315	28,453,871	28,436,702	29,098,845	28,771,241
Interior/Superfund	.....	.....	62,850	70,212	83,515	78,300	79,836	79,108	79,108	79,117	78,434
Total, Budget Authority	15,643,275	17,813,739	20,513,056	23,188,233	26,739,905	28,099,772	28,626,151	28,532,979	28,515,810	29,177,962	28,849,675

[1] Obligations for actual years exclude lapse. Includes funds for Type I Diabetes Initiative.
[2] Fiscal year 2006—Comparable includes all comparable adjustments.

HISTORY OF OBLIGATIONS BY TOTAL MECHANISM [1]—FISCAL YEARS 1999–2008

[In thousands of dollars]

Budget mechanism	Fiscal year										
	1999	2000	2001	2002	2003	2004	2005	2006 actual [2]	2006 comp.[3]	2007 revised joint resolution	2008 revised President's budget
Res. Project Grants	8,779,019	10,118,249	11,557,511	12,995,051	14,239,043	15,165,836	15,426,097	15,313,663	15,332,997	15,417,256	15,080,819
Research Centers	1,380,117	1,547,152	1,859,600	2,123,723	2,425,448	2,545,972	2,647,355	2,659,653	2,804,893	2,895,051	2,917,412
Other Research	808,100	1,013,499	1,218,906	1,450,750	1,587,841	1,651,823	1,655,743	1,650,974	1,669,351	1,767,797	1,747,167

HISTORY OF OBLIGATIONS BY TOTAL MECHANISM [1]—FISCAL YEARS 1999–2008—Continued

[In thousands of dollars]

Budget mechanism	Fiscal year										
	1999	2000	2001	2002	2003	2004	2005	2006 actual [2]	2006 comp. [3]	2007 revised joint resolution	2008 revised President's budget
Subtotal Res. Grants	10,967,236	12,678,900	14,636,017	16,569,524	18,252,332	19,363,631	19,729,195	19,624,290	19,807,241	20,080,104	19,745,398
Research Training	509,185	539,510	589,624	650,686	711,441	740,506	743,861	731,121	748,641	771,600	769,413
R & D Contracts	1,067,197	1,147,672	1,387,989	1,642,046	2,299,140	2,691,897	2,516,611	2,582,606	2,667,066	2,783,528	2,975,285
Intramural Research	1,564,547	1,746,220	1,950,859	2,225,292	2,564,664	2,658,853	2,737,865	2,745,676	2,772,036	2,791,706	2,774,311
Res. Mgt. & Support	542,188	600,203	690,929	786,647	927,297	977,771	1,014,754	1,098,953	1,108,615	1,132,127	1,142,492
Cancer Control	306,734	389,425	459,482	501,208	533,173	529,980	531,634	505,705	505,705	516,565	516,565
Construction	32,734	76,181	78,000	117,600	496,782	118,148	178,560	29,700	29,700	.....	.....
Library of Medicine	181,014	213,730	239,068	275,395	299,771	310,165	312,980	311,721	311,264	320,229	308,415
Office of the Director	255,584	281,587	212,482	234,784	266,161	327,267	533,673	724,831	393,009	613,985	395,522
Subtotal	15,426,419	17,673,428	20,244,450	23,003,182	26,350,761	27,718,218	28,299,133	28,354,603	28,343,277	29,009,844	28,627,401
Buildings & Facilities	216,856	140,311	205,756	114,839	305,628	303,254	247,182	178,376	93,425	89,001	143,840
Total	15,643,275	17,813,739	20,450,206	23,118,021	26,656,389	28,021,472	28,546,315	28,532,979	28,436,702	29,098,845	28,771,241
Interior—Superfund	62,850	70,212	83,515	78,300	79,836	79,108	79,108	79,117	78,434		
Total Budget Authority	15,643,275	17,813,739	20,513,056	23,188,233	26,739,904	28,099,772	28,626,151	28,532,979	28,515,810	29,177,962	28,849,675

[1] Obligations for actual years exclude lapse.
[2] Fiscal year 2006 Actual Obligations include Interior (previously VA/HUD) Superfund activities within the Mechanism amounts.
[3] Fiscal year 2006 Comparable includes all transfers and comparable adjustments.
[4] B&F Budget Mechanism includes the B&F appropriation plus the following included in NCI: Fiscal year 2005—$7,936,000; fiscal year 2006—$7,920,000; fiscal year 2007 (est.)—$7,920,000; fiscal year 2008 (est)—$7,840,000.

Note.—All amounts include funds for Type I Diabetes Initiative.

OPASI

Question. I understand that you envision a significant role for the Office of Portfolio Analysis and Strategic Initiatives in future NIH activities. At present, the Office has a relatively small dedicated budget and workforce. Please provide us with an updated mechanism table for OPASI showing the enacted fiscal year 2007 enacted level and the fiscal year 2008 President's budget request. Please also provide narrative regarding your vision for OPASI's future role at NIH including, but not limited to, the following: The activities you envision OPASI performing.

Answer. The Office of Portfolio Analysis and Strategic Initiatives (OPASI) is a policy office within the NIH Office of the Director. Related grant-making activities are carried out within the Common Fund/Roadmap.

The goal of the Office is to support the ICs in their collaborative efforts. OPASI accomplishes its mission through the efforts of three Divisions: the Division of Resource Development and Analysis, the Division of Strategic Coordination, and the Division of Evaluation and Systemic Assessments. These divisions work together to analyze the existing NIH research portfolio, collaborate with the ICs to plan and manage new research initiatives via the Common Fund, and provide evaluation support to the ICs so that future programs can be improved. The NIH has also established a Council of Councils (CoC) to give advice on OPASI activities. The CoC is composed of scientific and lay council members from the IC Advisory Councils and the NIH Council of Public Representatives who simultaneously serve on the CoC and their home councils.

Division of Resource Development and Analysis: This Division develops tools, analyses, and resources that can be used within OPASI and in the ICs to monitor and report on spending in specific areas; performs portfolio analyses, particularly with respect to a wide variety of scientific areas in which multiple ICs are active; collects, distributes, and analyzes data on public health burden of disease as well as the impact of research on disease burden. One portfolio analysis tool being developed by this division, is the RCDC (Research, Condition and Disease Categorization system, formerly known as the Knowledge Management and Disease Coding system, KMDC) This system is a state of the art reporting tool that streamlines the process of identifying grants, contracts, and intramural research projects that are relevant to particular diseases, conditions, or scientific topics. The tool will first be used for category reporting for the fiscal year 2010 budget.

The RCDC use as a portfolio analysis tool for planning purposes will expand beyond OPASI to the ICs in fiscal year 2008 as personnel are trained in the use of the system.

Division of Strategic Coordination.—This Division works closely with the ICs to manage the Common Fund, which funds the NIH Roadmap. Since many cross-cutting areas are funded through IC collaborations outside the context of the Common Fund, special criteria have been established for Common Fund initiatives. OPASI staff in this Division work closely with ICs to gather ideas for possible Common Fund initiatives, to determine the responsiveness of these ideas to the Common Fund/Roadmap criteria, and to prioritize the ideas based in part on analysis of current funding in these areas using tools from the Division of Resource Development and Analysis. Those areas not selected for Roadmap emphasis may be addressed through multi-IC collaborations outside the scope of OPASI management. Staff in this Division will also increasingly be involved in post-award management of Common Fund initiatives, reviewing progress of individual projects as well as providing an overall assessment of whether program goals and milestones are being met.

Division of Evaluation and Systemic Assessments.—This Division manages the NIH portion of the PHS Evaluation Set-Aside funds and works with ICs to develop evaluation plans for their programs. In addition, the Division provides expertise for the evaluation of multi-IC-supported programs, including those that are supported via the Common Fund. This activity will expand in future years to include an In-House studies team that will conduct evaluations of Common Fund/Roadmap and other trans-NIH programs. This Division also manages the coordinated development and submission of Systemic Assessment documents in response to the Government Performance Results Act (GPRA) and the Office of Management and Budget's Performance Assessment Rating Tool (PART).

Question. Any grant-making or grant-administering activities you envision OPASI performing?

Answer. A fundamental tenet of the Common Fund is that the initiatives should benefit and synergize with the missions of multiple or all ICs. The management of Common Fund initiatives is therefore inherently of interest to the ICs and is best served by highly engaged scientific program staff working in the ICs. For this reason, the grant-making authority and much of the grant administration of Common

Fund initiatives lies in the ICs. However, IC staff work on individual initiatives that are of particular interest to their IC and therefore may not maintain perspective on the program as a whole. The role of OPASI throughout the process of Common Fund management is to provide an over-arching view and perspective of the Common Fund and the scientific goals that all of the initiatives are expected to meet. OPASI staff work on teams that consist primarily of IC staff to plan each of the initiatives, to review progress, to develop specific budgetary plans, and to develop evaluations for individual initiatives; their participation in all of the teams provides an over-arching central level of management that insures that the trans-NIH nature of the initiatives is maintained.

In addition to the Common Fund, OPASI oversees funding available to NIH from the PHS Evaluation Set-Aside. These funds are administered and managed by the Division of Evaluation and Systemic Assessment. The Division assesses funding requests from ICs for technical and conceptual merit as well as policy relevance. This is an internal process designed to ensure high quality program evaluations rather than a grant-making authority.

Question. Broad strokes estimates for future growth of the office in terms of FTE's and budget (not including amounts appropriated separately for the Common Fund).

Answer. OPASI future growth will occur in all three Divisions. Recruitment is underway in the Division of Strategic Coordination to allow central scientific staff involvement in all of the Common Fund initiatives. The current staffing level will be re-evaluated in fiscal year 2008 after the second cohort of initiatives is funded and while a third cohort is being planned to determine whether additional staff are needed in fiscal year 2009 and beyond. The Division of Resource Development and Analysis is expected to grow in fiscal year 2008 to accommodate increased portfolio analysis and planning both within OPASI and in the ICs. Its growth beyond fiscal year 2008 will involve the recruitment of staff to develop new tools to enhance the ability to plan for, assess, and manage complex portfolios and to expand the capacity to analyze Public Health Burden. The Division of Evaluation and Systemic Assessment will expand in fiscal year 2008 to increase the capability of doing evaluations in-house. FTEs are expected to grow consistent with the funds available for OPASI, currently funded at $7,826,000 (includes one-time funding of $4,550,000 for Research, Condition and Disease Categorization) in fiscal year 2007 to $4,450,000 in fiscal year 2008, a decrease of $3,376,000 over fiscal year 2007.

QUESTION SUBMITTED BY SENATOR DANIEL K. INOUYE

BEHAVIORAL RESEARCH

Question. Every year since fiscal year 1999, this Subcommittee has urged the NIH to support basic behavioral research and to find an organizational home for this activity. Basic research is the building block for subsequent discoveries that lead to improved treatments and cures. This, of course, is also true for behavioral research. How do you intend to ensure dedicated scientific leadership for basic behavioral research at the NIH?

Answer. Basic behavioral and social sciences research (BSSR) is critical to the NIH mission and the Agency will continue to support work in these disciplines. We estimate that NIH support for basic BSSR has been over $1.0 billion annually since fiscal year 2004. NIA, NIDA, NICHD, NIMH and NIAAA have provided particularly strong funding in this area.

The Office of Behavioral and Social Sciences Research (OBSSR), located within the Office of the Director, is key to leading, coordinating and participating in NIH BSSR activities, including basic BSSR. OBSSR participates in funding opportunity announcements developed by individual or small groups of Institutes and Centers (ICs) and also leads in the development of such initiatives. However, OBSSR does not fund initiatives directly or entirely and is dependent on individual ICs for support and funding of specific programs. The Office participates in the Genes, Environment and Health Initiative, the NIH Blueprint for Neuroscience Research, and the NIH Roadmap for Medical Research. It has taken the lead on several Roadmap initiatives, including RFA RM 07-004, Facilitating Interdisciplinary Research via Methodological and Technological Innovation in the Behavioral and Social Sciences (R21) (http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-004.html). Slated for funding in fiscal year 2007, this initiative seeks to foster better integration of the behavioral and social sciences with biomedical research with the ultimate goal of improving health.

Under the leadership of its Director, Dr. David Abrams, OBSSR has recently completed a two-year strategic planning process that identified four major pro-

grammatic directions for the Office. As articulated in the Strategic Prospectus (http://www.conceptsystems.com/OBSSR/OBSSR-Prospectus-final.pdf), the first programmatic direction is "next generation" basic BSSR that will be informed by breakthroughs in complementary areas such as genetics, informatics, and multilevel analyses. Specific priority areas include but are not limited to the following:

—*Gene-Environment interactions*.—How are genetic traits and early life experiences linked to physical and emotional health later in life?

—*Biosocial stress markers*.—What are the biological sequelae of stress, and how do they relate to long-term mental and physical health?

—*Technology, Measurement and Methodology*.—How can we improve biomarker, behavioral and environmental data collection to better understand pathways linking biology, behavior, environment, and society?

—*Spirituality and health*.—How do individual belief systems or social religious norms affect health?

—*Work-related stresses*.—How are conflicts between work and family associated with social stress and health?

—*Social integration and social capital*.—How have advances in technology and mobility affected neighborhood social networks, health behaviors and health outcomes?

—*Inequality and health outcomes*.—How do large-scale societal structures (e.g., racial segregation, immigration and acculturation patterns, socioeconomic status) impact health?

As a first step in the realization of "next generation" basic BSSR, OBSSR is currently leading a partnership among several ICs and the Centers for Disease Control and Prevention to issue new funding opportunity announcements to support behavioral and social science research on understanding and reducing health disparities (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-063.html). The Office is also working with IC partners on activities to support research on gene-social environment interactions and in fiscal year 2008 plans to sponsor a summer institute to train behavioral and social scientists in genetics/genomics.

The senior leadership at NIH believes that the current NIH-wide approach of having basic BSSR within and across many ICs, and having OBSSR play a coordinating or leadership role, is the optimal arrangement for this area of research. Moreover, the NIH Reform Act of 2006 established the new Division of Program Coordination, Planning, and Strategic Initiatives, of which OBSSR will be a part. This change will enhance OBSSR's coordinating and leadership roles, working in the new Division and with ICs to ensure the support of the highest quality basic and applied BSSR throughout the NIH.

SUBCOMMITTEE RECESS

Senator HARKIN. So, thank you all for being here. The subcommittee will stand in recess to reconvene at 3:30 p.m., Monday, March 26, in room SD–116.

[Whereupon, at 3:05 p.m., Monday, March 19, the subcommittee was recessed, to reconvene at 3:30 p.m. Monday, March 26.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

MONDAY, MARCH 26, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 3:30 p.m., in room SD–116, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF HON. THOMAS R. INSEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Appropriations Subcommittee on Labor, Health and Human Services, and Education and Related Agencies will come to order. This is the subcommittee's second hearing on the National Institutes of Health this year. Last week we heard from NIH Director Elias Zerhouni and several top extramural scientists as we discussed the need for more NIH funding. Starting today and over the course of the subcommittee's next five NIH hearings, we will hear from each of the Institute and center Directors, usually in groups of four or five.

We had actually done this before. I like this room, I like the setting, I like the way that we are at a table here, which makes it more conversational, rather than just sitting at a podium, that type of thing. So I like this much better. This is one of our Appropriations rooms. In fact, our predecessor on this when I first came to this committee used this room and we had those hearings at that time. I like the idea. I like the setting of it, so I am going to try to use this room as often as possible for these kinds of hearings. It is not as formal, it is more relaxed, and we can have a conversation.

I will ask each of the Directors to speak for about 5 minutes. We have your statements. We will make them a part of the record in their entirety. So I am just going to ask you for about 5 minutes to talk about some of the most important functions that you see in what you are doing, and then we will have a discussion with you,

and we will do each Director's time. So I am thinking about 15 minutes per person, and we will do it that way. Then at the end, maybe if there are some wrap-up things, then we will just kind of open it for a general thing at that time.

So the five Institutes that are here today—NIMH, Mental Health; National Institute on Drug Abuse, NIDA; the National Institute on Alcohol Abuse and Alcoholism, otherwise known as NIAAA; National Institute on Deafness and Communication Disorders; and the National Institute of Neurological Disorders and Stroke, Dr. Landis. We grouped these together because all of these have to do with mind-brain behavior, and I am going to try to continue this kind of lumping together of different Institutes as we have these hearings.

However, I just say that if you have other things you want to bring up, please do. Anything happening in your Institutes is fair game for us to discuss.

With that, I turn to Senator Specter if you have anything in opening.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman.

We continue our hearings on the National Institutes of Health, and I consider this to be a matter of priority second to none in our budget. Health is our principal capital asset and the work which has been done by NIH has been truly spectacular. Senator Harkin and I have taken the lead, as is fairly well known, in increasing the funding for NIH from $12 billion to almost $30 billion, and we have done that by taking a very sharp pencil and establishing priorities and eliminating items from a very important budget in deference to the greater importance of health care.

We have three major Departments that we are responsible for funding: Health and Human Services, Education, and Labor. So that we have had to evaluate education priorities and worker safety priorities and health care priorities. But NIH has the potential to be a fountain of youth, in my opinion, and to really find ways to fund cures for many, many ailments.

I say with some frequency, but not often enough, that when President Nixon declared war on cancer in 1970—had that war been pursued with the same intensity as other wars—my chief of staff, a beautiful young woman named Carie Lackman, at 48 would not have died of breast cancer, and last year one of my best friends, the Chief Judge of the Third Circuit emeritus, would not have died of prostate cancer; and I would not have gotten Hodgkins.

When we talk about containing costs, the best way to contain costs is to prevent disease and to prevent illness. Senator Harkin and I are leading the fight for embryonic stem cells. It is scandalous when you have the major responsibility for funding health programs in the Federal Government but are not able to use any funds for stem cell research. Now, if these embryos would produce children we would be the last to suggest they be used. But we have taken the lead in putting up $2 million to have adoptions, but only about 100 of some 400,000 have been adopted. So it is a matter of useing them to save lives or having them ultimately discarded.

Senator Harkin and I added an amendment to the budget resolution last week for $2.2 billion and that is only to stay afloat and tread water from the cost of living adjustments. But do not draw too much encouragement from it because the budget resolution is only Confederate money. The money does not materialize until there is an allocation. Then it does not materialize until there is an appropriation, and to call it Confederate money may be giving it too much credit. It may be more accurately called Monopoly money.

But we are determined to fight this through. You can help us. As we said to Dr. Zerhouni last week, we need to have the best estimates you can make as to what this research means in terms of saving lives and quantifying—I know it is hard to do—how long it will take to find a cure for a given malady and how much it will save. For example—if you delay the onset of Alzheimer's—I have seen some statistics that shows health care cost savings into the billions of dollars. But that is what motivates the other 535 Members of Congress, if you can be specific and show them some savings.

So thank you for what you are doing and I look forward to your testimony.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

So we will start with Dr. Insel, then Dr. Volkow, Dr. Battey, and then Dr. Landis.

Dr. Thomas Insel has been the Director of the National Institute of Mental Health since September 2002, received his B.A. and M.D. degrees both from Boston University. So Dr. Insel, welcome. As I said, your statement is part of the record. Tell us what you are doing, what is important, and what we ought to know about.

SUMMARY STATEMENT OF DR. THOMAS R. INSEL

Dr. INSEL. Thank you. First of all, Mr. Chairman, let me say how much we all appreciate being here. I have been in my job now for about 4½ years. I think this is the first time I have had a chance to talk with this subcommittee and update you with the kinds of things we are interested in.

At the beginning, I would like to just very quickly run through where we see the biggest needs and then tell you a little bit about what we hope to do about them. There is no question that the needs across all of these Institutes in terms of the public health burden is very great. You will be hearing from all five of these NIH Institutes that focus on neuroscience and behavior. Together we cover about 1,000 disorders of the nervous system affecting about 70 million Americans. These result in more hospitalizations than any other class of illnesses, including cancer and heart disease. You will hear about some of the costs, which in aggregate are about $800 billion per year. For my Institute, the mental health piece of this alone, represents for all health care about 6.2 percent of the overall cost, and some parts of that are going up, such as medications, at a rate of about 20 percent per year.

PREPARED STATEMENT

I think you know that the health care costs have now become about 16 percent of the GDP, predicted to go up to 20 percent by 2016. So these are very significant costs in the entire economy.

[The statement follows:]

PREPARED STATEMENT OF DR. THOMAS R. INSEL

Mr. Chairman, and members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute of Mental Health (NIMH). The fiscal year 2008 budget includes $1,405,421,000. In my statement, I will call to your attention our Nation's most prevalent mental and behavioral disorders and include a brief review of our research activities and accomplishments.

MENTAL DISORDERS ARE CHRONIC BRAIN DISORDERS

The NIMH mission is to reduce the burden of mental and behavioral disorders, such as depression, schizophrenia, autism, and bipolar disorder, through research on mind, brain, and behavior. Research is demonstrating that these illnesses are brain disorders, accessible by the tools of modern neuroscience. These disorders frequently begin in childhood and are chronic,[1] affecting people of all races and ethnicities, in both rural and urban settings. To prevent a lifetime of disability for millions of Americans, NIMH research is identifying the biological basis of mental disorders, and pinpointing targets for diagnosis, prevention, and treatment.

PUBLIC HEALTH BURDEN OF MENTAL ILLNESS

In the most recent national household survey, as many as 44 million Americans met criteria for some mental disorder, with roughly 12 million reporting symptoms so severe as to cause significant disability in the past year.[2] According to the World Health Organization, mental disorders are also the leading cause of medical disability in the United States and Canada for people ages 15–44. The annual economic cost of mental illness in the U.S. is estimated at well over $150 billion, with most due to the indirect costs of social services.[3] The direct costs of mental health care represent 6.2 percent of the overall health care costs,[4] which totaled 14.5 percent of the gross domestic product in 2001 according to the Centers for Medicare and Medicaid Services (CMS).

ADVANCING CLINICAL RESEARCH IN MENTAL HEALTH

New tools in genomics, imaging, and behavioral science have given us traction for progress towards reducing this tremendous public health burden. NIMH has adopted the NIH clinical research vision, which focuses on the four *P*'s of medical research: increasing the capacity to *P*redict who is at risk for developing disease; developing interventions that *P*re-empt the disease process; using knowledge about individual biological, environmental, and social factors to *P*ersonalize interventions; and, ensuring that clinical research involves *P*articipation from the diversity of people and settings affected.

The Institute's focus on practical, or "effectiveness," clinical trials embodies this research vision. Although traditional clinical trials are useful in determining if groups of patients respond to a treatment, NIMH's practical clinical trials, conducted with 10,000 patients at 200 sites across the nation, have helped us to understand individual responses to treatment. DNA collected from participants in one such trial, the Sequenced Treatment Alternatives to Relieve Depression (STAR*D), led to the discovery of genetic variations associated with response to antidepressants. Through the inclusion of a diverse population, this research also found that the genetic variation that predicted a favorable response was less com-

[1] Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM–IV disorders in the National Comorbidity Survey Replication. Archives of General Psychiatry. 2005 Jun;62(6):593–602.

[2] Kessler, RC, Chiu, WT, Demler, O, Merikangas, KR, Walters, EE. Prevalence, severity, and comorbidity of 12-month DSM–IV disorders in the National Comorbidity Survey Replication. Archives of General Psychiatry. 2005 Jun: 62, 617–627.

[3] New Freedom Commission on Mental Health, Achieving the Promise: Transforming Mental Health Care in America. Final Report. DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

[4] Mark TL, Coffey RM, Vandivort-Warren R, Harwood HJ, King EC; MHSA Spending Estimates Team. United States spending for mental health and substance abuse treatment, 1991–2001. Health Affairs (Millwood). 2005 Jan-Jun;Suppl Web Exclusives:W5–133-W5–142.

monly found in African-Americans. This pharmacogenomic approach can transform the treatment of mental disorders, allowing clinicians to personalize therapy choices based on a patient's unique biology.

Results from these practical trials and related studies have taught us that current medications are helpful but not sufficient for most people with schizophrenia, depression, and bipolar disorder. While research on non-drug therapies is showing impressive results in treating a variety of mental illnesses, we clearly need a new generation of medications that are more effective and better tolerated. NIMH research during the past year reported on new classes of antidepressants that work within hours rather than weeks. These findings suggest that we can expect new medications that will transform the treatment of mental illnesses by influencing recently discovered targets in the brain.

New treatments like these antidepressants are based on the emerging science of pathophysiology, the study of how brain structure and functioning are involved in mental disorders. For instance, research on fear has revealed a class of brain receptors and specific brain circuits involved in traumatic memories. Clinical trials with medications that specifically target those receptors and circuits have shown positive effects in reducing stress in response to reminders of trauma and, thereby, offer a new treatment for PTSD. Working with the Department of Defense and the Department of Veterans Affairs, NIMH is supporting research that will treat PTSD and may also prevent the persistence of fearful memories, thus pre-empting the development of PTSD altogether. With 13 percent of returning soldiers diagnosed with PTSD,[5] we recognize the urgent need for safe and effective pre-emptive interventions.

PARTNERSHIPS FOR RESEARCH PROGRESS

NIMH also aims to accelerate research discoveries through collaborative partnerships. Fifteen NIH Institutes invested in research on the nervous system have pooled resources to create the NIH Blueprint for Neuroscience Research, a framework to enhance collaboration in the development of research tools, resources, and training, all of which will be made available to the neuroscience research community. Initiatives will focus on neurodegeneration in 2007, neural development in 2008, and neural plasticity in 2009.

Through public-private partnerships and additional grants coordinated by the Foundation for the National Institutes of Health (FNIH), the Genetic Association Information Network (GAIN) program will investigate the genetic roots of several common diseases and to provide the immediate, broad release of scientific information through a publicly accessible database. Four of the six current GAIN initiatives are related to brain disorders: attention deficit/hyperactivity disorder, schizophrenia, bipolar disorder, and major depressive disorder.

The Biomarkers Consortium is a public-private research partnership of the FNIH that includes NIH, CMS, the Food and Drug Administration, and industry and advocacy organizations to help identify new and valid biomarkers that will advance the creation of innovative technologies and therapies for early detection, diagnosis, and treatment of disease. Some of the first research findings from the Biomarkers consortium and GAIN are expected later in 2007.

These joint initiatives offer translational opportunities for further developing interventions and treatment options that can deliver more effective, personalized care across diverse populations and settings.

In summary, this is a time of unprecedented excitement in mental health research. Neuroscience and genomics are yielding new insights and new treatments, providing great hope for the future. Large-scale, practical trials are helping us optimize the treatments available today. I appreciate this opportunity to tell you about those exciting breakthroughs in the science of mental illness. I look forward to your questions.

INDIRECT COSTS OF MENTAL ILLNESSES

Senator HARKIN. You are saying that mental health is 6.2 percent overall? It is not—

Dr. INSEL. It is 6.2 percent of the overall costs of health care.

Senator HARKIN. Of the 16 percent.

[5] Seal KH, Bertenthal D, Miner CR, Sen S, Marmar C. Bringing the War Back Home: Mental Health Disorders Among 103,788 U.S. Veterans Returning From Iraq and Afghanistan Seen at Department of Veterans Affairs Facilities. Archives of Internal Medicine. 2007 Mar 12;167(5):476–482.

Dr. INSEL. Of the 16 percent, right, of the GDP.

Now, you have to recognize that when I talk about the costs of health care for mental illness, that is telling you a very small part of the story. Many of the costs here are not in the health care system per se, but in the social services, what we call the indirect costs of these disorders. According to the President's New Freedom Commission, which was a report issued in 2003, people with mental illness are the largest single group of patients in our public assistance programs, like SSI and SSDI. They are a large part of our homeless population and, according to the Department of Justice program on statistics there, our prisons and jails have increasingly become really the institutions for those with chronic mental illness, at least half of the people incarcerated having a serious mental illness, which is just extraordinary.

Now, how you capture those costs is quite difficult. None of them are captured when we talk about the costs of health care. At the very least, I think it is fair to say that these indirect costs of mental health care swamp whatever it is that we are paying in the direct costs of providing medical care to those with mental illnesses. As you will hear, this is also true for addiction and alcoholism.

CHRONIC DISEASE

It is probably equally important for you to realize that the real costs are not just in dollars, but in lives lost. As Senator Specter was saying, this is really a question of saving lives. You probably heard from Dr. Zerhouni that we are now thinking of the 21st century as the era of chronic disease, and that is undoubtedly true. Diabetes, hypertension, and heart disease are all chronic diseases which will become the big challenge of this century.

But as you will hear from Dr. Volkow and others, mental and addictive disorders, are also chronic diseases. What sets them apart is they begin early in life. In a recent study, 50 percent of adults with mental illness reported onset by age 14, 75 percent by age 24.

What that really means is that these are in fact the chronic disorders of young people in this country, mental illness and addictive disorders. They start early. Many are chronically disabling. This is why the World Health Organization, when it was looking at the largest sources of medical disability, ranked these disorders—mental illness and addiction—the number one cause of disability for Americans between 15 and 44. So it is an extraordinary saga that is largely untold. We often say that the costs in dollars and in lives are unacceptably large and largely unrecognized.

Finally, let me just say before I turn this over is that one of the aspects of this, of these disorders being recognized as brain disorders, is that the group of people who are here at the table are now very much all of one mind. We can work together and collaborate in a way that was not as obvious a decade ago. You can see that in a number of ways. Not only do we recognize that there is a lot of comorbidity—Parkinson's and depression, certainly PTSD and addiction, bipolar illness and alcohol abuse—but it is also in the tools that we need.

NEUROSCIENCE BLUEPRINT

So we have come together to form the Neuroscience Blueprint, which I believe Dr. Zerhouni may have mentioned. It is an attempt to collaborate and to develop resources and tools that will serve all these Institutes and will make a difference for people with brain disorders. We have also got the embodiment of this collaborative effort in a new facility, the Porter Neuroscience Building, under the NIH intramural program, which is a very exciting effort that I hope I can tell you more about during the question period.

So I am going to stop here so we have more time, but I do want to say how much we appreciate the opportunity to be here.

DRUGS AND MENTAL HEALTH

Senator HARKIN. Dr. Insel, thank you very much.

Let me just lead this off. First of all, just a general question. On mental health, are we putting too many eggs in the basket of finding a drug that masks, that perhaps gets someone through a tough time to respond to the immediacy of a mental illness? Are we putting too much in just finding these kind of drugs rather than getting to the underlying cause and taking the time and research to understand what led to that point?

I say that because it just seems to me that more and more people with mental illness are just taking more and more drugs. I will tell you of a case I know vaguely, someone I happen to know. I do not want to get too specific because I want to protect privacy. Someone who is on a drug that was—I wish I could remember the name. I came here equipped to ask you about it. But it was a powerful antidepressant type drug. When that person decided to get off that drug, it was like getting off of heroin or something. The bodily reactions and the mental reactions of that person getting off that drug was just awful. I wondered, why would a doctor prescribe this in the first place?

So again, general question: Are we putting too much into just going after drugs or should we be looking at some of the underlying causes?

Dr. INSEL. The quick answer is yes. Let me explain that. This field in some ways has been cursed by having medications that are pretty good. These were not designed rationally. They were all discovered by serendipity. But surprisingly, some of them actually helped quite a few people. The down side is that much of the field of research has really focused on trying to improve the existing drugs instead of trying to understand the basic pathophysiology of the disorders. Understanding that would allow us to know how to design medications that really go after the core lesion, the core problem here. It also gives us some hints about how to get into preemptive care, how to get there before the psychotic part of schizophrenia emerges. We know schizophrenia is an illness that has many phases, just like heart disease. But we tend to intervene with heart disease before a myocardial infarction. We do not wait for someone to have a heart attack.

In this field, we are waiting for someone to have a psychotic break before we really intervene. We do not need to do that.

EATING DISORDERS

Senator HARKIN. You and I discussed this once before, but I was told—I am going to repeat this without knowing whether it is factual or not, but I was told on more than one time or occasion that what I am about to say is true: that the single largest cause of young women dropping out of college is eating disorders. A lot of this has to do with mental health problems.

So what is happening here? What is the Institute doing on this? Are you looking into eating disorders and the underlying mental health problems that either lead to it or exacerbate it?

Dr. INSEL. This is one of the places where, in contrast to what I just said about having pretty good medications that work for most people, we actually do not have medications that work for most people with eating disorders, nor do we have very rapid effective targeted psychotherapies or psychosocial therapies. This is one of the areas where we have the greatest difficulty with treatment.

Dr. Volkow and I have talked a lot about this and in some ways eating disorders resemble an addictive disorder, where a lot of women diet, only a few get hooked and start dieting to the point where they actually become—it becomes a life-threatening problem. We do not know how to treat that in a quickly targeted way, effectively, as well as we do many other disorders.

We also do not know how to predict who is at risk, and that is one of the biggest questions for us. What we would like to do is not come up with necessarily the optimal treatment after somebody is already down to 65 or 70 percent of their normal body weight. We would like to be able to find out how do you keep them from getting to that point by intervening very early in the process, perhaps before this kind of addictive component gets started.

EPIGENETICS

Senator HARKIN. The last question before I turn it over to Senator Specter. You are expanding a program called Human Genetics, Epigenetics, and Genomics Underlying Mental Disorders. I know what genetics means, I think I know what genomics means, but I do not know what epigenetics is. What is that?

Dr. INSEL. It is a new and exciting area which several people at this table care a lot about. In a word or in a sentence, genetics and genomics have to do with the sequence of the genome, so what is the text. Epigenetics are those things that modify the text. Think of it as a highlighting pen that causes certain parts of the genome to be expressed in a certain cell. In any given cell, only about 20 percent of your genes get expressed. Now, why is that?

Now, we partially know there are things that lay on top of the sequence. In some cases they reduce expression, in some cases they enhance it. That is the epigenetic tag or those are the modifiers to gene expression. We want to understand much more about how they work.

Senator HARKIN. Have you done much in that area in the past?

Dr. INSEL. Well, we have done quite a bit because we are interested in those parts—and we know that early experience does have something to do with whether you become addicted later, whether you develop depression or some of these illnesses. But we do not

have the tools yet to do this at the kind of high throughput, high resolution stage of what we can do with genomic sequence. So right in that area we are a little bit inhibited from being able to make the kind of progress we like. So the next step is going to be tool development.

Senator HARKIN. Senator Specter.

Senator SPECTER. Well, thank you, Mr. Chairman. If I may say so, I would prefer to hear what the witnesses have to say. I am going to have to excuse myself at about 4:30, and my preference, if it is acceptable to the chair, would be to hear them and then ask a question or two.

Senator HARKIN. Well, the only reason I wanted to do it this way is because then it is fresh on our minds. When he says something, I can interact with him. I thought we would go down each one. I would rather, if you do not mind, do it this way. But if you have to leave—and believe me, I understand everybody has got different schedules—if you have something for one of the directors, if you want to direct it, that would be fine.

Senator SPECTER. Okay. When it is more pressing than hearing them, I will do so. If that arises, I shall.

Senator HARKIN. No, but if you had something you wanted to ask someone now, if you have got to go, if you want to ask someone now, that would be fine.

Senator SPECTER. Well, let me hear Dr. Volkow. I do have one question which is very much on my mind, and there may be others. But let me defer to Dr. Volkow.

Senator HARKIN. Well, then next we will turn to Dr. Volkow, Director of the National Institute on Drug Abuse. Dr. Volkow received her B.A. from the Modern American School in Mexico City, Mexico, her M.D. from the National University of Mexico, Mexico City. Dr. Volkow, welcome. Please take 5 minutes and let us know what you are doing out there.

STATEMENT OF NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Dr. VOLKOW. Mr. Chairman, it is a privilege for me to be here with my colleagues to share some of our initiatives at the National Institute on Drug Abuse. As you know, the social and individual costs of substance abuse and addiction to the society are nothing less than staggering and utterly unacceptable. On economic costs alone, the Institute of Medicine estimated that substance abuse, legal and illegal, including nicotine and alcohol, costs this country over half a trillion dollars annually, which includes not only medical costs but costs associated with the criminal system.

NIDA's strategy to alter the course of this epidemic is based on a multi-pronged approach designed to understand how genes shape our brain, how environmental factors affect this process, and how brain function links to behavior, including that which characterizes addiction, which is the compulsive intake of the drug despite its catastrophic consequences.

From the science we have learned that repeated drug use affects the function of multiple systems in the brain, including those involved with reward and pleasure, which motivate our behaviors on a daily basis, systems involved with learning and memory, which

change our behavior as a function of experience, and systems involved with inhibitory control, which allow us to exert volitional control of our behaviors and emotions.

Today I will stress and highlight how stress, one of the key environmental factors influencing the vulnerability for addiction, affects brain development and how in turn that affects the propensity for taking drugs. We have learned that addiction is not just a result of chronic drug use, but that genetics and, as I say, environmental factors play an extraordinarily important role. However, because we can currently not change our genes, which actually account for 50 percent of the vulnerability to become addicted, a better understanding about how environment affects how our genes and brain develop offers an extraordinary opportunity for prevention.

It is particularly relevant because drug addiction is fully preventable even in those that have a genetic predisposition to become addicted, provided they do not get exposed to drugs. However, the challenge is how you interfere with young people's taking drugs. I say young people, and that is because drug experimentation basically starts in adolescence and the earlier you start taking drugs the greater the vulnerability to become addicted. Why is that so? Multiple factors.

One of them is that the brain when you are an adolescent is still in full development and many of the connections that link it with one another are not there. For example, the connections that associate your limbic brain, that is responsible for emotions and desires, with the thinking part of your brain, the prefrontal cortex, will not be fully formed until you are in your early 20s. As a result of that, adolescents are much more prone to engage in risky behaviors such as substance abuse.

Unfortunately, the consequences of environmental stressors that influence the vulnerability for drug abuse start as early as in utero. Now we know, for example, from studies in laboratory animals that early exposure during pregnancy of animals to marijuana leads to a dysfunction of the newborn that continues to adulthood.

Also, some very simple social stressors, such as we now know that if there is no physical contact between the newborn and the mother, physical contact, that will lead to silencing of a gene, what you were speaking about, epigenetics. That lack of physical contact silences a gene that is important in regulating our response to stress. These newborns then grow up to be very, very sensitive to stress, which is one of the factors that makes them vulnerable to addiction.

Unfortunately, we know too well that childhood exposure to social and environmental stressors are extremely deleterious. Indeed, our studies, for example, show that children that were exposed to five or more social stressors that include a parent in jail, a parent that takes drugs, physical sexual abuse, neglect, are 10 times, 10 times more likely to become addicted than those that are not.

Unfortunately, social stressors occur throughout all of our lives and at any age can lead to substance abuse, to the transition between substance abuse and addiction, and to relapse to those in recovery. Why? Because the systems that project stress have tremen-

dous overlap with the systems in the brain that project these drugs.

PREPARED STATEMENT

So in summary, we know, we recognize that drug addiction is a chronic disease that changes the brain in long-lasting ways, that profoundly affect behavior. We know that it is fully preventable, even in those that have a genetic vulnerability. Inasmuch as predisposition does not equate with predetermination, that knowledge about how environment affects our genes and our brain biology provides an extraordinary opportunity to tailor preventions to those that are at high risk because of their genetics or because of their environmental factors.

So thank you for your attention. I will be happy to answer any questions you may have.

[The statement follows:]

PREPARED STATEMENT OF DR. NORA D. VOLKOW

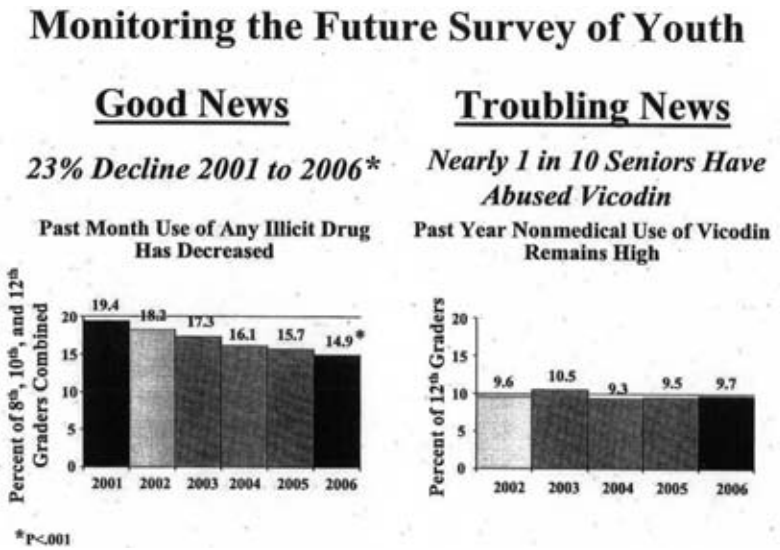
Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute on Drug Abuse (NIDA). The fiscal year 2008 budget included $1,000,365,000. Today, I will discuss NIDA's multifaceted strategy to help reduce the enormous toll that drug abuse and addiction take on this Country, highlighting recent scientific accomplishments, novel approaches to prevention and treatment, as well as our strong collaborations with other NIH institutes and with the Substance Abuse and Mental Health Services Administration (SAMHSA).

INTRODUCTION

Drug abuse and addiction are a major burden to society; economic costs alone are estimated to exceed half a trillion dollars annually in the United States—including health, crime-related costs, and losses in productivity.[1] However, as staggering as these numbers are, they provide a limited perspective of the devastating consequences of this disease.

The National Institute on Drug Abuse, within the National Institutes of Health, is pleased to again report continuing declines in both licit and illicit drug use, particularly among our Nation's youth. In fact, NIDA's latest Monitoring the Future (MTF) survey results show a 23 percent decline over the last five years in any past-month illicit drug use by students in the 8th, 10th, and 12th grades combined. Declines in teen cigarette smoking, now at its lowest rate since the survey began in 1975, signal particularly good news since this will translate not only into decreases in cancer-related mortality but also decreases in deaths associated with the myriad medical consequences of smoking (i.e., chronic obstructive pulmonary disease, asthma, premature birth, sudden infant death syndrome, and more).

[1] Office of National Drug Policy (2004). The Economic Costs of Drug Abuse in the United States: 1992–2002. Washington, DC: Executive Office of the President (Publication No. 207303). 2004. Centers for Disease Control and Prevention. Annual Smoking—Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 1997–2001 Morbidity and Mortality Weekly Report 54(25):625–628, July 1, 2005. Harwood, H. Updating Estimates of the Economic Costs of Alcohol Abuse in the United States: Estimates, Update Methods, and Data Report prepared by the Lewin Group for the National Institute on Alcohol Abuse and Alcoholism, 2000. 2000.



Although abuse of most licit or illicit substances has decreased, such is not the case for prescription medications, particularly for opiate analgesics, which have produced steep increases in abuse-related emergency room admissions. The abuse of prescription medications occurs at all ages. However, it is particularly problematic in adolescents since this is the time when individuals are most vulnerable to addiction. The MTF revealed that in 2006, prescription medications, along with over-the-counter drugs (cough medicine), accounted for five of the top six drug abuse categories reported by 12th graders, marijuana still the most frequently abused illegal drug. Second in frequency of abuse was the prescription painkiller Vicodin, with roughly 1 in 10 seniors reporting abuse during the past year. Amphetamines ranked next, followed by over-the-counter cough medicines, with roughly 8 and 7 percent of 12th graders, respectively, reporting past-year abuse in 2006.

PREVENTION EFFORTS—GENES, ENVIRONMENT, AND DEVELOPMENT

Because adolescence is typically when drug abuse and addiction take hold, NIDA continues to focus research on this vulnerable period of development. Given that the brains of adolescents have not fully developed, including the connections between brain areas involved with emotions and areas involved with judgment and decision-making, adolescents are less able to exert inhibitory control over emotions and desires and are hence more likely to engage in risky behaviors, including drug experimentation. However, the brain at this stage is also inherently more plastic, which offers opportunities for prevention interventions that could lead to greater resilience.

Addiction results from the complex interaction of drugs, genes, and environmental and developmental factors. Thus NIDA has made the study of these interactions a priority, joining with other Institutes and organizations to support relevant research. Particularly relevant to substance abuse is the social environment, as genetic and imaging studies continue to reveal how the interplay of biological (i.e., genes, developmental stage) and social influences (i.e., family, peers, culture) affect individual choices and decisions about drugs. This knowledge is crucial to our future ability to tailor prevention interventions to address the risk areas of a given individual.

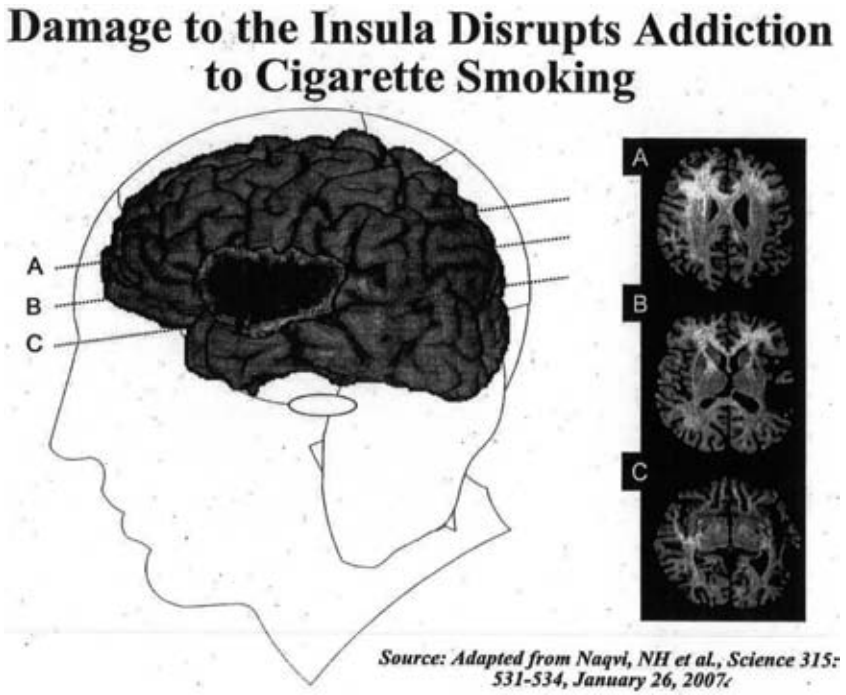
NIDA also encourages and supports the development of next generation technologies to identify and catalogue the multiple functional changes to the DNA (i.e., "epigenetic" modifications) that can result from environmental variables, such as quality of parenting, stress, and exposure to drugs. This avenue of approach requires support of research to develop standardized and comprehensive "phenotypes" of social environments (including family, peers, school, neighborhood, community, and culture) that can be monitored at various stages of a person's life. A better understanding of the neurobiology of social behaviors is relevant both for the treat-

ment of drug addiction as well as mental illness, which also involves social aspects of human behavior and frequently co-occurs with substance abuse.

TREATMENTS—NOVEL APPROACHES

Historically, addiction therapies have targeted the brain's reward system to try and interfere with the pleasurable effects of drugs of abuse. Now, however, scientists have also identified the broader brain circuits that underlie fundamental aspects of drug abuse and addiction, such as craving, euphoria, motivation, learning, memory, interoception (i.e., sensitivity to internal stimuli such as hunger, pain), and inhibitory control—key contributors to addiction. These discoveries open wide the range of novel targets for different treatment approaches.

The recent discovery that stroke victims who suffered damage to their right insula (a brain area involved in emotional experience and interoception) dramatically reduced their smoking behavior points to new directions in addiction treatment. Specifically, findings suggest that strategies to noninvasively affect activity in the insula may be beneficial for addiction. These include use of technologies such as rTMS (repetitive transcranial magnetic stimulation), a noninvasive method to influence brain activity in specific regions, or "neurofeedback," where patients learn to regulate specific regions in their brains by getting feedback from real-time brain images. Though not yet demonstrated for addiction, these techniques have shown promising results in depression and in the management of pain. They also open up a completely new way to develop psychotherapeutic interventions to target specific brain regions or circuits.



New knowledge of how proteins interact with one another in circuits implicated in addiction has prompted the development of novel addiction medications. For example, the cannabinoid receptor system, which regulates the activity of the dopamine system—the common target for the reinforcing effects of all drugs of abuse—holds promise for treating various drug addictions and, interestingly, for obesity as well.

Immunotherapeutic strategies offer another unique approach to relapse prevention. Such strategies are based on the development of vaccines to generate antibodies to the drug that block its entry into the brain and thereby interfere with its effects. Cocaine and nicotine vaccines are already in clinical trials, and NIDA has requested proposals to develop a methamphetamine vaccine.

PUTTING RESEARCH INTO PRACTICE

A major NIDA objective is to translate findings from basic and clinical research to guide and inform the design of prevention and treatment interventions that can be successfully implemented in real-world settings. People involved with the criminal justice system (6.9 million adult Americans) represent one such group. Approximately half of prison inmates meet criteria for alcohol/drug abuse or dependence, and yet the vast majority return to the community with no treatment.[2] In addition to the resulting high rate of recidivism for drug abuse and re-arrest, a recent study of inmates reported that untreated offenders were 12.7 times more likely to die within 2 weeks post-release than other state residents and that drug overdose accounted for 70 percent of those deaths.[3] Because research has shown that treatment in the criminal justice system works, one of NIDA's initiatives is to support services research to help develop interventions that will be acceptable and sustained in the criminal justice system.

To this end, NIDA created and supports the Criminal Justice Drug Abuse Treatment Studies (CJ–DATS) initiative, an inter-agency collaboration aimed at bringing new treatment models into the criminal justice system to improve outcomes for drug-abusing offenders. To facilitate the translation of treatments to the criminal justice setting NIDA released a landmark publication entitled Principles of Drug Abuse Treatment for Criminal Justice Populations, designed to advance the concept of addiction as a brain disease and to summarize evidence-based principles for treating addiction in criminal justice settings.

NIDA's Drug Abuse Treatment Clinical Trials Network (CTN) also plays a key role in bringing evidence-based treatments to community settings by testing the effectiveness of new interventions and by training providers in the implementation of research based practices in order to promote their acceptance and adoption in the community. To further enhance the dissemination and utilization of research findings and to expand the involvement of the medical community in the screening and treatment of drug abuse, NIDA has launched a new "NIDA Goes to the Doctor" initiative. As part of this initiative, NIDA recently established four Centers of Excellence for Drug Abuse Information, in collaboration with the American Medical Association, with the aim of advancing addiction awareness, prevention, and treatment in primary care practices.

HIV/AIDS

Drug abuse plays a significant role in the spread of HIV, not only via injection drug use but also by increasing risky sexual behaviors. The addictive and intoxicating effects of many drugs can alter judgment and inhibition and lead people to engage in impulsive and unsafe behaviors. Drug abuse and addiction can also worsen the progression of HIV and its consequences, especially in the brain. Thus NIDA is supporting preclinical and clinical studies that examine the interactions between: drugs of abuse and HIV medication, HIV and plasticity (relative to changes that lead to addiction), and HIV and neurotoxicity (with regard to the adverse drug effects that result in neurodegenerative conditions such as dementia and parkinsonian symptoms).

While all groups are affected by HIV/AIDS, not all are affected equally. African Americans bear a disproportionate burden of HIV/AIDS in the United States, which may in part reflect data showing that African Americans are predominant among those who become aware of their infection at later stages in the disease process, and who therefore represent lost opportunities for treatment. Because early HIV detection helps prevent its transmission and increase health and longevity—and is as cost-effective as screening for other conditions such as breast cancer and high blood pressure—NIDA is supporting research to make testing more acceptable in communities nationwide. To this end, NIDA recently held a meeting aimed at improving the rates of HIV screening, and is now incorporating the resulting recommendations, which include addressing associated stigma and optimizing early diagnosis and follow-up linkages to care.

CONCLUSION

NIDA's comprehensive research portfolio is strategically positioned to capitalize on new scientific opportunities. Groundbreaking developments in the field of

[2] Mumola CJ and Karberg JC (2006) Drug use and dependence, state and federal prisoners, 2004 (NCJ 213530). Washington, D.C.:Bureau of Justice Statistics, U.S. Department of Justice.

[3] Binswanger IA, Stern MF, Deyo RA, Heagerty PJ, Cheadle A, Elmore JG, Koepsell TD (2007) Release from prison—A high risk of death for former inmates. New Engl J Med 356:157–65.

genomics signify an exciting era of research whereby we will be able to identify genes that make a person more vulnerable to drug abuse and addiction and devise counter strategies. We work toward a future in which early recognition of risk for addiction is no different than early recognition of other chronic medical diseases. Innovative use of imaging techniques allow scientists to design better treatments and more precisely judge their effectiveness, even predicting who would be most likely to benefit from selected therapies and who might be expected to relapse, so that preemptive interventions can be applied. Finally, advances in proteomics will help in designing much more sensitive tools to detect drug exposures and their consequences for individuals, heralding a future where diagnostic kits may be used to screen for drug abuse in the medical setting.

Thank you, Mr. Chairman. I will be pleased to answer any questions the Committee may have.

DRUG ABUSE FACTORS

Senator HARKIN. You were talking about adolesents who are exposed to a parent who is on drugs. What were the other factors that can increase the likelihood of addition?

Dr. VOLKOW. A parent that is not there because he or she is incarcerated, physically abused, sexually abused, neglected, mental health problems in the family, low socioeconomic status, or poor access to education. These social stressors are increasing the risk of substance abuse.

Senator HARKIN. So a factor of 10 is pretty important.

Dr. VOLKOW. It is, dramatically.

Senator HARKIN. That is dramatic. So again it seems that drug abuse leads a lot of times I think to mental illness—am I correct in assuming that?

Dr. VOLKOW. Certainly there is unequivocal evidence that early exposure, for example, to nicotine can trigger anxiety disorders, even with those that do not have the genetic predisposition. There is also evidence that it increases the risk of depression. There is an enormous amount of discussion about the involvement of marijuana smoke on triggering psychosis or schizophrenia.

The thing is that it is happening, but probably depends upon having genetic vulnerability. What we do not know is can it trigger a schizophrenia-like disorder in someone that does not have the genetics.

So your answer is yes.

ADDICTION IN OTHER COUNTRIES

Senator HARKIN. Well, it seems to me that we ought to be paying more attention to this other area also.

Have you looked at addiction in the United States versus other countries?

Dr. VOLKOW. Yes, I have looked at this and the data are disturbing. The United States is at or near the top of most international prevalence comparisons across several types of illegal drugs.

Now, with respect to——

Senator HARKIN. That is illicit drug abuse?

Dr. VOLKOW. Illicit drug abuse. For nicotine, for example, the United States does much better than other countries in Europe and in Latin America. With alcohol there is tremendous variability. There the United States is not so high-ranking. There are certain

countries where the rate of abuse of alcohol is higher. It is in illicit substances that we are very, very high.

DRUG ABUSE BEING A CHRONIC DISEASE

Senator HARKIN. The only other point, just a very basic question. You talked about drug abuse being a chronic disease. How do we know it is really a disease?

Dr. VOLKOW. Well, there have been studies both in laboratory animals and in humans. In laboratory animals, for example, if you do repeated administration of drugs you can lead to compulsive administration of drugs in those animals. In animals you can actually sacrifice them and look at the biochemical changes linked with drug use and they have been shown to persist months after the animal has been discontinued from the drug intervention.

In humans now, with imaging technologies we can characterize the changes, both functional and biochemical, in the brain of people that are addicted. We followed—I used to do that before I became Director—these changes after the patients go through rehabilitation, and unfortunately many of them persist actually years after the person has stopped taking the drugs.

This is consonant with the phenomenology where we see individuals that have been able to stop taking drugs for years after rehabilitation, where something happens, usually a stressor—social stressors are one of the most powerful—and they relapse, even though they had not touched a drug in years, accentuating the notion that changes are still there, and so you become vulnerable. As long as you can manage the situation in your environment, you are okay, but if there is the stressor that puts you at very high risk.

Senator HARKIN. Senator Specter.

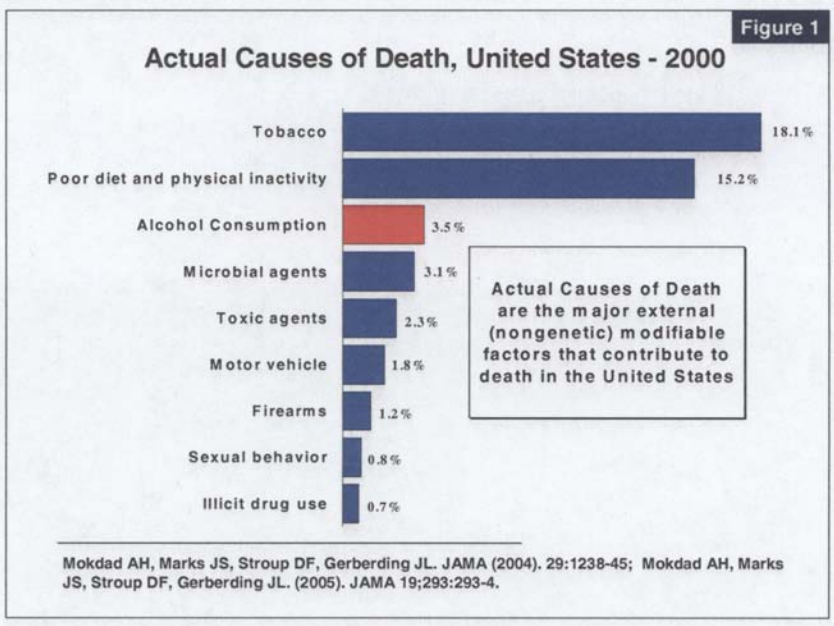
Senator SPECTER. No questions at this time.

Senator HARKIN. Now we move to Dr. T.K. Li. Appointed Director of the National Institute on Alcohol Abuse and Alcoholism in November 2002, Dr. Li got his undergraduate degree from Northwestern University, his M.D. from Harvard. Dr. Li, welcome. Please take about 5 minutes.

STATEMENT OF TING-KAI LI, M.D., DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

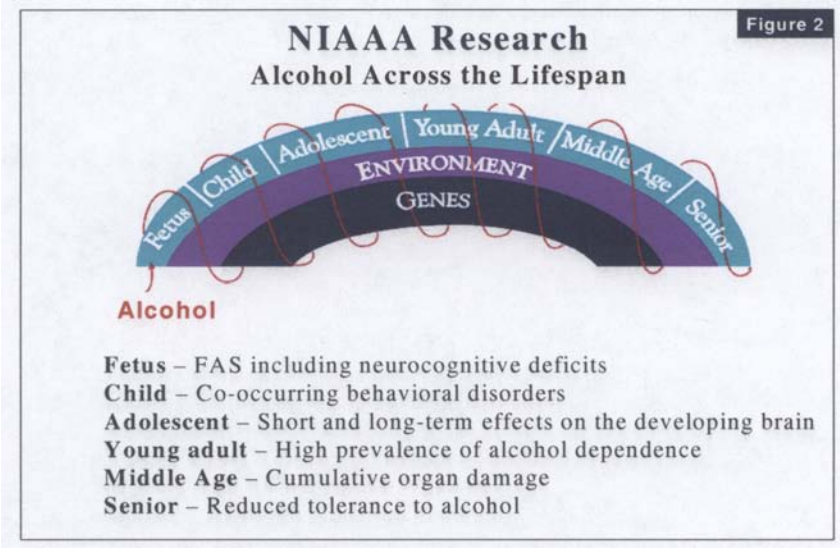
Dr. LI. Thank you, Senator Harkin, Senator Specter. I am pleased to be here with my colleagues to tell you about what NIAAA does and to update you on some of the new findings.

Let me first quantify the burden of illness attributed to alcohol. I think you have heard about the burden of illness due to mental health disorders and drug abuse. In terms of alcohol, let me just tell you that the HHS Centers for Disease Control and Prevention rank alcohol as the third highest actual cause of death, meaning that it is the third most preventable cause of death over this country, the first being tobacco and the second being poor diet and inactivity. See figure 1.



Alcoholism also is worldwide and is ranked as the third leading cause of disease in developed countries. It is a common disease. In this country, actually 1 out of 4 children are exposed in a family that has either alcohol abuse or alcohol dependence. Eighteen million people over the age of 18 have alcoholism and alcohol abuse. The cost estimated is $185 billion.

Now, what I will show is a recent realization. See figure 2.



That is the variety and the kinds of alcohol problems people have is actually different depending on the stage of life. So we have crafted our research mission for alcohol across the lifespan, from fetus all the way to seniors. Again, as indicated, when ill health or diseases appear early in life, the burden of illness is high because of the long duration of the illness. That is a very important factor.

Therefore our mission is really to prevent and reduce harm as early in life as possible. This is preventing abnormal or high level patterns of drinking in pregnant mothers to those harmful patterns of use in children and adolescents, and then being able to predict the vulnerability factors as both you and Dr. Volkow have talked about and then target intervention for those who are at high risk for alcohol use disorders. Finally, we also want to personalize treatment in the afflicted individuals.

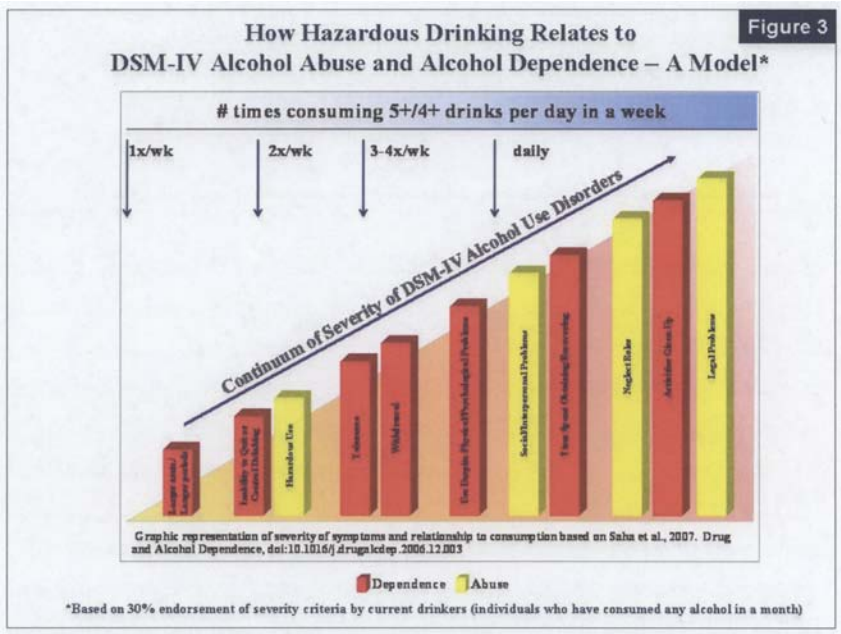
I will give you three examples of what it has been and what it is now and what we have for the future. First is that we have always thought—that is what I was taught and I think all of us at the table probably were—that alcoholism is a disease of mid-life, in other words people in their 40s and in their 50s. We now know that is not so. The highest prevalence of alcoholism is actually in our young people from age 18 to 24.

So in order to be able to be effective in treating and preventing the problem, we really should be looking to even the younger population. Therefore we are concentrating on and have a major initiative to study under-age drinking problems and how to prevent the problem. We are pleased to announce that on March 6 the Surgeon General issued a call to action to prevent and to reduce under-age drinking problems and our Institute was responsible for providing the science base for that report and we are going to be working with the Surgeon General in disseminating the actions that are proposed in that call to action.

Now, what is in the future? In the future, we are working actually with NIDA and with NIMH to look at what are the personality and temperament characteristics that predispose to harmful patterns of behavior in adolescence. I think this is an important common thread that speaks to comorbidity in this regard.

The other thing, the second thing we are trying to do, is to improve our way of diagnosing the problem. Again, the criteria we use to diagnose alcohol, drug and mental health disorders is really 1990s vintage. For example, for alcoholism it is called a maladaptive pattern of drinking that leads to significant impairment and stress, but it does not say what pattern or how much, nor can the diagnostic criteria be scaled.

Our research shows convincingly that we can scale it, the way of scaling both alcohol use and alcohol abuse and alcohol dependence by current diagnostics criteria and, as you can see in the figure here there is a single continuum of severity. See figure 3.



Shown here in red and yellow are the different criteria for abuse and dependence, scaled by severity.

The important question then is what pattern of drinking will predict this kind of severity of alcohol dependence? From our database we can say that if one drinks in a certain pattern, like drinking five or four drinks on an occasion, and you repeat this, then you can tap into the severity of alcohol use disorder scale, and this may be an important way of identifying those who are susceptible from their pattern of drinking.

How does this compare to the rest of medicine? Well, it is similar to being able to measure blood pressure and to measure cholesterol as a risk for having a future heart attack. Therefore, knowing what the blood pressure and cholesterol is, then you can treat that and you can interdict in terms of future problems.

So these are some of our current state of knowledge. We hope that we can be able to verify this pattern in the future and to use this in a clinical setting.

PREPARED STATEMENT

Finally, just to talk a bit about personalized medicine. Because of the advances in knowledge of molecular medicine, we are developing better and better medications to treat alcohol dependence once it has developed. These are our goals for the future. Thank you very much.

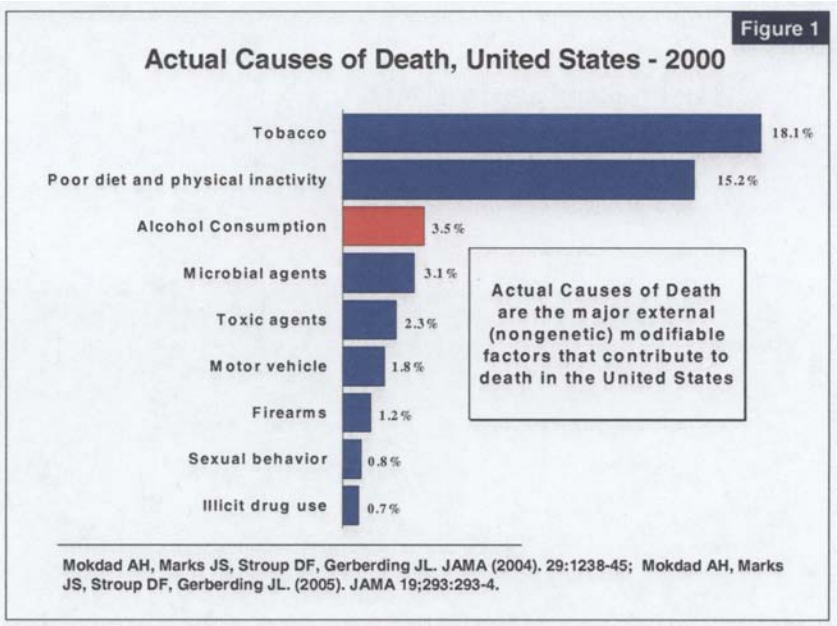
[The statement follows:]

PREPARED STATEMENT OF DR. TING-KAI LI

Mr. Chairman and Members of the Committee, thank you for giving me the opportunity to update you on the activities of the National Institute on Alcohol Abuse and

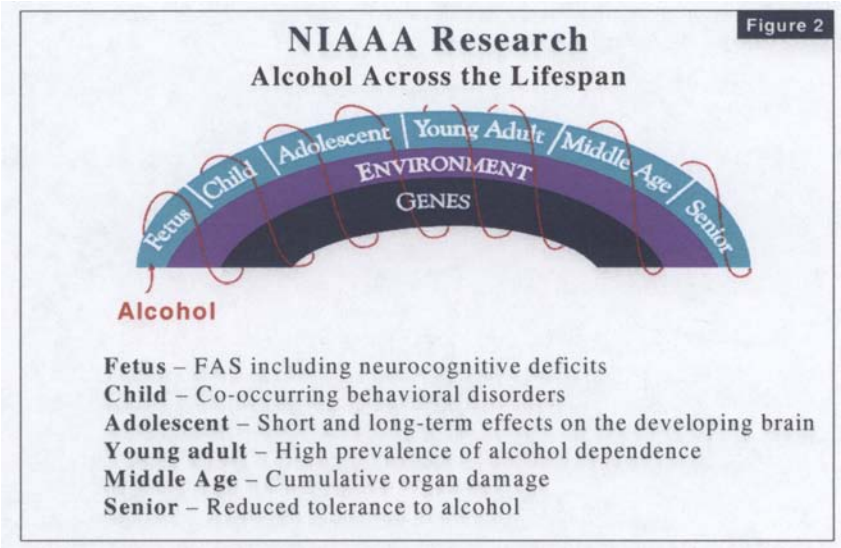
Alcoholism. I am Ting-Kai Li, Director of NIAAA, the lead agency for research on the health effects of alcohol. I am pleased to be here today with my distinguished colleagues from NINDS, NIMH, NIDA, and NIDCD to speak to the theme of Mind, Brain and Behavior. Those of us addressing you today have a fundamental mission—to reduce the substantial burden of illness caused by neurological and mental disorders, and by drug and alcohol abuse. Many of these disorders tend to manifest early in life, produce lifelong disability, derail individual potentials, and create tremendous burdens for families and significant cost to society. In fact, excessive alcohol use alone costs the United States an estimated $185 billion annually.[1] The fiscal year 2008 budget for NIAAA includes $436,505,000.

The HHS Centers for Disease Control and Prevention ranks alcohol as the third leading cause of preventable death in the United States (figure 1), and the World Health Report ranks alcohol as the third leading risk factor for disease in developed countries. Although alcohol primarily targets two organs, the brain and liver, it has a wide range of effects throughout the body and NIAAA's research portfolio encompasses all aspects of alcohol and health. In keeping with the theme of this Hearing, I will focus on the brain and behavior.



As illustrated in figure 2, alcohol can negatively affect the body and brain at all stages of life resulting in a range of consequences, including consequences from maternal alcohol consumption on the developing embryo/fetus to alcoholic liver disease and dementia in later life. Throughout the lifespan, it is important to recognize the contribution of developmental stage, individual differences—both genetic and environmental, and dose and duration of alcohol exposure to potential outcomes. The substantially different effects and consequences of alcohol exposure at different stages of life necessitate different research strategies.

[1] Harwood, H. Updating Estimates of the Economic Costs of Alcohol Abuse in the United States: Estimates, Update Methods and Data (2000). http://pubs.niaaa.nih.gov/publications/economic-2000/



Today I would like to give you an overview of NIAAA's progress in three areas to reduce the burden of illness due to alcohol. First, I will describe prevention efforts focused on early life stages. Second, I will describe new findings that can be used to improve the diagnosis and early detection of alcohol use disorders (AUDs). Finally, I will describe efforts to personalize medicine for those suffering from alcohol dependence.

PREVENTION

Prevention is a key focus of NIAAA, especially for pregnant women, children and adolescents. By altering harmful drinking behavior we can significantly reduce the burden of illness due to alcohol. Exposure of the developing embryo/fetus can result in alcohol-induced birth defects, the most severe of which is fetal alcohol syndrome (FAS), a devastating developmental disorder that may include mental retardation. Individuals who do not exhibit the extent of symptoms characteristic of FAS may still have lifelong physical and/or neurological deficits as a result of in utero alcohol exposure. In addition, prenatal alcohol exposure itself may be a risk factor for subsequent alcohol dependence later in life. Therefore, NIAAA is supporting research to develop effective outreach to pregnant women, and approaches to intervene to protect against injury in the affected fetus and ameliorate deficits in the affected child.

Prevention in young children is also important, especially for those at high risk for early alcohol use. The period from birth to age 10 is a remarkable period of development, and although relatively few children in this age group are drinking alcohol, much is happening that will influence their path toward or away from early alcohol use. A number of the factors that put children at risk for early alcohol use are common to a wide range of adverse behavioral outcomes such as delinquency and other substance use. Even as young as preschool age, such children often have difficulties with impulse control and exhibit unusually high levels of aggression. NIAAA, NIMH, and NIDA are working to understand the personality/temperament characteristics that predispose to early-onset mental and alcohol/drug use disorders.

It is also essential to prevent and reduce underage alcohol use. Analyses of NIAAA's National Epidemiologic Survey on Alcohol-Related Conditions (NESARC) showed that 40 percent of individuals who reported drinking before the age of 15 also described their drinking behavior in a way consistent with a diagnosis of alcohol dependence. In fact, the highest prevalence of alcohol dependence in the United States occurs in the 18–24 year old age group. In addition, binge-drinking (i.e. drinking five or more drinks per occasion), which is popular with today's young people, results in acute consequences such as traffic fatalities, alcohol poisoning, suicides, homicides and drownings. Non-fatal, but potentially life altering consequences such as sexual assault and violence also result. As part of a larger effort focused on underage drinking research, NIAAA provided the scientific foundation for the

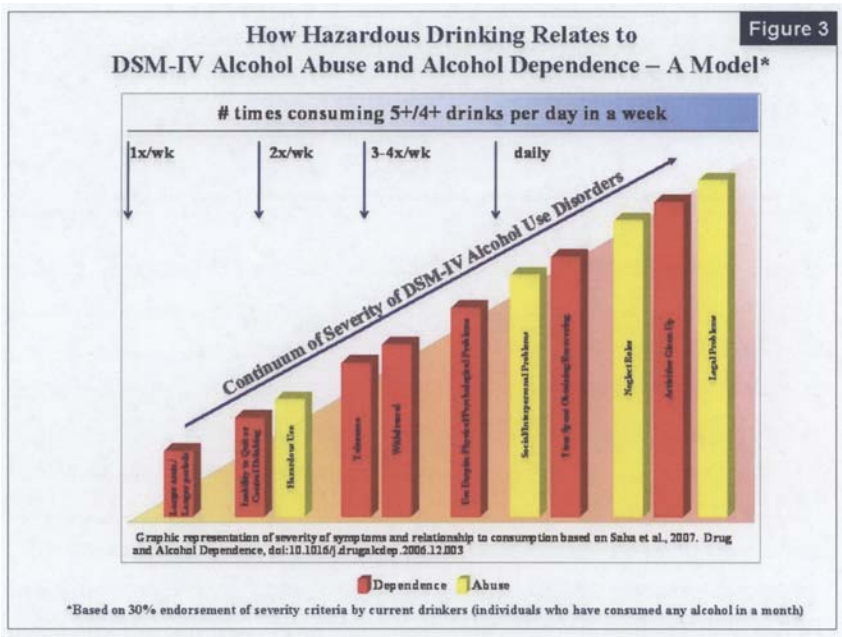
Surgeon General's Call to Action to Prevent and Reduce Underage Drinking and continues to inform the work of the Interagency Coordinating Committee on the Prevention of Underage Drinking.

Recognizing that the brain continues to develop throughout adolescence and into early adulthood, NIAAA is investing in research to determine the short and long-term effects of alcohol on the developing brain and the degree to which it can recover from these insults. Such studies, including one in collaboration with NIMH intramural scientists, may identify changes in brain wiring that are associated with dependence or affect cognitive functioning. In addition, given the difference in patterns of alcohol use between boys and girls as they move through adolescence, NIAAA is investigating the interplay of hormones, brain development and alcohol use.

DIAGNOSIS

It is important to identify individuals who are at risk for adverse alcohol-related health outcomes because of their drinking behavior. Excessive alcohol intake over time leads to cumulative organ damage, especially alcoholic liver disease and increased risk of coronary artery disease, stroke and dementia. Early diagnosis of harmful drinking would enable health care providers to intervene to prevent a range of adverse health outcomes.

As shown in figure 3, diagnostic criteria for Alcohol Abuse currently rely on an individual experiencing one or more alcohol-related problems associated with either the social or legal system, such as being cited for Driving While Intoxicated or problems with a spouse or family member. Diagnosis of Alcohol Dependence requires meeting three of seven criteria relating to physiological changes such as the development of tolerance to increased amounts of alcohol or the experience of withdrawal symptoms, behavioral maladaption characterized by loss of control and compulsion to drink, and negative consequences from this drinking pattern. This categorical approach does not favor early diagnosis and intervention.



Today I report recent findings from analyses of NESARC that will improve the diagnosis of alcohol dependence. Further, alcohol abuse and dependence have long been treated as independent disorders. New findings indicate that they represent a continuum of severity of alcohol use problems. The analyses suggest we may be able to use questions that reveal an individual's pattern of drinking to identify the risk of developing AUDs. In much the same way that numerical measurements of blood pressure, cholesterol and triglycerides relate to relative risk for cardiovascular

disease, the best indicators of developing alcohol problems are measures of how frequently an individual engages in a harmful pattern of drinking. Specifically, recent findings relate data on the frequency of binge drinking and the maximum number of drinks consumed to risk for organ damage and to alcohol dependence. Through clinical studies, we may be able to determine appropriate cut points to define AUDs and also to gauge one's risk of developing alcohol problems. Just as physicians treat high cholesterol before an individual experiences a heart attack, they will be able to intervene before an individual loses control of drinking. Diagnosis centered on harmful drinking patterns should also help health care providers differentiate between alcohol related neurocognitive deficits in the elderly and Alzheimer related dementia.

MEDICATIONS DEVELOPMENT

NIAAA is supporting research on a number of fronts to improve treatment options for alcohol dependence. Studies in animal models focusing on signaling pathways in the brain have produced additional targets for human studies. For example, the anxiety that people with alcohol dependence experience when they stop drinking is a powerful motivator for them to resume. In addition, stress can trigger relapse to heavy drinking after a period of abstinence. Therefore, medications are being tested that target molecules involved in biological pathways that mediate stress and anxiety such as corticotrophin-releasing factor, neuropeptide Y, and nociceptin receptors. Also being tested are medications that target the metabolism of endocannabinoids, naturally occurring substances in the brain that act on the same receptors as the active ingredients of marijuana and have been shown to play a role in regulating appetite for alcohol.

TREATMENT RESEARCH

In addition to developing new medications and determining the genetic and environmental factors that contribute to the initiation and escalation of drinking, it is equally important to understand how individuals change harmful drinking patterns. The majority of young adults change harmful drinking behaviors without treatment. Adults seek treatment when alcohol dependence becomes chronic and relapsing, generally in the period of midlife. Data from clinical trials raise the question of whether treatment itself is responsible for the improvement in drinking behavior or if the positive motivation to seek treatment actually underlies a substantial part of the treatment success. Further, evidence has shown that a wide array of available therapeutic approaches yields similar results, suggesting that it is not the particular technique that is responsible for change but other common underlying factors. As a result, NIAAA is focusing on addressing underlying mechanisms of change across all behavioral treatments, identifying the factors that contribute to behavioral change and lead to sustained recovery. This research will improve clinical practice both by identifying key aspects of therapy that must be present for maximum effectiveness and by facilitating the delivery of more finely tuned individualized treatment. We also need to be particularly mindful of health disparities. A recent study suggests that Hispanics and Blacks with higher levels of problem severity were less likely to have used treatment services than Whites with problems of comparable severity.

Taken together, these strategies of improved prevention, better diagnosis and personalized treatment are expected to reduce the burden of alcohol-related illnesses over the long term and lead to better health outcomes for the nearly 18 million American adults who, in any year, struggle with alcohol use disorders.[2]

MEDICATIONS FOR ALCOHOL DEPENDENCE

Senator HARKIN. Well, now that you are on that, what medications?

Dr. LI. Well, we have several. Fifteen years ago all we had was Antabuse. Now in the last 8 years or so we have approved two other medications. One is Naltrex, both orally taken and also by injection; and third is a medication called Acamprosate. So these drugs seem to work better for certain aspects of alcohol dependence based on severity. We have others in the pipeline being developed

[2] Grant BF, Dawson DA, Stinson FS, Chou SP, Dufour MC, and Pickering RP. Drug and Alcohol Dependence 2004. 74: 223–234.

that will target different molecules, different receptors, and these are an important vision for the future.

NIAAA OUTREACH

Senator HARKIN. Doctor, every Institute out there needs to do outreach. Every Institute does outreach to the communities around the country.

Dr. LI. Yes, sir.

Senator HARKIN. How well are you doing in reaching out to States and local communities to put into practice some of your findings?

Dr. LI. The three so-called ADM Institutes, we are fortunate in that we have a partner in this regard. That is SAMHSA. This was created before the three Institutes joined NIH. So we do have a partner out there that does the outreach. We work with them as well as ourselves in promoting, providing the outreach to the public. I think that we do this together. There is an inter-agency group that does this.

Senator HARKIN. So you are doing outreach?

Dr. LI. Yes, sir.

ALCOHOL ADVERTISING

Senator HARKIN. Well, I would like to know more about how that is done. I will get my staff to get some more information on it.

I wonder about messages that young people receive about drinking, all the advertising about the glamorizing of drinking alcohol. Of course, it is a free country. People can advertise. But I just wonder about the impact of these messages and how they are reinforcing young people that it is all right to drink and it is all right to maybe even drink a lot, although I noticed that some of the beverage companies, if they want to be called that, are now putting out things about being responsible in drinking. I see a lot of that advertising going on.

But I am just wondering about the messages young people get about drinking. What have you looked into that? How have you looked into that?

Dr. LI. I think this is a very complex issue because there are a lot of background of messages coming in, and the advertising is only one part of it. So how children respond to advertising is a little different depending on how old they are and what their context.

Senator HARKIN. Are you doing any research into this?

Dr. LI. Yes, sir.

Senator HARKIN. You are doing some research in that, the different messages and how young people are affected by this?

Dr. LI. Yes.

Senator HARKIN. Any results?

Dr. LI. Well, we have some, but as I said, it is difficult to be able to dissect out which part is advertising that causes an increase in drinking or whether all they are doing is changing brands. I think the issue is whether there is an increase in drinking because of advertising but data on that is very, very slim. I mean, the result is that it is not a major influence.

BINGE DRINKING

Senator HARKIN. What kind of research are you doing into binge drinking, especially among college students?

Dr. LI. Binge drinking on that model there is the most harmful pattern, because physiologically it makes sense. You need that much drinking in order to get your blood alcohol to a level that is impairing and that is the nature of binge drinking, namely drinking to intoxication. Why people do it is something we would love to find out.

Senator HARKIN. Are you doing research into this?

Dr. LI. Yes, we are. It has to do with expectancies, it relates to problems which are stress and stressors. When we talk to people, young people, why are you drinking, they say, I want to drink because I want to get drunk. So it is a different approach.

You must understand that alcohol is the most ancient intoxicant, mind-altering drug. There is a lot of history there, and to be able to change the culture and what people think of it is not easy.

Senator HARKIN. One of the biggest fears that parents have when their kids go off to college is just this, binge drinking. I do not know the answer to it, but I just wonder if we are doing any research into that, what is happening, how it is happening, what is motivating young people to do this. I do not know. I do not have the answer to that.

Dr. LI. We have, for example, a site demonstration project on college drinking. This is a cooperative agreement. It is a demonstration project to look into that, and the study is now in its fourth year. I have been on the job 4 years. This is something we started when I took over.

We also have eight or more sites to study under-age drinking, meaning in adolescents, in high school level and middle school level.

CRIMINAL JUSTICE SYSTEM

Senator SPECTER. A few questions now, Mr. Chairman.

Dr. Volkow, since I was district attorney in Philadelphia many years ago the incidence of drug addiction has been a causative factor in 70 percent of the crimes, and we have not been willing to invest in realistic rehabilitation to try to stop the chain of recidivism. Is there any answer from your research to deal with drug addiction which is within the financial reach of what society is prepared to spend on corrections?

Dr. VOLKOW. Absolutely. In part one of our priorities is the criminal justice system, because——

Senator SPECTER. You said absolutely not?

Dr. VOLKOW. No. Absolutely. It is extraordinarily important to actually target substance abuse treatment in the criminal justice system. Data have——

Senator SPECTER. How do we deal with it effectively within some reasonable cost parameter?

Dr. VOLKOW. You save out of every $4—out of every $1 that you spend on treatment in the criminal justice system, you save $4.

Senator SPECTER. I am not interested in how much you save. I am interested in how much we spend. I am interested in how we

get my colleagues to spend money for corrections, and the inquiry goes to whether there is any answer within what the cheapskates in government are willing to spend, to ask the question more specifically.

Dr. VOLKOW. The cost, what I can tell you, the cost for a treatment program on substance abuse is around $10,000 in the criminal justice system, and it is $20,000 to incarcerate an individual, correct, more or less, on average? So that gets you an idea.

Senator SPECTER. There is a willingness to spend money for incarceration.

Dr. VOLKOW. Correct.

BRAIN INJURY AND ALCOHOL

Senator SPECTER. But not for rehabilitation.

Dr. Li, I have heard martini drinkers, illustratively, express concern about killing brain cells with the alcohol. Is that a real risk?

Senator HARKIN. Just martinis?

Senator SPECTER. That is what I drink.

Dr. LI. We know alcohol kills brain cells.

Senator SPECTER. It does kill brain cells?

Dr. LI. Yes, sir.

Senator SPECTER. How many and at what rate?

Dr. LI. I do not know the rate or the number. But we certainly——

Senator SPECTER. Is it a real danger?

Dr. LI. It is a result. Is it a real danger to whom?

Senator SPECTER. To the people who drink the martinis.

Dr. LI. Certainly over long periods of time, yes, sir.

Senator SPECTER. What would be consumption so that you do not become an alcoholic or to a lesser extent impair your brain?

Dr. LI. Well, this is exactly the kind of research we want to do, to be able to do to put a quantitative basis to the clinical observations——

Senator SPECTER. How much more money do you need than $30 billion that Senator Harkin has provided for you?

Dr. LI. We have just over $400 million for our Institute's appropriation.

Senator SPECTER. Dr. Landis, you are the chairman of the stem cell——

Senator HARKIN. Could we just finish their testimony so I can get their testimony before?

Senator SPECTER. That was my suggestion.

Senator HARKIN. I would like to turn to the other Institutes and have them at least make their presentations before we ask for questions.

TRAUMATIC BRAIN INJURY

Senator SPECTER. All right. I will go to Dr. Insel.

We talk a lot about the 3,200 or more men and women killed in Iraq. We now find that there are an enormous number coming back from Iraq with brain injuries. We do not focus as much on the 24,000-plus who have been injured in Iraq. Now medical procedures can save lives, but with very material brain impairment. There are reports that these young men and women are coming

back in their 20s, teens, and that they are going to need care for a lifetime.

To what extent can you evaluate those kinds of brain injuries and what might be done to provide therapy from the kind of research you are undertaking?

Dr. INSEL. I am going to leave the traumatic brain injury question to Dr. Landis, whose Institute is more involved with that. Let me add what you did not say, which was that the greatest proportion are coming back with what looks like post-traumatic stress disorder. The numbers are significant: 1.4 million individuals have served in Iraq and Afghanistan. The rate now already is about 12–13 percent PTSD. My calculation is about 170,000 people who will have PTSD currently or in the next couple of years.

We know that after the Vietnam War the rate went up to between 20 and 30 percent overall, so even higher than where we are now. So you are talking about a very significant amount of disability and high cost. Eighty percent of the time in the Vietnam case this was associated with substance abuse, usually drug addiction, often leading to criminal behavior as well—a tremendous disability at a very high rate from a mental disorder that is trauma-induced.

Senator SPECTER. Well, what should be the governmental response, either through the Veterans Administration of the Department of Defense, so that these young men and women and their families do not have to bear the burden and the cost when it is really not a war of their choosing and their making, but a war for the Government, that ought to be borne by the Government? What is an equitable response by the Government to these kinds of injuries?

Dr. INSEL. Let me talk about what the science can tell us, because I think that is where the biggest hope may be. I think we can use the science we have now to develop better treatments, and that is part of why we have got a major effort with the VA and DOD to do just that. More importantly, what we do not know is who is going to be sensitive to this. So if 100 people come back, 13 of them will develop PTSD currently. We would like to know who those 13 are and be able to preempt this, actually help them to recover before they develop the full syndrome. That is right now the target for the intervention.

Senator SPECTER. Thank you very much.

Thank you, Mr. Chairman. Let me comment that I think this procedure is a good one and the informality is conducive to a little easier reparte. I regret that I have to excuse myself. We are very heavily engaged right now with the U.S. Attorneys and I have to tend to that this afternoon. But Senator Taylor will be here in my place and I will be following it closely. I know that Senator Harkin joins me in this. We will provide the kinds of resources you need to the maximum extent of our capabilities, which is now more limited than it used to be. Thank you.

Senator HARKIN. That is true. That is very true. Well, thank you very much.

Now we will turn to Dr. James Battey, who has served as Director of the National Institute on Deafness and Other Communications Disorder since 1998. Dr. Battey got his B.S. from the Cali-

fornia Institute of Technology and his M.D. and Ph.D. degrees from Stanford.

Dr. Battey, please proceed.

STATEMENT OF JAMES F. BATTEY, JR., M.D., DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATIONS DISORDERS

Dr. BATTEY. Thank you very much, Mr. Specter and Mr. Harkin. It is a pleasure to be here today and I would like to begin by thanking you for your time, interest, and support over the years. It is deeply appreciated by those of us at NIH and in particular by the research community that we serve.

If I could direct your attention to figure 1. I am going to refer to some things on them.

Senator HARKIN. By the way, I want you to know I appreciate the fact that all of you gave me your testimony last week. I was able to look at it over the weekend. I appreciate that very much.

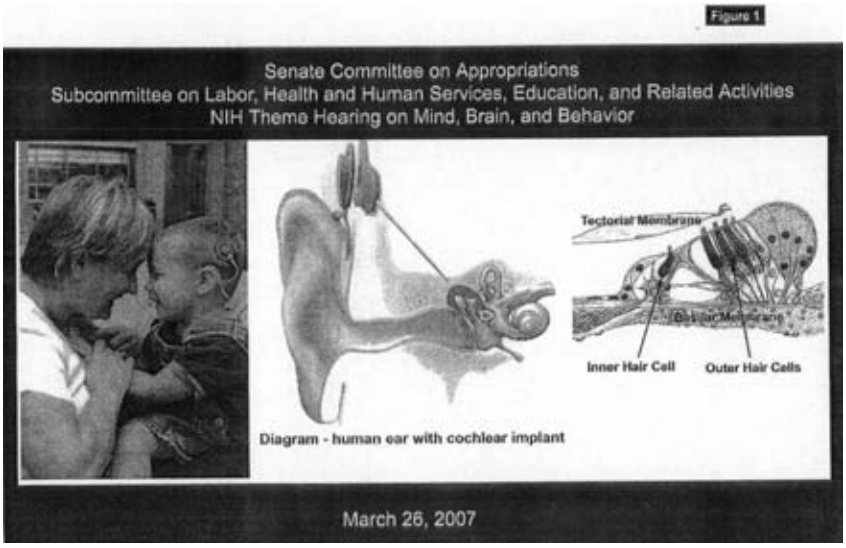
Dr. BATTEY. It is a particular pleasure to be here with my colleagues with whom I work every single day and to share the wonderful things that are happening in their Institutes and tell you a little bit about what is happening with NIDCD.

If you turned back the clock to the beginning of the 20th century, most Americans made their living with physical labor and did not really need great communications skills or a well-trained mind. But here as we enter the 21st century the situation is entirely different. The good jobs, the interesting jobs, the important jobs, the high-paying jobs, all involve an intact mind that is not impaired by drugs or alcohol, that is not bedeviled by mental illness, that allows one to communicate effectively.

One of the most important issues with communicating effectively is hearing impairment. It is one of the most common causes of a communication disorder and we estimate that roughly one American in six has a significant communication disorder that compromises their ability to access these high-paying, high quality jobs.

HOW HEARING HAPPENS

Now, to help you understand what we are trying to do about this problem, I would like to introduce you to the science behind how we hear. Now, if you can focus your attention for a moment on the center image, you will see a pink snail-shaped structure. See figure 1. That is the cochlea. A cross-section across that cochlea is shown in the right-hand image.



You will see four little blue cells with some little projections coming out of the top of them. Those four cells are called hair cells, and it is nanometer deflections of those little tufts that signal hearing and tell those cells to send an electrochemical impulse to the brain. That is how we hear.

These hair cells are the weak link. They are the vulnerable aspect of the hearing organ. They are what is generally lost or never developed in individuals who either cannot hear from birth or lose their hearing progressively throughout their life.

As long as there are some hair cells left we can amplify sound with a hearing aid and help those individuals hear. But when virtually all the hair cells are gone, amplification simply does not work. That is where research, supported initially by NINDS and then by NIDCD after we became an institute in 1988, on the cochlear implant has changed everything.

COCHLEAR IMPLANTS

There is a picture of a child on the left-hand side wearing a cochlear implant, which is also shown in an image in the center. It is an array of 22 electrodes that a surgeon inserts into that snail-shaped cochlea. See figure 1. It coils around and bypasses the damaged hair cells, stimulating the hearing nerve directly.

In an adult that loses their hearing, the cochlear implant can often restore the ability to understand speech to the point where that deaf individual can now use the telephone. In a young child who is born unable to hear, cochlear implantation before the second year of life can result in that child being mainstreamed in normal schools and be on grade level for language literacy and spoken skills. This is really an enormous testament to the plasticity of the human brain, to be able to go from losing 30,000 hair cells, replace it by stimulation from 22 electrodes, and still have the brain be

able to interpret what it hears as speech. I consider this to be simply remarkable.

HAIR CELL REGENERATION

But it would be far better to replace the hair cells that have been lost, to undo the damage, rather than simply bypass it with an array of electrodes. Birds and fish can regenerate their hair cells if they are damaged. Mammals and humans cannot. We are looking to understand why there is this difference between species who can regenerate hair cells and why others cannot. We are beginning to understand the molecular mechanisms that underlie how hair cells develop in the first place and also how potentially regenerated.

PREPARED STATEMENT

For example, recent studies supported by NIH have shown that there is a master regulatory gene called *Math-1* whose expression is necessary and sufficient for hair cells to develop in the first place. Animal models missing the *Math-1* gene never develop hair cells and are deaf. We have preliminary data from one laboratory that they can, by stimulating the expression of *Math-1* in an animal model that has been deafened by damaging the hair cells, that partial hair cell regeneration could take place and perception of sound can be restored, which gives us the hope that the day may come some day when, instead of simply bypassing damaged hair cells, we can regenerate new ones and provide a whole new approach to helping individuals who have lost their hearing.

Thanks very much for your attention and I will do the best I can to answer any questions you might have.

[The statement follows:]

PREPARED STATEMENT OF DR. JAMES F. BATTEY, JR.

Mr. Chairman and Members of the Subcommittee: I present the President's budget request for the National Institute on Deafness and Other Communication Disorders (NIDCD). The fiscal year 2008 budget for NIDCD includes $393,682,000. The NIDCD conducts and supports research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. These processes are fundamental to the way we perceive the world and to our ability to communicate effectively in modern society. Disorders of communication impose significant economic, social, and personal costs. Accordingly, the goal of the NIDCD strategy is to produce outcomes with a significant impact on the health of Americans. Driven by the public health need and scientific opportunity identified in the NIDCD Strategic Plan, NIDCD prioritizes its research investment to fund the most promising scientific opportunities in diagnosis and treatment of communication disorders. The following are notable highlights from the past year that are the result of NIDCD support:

GENES AND COMMUNICATION DISORDERS

The NIDCD recognizes that functional genomics—determining the identity, structure, and function of genes—is one of the most rapidly developing areas of research. Inherited genes account for approximately 50–60 percent of the severe to profound cases of childhood hearing loss. NIDCD scientists are working to understand the normal function of these genes, and how they are altered in individuals with communication disorders (such as hearing loss, stuttering, speech-sound disorders, autism, and dyslexia). These research investments to understand the genetic basis of communication disorders will help scientists develop diagnostic tests and better treatments for the millions of Americans with hereditary hearing impairment.

PREVENTING AND DIAGNOSING COMMUNICATION DISORDERS

The Centers for Disease Control and Prevention (CDC) reports that two to three out of 1,000 babies born each year in the United States have a detectable hearing loss, and estimates the average lifetime cost for one individual with hearing loss to be $417,000 (in 2003 dollars). Accordingly, NIDCD places a high priority on understanding causes, possible treatments, and progression of hearing loss during early childhood. NIDCD-supported research demonstrates that children not exposed to language during their first 3 years of life due to hearing loss will have more difficulty developing spoken or signed language and reading skills. Early identification of hearing loss enables parents to pursue interventions early enough that their child can learn to communicate on par with his or her hearing peers.

However, childhood hearing loss does not always show up right away. Congenital cytomegalovirus (CMV) is the most common viral infection passed from a mother to her unborn child, with 40,000 infants born infected each year. According to the CDC, approximately 10 to 15 percent of these children have some degree of hearing loss. Scientists believe that CMV infection present at birth is a leading cause of sensorineural hearing loss in children. Hospitals do not test newborns for CMV unless they already show signs of the disease. NIDCD is funding the CMV and Hearing Multicenter Screening (CHIMES) Study to identify asymptomatic children and follow them to determine if hearing loss develops. Scientists will screen approximately 100,000 children at birth for CMV infection, and those who test positive will undergo follow-up diagnostic hearing testing to determine the onset, severity, and progression of hearing loss. The scientists will use these data to understand the relationship between CMV infection and hearing loss and to determine whether CMV screening together with hearing testing can improve the detection and prediction of permanent hearing loss in children.

Although success in establishing early screening programs has identified a new population of children with hearing loss, we do not know which interventions provide the best outcomes. Current intervention and outcome data are limited to those children whose hearing loss was detected later in life. Hearing health specialists need research data that considers not only the intervention strategy but also the parent-child interaction, socio-economic factors, and language exposure. To address this need, NIDCD held a workshop on "Outcomes in the Child with Hearing Loss" in December 2006. NIDCD is using information from this workshop to develop fiscal year 2008 initiatives focused on prospective and longitudinal research. These initiatives will be part of a multi-agency collaboration designed to close the gap between children with hearing loss and their hearing peers, and will provide sorely-needed information on the best strategies to achieve this goal.

DEVELOPING ASSISTIVE DEVICES

NIDCD-supported basic research on the ears of the tiny fly Ormia ochracea has inspired a new generation of hearing aids. The fly's ear structure permits ultra-sensitive time coding and localization of sound, and scientists used it as a model to develop miniature directional hearing aid microphones that can selectively amplify speech rather than amplifying all sounds. NIDCD-supported scientists are now working to make these directional hearing aids widely available. Individuals with hearing loss who use hearing aids fitted with these improved directional microphones will experience improved quality of life because the aids will do a better job of helping them to understand spoken language amidst background noise.

Some individuals with severe to profound sensorineural hearing loss may benefit from a cochlear implant (CI). The NIH's support has played a significant and important role in the development of CI technology over the last three decades. A CI converts sound into electrical impulses on an array of electrodes surgically inserted into the inner ear, bypassing the damaged hair cells that normally detect sound. The CI stimulates the auditory nerve directly and restores the perception of sound to individuals who are deaf.

The Food and Drug Administration (FDA) estimates that approximately 36,000 Americans have received CIs, and one-half of the recipients were children. The FDA approved the use of CIs in children as young as 12 months of age. NIDCD-supported research demonstrates that the sooner a child with profound hearing impariment receives the benefit of a CI, the greater the benefits and improvements in speech perception and language production. Because of the rapid development and plasticity of their brains, young children implanted with a CI usually show age-appropriate brain responses within 6 to 9 months after the CI is turned on.

CIs are expensive (costing approximately $60,000 for the device, associated surgical expenses, and postoperative fitting and training) and many insurance companies were initially unwilling to reimburse for this cost, citing a lack of evidence that

the device is cost-effective. To address this concern, NIDCD-supported scientists conducted an initial cost-utility analysis of the CI in children to examine whether the benefits of the implant outweigh its costs. The study showed that CIs improve the children's quality of life, and result in a net saving to society. The cost benefit is the result of fewer demands on special education and greater wage-earning opportunities for CI recipients, providing an estimated life savings per child at $53,198. This landmark study has helped make CIs a standard treatment for severe-to-profound nerve deafness, and many insurance companies now cover them.

An NIDCD-supported study assessed the sound-localization abilities of children (ages 5 to 14 years) wearing two cochlear implants as compared to one. Children in the study located the source of a sound more accurately when they were wearing two implants as opposed to one. The greater the experience with two implants, the more adept he or she became at localizing sound. The research team is now investigating the effects of bilateral implants on word learning and language acquisition in infants and toddlers receiving CIs at a young age.

NIDCD-supported scientists are currently using lessons learned from their cochlear implant research experiences to develop an implanted device to help restore the sense of balance. The prototype vestibular implant has the potential to benefit over 90 million Americans who have experienced a dizziness or balance problem.

STRATEGIES TO PROTECT YOUR HEARING

The NIDCD shares Congress's concerns that approximately 10 percent (over 22 million) of American adults have suffered permanent damage to their hearing from exposure to loud sounds or noise at work or in leisure activities (CDC NHANES). In 1999, the NIDCD collaborated with the National Institute for Occupational Safety and Health (NIOSH) to launch WISE EARS!. WISE EARS! is a national campaign to prevent noise-induced hearing loss (NIHL) in the general public, including the workplace. NIDCD has built a coalition of nearly 90 partner organizations and disseminated information and promotional materials through the media, at professional conferences and health fairs, and over the Internet. In 2006, the NIDCD conducted an evaluation on the WISE EARS! Public Health Campaign to obtain an accurate picture of how far WISE EARS! has progressed in achieving its goals and to identify those needs that have not yet been addressed through current educational and promotional methods.

Finally, Mr. Chairman, I would like to thank you and members of this subcommittee for giving me the opportunity today to present exciting scientific advances from the NIDCD. I am pleased to answer any questions that you have.

REGENERATION OF HAIR CELLS

Senator HARKIN. Dr. Battey, thank you very much.

Let us get into the whole thing of regeneration of hair cells. I do not remember the exact year, but somewhere around 1990, 1991, I remember getting a paper on the regeneration of hair cells and how certain birds exhibited the fact that they could regenerate hair cells.

I engaged in questions with the then-Director——

Dr. BATTEY. Is that James Snow?

Senator HARKIN. Dr. Snow, thank you very much. Dr. Snow, about that. Yes, and I have asked that question repeatedly. That is at least 17 years ago and almost what I hear you saying is what I heard 17 years ago. Are you telling me——

Dr. BATTEY. Seventeen years ago we were not regenerating hair cells in mammals.

Senator HARKIN. Are you now?

Dr. BATTEY. Yes, we are. In a guinea pig model——

Senator HARKIN. I thought you told me that it was just birds.

Dr. BATTEY. They can do it spontaneously. In a guinea pig animal model that is deafened—I do not do it; Yehoash Raphael does it at the University of Michigan—that deafens the animal in one ear by administering a drug called gentomycin, he can then express *Math-1* in that inner ear and see hair cells regenerate, and can

show physiological evidence of auditory percept in the ear that had been deafened.

Senator HARKIN. How long has he been doing this?

Dr. BATTEY. I would have to go back to look. I think Yehoash's paper is from 2005.

Senator HARKIN. Recent.

Dr. BATTEY. Yes.

Senator HARKIN. Is there more than one locus of this research going on right now?

Dr. BATTEY. It is now being studied in other laboratories and others are hopefully going to replicate his findings. And then maybe if that works out we will move forward to non-human primates, with the hope of ultimately moving into phase 1 clinical trials.

Senator HARKIN. When do you think you will be ready to go to higher mammals?

Dr. BATTEY. I really do not know. I could give you a guess, but it would be nothing better than a guess.

Senator HARKIN. Well, you are funding this research?

Dr. BATTEY. Yes.

Senator HARKIN. Where is that? University of where?

Dr. BATTEY. University of Michigan.

Senator HARKIN. Michigan. Well, if they have been doing guinea pigs for a couple years and they have gotten some pretty good results, I am just wondering how soon they might be ready to take it to a higher order of mammals.

Dr. BATTEY. I would say if it replicates nicely in several other laboratories, which is the cornerstone of good science, then we would be ready to try to stimulate research in non-human primates. It is a couple of years.

Senator HARKIN. This is a genetic intervention?

Dr. BATTEY. Yehoash's work—I am going to get technical here a little bit—it is a viral vector that expresses a gene called *Math-1*, which is a master regulatory gene.

Senator HARKIN. Are you saying "MATH?"

Dr. BATTEY. MATH, M-A-T-H, dash 1.

Senator HARKIN. *Math-1*.

Dr. BATTEY. It stands for Mouse Atonal Homolog 1.

Senator HARKIN. That is a little bit hard for me, okay.

Dr. BATTEY. I warned you.

Senator HARKIN. It is a viral vector. I understand that. Yes, I do have a good feel for that. But I do not know that much about how much regeneration they have had and a percentage. Is it like 10 percent of the hair cells are restored, is it 20, 30? Do you have any idea?

Dr. BATTEY. Roughly a third.

Senator HARKIN. About a third?

Dr. BATTEY. Yes. Again, it varies from animal to animal exactly how well this works.

Senator HARKIN. I thought you said they were just doing it in guinea pigs.

Dr. BATTEY. I am sorry, from guinea pig to guinea pig.

Unfortunately, you have to do it in a number of guinea pigs to show if the result is reproducible.

Senator HARKIN. A big question then, why is it more in some and less than others.

Dr. BATTEY. It is a great question. Probably there are other genes involved as well. The genetic background may be different in one guinea pig than another.

Senator HARKIN. But that is kind of the holy grail of this, of what we are looking at in terms of deafness, right?

Dr. BATTEY. Hair cell regeneration would be wonderful, not just for hearing impairment, but also for balance disorders, because there are another class of hair cells in the balance organ, which is that part of the inner ear that is right next to the snail-shaped cochlea.

Senator HARKIN. Which is why so many older people fall and break hips and stuff. As you get older you lose your sense of balance.

Dr. BATTEY. Yes, roughly—well, dizziness is the most common reason why an elderly person consults a physician.

Senator HARKIN. Well, I would like to know more. Anything that you have got on what they are doing at Michigan in any kind of a form that I can halfway understand, I would appreciate seeing it.

Dr. BATTEY. I will have my staff abstract something in educated lay terms describing the results from the University of Michigan.

Senator HARKIN. I appreciate that. How many more universities are doing this? What is their timetable, that type of thing.

Dr. BATTEY. We will get that information for you.

Senator HARKIN. I would like to know about that. Understand my concern. I have been hearing about this. Seventeen years I have been hearing about regenerating hair cells.

Dr. BATTEY. It is a hard problem.

Senator HARKIN. Well, I understand.

Dr. BATTEY. I wish that science progressed faster, but usually our understanding is incremental and often it is serendipitous. For example, the discovery of the importance of the *Math-1* gene took place in a lab that was not interested in hearing at all. They simply knocked the gene out in a mouse and the mouse was deaf.

Senator HARKIN. Fascinating.

Well, that is all I have for right now. I may have others. Now we will turn to the National Institute of Neurological Disorders and Stroke. Dr. Story Landis has been Director since September 2003. Dr. Landis received her undergraduate degree in biology from Wellesley and her master's and Ph.D. from Harvard.

Dr. Landis, welcome and please proceed.

STATEMENT OF STORY LANDIS, Ph.D., DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Dr. LANDIS. Thank you very much. I, like my colleagues, am delighted to have this opportunity to be able to testify today about research on mind, brain, and behavior. As I have heard from each of us, disorders of brain function are leading causes of disability in the modern age, and I think that Dr. Batte did a very good job of pointing out some of the issues.

NINDS is responsible for reducing the burden of several hundred neurological disorders. These range from very common disorders,

like stroke, Parkinson's, epilepsy, to relatively rare but individually devastating disorders like ALS—amyotrophic lateral sclerosis—and spinal muscular atrophy. So in addition to the burden in terms of lost life, disability and suffering, neurological diseases cause billions of dollars each year in medical expenses and reduced productivity.

Neurological disorders affect people of all ages. We have increasing disability in children as a growing problem because of brain injury in premature infants who now survive when they would not have before. As Americans live longer lives, age-related disorders like dementia, stroke, Parkinson's, and epilepsy are increasing in incidence. Meeting the challenge of neurological disorders therefore has never been more important. The good news is that the advances in basic and clinical neuroscience provide enormous opportunities.

Now, 20 years ago neurology was really regarded as a diagnostic discipline because neurologists had relatively few therapies to offer patients. They could tell you what the lesion was, but they could not necessarily do anything about it. Through NINDS-funded research we have actually made extraordinary progress. For example, there used to be only a handful of drugs to treat epilepsy and now we have more than 20. Steroids used to be the only treatment for multiple sclerosis, but now there are three FDA-approved drugs and more in the pipeline. Deep brain stimulation (DBS) dramatically helps many people with Parkinson's disease who are no longer benefited by medicines. Turn off the stimulator and they are frozen, unable to walk. Turn on the stimulator and in the best cases, the ones that make it to "Dateline", they can dance.

Now, while DBS is very exciting, it, like other treatments for Parkinson's disease, addresses the symptoms but not the underlying causes. The underlying cause is death of brain cells. So we need desperately to figure out treatments that will protect the neurons that remain. Just last week, NINDS began to enroll patients in large phase 3 clinical trials to determine whether we can slow the loss of brain cells and prevent the slow decline of patients with Parkinson's. We hope to begin a second trial of a neuroprotective agent soon.

As you or someone else alluded to, even just the small change in the rate of progression of any of these chronic neurodegenerative diseases would make a very big difference in the quality of life and how people fared.

Now, the scientific rationale for the two drugs that we are studying in these neuroprotective trials is strong or else we would not be funding them. But we really believe, because of the discovery of eight genes that cause familial Parkinson's disease and our ability to understand how the proteins that those genes encode for, we should have much better and more targeted drugs soon, and we would then put these drugs into neuroprotective trials that would prevent neuron loss.

So I would like to talk a little bit about stroke. NINDS is the lead Institute for stroke. It is in our name. Stroke is the third leading cause of death and disability in the United States. The good news is that CDC data demonstrate that age-adjusted stroke deaths have declined from 180 per 100,000 in 1950 to 50 in 2004.

That is age-adjusted, though. So the bad news is actually that because our population is aging we are barely keeping pace in terms of incidence of stroke.

NINDS has three strategies for stroke. First is prevention, then minimizing damage when a stroke occurs, and finally developing better strategies for recovery. In terms of prevention, the most important thing is to know what increases your risk of a stroke. NINDS has a number of epidemiological studies that look at that. The largest of these is called REGARDS which has recruited over 30,000 people, half of them African American, many in the stroke belt. The goal is to study how race and geography influence the incidence of stroke.

Now, there are already two important findings in this study. The first is that there are many more silent strokes—that is a stroke that does not take someone to the hospital or give you an obvious disability—than anybody expected, particularly in the middle aged population. The second is that, while we have always thought of hypertension as the principal risk factor for stroke, we now, based on this REGARDS study, understand that diabetes is also very important. So obviously NINDS not only needs to partner with NHLBI and the American Heart Association for reducing hypertension, but we also need to look at partnering with NIDDK and diabetes groups for reducing diabetes.

DIABETES AND STROKE

Senator HARKIN. Excuse me for interrupting at this point. Are you saying that diabetes is a leading indicator for having a stroke?

Dr. LANDIS. In this population, being diabetic significantly increases your risk of having a stroke.

Senator HARKIN. In this population.

Dr. LANDIS. In this population of 30,000 people, many of them who are not patients yet. We did not expect that but we knew about hypertension and not about diabetes. This is not surprising. Diabetics are often overweight and do not exercise so it is not surprising, but it had not actually been demonstrated.

Senator HARKIN. I am just curious again to take this a step further. Okay, diabetic, but then have you screened all those to look at what has been their cholesterol levels, all the other factors?

Dr. LANDIS. This has been a recent study, 4 years old, and we are just beginning to see the fruits of these initial analyses of data. So the first publications are just beginning to come out and we are in the process now of accepting an application to refund the study. Obviously, the more things that we could look at, the better data we would get in terms of identifying risk factors and being able then to think about interventions.

So if prevention fails, obviously we want to minimize damage when someone has a stroke. The NINDS Institute a decade ago had a clinical trial that showed that the clot-busting drug, TPA, could restore blood flow to the brain and prevent brain damage if it was given within 3 hours of stroke onset. I can tell you very honestly that this transformed acute stroke care in this country. You did not get shuttled off to a dark room and given an aspirin. You actually got aggressively treated. I think it has been a model for how other neurological diseases can be treated.

Now, this treatment really benefits patients, obviously. A third of the patients who get this treatment leave the hospital with no sequelae whatsoever. It reduces long-term disability-related costs and there is a net savings of more than $4 million for each 100 patients treated because you do not have to do long-term care and rehabilitation.

We are currently running clinical trials to boost the effectiveness of TPA, to select patients who might benefit beyond the current 3-hour limit, and to determine whether if you inject the TPA into the blocked brain artery you get more benefit than if you just do it intravenously.

Now, if you have a stroke, we need to help people recover from it. Because of animal studies, we know that there is remarkable plasticity in the adult brain. Because of that plasticity, investigators that were funded both by NINDS and NICHD forced stroke patients to use the affected arm and this stimulated the formation of new brain connections, and a 2-week study of rehabilitation based on this insight showed lasting clinical improvement in arm function for stroke survivors.

So it is very clear that increasing the brain's latent capacity to rewire and/or repair itself is an extremely exciting area for research in NINDS, and will also impact many other brain disorders.

I want to, in closing, underscore two points that were made by the panel of outside scientists at last week's hearing. I thought they were very impressive. I watched it on C-SPAN. The first is we need to encourage new ideas and new investigators. You go to any scientific meeting and most of the people in the audience, who are speaking and presenting have grey hair and, while they will make advances—I mean no offense to the grey hair because I have it myself—they will make advances over the next decade, but we will not cure many of our diseases. We will improve treatment, but not cure them in the next 10 years so that is a very important issue.

The second is the importance of NIH basic research, both for the public health of the Nation and the competitiveness of our private sector. Now, while each of the institutes that we represent has a distinct mission, the structure requires that we answer fundamental and shared questions about the brain, such as how genes and the environment shape the brain and how the brain represents thoughts, emotions, memories, sounds, and leads to behavior. Answers to these questions are key to preventing all kinds of brain diseases, as well as learning how to optimize brain health and help all our citizens realize their full potential.

PREPARED STATEMENT

So recognizing that we share the brain and the significant synergy that will come from collaboration, the institutes represented here along with others who will testify in different hearings created the Neuroscience Blueprint for the extramural community and the Porter Neuroscience building in the intramural program, which I would say is not completed. We would be pleased to tell you more about the blueprint and the Porter building during the question period.

I would like to thank you very much for your attention and your support.

[The statement follows:]

PREPARED STATEMENT OF DR. STORY C. LANDIS

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for NINDS. The mission of NINDS is to reduce the burden of neurological disorders by developing ways to prevent or to treat these diseases. The fiscal year 2008 budget is $1,537,019,000.

Disorders of the nervous system, common and rare, affect people of all ages. They cause an enormous burden in lost life, disability, and suffering, as well as billions of dollars each year in medical expenses and reduced productivity. Because Americans are living longer, stroke, dementias, Parkinson's disease, epilepsy, and other neurological disorders that rise in frequency with age are increasing. Abnormalities in nervous system development rob many children of a normal life. As more premature infants survive through intensive care, neurological disability in children is a growing problem. Many people, often young adults, now survive trauma to the spinal cord or brain, but confront a lifetime of disability. Meeting the challenge of neurological disorders has never been more important, but the opportunities for progress have never been greater. Advances in neuroscience are transforming the practice of neurology from diagnosing patients, with only inadequate treatments to offer, to intervening to stop or prevent disease, with treatments tailored to each person. Neurosurgery is likewise increasingly capable of preventing or repairing damage to the brain.

IMPACT OF CLINICAL RESEARCH

NINDS has its most immediate impact on public health through phase III clinical trials, which test the safety and efficacy of interventions. It is essential to assess the return on this investment in improving quality of life. At the request of the National Advisory Neurological Disorders and Stroke Council, the institute contracted for an independent evaluation of the costs and benefits of all NINDS phase III clinical trials conducted from 1977 to 2000 [The Lancet 367:1319–27, 2006]. The total cost of the clinical trials in the study was $335 million (adjusted to 2004 dollars). Over 10 years, the benefits exceeded $15 billion and added 470,000 healthy years of life to people in the United States. For the entire period of the study, the benefits surpassed $50 billion, which was greater than the total NINDS budget over that period ($29.5 billion). Advances in neuroscience are yielding more clinical trial opportunities than ever before, but trials are expensive and take years to complete. NINDS is developing computer models to estimate in advance which trials would have the most impact on public health.

TRANSLATING PROMISE INTO PROGRESS

Because of progress over the last decades, thousands of strokes are prevented each year and emergency treatment lessens chronic disability for many people who do have a stroke. Data this year from the Centers for Disease Control and Prevention (CDC) show that age-adjusted stroke deaths are continuing to decline, from 65.3/100,000 in 1990 to 50.0/100,000 in 2004, compared with 180/100,000 in 1950. Better surgical treatments and drugs also help people who have chronic pain, dystonia, epilepsy, migraine, multiple sclerosis, neuropathies, Parkinson's disease, and many other diseases. Brain imaging has revolutionized neurology and neurosurgery. For many people, genetic testing eliminates arduous and expensive diagnostic odysseys to determine which of the hundreds of neurological disorders is responsible for their problems. NIH research drives this progress.

A decade ago an NINDS clinical trial showed that the clot busting drug tPA was the first emergency treatment that could improve the outcome from stroke. This engaged the community in stroke education, stimulated the organization of more than 250 certified primary stroke centers nationally, and energized researchers to develop even better emergency care. In the future, combinations of tPA and neuroprotective therapies will rescue brain tissue from permanent damage, and rapid diagnosis will identify which patients will benefit from what interventions while the critical time window for intervention is still open. This year NINDS investigators showed how MRI brain imaging can improve diagnosis for patients who come into emergency rooms with suspected strokes, and other scientists are developing rapid blood tests for stroke using genomic fingerprinting. Several strategies to boost tPA's effectiveness are in development, including clinical trials of ultrasound to help break clots quickly, and direct injection of tPA through a catheter threaded into the blocked brain artery for patients with large clots that are difficult to clear. Clinical trials of interventions, studies of risk factors, and gene studies will also continue the mo-

mentum of stroke prevention, with increasingly personalized guidance. This year, to illustrate that trend, NINDS-funded researchers discovered a gene variation, more common in African-Americans, that predisposes young women who smoke to have strokes.

For people who do have a stroke, neuroscience is offering new approaches to recover lost functions. New understanding of brain plasticity suggested that, counter to intuition, forcing patients to use an affected arm would stimulate adaptive changes in the brain. A two week behavioral rehabilitation regimen based on this insight yielded lasting clinical improvements for stroke survivors who had chronic weakness in one arm. Studies are building on this strategy, using behavioral methods, drugs, and brain stimulators to engage the brains' natural capacity to adapt, and even generate new brain cells. Enhancing the brain's latent capacity to repair itself may also help people recover from traumatic brain injury and many other disorders.

A decade ago, spinal muscular atrophy (SMA) was one of hundreds of poorly understood inherited disorders that affect the nervous system, and the outlook for developing treatments was bleak. The discovery of the gene defect that causes SMA revealed a rational strategy for developing drug therapy. In just a few years, the NINDS SMA Project developed a detailed drug development plan and tested hundreds of new compounds in laboratory tests. Most recently, some of these potential drugs increased the amount of the critical missing protein to normal levels in cultured cells from patients who have SMA. The SMA Project is testing the effectiveness of these compounds in animals with SMA and assessing their safety to bring these potential drugs to clinical trials, offering significant promise for helping people who have SMA.

Research on SMA illustrates the path from gene to understanding to treatment. Researchers have now characterized well over 200 mutations that cause neurological disorders. For inherited ataxias, Batten disease, Down syndrome, Huntington's disease, muscular dystrophy, Rett syndrome, neurofibromatosis, and many other previously baffling disorders, researchers have genetically engineered animals that mimic the human disorder and then replaced genes, turned harmful genes off, turned up compensatory genes, or counteracted gene defects with drugs that target the affected cellular functions. In the future, application of these strategies to patients could preempt or even reverse the damage caused by gene defects. NINDS is aggressively pursuing opportunities to translate science advances such as these to treatments.

The goal for epilepsy is "no seizures, no side effects," or better yet, to prevent epilepsy from developing. In the 1960's only a handful of drugs were available to treat epilepsy. Today there are more than 20, which control seizures in about two-thirds of people who have epilepsy. Ten were developed with special programs at the NIH, and the NINDS Anticonvulsant Screening Program continues to catalyze academic and industry efforts. New animal models will allow screening potential drugs for people who have treatment-resistant epilepsy and for blocking epilepsy development. Clinical trials are now testing interventions to prevent epilepsy after head trauma, a major risk factor. Gene studies, now underway, will enable physicians to personalize treatment, choosing the best drugs or other therapies for each person with epilepsy, avoiding the current trial and error process.

Drugs that are the mainstay of Parkinson's disease treatment mask symptoms but ultimately fail because they do not slow the underlying neurodegeneration. Deep brain stimulation (DBS) dramatically helps many people with advanced Parkinson's disease. NIH research, from technology development to clinical trials, is improving DBS and expanding its use for other neurological and psychiatric diseases. Researchers are also developing drugs to slow neurodegeneration itself. NINDS assessed candidate neuroprotective drugs for Parkinson's disease, conducted early phase clinical trials, and is beginning a large clinical trial of a neuroprotective drug. Even a modest slowing of Parkinson's or other neurodegenerative diseases would have an immense impact on public health, so drugs to forestall neurodegeneration are a high priority.

Stem cell research has captured the public's attention. Research on animals with Parkinson's-like disease illustrates the promise and challenge of stem cell therapy. In recent tests, stem cell-derived transplants dramatically improved movement, but also produced tumors in some animals. Stem cell therapies for spinal cord injury, muscular dystrophy, and many other neurological disorders continue to advance toward the clinic. However, better control of stem cells is necessary before these therapies are ready for people, so understanding the basic biology of stem cells is essential.

Scientists are also making progress in answering fundamental mysteries, such as how genes and the environment shape the brain and how the brain represents

thoughts, emotions, and memories. Answering basic questions such as these is the key to not only treating disease, but knowing how people can maintain a healthy brain and realize their full potential at every age.

PLANNING FOR THE FUTURE

NINDS continuously monitors research needs and opportunities. The institute recently posted a mid-course review of the Stroke Progress Review Group and a new plan for Parkinson's disease. An epilepsy conference this month will follow up the meeting that launched the epilepsy benchmarks planning process. More broadly, NINDS is beginning a process to update its strategic plan. With input from all stakeholders, we will identify aspirational goals that will guide us to best achieve our mission and then focus on what steps NINDS can take to realize this vision. In order to achieve our paramount goal of reducing the burden of neurological disorders, we must certainly continue to support young scientists, to engage the ingenuity of the scientific and medical community, to work with the private sector, and to collaborate with other components of the NIH, as we now do through the NIH Roadmap, the NIH Blueprint for Neuroscience, working groups on specific diseases, as well as dozens of specific inter-institute initiatives.

Thank you, Mr. Chairman. I would be pleased answer questions from the Committee.

Senator HARKIN. Dr. Landis, thank you very much.

Let me—I have got quite a few questions here. First of all, talk to me about something that you mentioned in your written statement. I am hearing more and more about the debilitating effects of migraine headache.

Dr. LANDIS. Right.

MIGRAINE HEADACHES

Senator HARKIN. I saw some figures, I cannot repeat them here because I do not have them here, but just how prevalent migraine headaches are. More and more I am meeting people who have migraine headaches. I have had some people who have worked for me in the past who have had them and it is just very debilitating.

So what is happening? Why? What is the story?

Dr. LANDIS. It is not completely clear. What is completely clear is that there are several different causes of migraine headaches and that if you have mutations in particular kinds of ion channels you can have migraine, and that it can be a spreading depression. We have, fortunately, over the past decade developed a number of treatments which can forestall a migraine once it begins. We also have learned in some cases that long-term treatment with calcium channel blockers can prevent migraines.

We do not know as much as we should. It is an area that has not received as much attention as it might. NINDS recently released a request for applications specifically in the area of migraine headaches. We recognize it is an underserved area and hope to stimulate research in it.

Senator HARKIN. I do not know whether I am just hearing more about it now and finding more people. Is it increasing in prevalence?

Dr. LANDIS. I do not think it is increasing. I think people are more attentive to it than they have been before. One of the problems with being an Institute like NINDS is making choices between stroke and Parkinson's and migraine. We are hoping in our planning process to undertake over the next 2 years, a look across all the diseases that we are responsible for and see the ones that we have perhaps not invested in as much as we might.

Senator HARKIN. One disease that you know that I have been interested in, I did not even know about it until a few years ago, but the more I have looked at it the more I have seen what you have been doing at the Institute on it. It seems to me that you are making great progress in understanding spinal muscular atrophy, which I had not heard of until a few years ago. I have met with some people in my home State with children who have that and others.

The more I have learned about it, the more I think that there may be in this research area applicability to other diseases. You have identified the gene, I think.

Dr. LANDIS. We did not, but it has been identified.

Senator HARKIN. It has been identified. Somebody did.

Dr. LANDIS. Right. The Europeans actually, I think.

SPINAL MUSCULAR ATROPHY

Senator HARKIN. Oh, is that right? Sorry to hear that. But that is all right.

Tell me about the progress on spinal muscular atrophy, because I keep hearing that this has some connectivity to other types of diseases.

Dr. LANDIS. There are two pieces of our investment in research in spinal muscular atrophy that I think are important. The first was the Institute decided a number of years ago that we would try an experiment, which was to identify a particular disease, a devastating disease. In SMA, kids lose their motor neurons, and in babies many of them die within the first year. Some of them die within 4 to 5 years depending on the type. We would try to identify a particular disease which was amenable to a concentrated investment, a focused effort in therapeutics development.

After a survey of many of the diseases that we were responsible for, SMA emerged as the likeliest candidate for this experiment. Mutation occurs in the SMN–1 gene. There is a second gene, SMN–2, which codes for the same protein, but does it much less effectively. We had compounds which we knew could increase the levels of SMN, Survival of Motor Neuron protein. So we put a big chunk of money, $20 million, into a contract to actually come up with at least one drug that would have an investigational new drug designation within 4 years, or the end of 2007. We are not going to make the end of 2007 because it turned out that what we had to do is actually create a virtual biotechnology company through this contract.

But we are making significant progress. We recently filed a patent for one chemical backbone and have a number of compounds in there which cross the blood-brain barrier which significantly increase the amount of SMN protein. We are taking those compounds to animal studies to see which is the most effective in increasing the survival of these animals.

So it is an experiment for the Institute to see if we can actually push forward therapeutics in a very significant way and make a difference. Then the other issue is that these are the same neurons that die in ALS. The kinds of things that might promote survival of motor neurons in SMA might also be instructive for ALS. The mechanism—the failure to make a splice—again a technical term—

is apparent in a number of other diseases we are responsible for. If we can figure out a way to make the splice work, we might use that same strategy in other diseases.

So it has a number of very interesting implications for the Institute in how we manage rare diseases and how we move from one rare disease to another.

STROKE

Senator HARKIN. You mentioned that deaths have declined due to stroke, but I just wonder about the incidence of stroke. I do not think the instance of stroke is down.

Dr. LANDIS. No. Age-corrected deaths due to stroke have decreased. The incidence is not decreasing because our population is aging.

Senator HARKIN. Well, also I think we have better interventions, too, for stroke.

Dr. LANDIS. Right.

Senator HARKIN. I think stroke remains still one of the feared things that can happen to someone. They are just so unexpected and can happen to anyone at any time. It is that early intervention if you can get to it right away that helps, if you get that——

Dr. LANDIS. TPA.

Senator HARKIN. What is it called? TPA.

Dr. LANDIS. Tissue Plasminogen Activator.

Senator HARKIN. TPA.

Dr. LANDIS. TPA.

Senator HARKIN. I am also interested in Parkinson's disease. In your testimony you talked about deep brain stimulation for Parkinson's disease. Again, how much progress is being made in this?

Dr. LANDIS. We are presently conducting with the Veterans Administration a clinical trial to determine whether deep brain stimulation is better than best medical treatment. A group in Europe has already produced some data that are consistent with that, but we want to make sure that that is in fact true.

The second issue is where do you put the stimulating electrode. So some people, some surgeons, put it in something called the GPI and others put it in the STN, and we do not know which locus is better. So the second part of this NINDS–VA study is to determine where is the best place to put it.

One of the most surprising things is that deep brain stimulation actually works for a number of other neurological diseases—dystonia, Tourette's—and has shown to have benefit for chronic untreatable depression. So the notion of putting stimulating electrodes in the brain and altering patterns of brain activity may be applicable to more than just neurological diseases.

TRANS-CRANIAL MAGNETIC STIMULATION

Senator HARKIN. A year ago or so maybe, I was visiting my office. A friend of mine brought a person in, a woman who had been to Greece—she had Parkinson's disease—to undergo some new therapies. The way she described it to me, she had pictures of it. It was some doctors in Greece, some scientists, had developed like a helmet they put over her head, but it did not penetrate the skull, but it was like——

Dr. LANDIS. Trans-cranial magnetic stimulation probably.

Senator HARKIN. Thank you. I had no idea. Probably so if you say so.

Dr. LANDIS. Well, that is a strategy that we are looking at in this country as well.

Senator HARKIN. This woman came back, and it did not cure her of Parkinson's, but it really alleviated the symptoms greatly for her. So I do not know if you are looking at anything like that.

Dr. LANDIS. Obviously, if you could get changes in activity, circuitry, without having to stick electrodes in the brain, that would be preferable. NINDS and the Department of Defense are exploring the use of trans-cranial magnetic stimulation as an alternative to deep brain stimulation.

Now, the problem with deep brain stimulation is it does not stop neuron cell death. I think Dr. Fischbach when he testified and said that we would have a cure for Parkinson's in 5 or maybe 10 years actually really believed in his heart that the change in activity from deep brain stimulation would promote survival of neurons in Parkinson's, and that has been a disappointment. It has not done that. But it does provide symptomatic relief.

POST-TRAUMATIC STRESS DISORDER

Senator HARKIN. Dr. Insel, I have been told that 1 out of every 3 returning Iraqi veterans—this is sort of a follow-up on what Senator Specter asked—1 out of 3 seeks mental health help some time during the first year. Now, whether that is 1 out of 3 or 1 out of 4, it is very high. That is just those who actually seek it. What about those that do not? How many more out there that are trying to tough it out?

Any thoughts on why it is so prevalent and why these returning vets are having mental health problems and why the incidence? It seems to me—now, maybe I am wrong, but the incidence of post-traumatic stress disorder is going up, and sometimes PTSD does not exhibit itself for months afterward, 5 months, 6 months, 7 months afterward.

Talk to me a little bit more about post-traumatic stress disorder. What is it? Is it more prevalent now than in the past? How about all these returning veterans who are having mental health problems? Is this more than any war in the past? Do we know? Maybe we do not even know that. I do not know.

Dr. INSEL. We do not know yet. Post-traumatic stress disorder plays out over many, many months and sometimes years. We often now think about post-traumatic stress disorder as a failure of recovery. Everyone after a traumatic event is, in lay terms, shell-shocked. They have symptoms. They have trouble sleeping. They may be preoccupied by the event. They have a need to talk about it all the time. We would all feel negative impactly if the event is traumatic enough, and it does not have to be combat. It could be a car accident. We have all experienced this.

Most people can talk it through and recover and 6 months later, it is a distant memory. They are able to sleep and not use alcohol or illicit drugs to cope with this. For some reason, and it is not due necessarily to the degree of trauma. It has more to do with the individual vulnerability to traumatic events and their psychological

sequelae. Some people do not recover in the way that most of us do. Those are the people who develop PTSD. The numbers range from 13 to 16 percent in the current war. In the Vietnam War the numbers were higher. But that is over a longer period of time.

We will have to see. The assumption would be that if the numbers are 13 percent now—and as I mentioned before, that equates to about 170,000 affected individuals. One would think that they will go up even further over the next year or so. Often the way it happens is that people are coping well enough until there is a second hit. They watch a movie that reminds them of the trauma. They have a loss in their life. They have some stressor that then tips the balance, and they then emerge with full-blown symptoms.

Senator HARKIN. Of course, your institute is actively doing research in post-traumatic stress disorder?

Dr. INSEL. Absolutely. We have decided through much of this effort to collaborate with DOD and with the VA. So we have a large effort. Actually we have a joint RFA, a request for applications, that has been funded, where we have half the grants and they have the other half. We work together with them because this is where we think the need is greatest.

Where we would really like to go with this is to understand this individual pattern of vulnerability, to identify who needs the early intervention, before the point where someone develops all of the secondary aspects of PTSD, the depression, the alcohol abuse, the substance abuse, and at that point preempt all of that by being able to get to them early.

NIMH BUDGET

Senator HARKIN. Your Institute's budget for next year is $1.4 billion.

Dr. INSEL. Right.

BASIC NEUROSCIENCE

Senator HARKIN. What would be the largest sector where that money would go for research?

Dr. INSEL. The single largest—we have five research divisions and the largest one of them is in the basic neuroscience arena. We really are trying to get at the question you asked before, actually the critical question, understanding the pathophysiology of these illnesses. It is not just a matter of tweaking the drugs that we have now and figuring out how to use them best. That is important, but we want to get to a point where we have a new generation of compounds that we can think of as either preventive interventions or cures, really raising the bar on what we expect for interventions. That is going to require having a much better fundamental understanding at the level of molecules and cells and brain systems about how something goes wrong to give you the psychosis of schizophrenia, the hopelessness of depression, the symptoms of PTSD. We do not know that. We know a little bit about how to treat them, but we need to know a lot more of the fundamentals.

That has been our biggest effort.

STRESS

Senator HARKIN. Dr. Insel, would you be the proper person that I would ask this question of? I am going to ask it, but maybe it is another Institute. I do not know. The effect that stress plays in diseases. I have read a lot about in science magazines and other things that more and more the high factor of stress, both in perhaps getting a disease, but in the generation of that disease after you get it and how it progresses, that stress is an indicator for how ill you might become.

So are you looking at stress? Is this part of your $1.4 billion, looking at stress and how stress levels affect a person's ability to ward off diseases and illnesses or become more susceptible because they have a higher level of stress? Is that you or is that somebody else?

Dr. INSEL. That is a number of us. Dr. Volkow talked about that at great length and her specific interest is on developmental stress and how it can tease up an individual to be responsive later with pathological behaviors like addiction. NIMH has a similar interest, but it is more focused on depression, where we know that children who have been stressed, particularly at certain vulnerable times in development, are at much, much greater risk for depression after puberty or even into young adulthood.

The mechanism by which that happens is where our interest now is taking us. We want to know, what is it about stress that affects one individual to make them subsequently very depressed or drug addicted and the next individual takes the same event and they somehow get immunized, they get stronger from having been challenged in some way. We do not know enough to understand those individual differences.

So that is where a lot of our effort is going, finding again the molecular and cellular substrates of how stress affects the brain is we think one of the ways to get there.

Senator HARKIN. But you are—somewhere in this whole big $1.4 billion, you do have research on stress that is ongoing, dealing with how stress relates to physiological problems?

Dr. INSEL. Absolutely. It is a big part of our effort in terms of mechanisms, understanding mechanisms, and a lot of that is going on in animal research, where we can really control many of the variables and look specifically at what stress is doing. Dr. Volkow can tell you about some of the work they are doing as well in looking at the long-term effects of stress.

GENETIC FACTORS FOR ADDICTION

Senator HARKIN. I was going to ask Dr. Volkow about that. Oh, yes, I know. You were talking about the environmental factors to drug abuse, but you said that genes—I wrote this down because it really sounded almost too neat—50 percent of the factors are genetic for addiction.

Dr. VOLKOW. Correct.

Senator HARKIN. You really hold that it is 50 percent?

Dr. VOLKOW. 50 percent, and actually this is very consistent and reproducible. The vulnerabilities for becoming addicted is at least 50 percent, analytically determined. The other 50 percent is your

environmental factors involved with it. You know, with animal experiments what we are trying to do, of course, is identify which genes make you vulnerable. We have come to recognize that there are going to be genes that make you vulnerable to experiment with drugs which are going to be different from those genes that are going to make you vulnerable—if you get repeated exposure, you may or may not become addicted. Approximately 10 percent of people will. Those genes that we identified evidently are linked with the process of plasticity and also involving learning and memory.

So it appears that for you to have the vulnerability, you have the genes that will be much more likely to be modified by environmental exposure to drugs to create new connections, but then are likely to be driving the compulsive intake of drugs.

STRESS AND ADDICTION

Senator HARKIN. Following up on that, it would seem that stress does play a high part, a big part, in people getting addicted to drugs, to relieve stress or they get stressed out. They want to smoke or they want to drink or they want to——

Dr. VOLKOW. Take marijuana.

Senator HARKIN [continuing]. Take marijuana or more serious drugs.

Dr. VOLKOW. Yes, and we are very much interested, and we have from the perspective of basic science, we have known for many years with the epidemiological data that environmental stressors, and in particular social stressors are some of the most profound in human subjects. We are very, very sensitive to social stressors. We have known that they affect our vulnerability to addiction. It is clear when people are in war, for example, which is very stressful, drug abuse can go up in a way to cope with the stress. Or if you come up with an environment where you have been physically abused or sexually abused, more likely to take drugs.

What we did not know is why and what is the social stressor doing to your brain that makes you more vulnerable. For example, there have been studies now both in rodents and in primates that show that social hierarchical structure and pending on the level, if you are dominant versus subordinate, can modify specific proteins that regulate, modulate your vulnerability to take drugs.

So if you are in an environment and very subordinate in a system that is very stressful to be a subordinate, then those proteins go down and that leads you to a facilitation of taking drugs. That is what I was highlighting. Of course, the challenge now is how can we buffer. If someone is born into that environment, if we learn how does that stress produce those changes, how can we buffer an intervention to be able to rehabilitate, to go back to recover some of those changes that is the basic perspective.

We are also very interested in the mean time to do interventions and to evaluate the extent to which specific prevention interventions are useful. For example, we take for granted social skills. A child that has poor social skills predicts higher likelihood that they will take drugs. So something that makes a lot of sense, intuitive sense. Why do we not as a prevention strategy identify those kids that are unable to negotiate interactions with their peers as a pre-

vention effort? It will be beneficial not just for drug use, but also for mental illness.

So that is the sort of thing that we are also encouraging from the prevention behavioral intervention.

HEAD START

Senator HARKIN. That is what the Head Start program is for. Yet Head Start I think gets about half of the eligible preschoolers now. By the way, Head Start is not an educational program; it is a social skills program with education added in. A lot of people think Head Start is education. It is not that. That is why it is in the Department of Health and Human Services, not in the Department of Education. I do not know why I am telling you all this, but anyway.

But the idea was to give these kids that kind of social interaction and that type of thing. But the problem is that we do not pay Head Start teachers well enough. We do not get qualified, a lot of qualified people in there with Head Start.

So anyway, it just goes back to what you say about getting those early interventions.

Dr. VOLKOW. Correct.

Senator HARKIN. Which we know are predictors for drug abuse and for mental health problems and for drug abuse.

Dr. VOLKOW. Also can, for example, prevent criminal behavior, which is something that of course we just hinted at.

NIH BLUEPRINT

Senator HARKIN. Well, that is for a different thing.

One last question and this is for all of you. All the Institutes here today have been involved in a collaborative effort called the NIH Blueprint for Neuroscience Research. Dr. Landis, I will start with you and we will just go down. What is this effort? What has been achieved? What are you doing, and what are the plans for next year, and how do you all participate and kick into this? So just tell me about the NIH Blueprint for Neuroscience Research so I can better understand it.

Dr. LANDIS. A number of years ago we recognized that Institutes which funded research in the neurosciences had common interests, common goals, and common needs, and set out to actually create a collaborative environment. Once a month all the Institute Directors or Center Directors participate in this meet to discuss important initiatives, fund workshops and requests for applications and share best practices.

We have a modest budget. Each of us chips in money to a central pot that represents a fraction, a very small fraction, of the amount of money from our budget that funds neuroscience. We discuss as a group what are the most important and the most interesting ways we can spend that money. We have funded training programs that benefit all the institutes. We have funded the generation of mutant mice which benefit all the Institutes.

Several years ago we thought, instead of just investing in tools, that we might want to invest in some science. We picked three themes, neural degeneration, neural development, and plasticity, and have been working through those themes once a year. I have

to say, you know, it is pretty amazing that we can get each of the Institute Directors to show up once a month to talk about science and initiatives, but we have done it. I think all the institutes in the neurosciences are a lot stronger for having done this.

I am sure this is a little like an elephant, where I have just given you the trunk, someone else might give you a leg.

Senator HARKIN. Are you a leg, or what are you?

Dr. LANDIS. He is the ear.

Senator HARKIN. Oh, he is the ear, of course.

Dr. BATTEY. There is not a lot I can add to Story's beautiful description of the blueprint, other than to maybe make two observations. We were talking earlier about *Math-1* and the mouse knockout that led us to the discovery that it was essential for hair cell development. That was not my grantee. That was her grantee [indicating], Louis Ogbee in Texas, did that.

Dr. LANDIS. He actually was picking up on a gene discovered in drosophila that is required for the development of a particular kind of external sensory neurons, and he said, gee, why do we not figure out what it does in mammals.

Dr. BATTEY. So my point is that the neuroscience Institutes have remarkable overlap in the experiments that need to be done to move this forward. We also have remarkable overlap in the needs. For example, Story has mentioned many times neuronal degeneration and I have told about hair cell degeneration. It is almost certain that many of the mechanisms that underlie degeneration of neurons are going to be the same ones that are going to be involved in degeneration of hair cells.

So by pooling our resources and generating common reagents and resources, we leverage each other's science and advance the science of my relatively modest sized Institute is advanced enormously by the discoveries made in mental health, neurology, and the other neuroscience Institutes.

So in particular for the smaller Institutes, the blueprint has been a really wonderful thing.

Senator HARKIN. Anybody else? Dr. Volkow, Dr. Li?

Dr. LI. I would echo what Dr. Battey said. The NIAAA being a small Institute, we benefit tremendously from this collaboration, especially when it comes to not only just providing resources, but in having projects that are of joint interest, such as neural degeneration, neural development, and neural plasticity. This is the value of it.

Dr. VOLKOW. I think I want to commend the notion that the big frontier after the genome is to understand how the human brain works, which is extraordinarily complex. We now have extraordinary tools to actually look inside the human brain, and not just look at its morphology but how it functions. So this has given us an opportunity, all of us together, to invest resources to understand how, for example, the brain changes as a function of development, something that would have been extraordinarily costly for one single institute. By putting our funding together, we can start to get the standardized data set that any investigator outside can go in to query, and that gives us the perspective to start with, for example how does the brain change as we grow from childhood to ado-

lescence to adulthood. This is just an example about how powerful it is to integrate our efforts.

Dr. INSEL. I know we are going to be having to stop in a moment, so I would say that in terms of both the Neuroscience Blueprint and everything else that you have heard for the last almost 2 hours, we could not have done any of this without your support and the support of Senator Specter when he served as chair. I think I speak for all of us to say how grateful we are for all that you have done on our behalf.

We are entirely committed to making a difference for the American people, but we only do it because you are there to help us along. We are delighted to have a chance to tell you a little bit about, and this is really a very little bit, about what all of us have been involved with. But most of all, we want to say thank you for being such a leader for us in this regard.

Senator HARKIN. You are very kind, Dr. Insel, but I will not let you have the last word on that.

I want to thank all of you. It has been very enlightening. I enjoy this kind of a setting. I just learn things. I think it is very helpful to have this kind of a discussion among the institutes over at least a couple hour period of time. We will be continuing this process with other institutes.

But in that regard of what you were just saying, Dr. Insel, let me return the favor and the compliment by thanking each one of you, each one of you, for a lifetime of dedication to research, to science, to doing the things that help to try to improve our quality of life and the way people live, to cure illnesses and diseases, to help people who may be at rope's end, and especially in mental health. They just have nowhere to go and they do not know what to do. You have been making great progress in these areas, all these areas. There is great hope out there for all of the things we have done, the genetics and stem cells, with new interventions coming on, some of the things that you talked about, Dr. Landis. Of course, you know of my intense interest in deafness and communications disorders. We are making significant progress in areas, although I want to move faster, as you can imagine.

Dr. BATTEY. So do I.

Senator HARKIN. I know you do, Dr. Battey.

Alcoholism, drug abuse, again all these areas.

I just close by saying thank you. I thank each of you. I just hope that young people today will look upon each one of you as role models, as something to aspire to, to get involved in research, to get involved in science, to take it up as life work, and to think about the good that they can do during a lifetime of service.

What we do at NIH, what each of you do, leaves a legacy that just cannot be expressed in monetary terms. It can only be expressed in terms of people's lives and how much better kids are today and how much better their lives are. To me it is just the best work that I can imagine anyone doing. I hope that we have another generation of Dr. Insel's and Volkow's and Li's and Battey's and Landis's coming along.

That is my way of saying thank you very much, and I look forward to continuing our discussions and information that you would have for the subcommittee at any time. We will be doing our budg-

et, getting our things worked out. But I think you have a lot of support here and I know that Senator Specter and I have worked together on this now for, we are going on almost 20 years together on this committee. We have a great partnership. I could not ask for a better friend and partner. Whether he is chairman or I am chairman, it has not made a lick of difference. I just hope that we will have the finances and the budget and the money in order to help you do your work and to encourage these younger scientists coming along to know that this is something that they can dedicate their lives to and that they will be able to get the funding that will enable them to do their research and to do their work.

It is going to be very tough. It is going to be very tough. I remember when I was a kid watching—it is funny I would think of this right now, but we used to watch GE Theater on television and the host was Ronald Reagan. I remember GE's theme at that time was "At General Electric Research Is Our Most Important Product." I think that is what we have got to be about here. Research is our most important product, and you do it well.

ADDITIONAL COMMITTEE QUESTIONS

There will be some additional questions which will be submitted for your response in the record.

[The following questions we not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

CLINICAL TRIALS NETWORK AND NIMH

Question. Dr. Insel, I understand that the large clinical trials that NIMH has undertaken in recent years (CATIE on schizophrenia, STEP–BD on bipolar disorder, STAR–D on treatment resistant depression, TADS for child and adolescent depression) are now coming to an end. Each of these studies involved development of multi-site clinical trial networks that served a large number of subjects in real world treatment settings. What efforts are underway at NIMH to ensure that the important clinical research infrastructure that has been developed continues to help answer important questions about new treatments for mental illness?

Answer. The National Institute of Mental Health (NIMH) is providing infrastructure support to maintain three large networks of investigative clinical teams that have evolved from the practical clinical trials on major depressive disorder (Sequenced Treatment Alternatives to Relieve Depression—STAR*D); schizophrenia (Clinical Antipsychotic Trials of Intervention Effectiveness—CATIE); and bipolar disorder (Systematic Treatment Enhancement Program for Bipolar Disorder—STEP–BD). At the same time, NIMH has been funding a child and adolescent clinical practice network. The networks comprise over 60 sites throughout the United States with continual outreach and engagement to diverse groups of patients and families with mental illnesses. Therefore, the networks are ideally suited for addressing the kinds of real-world "effectiveness" questions that require large and diverse samples and aim to have an impact on clinical practice.

The overarching principle guiding the networks is to conduct research designed to improve the mental health of the public and help better inform clinicians. To accomplish this, research must be informed by broad scientific and public input. In December 2006, NIMH issued a Request for Information (RFI) to solicit suggestions for the most important research directions and projects for the networks. The RFI sought input from investigators, stakeholders, and individuals living with mental illnesses, as well as additional expert advice and guidance from the National Advisory Mental Health Council. Advice was also sought from the NIMH Alliance for Research Progress—a group of patient and family advocates representing national voluntary organizations devoted to public mental health. Feedback from these efforts is being used to develop a list of key research questions and topics. The Institute is currently reviewing this input and will give high priority to those that have the

greatest potential for using resources of the networks to improve the effective use of existing treatments and further development of new interventions.

BIPOLAR DISORDER RESEARCH

Question. Dr. Insel, several years ago, Congress requested NIMH to undertake a national research plan on bipolar disorder. This request resulted in the current research plan on mood disorders at NIMH. Please update the subcommittee on the mood disorders research plan and what NIMH is learning about the causes and new treatments for bipolar disorder.

Answer. NIMH continues to make strides in elucidating the causes of and determining new treatments for mood disorders, including bipolar disorder (BD). Much of this work is guided by goals laid out in "Breaking Ground, Breaking Through: The Strategic Plan for Mood Disorders Research." In addition, yearly progress in research on depression is reported through the Government Performance and Results Act as one of the stated goals for GPRA is to demonstrate through research, reductions in the burdens associated with depression. As one example, in fiscal year 2006 NIMH and its NIH collaborators were able to report significant progress as a result of the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study of nearly 2000 depressed patients treated at 41 sites across the nation, including several primary care sites. This landmark study showed that up to 70 percent of those with persistent depression can be successfully treated, yet may need to try several different treatment strategies. By analyzing specific individual patient characteristics, including genes, NIMH funded scientists are now discovering the keys to personalizing and optimizing treatments for depression.

As outlined in the mood disorders strategic plan, NIMH undertakes numerous approaches toward the determination of the underlying causes of BD. While BD has long been known to be heritable, scientists have been unable to identify the key genes involved. Recently, BD has been the focus of a large international effort using whole genome association, a powerful, new approach that permits a screen for variations across the entire genome. Results from 7,000 BP patients and controls should be available later this year, providing the first large-scale, comprehensive scan of genes which contribute risk for BD. Even with these genes, we know that bipolar disorder is not easily diagnosed, especially in children. A recent NIMH-supported study found that BD could be distinguished from another similar childhood syndrome, severe mood dysregulation, through the measurement of the brain's electrical signals. This finding could significantly inform future efforts in diagnosing BD as early as possible.

In terms of improving treatment, in 1998, NIMH undertook a large, national research program to determine best treatment practices for BD. Concluded in 2005, the Systematic Treatment Enhancement Program for Bipolar Disorder continues to inform the field. Recent publications addressed predictors of recurrence for those that had achieved recovery and the effectiveness of different medications in treating those patients who had not shown improvement despite several treatment attempts. According to another recent report, for depressed people with bipolar disorder who are taking a mood stabilizer, adding an antidepressant medication is no more effective than a placebo. These results indicate that careful management of mood stabilizer medications is a reasonable alternative to adding an antidepressant medication for treating bipolar depression. In addition, patients taking medications to treat bipolar disorder are more likely to get well faster and stay well if they receive intensive psychotherapy.

OBSESSIVE-COMPULSIVE DISORDER

Question. Dr. Insel, what recent advances have been made in the area of obsessive-compulsive disorder?

Answer. Obsessive-Compulsive Disorder is an anxiety disorder that is characterized by recurrent, unwanted thoughts (obsessions) and/or repetitive behaviors (compulsions). NIMH has funded several areas of research to understand the causes of and potential treatments for OCD. By studying families with members affected by OCD, NIMH-funded scientists have discovered regions of several chromosomes that may contain OCD susceptibility genes. Previous studies have suggested that the brain chemical serotonin may mediate the compulsive behaviors associated with OCD. Recent work has shown that mice with deletion of certain serotonin receptor genes exhibit impulsive and compulsive behaviors (e.g. burying marbles), suggesting that these mice could be used as models of OCD, and further studies of the serotonin system may provide clues to the etiology of OCD.

Using magnetic resonance imaging, NIMH-funded researchers found that the pituitary glands of children with OCD were smaller than those of healthy children.

The investigators speculate that the smaller volume in patients with OCD might be an effect of abnormal regulation of endocrine function. Further studies might lead to methods for early detection of the disorder.

OCD in adults is known to be a disorder of many different symptoms, but studies have shown that certain symptoms tend to cluster together. Recent NIMH-funded research has revealed several types of symptom clusters—or symptom dimensions—in children and adolescents (e.g. hoarding obsessions and compulsions; symmetry, ordering, and repeating). These symptom dimensions closely mirror those reported in adults with OCD, suggesting relative stability across the course of development. Understanding how these symptoms cluster may help researchers identify the underlying causes of OCD.

Other NIMH-funded studies have suggested a possible link between psychosocial stress and exacerbation of OCD symptoms. In a recent study of children who had OCD, Tourette syndrome (TS), or both OCD and TS, psychosocial stress significantly predicted whether OCD symptoms would worsen in the future. The results suggest that monitoring parental reports of stress, and intervening as appropriate, may help to prevent symptom exacerbations.

Several NIMH-funded studies have focused on treatments for OCD. A recently completed study led to the development of a manual for psychosocial treatment of young children with OCD, with encouraging results on the efficacy of its use. A newly funded study is testing a treatment approach that incorporates self-administered, exposure-based behavior therapy as a low-cost option before implementing therapist-administered exposure. Another study has yielded encouraging pilot results on the efficacy of deep brain stimulation for severe treatment-refractory OCD. Finally, NIMH intramural researchers have evaluated azithromycin and penicillin as a prophylactic treatment for a subtype of OCD; both treatments appeared to reduce exacerbations of OCD symptoms.

STROKE

Question. Dr. Landis, the NINDS made a great advance against stroke with the advent of tPA, the clot-busting drug that can reduce devastating disabilities if given within three hours of the onset of stroke symptoms. Please highlight any recent advances that will help alleviate the burden of this disease.

Answer. Researchers funded by the National Institute of Neurological Disorders and Stroke (NINDS) are making considerable headway into alleviating the burden of stroke, both in preventing new strokes and in treating strokes acutely and chronically. With respect to stroke prevention, NINDS-funded researchers have recently demonstrated that individuals at risk for stroke may benefit from taking multiple preventative therapies, including antiplatelet inhibitors like aspirin, angiotensin-converting enzyme (ACE) inhibitors, and/or statins. These agents exhibit a variety of effects that may lower the risk for future strokes, including reducing cellular stress and inflammation and improving blood flow in the brain. To test the impact of these therapies in combination, investigators conducted a retrospective study of more than 200 patients who presented within 24 hours of stroke onset. Results indicated that individuals taking all three drugs exhibited less severe strokes than did people on a two-drug combination, antiplatelet inhibitors alone, or no stroke prevention therapy. Imaging data also suggested that patients on triple therapy had less at-risk tissue surrounding the damaged regions of their brains and that triple therapy appeared to be linked to shorter hospital stays and better function at hospital discharge. Although these data are preliminary, they provide support for the further exploration of the impact of this combination regimen on the prevention of severe strokes.

With respect to acute stroke treatment, many potential new therapies are in the pipeline. Research teams in the NINDS-funded Specialized Programs of Translational Research in Acute Stroke (SPOTRIAS) are exploring many different options to treat acute stroke, including a combination of ethanol, caffeine and hypothermia for neuroprotection; the efficacy of using a clot-removal device to improve post-stroke outcomes; adding extra drugs to the clot-buster tissue plasminogen activator (tPA) that may increase the potency of tPA in disrupting a clot, so that less tPA is needed; and the delivery of the potential neuroprotectant magnesium sulfate by emergency responders, to try to prevent cell loss by intervening as early as possible for acute ischemic stroke.

Rehabilitation following stroke has also entered a new era, since National Institute of Child Health and Human Development (NICHD) and NINDS-funded research demonstrated in 2006 that constraint-induced movement therapy—a rehabilitative technique that involves forced use of a partially paralyzed arm—could promote a 34 percent faster recovery in the affected arm than could standard therapy

if applied 3–9 months after stroke, and could contribute to an increased ability to perform tasks of daily living with the impaired arm and hand. These results provide evidence of significant intervention efficacy from one of the first major large-scale randomized trials of stroke rehabilitation and investigators are now hoping to test this therapy in a phase III trial at even earlier time points after stroke.

PARKINSON'S DISEASE

Question. Dr. Landis, despite the constraints presented by a flat proposed budget, there are agreed-upon, high-priority research areas for Parkinson's disease. Please describe what the NINDS is doing to ensure that those high-priority areas are getting treated as high priorities and are being funded, and in a timely manner. Do you have a strategic plan for Parkinson's disease research that includes a budget? Are you following it? Does it include funding for those high-priority research areas?

Answer. The National Institute of Neurological Disorders and Stroke (NINDS) leads the implementation of PD research efforts at the National Institutes of Health (NIH), in large part by following the priorities outlined in its 2006 PD Research Plan (http://www.ninds.nih.gov/funding/research/parkinsonsweb/PD_Plan_2006.htm). The Institute considers these needs, along with those in many other disease areas, each time it assesses potential grant solicitations and other programs for future implementation. While NINDS does take priorities from its PD planning efforts very seriously, it does not develop specific budgets for any of its disease plans prior to their implementation, since appropriations and other emergent public health needs and opportunities are not known in advance. In the past, the absence of specific budgets for disease priorities has not hindered progress. In the first five years of the implementation of the PD Research Agenda, NIH and NINDS-funded researchers made tremendous progress on several fronts, including advances in understanding the genes involved in inherited PD and the unexpected contributions made by screening large numbers of genes for clues regarding the role that genetic variability may play in sporadic PD. Researchers also made substantial progress in understanding how PD occurs at a cellular level and how treatments like gene therapy may be able to protect against further brain deterioration. NINDS is poised to continue this progress, and the Institute has already provided funding to address a number of priorities identified in the 2006 PD Research Plan. Examples of two of these programs are provided below.

First, the 2006 PD Plan highlighted further exploration of the non-motor aspects of PD—which can include sleep abnormalities, fatigue, behavioral and cognitive impairments, anxiety, and depression—as a major research priority. As just one example of possible implementation of this priority, the external scientists and members of the PD patient community who developed the Plan's recommendations strongly suggested that non-motor manifestations of PD be assessed in more clinical trials. The NIH Exploratory Trials in Parkinson's Disease (NET–PD) phase III trial—a large, randomized clinical trial of the potential neuroprotective agent creatine—will address this need directly, by exploring the ability of creatine to improve some of the non-motor features of PD in addition to its ability to slow the progression of the motor symptoms.

Second, the 2006 PD plan also identifies PD biomarkers, which enable clinicians and researchers to track disease risk, activity, progression and response to treatment, as a very high priority for the field. In October 2006, the NINDS and the other NIH Institutes and Centers participating in the NIH Blueprint for Neuroscience Research program addressed this recommendation by issuing a grant solicitation to encourage research on biomarkers for neurodegenerative diseases, including PD. This solicitation elicited a vigorous response from the research community and the grant applications are currently under review.

OUTREACH ON ADDICTION RESEARCH

Question. Dr. Volkow and Dr. Li, what are your institutes doing to infuse your research on addiction into local treatment centers—where the rubber meets the road? How does NIDA and NIAAA work with States, and the directors of State substance abuse systems, to ensure that the research done by NIDA and NIAAA reaches into our local clinics and treatment systems to make a difference?

Answer. NIAAA is engaged in considerable outreach to increase use of research-proven treatments in community treatment centers. First, NIAAA has produced a variety of research summaries and practical tools to assist in dissemination and implementation of research findings. The 2005 Edition of the NIAAA Clinicians Guide (updated in 2007) has been very popular for health care professionals. NIAAA staff are currently working on training programs for health care professionals centered around the Guide, a version of the Guide for non-prescribing professionals, and a

Self-change Guide (called "Rethinking Drinking") aimed at consumers and concerned others. Second, NIAAA staff work closely with SAMHSA staff, providing research summaries, advice, participation in various work groups, and written and computerized tools to assist SAMHSA staff in their interactions with States systems and directors. Third, NIAAA works with other federal agencies such as VA, AHRQ, DOD, CDC and CMS to facilitate implementation of new research on treatment.

NIDA is taking a collaborative approach aimed at proactively involving all entities invested in changing the system and making it work better—so that research results do not linger the customary 15–20 years before they are implemented as part of routine patient care. One way this occurs is through the testing of drug abuse treatment approaches directly in the community settings where they will be used with real-world populations by counselors trained to implement them. This is the work of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN), which not only involves practitioners from community treatment programs (CTPs) in formulating research protocols, but also in providing real-world feedback on their success and feasibility.

NIDA is taking a similar approach to enhance treatment for drug-addicted individuals involved with the criminal justice system through our CJ–DATS (Criminal Justice-Drug Abuse Treatment Studies) initiative. Research supported through CJ–DATS is designed to effect change by bringing new treatment models into the criminal justice system and thereby improve outcomes for offenders with substance use disorders. It seeks to achieve better integration of drug abuse treatment with other public health and public safety forums, and represents a collaboration of NIDA, the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention, Department of Justice agencies, and a host of drug treatment, criminal justice, and health and social service professionals.

In addition to testing and evaluating protocols in the settings in which they will be used, NIDA works with our colleagues to create change at multiple levels and bridge the divide between scientific findings and their implementation. Our Blending Initiative exemplifies this approach and involves regular stakeholder conferences, a partnership with SAMHSA to support the work of Addiction Technology Transfer Centers (ATTCs) in training and disseminating research-based practices to community practitioners, and our ongoing relationship with State representatives and substance abuse directors. The Blending Initiative is helping to catalyze change by "seeding" the field with research-based practices and innovative products to facilitate their use. Specifically, Blending Teams made up of practitioners and researchers develop training modules and other dissemination products based on NIDA research, and thereby help implement and sustain effective drug abuse treatments in myriad settings.

On way in which NIDA continues to build and enhance our productive partnership with state directors of substance abuse agencies is through annual meetings with their national association—the National Association of State Alcohol and Drug Abuse Directors (NASADAD)—to identify strategies for accelerating the adoption of evidence-based practices into State drug abuse prevention and treatment programs. We are gratified that State directors now consistently look to NIDA for credible information about selecting, implementing, and sustaining science-based and cost-effective treatment and prevention interventions.

For example, NASADAD has embraced the promise of buprenorphine as an opioid abuse treatment option, developing a State Issue Brief on the topic and probing States for their specific needs. In response, States have identified technical assistance needs and areas where their Addiction Technology Transfer Centers (ATTCs) could provide support (e.g., training, best practice guidelines, dissemination packets, and strategies to further partnerships with physicians). Their feedback suggests new and expanded roles for existing treatment program medical directors of State Alcohol and Drug Abuse agencies. Moreover, most States have already begun aggressive outreach programs to approved physicians to provide them with expanded training and educational opportunities, both directly and in partnership with other entities.

NIDA views the translational process as comprising systems-level factors aimed at continuous improvement. In that vein, a collaborative initiative—the NIDA–SAMHSA RFA, "Enhancing State Capacity to Foster Adoption of Science-Based Practices"—encourages state agencies to team with research organizations to optimize their research infrastructure for evaluating delivery of publicly supported drug abuse treatment or prevention services. Several grants received initial funding in fiscal year 2006 to facilitate adoption of meritorious science-based policies and practices, including developing ways to measure and track program fidelity, promote adoption of research-based practices in addiction treatment, and streamline data collection and reporting requirements.

Enhancing the adoption of research-based practices by state-based systems is a strong NIDA commitment and will continue to be a top priority since it ensures that new scientific discoveries are translated into prevention and treatment interventions that are adopted by the community.

ADDICTION AND OBESITY

Question. Dr. Volkow, how are findings from your research linked to obesity?

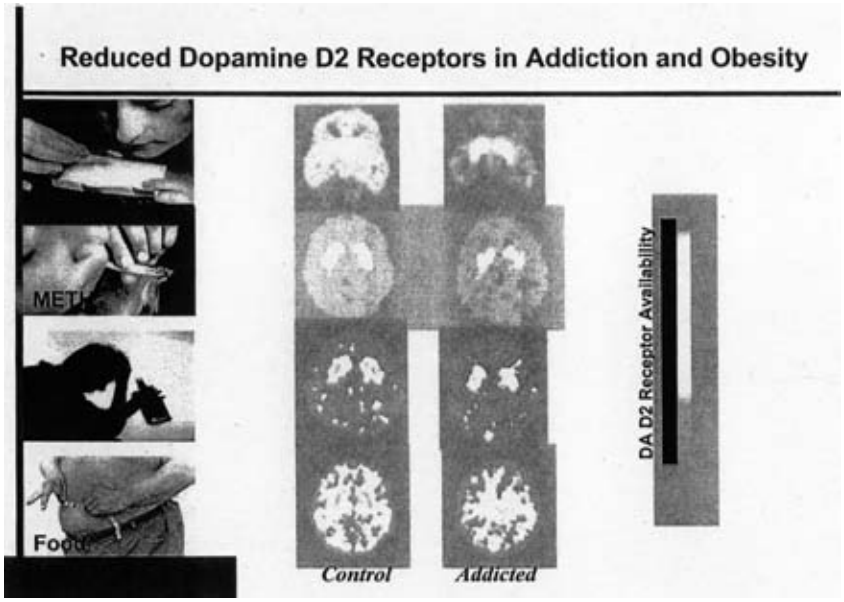
Answer. Animal studies and brain imaging studies in humans reveal similarities in the way circuits and neurotransmitter systems act in the rewarding effects of both food and drugs of abuse (e.g., opioids and other peptides, dopamine, cannabinoids). When imaged, the brains of both obese and drug-addicted people show a surge in dopamine when presented with food- or drug-related stimuli, respectively, and both show similar reductions in availability of dopamine receptors, suggestive of a less responsive reward system. Further, both obesity and drug addiction can be characterized by excessive, repetitive behaviors often marked by the inability to change or stop in the face of severe negative health consequences.

Given these parallels, few fields offer as much potential for cross-fertilization as addiction and obesity research. In the treatment arena, it is noteworthy that some of the behavioral interventions beneficial for treating drug addiction (e.g., incentive motivation, cognitive—behavioral therapy) may also be helpful in treating obesity, and several potential candidates for the pharmacological control of food intake (e.g., the cannabinoid receptor antagonist Rimonabant and the appetitive molecule orexin) also show promise for drug addiction.

UNDERAGE DRINKING

Question. Dr. Li, on March 6, the U.S. Surgeon General issued a "Call to Action on Underage Drinking", which underscored that alcohol "remains the most heavily abused substance by America's youth." It also calls for changing public attitudes toward youth alcohol use. That includes making it harder for young people to have access to alcohol. Are you doing any research on the most effective ways to reduce the availability of alcohol to underage youth?

Answer. NIAAA's comprehensive research portfolio on reducing underage drinking addresses both the demand for alcohol by youth as well as their access to it. Both components include approaches that target individuals, families, schools, communities and the overall environment. To reduce the appeal of alcohol to youth, NIAAA supports research on positive youth development including the ability to resist alcohol and other drugs. To address the supply of alcohol to youth, NIAAA supports a number of studies on the most effective ways to reduce the availability of alcohol to underage youth from late childhood through age 21. For example, some studies are testing the effectiveness of campus-community coalitions in reducing underage alcohol use by students in America's colleges and universities. These include promising studies comparing campuses that adopt comprehensive community interventions with control campuses that are doing business as usual. Other research studies are addressing neighborhood and community level interventions. For example, a recent study showed that an intervention for 15–29 year olds incorporating community mobilization, community awareness, responsible beverage service, underage alcohol access law enforcement and intoxicated patron-law enforcement was effective in reducing sales to minors as well as adverse outcomes related to alcohol in the targeted age group. At the community and state level NIAAA is funding studies evaluating the effects of policy changes on underage drinking. In addition, NIAAA is evaluating two separate community based OJJDP initiatives both of which include components aimed at reducing the availability of alcohol to youth. One is focused on rural communities in seven states and the other is focused on four Air Force bases and their surrounding communities.



Question. We all know that young people are exposed to a wide range of messages in the media about alcohol—both positive and negative. Are you doing any research on how their exposure to these messages affects whether they will become dependent on alcohol?

Answer. Given that early initiation of alcohol use, and especially early binge drinking, is associated with an increased risk of future alcohol dependence, it is important to identify factors that influence a young person's decisions about drinking. With respect to media influences, NIAAA funds research addressing the relationship between underage drinking and exposure to messages about alcohol, including advertising. However, assessing the effect of advertisements on the drinking behavior of individuals or populations is complicated. It is often difficult to ascertain the specific effects of advertising since they must be measured against a background dense in alcohol messages and images. Nevertheless some interesting findings have emerged. For example, in a widely-cited recent study, investigators interviewed a sample of youth aged 15 to 26, from 24 Nielsen media markets, on four occasions over a period of 21 months about their drinking. Advertising exposure in the study was measured both subjectively in terms of reported exposure and objectively in terms of advertising expenditures. It was concluded that each additional advertisement seen increased the number of drinks consumed in the past month by 1 percent. Further, youth in markets with greater advertising expenditures drank more: for each additional dollar spent per capita, the number of drinks consumed per month increased by 3 percent. More longitudinal studies such as this are needed.

In addition, who sees/hears alcohol advertising and who is affected by it is an important issue. While almost all persons are exposed to significant amounts of alcohol advertising, youth may be at risk for overexposure. Others such as dependent drinkers, or those in recovery, for whom alcohol ads may provide drinking cues or triggers, may be especially vulnerable to advertising. A recent study comparing teens with and without alcohol use disorders (AUD) found that teens with AUD showed substantially more brain activation to pictures of alcoholic beverages than controls (Tapert et al. 2003).

Additional research on adolescent decision-making will provide greater understanding of the factors that influence underage drinking behavior including initiation and escalation of alcohol use and binge drinking. This includes but is not limited to studies on media influence.

Question. This question is about treatment, and why some people improve their behavior. I was interested to read in your testimony that there's a debate whether the treatment itself is responsible, or whether it results from the positive motivation in seeking treatment. You also write that a wide array of approaches yield similar

results, suggesting that it's not the particular technique that's responsible for change but other common underlying factors. Tell me more about this—are most forms of treatment being used today generally equally effective? Is the most important thing simply getting the person into treatment?

Answer. Research has established that several forms of behavioral treatment (cognitive-behavioral treatment (CBT), motivational enhancement therapy (MET), and twelve-step facilitation (TSF), yield roughly equivalent outcomes. In the year following treatment with one of these therapies, drinking is reduced by about 85 percent compared to the period immediately prior to treatment. Overall, about one-third of alcohol dependent persons undergoing treatment will either be abstinent or not engaging in any high-risk drinking, about one-forth will not respond to that episode of treatment (although they may respond to future treatment), and the remainder have markedly reduced drinking and alcohol-related consequences, but are not entirely well. Over time, many of this latter group eventually become abstinent. Naltrexone, a medication for reducing relapse, yields similar results when combined with brief counseling by a doctor or nurse. Since there is no single type of treatment that is generally more effective than others, "simply getting the person into treatment" does seem to be more important than which treatment the engage in. However, on a practical level, people have clear preferences about what kind of treatment they would like, so offering a menu of currently supported approaches is likely to maximize the likelihood that one of them will be appealing enough to engage the affected individual.

How well treatment provided in the community compares with the treatments used in the studies undoubtedly varies. Although a precise estimate of the effect of this deviation is not available, there is evidence that some practices that are not helpful still persist in some community programs. Additionally, most treatment programs fail to make patients aware of various treatment options available, including medications. One study found that 93 percent of programs offer only twelve-step oriented behavioral treatment. Although this type of program may be as effective as others, it means that most people do not have a meaningful choice if they wish to receive treatment.

Although treatment appears to improve outcomes, the most significant are those commonly seen among all treatment-seekers. Common examples include a driving while intoxicated charge, an employer referral, or an ultimatum from a spouse. This process is the focus of an innovative new research program called the Mechanisms of Behavior Change Research Initiative.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

SUICIDE

Question. Dr. Insel, suicide is a major, preventable public health problem. In 2004, suicide was the 11th leading cause of death in the United States, accounting for 32,439 deaths. In Hawaii, for young people age 15–34 years, suicide is the second leading cause of death—second only to accidents. What type of research is NIH conducting with respect to the causes of and the best practices for the prevention of suicide?

Answer. NIMH has a long-standing commitment to supporting research on suicide risk and prevention. In response to the 2002 Institute of Medicine Report, "Reducing Suicide: A National Imperative," NIMH, NIDA, and NIAAA issued a request for applications and funded three centers focused on intervention and prevention of suicide. Now in their third year of support, the centers have conducted pilot intervention studies with patients suffering from mental and substance use disorders.

These centers have also engaged in a number of collaborative efforts. Federal staff (NIH, CDC, VA, SAMHSA, IHS) and investigators from the centers have interacted via workgroups focused on methodological challenges in suicide research, such as developing common measures of suicidality as well as understanding the role of impulsivity in suicide risk. The American Foundation for Suicide Prevention funded a pilot project with the centers to create a registry of suicide attempters. This registry will facilitate understanding of the quality of care across services settings, as well as the longer-term outcomes of acute treatment of adolescent suicide attempters. One of these centers also played a key role in re-reviewing suicidal events for the FDA's 2005 review of potential suicidal side effects of antidepressants. As a follow-up to the FDA review, in 2006, NIMH funded five research projects to examine the association between antidepressant medications, notably selective serotonin reuptake inhibitors (SSRIs), and suicidal thoughts and actions. These projects will help determine why and how SSRIs may trigger suicidal

thinking and behavior in some people but not others, potentially leading to new tools that can be used to screen individuals who are most vulnerable.

Suicide patterns in the United States vary significantly in terms of demographics and cultures. For example, older white males have the highest suicide rate; are likely to have had a late onset of major depression; and are likely to have been seen in a primary care setting within the month of their death, without being diagnosed or treated for depression. To address this issue, NIMH funded a study called the Prevention of Suicide in Primary Care Elderly: Collaborative Trial (PROSPECT) to test approaches to improve identification and treatment of older adults with depression in primary care settings. Results from PROSPECT indicated that a collaborative care approach to treating depression in primary care more effectively reduced suicide ideation as well as depressive symptoms, compared to treatment as usual.

American Indian, Native Alaskans, Native Hawaiians, and other indigenous peoples in the United States. Territories have the highest suicide rates among youth. To address the problem, NIMH, in collaboration with other NIH offices and Institutes, worked with the Indian Health Service, Health Canada, and the Canadian Institutes of Health to convene a bi-national conference in 2006 entitled "Indigenous Suicide Prevention Research and Programs in Canada and the United States: Setting a Collaborative Agenda." Community members and research partners discussed the importance of cultural knowledge in developing interventions and considered best practices that could be shared in developing partnerships and infrastructure.

NIMH-supported research has demonstrated that several promising treatments significantly reduce the risk for suicide re-attempts; these treatments include cognitive behavioral interventions provided to individuals who have made a recent suicide attempt, as identified through emergency room departments, as well as dialectical behavior therapy provided to individuals with borderline personality disorder. NIMH is also using knowledge gained from previous research studies to guide the conduct of clinical trials involving individuals at high risk for suicide. The Institute recently completed a series of practical clinical trials focused on treatments for schizophrenia, depression, and bipolar disorder. The individuals enrolled in these trials were closely monitored for suicidal behavior and were provided appropriate crisis treatment when necessary.

ALZHEIMER'S

Question. Dr. Insel, less than two weeks ago a new report was released indicating that there are now 5 million Americans with Alzheimer's disease and that this number is projected to increase by 50 percent to 7.7 million by 2030. Given that advancing age is the greatest risk factor for Alzheimer's disease and that the number of Americans surviving into their 80's and 90's is expected to grow, what specific studies are underway at NIMH to address the challenges posed by Alzheimer's disease?

Answer. NIMH supports research on a broad range of topics pertaining to older adults with Alzheimer's disease, ranging from basic research on the disorder to clinical interventions and services research that may assist affected individuals with their symptoms and problems in day-to-day living. A primary concern in NIMH research is to improve our understanding of, and techniques for managing, the psychiatric disorders and behavioral disturbances that often accompany Alzheimer's disease and related dementias.

Recently published results from NIMH's large scale Clinical Antipsychotic Trials for Intervention Effectiveness in Alzheimer's Disease (CATIE–AD) study highlight the challenge of managing agitation and behavioral problems in Alzheimer patients. Although some patients with these problems may benefit from treatment with atypical antipsychotic medications, the evidence from this study suggests that these medications hold limited value for the majority of patients and that the benefits are often offset by intolerability of medication side effects. These results indicate the need for research on alternative treatment approaches, including nonpharmacological interventions. Additional analyses of the data from the CATIE–AD trial are ongoing.

Earlier work supported by NIMH established criteria for assessing a specific syndrome of depression that is commonly manifested in Alzheimer's disease and making this a target for treatment. The Institute is now in the fifth year of supporting a multi-site clinical trial studying pharmacologic treatment of Depression in Alzheimer's Disease (DIADS–2) and its impact on functional capacities in Alzheimer patients.

NIMH supports various basic and intervention studies designed to improve clinical management of other psychiatric and behavioral disturbances associated with Alzheimer's disease, such as the common pattern of sleep disturbance and nocturnal agitation. For example, one current NIMH study investigates sleep disorder in peo-

ple who have mild cognitive impairment, a precursor to Alzheimer's disease, and an intervention trial is evaluating alternative treatments for insomnia among older patients with dementia.

Numerous NIMH studies examine potential risk factors for developing Alzheimer's disease in the hope that understanding these factors may inform efforts to develop preventive interventions. Research areas include genetics, brain structure, cognitive performance, and various other risk factors in young and middle-aged adults to determine whether it is possible to identify elements of risk prior to the appearance of clinical manifestations of illness. One study has been examining the deleterious effects that depression may have over time, potentially leading to central nervous system damage, cognitive decline, and the development of states of Mild Cognitive Impairment and dementia.

NIMH also supports basic neuroscience research on etiological and athophysiological actors in Alzheimer's disease, including numerous studies investigating key cognitive processes and how these are related to normal and abnormal brain functioning.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

FABRY DISEASE

Question. There are a number of individuals currently participating in efforts conducted by the Developmental and Metabolic Neurology Branch at NINDS. There is concern that when the Branch closes, as it will due to the retiring of Principal Investigator (PI) Roscoe Brady, the efforts that are benefiting the lives of so many, in particular those that are living with Fabry Disease, Gaucher Disease, Tay-Sachs and others, will also cease. Can you explain the rationale behind the NINDS' decision to close the Branch indefinitely and not continue these efforts under the leadership of another PI?

Answer. Following Dr. Brady's retirement, NINDS made the decision to close the Developmental and Metabolic Neurology Branch (DMNB), which is part of NINDS' intramural program (the component of the NINDS that is located on the NIH campus in Bethesda, MD). However, the closing of this branch certainly does not mean that NINDS efforts in lysosomal storage disorders (LSDs), including Fabry and Gaucher disease, will cease. Groundbreaking research on lysosomal storage disorders conducted by this Branch has provided a strong foundation for research in these areas to continue through the NINDS extramural program (research funded by NINDS that is carried out at universities, medical centers, and small businesses throughout the United States). In fact, the extramural program accounts for approximately 90 percent of NINDS' annual budget and NINDS already funds a large portfolio of extramural grants focused on understanding and treating these disorders. In addition to NINDS, a number of other Institutes and Centers at NIH also support research through their extramural programs on lyososmal storage disorders, including Fabry disease. These grants aim to better understand and treat these disorders, with a number of projects focused specifically on developing gene therapy approaches to treatment. Furthermore, based on the successes from forty years of research in the DMNB led by Dr. Roscoe Brady, companies have developed and marketed enzyme replacement therapy for several of these diseases and are conducting additional clinical trials to improve treatment using other therapeutic strategies. In terms of clinical care, there are currently over 100 medical centers across the country with experience in diagnosing, treating, and managing care of patients with lysosomal storage disorders.

NINDS' decision to close the DMNB was reached after much deliberation and after receiving input from the NINDS Board of Scientific Counselors, an external advisory group that reviews and evaluates the NINDS intramural program. NINDS and the Board of Scientific Counselors determined that the research and clinical care efforts that used to be unique to the Branch are now well represented at medical schools, research institutes, and tertiary care centers throughout the country. They recommended that the NINDS intramural program identify other rare neurological disorders that have lagged significantly behind Gaucher and Fabry disease and could benefit as they have from an intramural effort.

Question. Can you provide additional information regarding the efforts of the branch on solving the problems that still exist with enzyme replacement therapy? How will the progress that has been made on these issues continue if the efforts of this Branch are stifled due to its closing?

Answer. The DMNB was instrumental in developing enzyme replacement therapy, which is used to treat a number of the LSDs, including Fabry, Gaucher, and Pompe

disease. While enzyme replacement therapy significantly improves the quality of life for patients with these disorders, the treatment is not sufficient to address all the symptoms, particularly those resulting from deficits in the central nervous system. This is due in part to the incomplete access of the enzyme replacement to the central nervous system (CNS) because of the blood-brain barrier (a semi-permeable barrier that prevents materials in the blood from entering the CNS). NINDS, through its extramural program, funds a number of grants focused on facilitating the access of enzyme replacement to the CNS by protein reengineering, increased dosing regimen, and alternative delivery routes. NINDS also funds extramural research focused on developing other therapeutic approaches including substrate reduction (decreasing the production of the molecule that is accumulating in the disease), and pharmacological chaperones (small drugs that can specifically target and stabilize the defective enzyme, enhancing any residual activity). Longer-term therapeutic strategies such as stem cell transplantation and gene therapy are also being funded by NINDS.

One of the goals of the NINDS intramural program is that research conducted there lay the groundwork for a broader based research effort in the extramural community. Historically, closure of other NINDS programs has proven the intramural program's success and shown that the research initiated by these branches can be effectively graduated into the extramural research community. For example, research carried out in a branch that focused on therapeutics for Parkinson's disease set the stage for a rigorous therapeutics development program on Parkinson's disease through the NINDS extramural program. Similarly, work carried out by an NINDS lab that demonstrated the transmissibility of Creutzfeldt-Jakob disease (CJD) helped stimulate research in the extramural community to better understand this and other disorders in the class of transmissible spongiform encephalopathies. It is our expectation that ongoing and future research through NINDS's extramural program will continue to improve the lives of individuals with LSDs.

Question. What other work are you planning to do to improve both the quality and quantity of life of those living with Fabry disease?

Answer. As I have just described, NINDS, through its extramural research program, funds research projects focused on developing new and more effective treatment strategies to improve the quality and quantity of life for those individuals with Fabry and other disorders. A number of these grants have been submitted through an ongoing NINDS Program Announcement with Set-aside funds (PAS), entitled "CNS Therapy Development for Lysosomal Storage Disorders." This funding opportunity announcement was started in 2004 and since then many new promising therapeutic approaches are being investigated.

Partnering with patient voluntary groups is another way that NINDS hopes to advance research and improve the lives of patients with these disorders. The PAS mentioned above is co-sponsored by the Lysosomal Storage Disease Research Consortium (LSDRC), a collaborative research-funding group comprising LSD patient support groups and private family research foundations. In addition, the NINDS organizes a number of workshops in order to identify scientific gaps and opportunities related to various LSDs, and to foster collaboration between the researchers. Several of these workshops have been organized in conjunction with some of the patient voluntary groups. To promote the exchange of ideas on research across the many LSDs, the NINDS helped form the Lysosomal Disease Network. This consortium of scientists, healthcare professionals and clinics work to improve basic knowledge and understanding of LSDs, improve diagnosis, and advance therapeutic options for individuals affected by these disorders. The NINDS has supported the first two annual meetings of the Lysosomal Disease Network.

EPILEPSY

Question. I understand that last week, NINDS hosted the second Conference on the Cure for Epilepsy. What new information did this conference yield about epilepsy and are we any closer to finding a cure?

Answer. In March 2007, the NINDS co-sponsored a large conference, entitled: "Curing Epilepsy 2007: Translating Discoveries into Therapies." The Conference was well-attended by the basic and clinical research communities, and specific sessions at the Conference focused on research conducted by junior investigators; the translation of advances in the genetics of epilepsy and our understanding of how epilepsy arises (epileptogenic mechanisms) into therapies; cognitive and psychological issues in epilepsy; and emerging technologies in diagnostics and cellular and molecular therapeutics. The meeting also involved presentations from several patients and patient representatives on their personal experiences with epilepsy.

Several very exciting trends in epilepsy research were emphasized at the meeting. First, the ideal way to treat (and cure) epilepsy would be to prevent the development of seizures in the brain, not just to stop them from progressing or diminish their behavioral effects (e.g., seizures). A growing appreciation in the scientific community as to why neuronal circuits in the brain develop abnormal patterns of overexcitation is now enabling investigators to identify tangible therapeutic targets that may interfere with the earliest molecular events in the development of seizures. This shift heralds the availability of substantially more effective therapies for epilepsy. Second, advances in imaging are also making a dramatic impact on a number of disciplines in epilepsy research, including the development of biomarkers of seizure-prone brain regions, the characterization of the effects of epilepsy on brain development, and the cognitive impact of the disorder. The use of these techniques will facilitate epilepsy diagnostics as well as treatment. Third, completely new therapeutic approaches are emerging in epilepsy research, including the possibility that cell-based therapies may be able to restore normal patterns of activity in seizure-prone brain circuits and advancements in nanotechnology may improve devices that sense impending seizures with greater accuracy than ever before.

Question. Are we putting adequate resources toward epilepsy research at NINDS to find a cure for epilepsy? In addition, I understand that new cases of epilepsy are most prominent in seniors (those aged 65 and older). What are we doing to better understand the cause of seniors having seizures and will NIH partner with other entities to study this emerging area?

Answer. The National Institute of Neurological Disorders and Stroke (NINDS) has invested considerable funding to identify and test potential therapies for epilepsy. Currently, the NINDS is funding nine clinical trials in epilepsy, including phase III trials of drug therapy for childhood absence epilepsy and the use of progesterone therapy to reduce intractable seizures in women whose seizure severity is linked to their menstrual cycle. In addition to these and other ongoing trials, the NINDS also continues to support its Anticonvulsant Screening Program (ASP), a public-private partnership program designed to evaluate the potential efficacy and toxicity of preclinical candidate compounds in validated epilepsy model systems. In 2006, the ASP screened several hundred molecules for potential activity against epilepsy and related disorders. The Program has participated in the evaluation and development of eight currently marketed antiepileptic drugs, and nine new ASP compounds are currently in clinical testing.

In addition to these efforts, the NINDS has also funded a number of epilepsy grants as part of its broad translational research program, which is designed to accelerate therapeutics research towards early clinical testing. Topics of these awards range from a study of specific chemical pores on neurons and their role in neonatal seizures to the preclinical development of the anticonvulsant chlorokynurenic acid—which effectively accesses the brain when administered systemically—as a therapeutic agent for both adults and children with epilepsy.

With respect to the study of epilepsy and the elderly, the NINDS has provided funding to several grants including a large multi-investigator award focused on patterns of use of antiepileptic drugs in the elderly and the differences in breakdown of antiepileptic medications in older versus younger individuals. Understanding these patterns and differences is critical to their proper treatment (including dosing and avoidance of toxicity). In addition, stroke is a primary cause of epilepsy in the elderly, and NINDS-funded basic science researchers are developing a model of this form of epilepsy for subsequent use in understanding how seizures develop after stroke and how therapies might prevent and/or treat these events. The NINDS also meets regularly with a number of other National Institutes of Health (NIH) Institutes as part of the NIH Interagency Epilepsy Coordinating Committee meeting and would welcome potential collaborations in the area of aging and epilepsy as they emerge.

Question. In 2002 NINDS conducted research on TBI and epilepsy. Given the increased number of cases of TBI due to the war in Iraq, will NINDS be studying the relationship between TBI and epilepsy for updated statistics and data?

Answer. The primary role of the National Institute of Neurological Disorders and Stroke (NINDS) with respect to all types of epilepsy research—including that induced by traumatic brain injury (TBI)—is to provide support for research on the prevention, diagnosis, underlying causes, and treatment of this condition. The NINDS is currently supporting several studies that may reveal links between TBI and epilepsy, including an exploration of early post-injury changes in brain activity and its impact on affected neurons; the effects of structural changes in neuronal circuitry on the development of posttraumatic epilepsy—particularly in those circuits that help to prevent overexcitability in the brain—and the impact of head injuries on abnormal sprouting of undamaged neurons and the tendency of these new nerve

pathways to become overly active. In addition to these basic studies, the NINDS is also funding a pilot clinical trial to test whether very early administration of the anticonvulsant drug levetiracetam can prevent posttraumatic epilepsy in adults as well as children. In this early-phase trial, researchers will explore the safety and tolerability of the drug in individuals with TBI and the feasibility of initiating treatment within eight hours of injury. If the pilot data are promising, the research team will utilize the results to build a larger-phase clinical trial.

The mechanisms that underlie the development of epilepsy were also a focus of the March 2007 Curing Epilepsy Conference; specifically, the meeting included an entire session on the development of epilepsy, including TBI as a major environmental contributor. Discussions in this part of the meeting and during a session on the NINDS Epilepsy Benchmarks—a series of specific scientific goals for the epilepsy research community—confirmed that understanding how epilepsy develops is a very high research priority and should be a focus for the epilepsy community in the coming years.

Although these and other studies funded by the NINDS are likely to inform researchers and ultimately clinicians on the best way to prevent and/or treat posttraumatic epilepsy, it is the Centers for Disease Control and Prevention (CDC) that typically collect statistics and study trends on medical conditions. Because of the increasing number of war injuries that involve TBI and the urgency in addressing the medical needs of these soldiers, the NINDS staff has established a working group with relevant government partners, including the Department of Defense, the Department of Veterans Affairs, the CDC, and others to discuss scientific topics of mutual interest and develop collaborations in these areas. Following the first meeting of the group last September, NINDS set up a listserv for timely dissemination of information on TBI research across these multiple agencies. The NINDS staff is planning another meeting for the summer of 2007.

FUNDING RESEARCH ON SEVERE MENTAL ILLNESS

Question. What is NIMH doing to fund more research on severe mental illness, as called for by national organizations such as the National Alliance for Mental Illness and Mental Health America?

Answer. NIMH supports innovative research that promises to profoundly transform the diagnosis, treatment, and prevention of mental disorders, paving the way for a cure. Mental disorders are the leading cause of disability in the United States and Canada for ages 15–44,[1] and each year, roughly 12 million people report symptoms of mental illness so severe as to cause significant disability and interference with everyday living.[2] To address these critical health needs, the Institute supports, conducts, and promotes research that spans the continuum from basic research on brain and behavioral processes that provides the foundation for understanding mental disorders, to investigations of improved pathways for the rapid dissemination of evidence-based practices into mental health care and service efforts.

Along this continuum, the Institute is supporting several key areas to ensure that each step along the pathway from scientific discovery to the implementation of improved interventions is fully supported. For example, NIMH is providing infrastructure support to maintain three large networks of investigative clinical teams that have evolved from the recent NIMH practical clinical trials on major depressive disorder, schizophrenia, and bipolar disorder. These practical trials were "effectiveness studies" designed to examine not only changes in symptoms but changes in "real world" functioning. The networks comprise over 60 sites throughout the United States with continual outreach to, and engagement of, diverse groups of patients and families with mental illnesses. The overarching principle guiding the networks is to conduct research designed to improve the mental health of the public and to help better inform clinicians, families, and policy makers—efforts that require participation from the diversity of people and settings involved in health care.

NIMH continues its strong commitment to investment in research to elucidate the causes of and best treatments for schizophrenia. Although current medications are reasonably effective in treating symptoms such as hallucinations and delusions, these treatments provide little relief for the cognitive problems (e.g., memory, attention) responsible for much of the long term disability associated with schizophrenia. To address this issue, NIMH funded the Measurement and Treatment Research to

[1] The World Health Organization. The World Health Report 2004: Changing History, Annex Table 3: Burden of disease in DALYs by cause, sex, and mortality stratum in WHO regions, estimates for 2002. Geneva: WHO, 2004.

[2] Kessler RC, Chiu WT, Demler, O, Merikangas, KR, Walters, EE. Prevalence, Severity, and Comorbidity of 12-Month DSM–IV Disorders in the NCS–R. Arch Gen Psychiatry. 2005 Jun; 62: 617–627.

Improve Cognition in Schizophrenia (MATRICS) program. MATRICS brought together representatives from academia, industry, and government in a consensus process to address obstacles that are likely to interfere with the development of pharmacological agents for treating cognitive deficits associated with schizophrenia. As a result of MATRICS, researchers developed several comprehensive assessment tools to measure cognitive functioning abilities in patients with schizophrenia. To build upon the work from MATRICS, NIMH has also supported a network of Treatment Units for Research on Neurocognition and Schizophrenia (TURNS). The network is about to begin testing the safety and efficacy of new therapeutic compounds for treating the cognitive deficits of schizophrenia.

In fiscal year 2008, through a Requests for Applications, NIMH will invite research grant proposals focused on early detection, prevention, and treatment of schizophrenia. These initiatives will foster research to define critical moments in the disease course, such as a first psychotic episode, and will promote the development of unique early interventions to pre-empt the serious disability caused by schizophrenia.

SERVICES RESEARCH FOR SEVERE MENTAL ILLNESS

Question. How is NIMH working to promote more research on what services lead to recovery for people with severe mental illness, as called for by the President's Mental Health Commission?

Answer. NIMH supports research to establish an evidence-base for interventions and service systems that will provide citizens with the best possible care. Within this context, NIMH funds a program of research on disability and community reintegration, which focuses on ways to reduce the disability of people with mental illness through connective services within their communities. For example, an NIMH-funded study is identifying the most effective strategies for building a partnership between university-based clinical services researchers and practitioners and consumers from a psychosocial rehabilitation service agency. This research aims to improve the effectiveness of community-based psychosocial rehabilitation interventions for functional disability in schizophrenia.

NIMH supports a program of dissemination and implementation research, with the goal of building the knowledge base on how best to integrate effective mental health interventions into service systems. This research portfolio includes over thirty ongoing studies to better identify the means by which people with mental illness can receive the evidence-based services most likely to alleviate the burden of mental illness and lead to recovery. One recently funded project provided funding to the state of Illinois to determine the best way to implement supportive employment services for people with mental illness returning to the community. Another project is examining factors that improve the statewide implementation of an evidence-based treatment intervention for children in foster care across the state of California, using community development teams to optimize the use of the intervention for children and adolescents in the foster care system. Another study is determining the impact of consumer-run organizations to improve outcomes for individuals with mental illness in communities.

NIMH supports a program of systems research, which focuses on ways in which systems (e.g. criminal justice, schools, welfare) can improve the access to care of persons with mental illness. One NIMH-funded researcher is studying a service system that helps people with mental illness transition from the justice system into a community with services to support their recovery. Another investigator is studying how a nurse manager intervention might improve the health and reduce disability of homeless people with schizophrenia.

COLLABORATIONS WITH SAMHSA ON SERVICES RESEARCH

Question. How is NIMH working with SAMHSA to develop a research agenda focused as much on services research as on clinical trials research?

Answer. NIMH collaborates with SAMHSA on a number of activities to identify key priorities for services research. NIMH continues to collaborate with SAMHSA on research related to the transformation of mental health services in America. The Center for Mental Health Services, (CMHS) within SAMHSA, provides infrastructure support for nine states to collaborate across state agencies to determine how best to transform the delivery of services for people with mental illness. NIMH is supporting the cross-site evaluation of this program—an effort that will facilitate the augmentation of research to the state transformation efforts. In addition, SAMHSA established five interagency priority workgroups to address recommenda-

tions from the Commission Report.[3] NIMH and the Agency for Healthcare Research and Quality are working with each of these workgroups to better connect services research to priorities in the areas of emergency response, suicide prevention, employment, financing, and the integration of mental health care and primary care.

NIMH is actively engaged with SAMHSA to generate research based on SAMHSA's major services agendas. An example of this is the research program on "Effectiveness, Practice, And Implementation in CMHS' Comprehensive Community Mental Health Services Program for Children and their Families Service Sites." This three year research effort funds researchers who specifically work within CMHS funded service systems.

NIMH and CMHS have organized a series of Regional meetings for researchers, consumers, policymakers, clinicians, and other key stakeholders to identify research and services needs for state systems. NIMH is also working with CMHS on several meetings to identify the state of the science in specific services areas. The first, on shared decision-making, will bring together expert researchers, consumers, and service providers to discuss the current knowledge base regarding shared decision-making and to develop research priorities. A similar meeting on health promotion for people with mental illness is being planned.

RESEARCH ON SELF MANAGEMENT

Question. In light of the Institute of Medicine's endorsement of the importance of patient-centered mental health care, what is NIMH doing to promote research on models such as illness self-management, patient education, and self-help?

Answer. NIMH has a growing portfolio of research on approaches to improve patient education, self-help, and self-management of mental disorders. NIMH supports a Program Announcement titled "Information Technologies and the Internet in Health Services and Intervention Delivery" to test models of education and self-management for mental disorders.

Current medications used to treat those with chronic and severe schizophrenia often lead to significant metabolic side effects, so a number of NIMH studies are testing models of self-management to promote healthy lifestyles and to reduce diabetes and weight gain in this population. Obtaining evidenced-based care remains a challenge for many individuals with schizophrenia. One study tests an interactive web-based system that allows the individual consumer or family member to compare current treatment to evidence-based standards and to discuss treatment approaches with his or her clinician.

Peer- and community-based programs to support families of adults with serious mental illness typically incorporate elements of self-help, empowerment, trauma recovery, stress and coping theories, as well as mutual assistance for family members. NIMH currently supports several studies to provide scientific evidence that these programs effectively achieve their goals, including for example, the National Alliance for the Mentally Ill's Family-to-Family Education Program—a 12-week class with a highly-structured standardized curriculum developed and conducted by trained family members.

The collaborative care model, developed initially for diabetes medication management, has been successfully applied to depression treatments in primary care. Collaborative care combines patient education about the disorder and its treatment approaches with a depression specialist to assist in case management and treatment adherence. Collaborative care has been shown to be effective in reducing depression and suicidality in older depressed primary care patients, and is currently being studied among women with post-partum depression in two health care plans.

One aspect of patient-centered care is psychoeducation, providing information about mental illness and its long-term care to families and patients. Psychoeducational models originally used with adult patients and their families have been adapted and are currently being tested for use with youth with various mental disorders to strengthen the person's understanding of the illness, to improve treatment adherence, and to facilitate overall illness management. Family-focused treatment as an adjunctive treatment to medication management is being tested with adolescents with bipolar disorder in a three-site clinical trial. An adapted version of this same approach is also being pilot tested with younger youth with mood disorders who are at risk for development of bipolar disorder. A similar approach involved multi-family psychoeducation groups designed as adjunct to medication management was tested for use with families of 8–11 year old youth with mood disorders (depressive disorders or bipolar disorder).

[3] New Freedom Commission on Mental Health, Achieving the Promise: Transforming Mental Health Care in America. Final Report. DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

RESEARCH ON FAMILY-BASED TREATMENT PROGRAMS

Question. In light of the disproportional impact of meth on mothers with children, and the continued impact of crack among our poor and urban families, please discuss what research initiatives are being undertaken to recognize and expand the best practices of family-based treatment programs for substance abusing mothers and their children.

Answer. NIDA recognizes the importance of family support as part of drug abuse treatment, particularly for drug-abusing mothers with custody of children. Family therapy that addresses the needs of mothers and that involves their children and other pivotal family members in the treatment program can strengthen and extend program benefits. Findings from research on Brief Strategic Family Therapy (BSFT)—a treatment intervention aimed at adolescents—einforce the benefits of a family-based paradigm to change problem-sustaining family patterns and increase treatment engagement and retention, even in patients with multiple comorbidities.

NIDA supports a variety of research approaches to address the needs of substance-abusing mothers and their children. These include interventions that actively reach out to disadvantaged women at the community level, longitudinal studies that follow children prenatally exposed to drugs, services research to bring evidence-based treatments to the criminal justice system, and clinical research on medications and behavioral treatments in pregnant women and females of childbearing age.

Recognizing the need for culturally-appropriate and gender-sensitive interventions, NIDA-supported researchers are adapting behavioral treatments for substance-abusing female populations, including African American women who abuse crack cocaine, pregnant women in treatment, women with or at risk for HIV, and low-income women in community treatment programs. One study is adapting an empirically based behavioral therapy for drug abuse to a church-based system to intervene with cocaine-addicted African American women, while another is modifying an integrated family behavioral therapy for adolescents to intervene with pregnant women at risk for HIV. Other studies are looking at the quality of maternal-child feeding interactions (during the child's first year) among mothers who used cocaine during their pregnancy, as well as examining the serious risks faced by children exposed to methamphetamine use and manufacture. Results of such studies will help determine how to strategically intervene with mothers and their children.

BETTER TREATMENTS FOR WOMEN IN THE CRIMINAL JUSTICE SYSTEM

Question. Presently, the fastest growing prison population is women convicted of non-violent drug felonies. Most of these women are mothers and most of them are untreated addicts. At the same time, upwards to eighty percent of the families who come to the attention of child welfare are substance abusing. How can we work, or what is NIDA doing specifically, to stop this downward cycle of mothers being displaced into the prison system and children being placed in foster care while the underlying issue of parental addiction remains unaddressed.

Answer. As reflected in the answer to the previous question, NIDA supports research aimed at treating women and mothers with children in the community to prevent their entering the criminal justice system in the first place. These efforts involve a variety of approaches—from adapting evidence-based interventions for use in multiple settings to conducting trials of family-based therapies to using a combination of medications and behavioral approaches to treat drug abusers in the community and help them achieve a healthier lifestyle.

Unfortunately, far too often, drug abuse and addiction remain untreated and escalate to the point of criminal justice involvement, a problem intensifying for females. Indeed, the population of incarcerated women has more than doubled in this country from 1995 to 2005, the problem of female criminal justice involvement characterized by gender-specific factors related to the pathways to substance abuse and recovery, socio-cultural roles and responsibilities, and certain co-occurring mental illnesses. A primary concern for women, which this question addresses, is the greater likelihood of parenting and childcare responsibilities.

NIDA has addressed many of these differences in our recently released landmark publication—principles of Drug Abuse Treatment for Criminal Justice Populations—which conveys effective principles of substance abuse treatment to the criminal justice community and the treatment professionals working with drug-abusing offenders, including women with children. In addition to childcare services, female offenders are more likely than men to need medical and mental health services (given high rates of depression, anxiety, and trauma) and assistance in finding housing and employment. It is important to examine these special needs, for while treatment programs serving both genders can be effective for females, gender-specific programs

may be more effective, particularly for women with histories of trauma and sexual or physical abuse. For female offenders with children, parental responsibilities can conflict with their ability to participate in drug treatment—and yet regaining or retaining custody of their children can also motivate mothers to participate in treatment. Treatment programs may therefore improve retention by offering childcare services and parenting classes.

NIDA is examining these and other methods to make treatments more effective for women, including supporting development of a gender-specific re-entry model to help women reintegrate into the community once released. In addition, a drug court study is looking specifically at ways to improve treatment engagement for women and children. NIDA is also supporting studies of adolescents involved with foster care, identifying the prevalence and heightened risk of substance use disorders among this population. It is worth noting that involvement with foster care is often a marker of prior adversities, including parental addiction, and an antecedent of negative adult outcomes, most of which stem from childhood adversities rather than from foster care per se. In fact, research has shown that therapeutic foster care can be beneficial, particularly to adolescent girls.

VIOLENCE, TRAUMA AND FEMALE DRUG ADDICTION

Question. Please talk about the interrelationship between physical and sexual iolence, trauma, and addiction among women, and what research is being done to excavate that interrelationship, especially as it relates to the experience of maternal addiction.

Answer. It is well-established that childhood maltreatment (in the form of sexual abuse, physical abuse, or neglect) leads to enhanced risk for substance abuse, including earlier incidence of alcohol and drug abuse in adolescents. One study has shown that up to 65 percent of the variability in addiction risk is linked to childhood stress; with children who have been subjected to five or more "insults" (i.e., incidents of trauma) being ten times more likely to develop an addiction than those without such exposure. Many of the biological responses to stress have been implicated in the pathophysiology of both substance use disorders and Posttraumatic Stress Disorder (PTSD).

The relationship of substance abuse and addiction to female victimization by sexual violence or other traumatic abuse presents a vicious cycle that can turn both ways, sustained in part by long-lasting negative emotions and behaviors that elicit drug craving and use. Indeed, PTSD and depression are common results of sexual and/or physical abuse and primary risk factors for subsequent drug abuse in females. A multitude of factors influences these events, including age of exposure to physical or sexual abuse, family history, criminal justice involvement, race, co-occurring mental disorders, and other genetic and environmental variables—a tangle of risk factors that NIDA-supported research is investigating to help devise more effective interventions.

Prior research has revealed, disturbingly, that most rape victims (62 percent) are girls under the age of 18, with 28 percent of victims under age 11. This finding reflects the early age at which violence often occurs, and the importance of understanding a person's history in determining how best to provide treatment. For women, violence more often precedes substance use than the other way around, although both patterns can occur. Thus, treatment that evaluates family history and exposure to violence at various ages might yield important information about chronology of critical variables and relative contributions of environmental and biological factors to comorbid mental and substance abuse disorders.

The effects of trauma are complex and can be manifested in diverse ways. For example, longitudinal and developmental research suggests that girls' involvement in the juvenile justice system often follows from exposure to trauma and physical or sexual abuse and often co-occurs with anxiety and mood problems. In a recent longitudinal analysis of women who lived in shelters or experienced major violence, study participants had a two-fold increase in their risk of depression over a 6-month follow-up period. And because substance abuse and addiction also significantly increase the risk of subsequent victimization that could lead to PTSD (the reverse direction of the vicious cycle), NIDA also supports studies seeking to add a violence prevention component to substance abuse treatment, particularly for male perpetrators of intimate partner violence. Research on cohabitating substance-abusing patients is offering options to treatment providers who deal with intimate partner violence—40 to 60 percent of couples reporting episodes of partner aggression in the year preceding treatment entry.

Finally, NIDA research has revealed encouraging results for a trauma-focused cognitive behavioral therapy (CBT) known as "Seeking Safety," designed specifically

for women with trauma histories. Compared to standard substance abuse treatment, the therapy improved both substance abuse and PTSD symptoms in female patients who identified the trauma's effects on their lives and practiced techniques to ease emotional pain, stop self-blame, and cope with difficult interpersonal and potential relapse situations. NIDA is now testing "Seeking Safety" in its National Drug Abuse Clinical Trials Network, which uses "real-world" community treatment programs to validate treatment practicality and effectiveness. This therapy has also shown promising results in adolescent girls, suggesting the need for dual-diagnosis treatment that more directly targets trauma-related symptoms and areas of individual difficulty. Such findings with adolescents are encouraging, as they suggest that comorbid PTSD and substance abuse may be amenable to change early to counter its typical persistence into adult

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QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

EFFECTS OF PRESIDENT'S BUDGET

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKES

Question. If the President's budget were to be adopted by Congress and research funding were frozen or cut below existing levels, what specific research priorities at your institutes would be delayed or have to be set aside?

Answer. The first priority of NINDS at any funding level is to maintain our existing research commitments, and the President's budget allows us to do that. However, progress against neurological disorders depends on maintaining robust investigator initiated basic, translational, and clinical research programs, and, as you heard in testimony from academic scientists, new and established investigators are struggling. They are spending more time writing and rewriting grant applications than doing research, and too often are forced to drop innovative work, lay off highly trained staff, or close down labs entirely. Under this budget scenario, we would have to reduce or eliminate programs and pass up promising opportunities in order to sustain our core research and ensure that we have a scientific workforce for the future. NINDS would, for example, move fewer promising early phase clinical trials from our SPOTRIAS stroke centers to large phase III trials, move more slowly in developing the Clinical Research Collaboration and Neurological Emergency Treatment clinical trials networks, and not undertake new initiatives, such as applying the model of therapeutics development from the SMA Project to other disorders.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Question. If the President's budget were to be adopted by Congress and research funding were frozen or cut below existing levels, what specific research priorities at your institutes would be delayed or have to be set aside?

Answer. With the resources requested in the fiscal year 2008 President's Budget, NIDCD will be able to support its highest priority research. This includes support for a research contract for a multi-center study entitled the "CMV and Hearing Multicenter Screening (CHIMES) Study," on the role of congenital CMV in the development of hearing loss in children. The CHIMES study is one of the largest studies of its kind with approximately 100,000 children to be screened at birth for CMV infection. A major focus of this study is to identify asymptomatic children and follow their progress to determine if hearing loss develops. Those who test positive for CMV will undergo follow-up hearing screening to determine the onset, severity, and progression of hearing loss. If additional funds were to become available to NIDCD beyond these priorities, NIDCD would likely seek to increase the number of children who will be screened for CMV infection.

NATIONAL INSTITUTE OF MENTAL HEALTH

Question. If the President's budget were to be adopted by Congress and research funding were frozen or cut below existing levels, what specific research priorities at your institutes would be delayed or have to be set aside?

Answer. With the resources requested in the fiscal year 2008 President's Budget, NIMH will be able to support its highest priority research. While the President's request did not propose to decrease NIMH's budget, if additional resources became available for NIMH to support research beyond these priorities, NIMH would likely seek to expand its support for in-depth analyses of data collected from whole genome association (WGA) studies for major mental disorders. WGA studies evaluate the subtle differences between the genomes of healthy people and those suffering from disease in order to determine how genetic variability may contribute to disease

susceptibility. In addition to the WGA analyses, NIMH might invest in research to develop new compounds as fast-acting treatments for depression, with the ultimate goal of expanding treatment options so that physicians may offer more personalized care.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Question. If the President's budget were to be adopted by Congress and research funding were frozen or cut below existing levels, what specific research priorities at your institutes would be delayed or have to be set aside?

Answer. The first priority of NIAAA at any funding level is to maintain our existing research commitments, and the President's budget allows us to do that. In addition, in the fiscal year 2008 Congressional Justification, NIAAA has highlighted a number of promising areas for future research activity. For example, $3 million have been committed in fiscal year 2008 for research to investigate the short- and long-term effects of alcohol use on the developing adolescent human brain. This funding amount will allow us to conduct pilot studies to determine the best methodology for answering this critical question through future larger longitudinal studies. A second example relates to our funding of medications development. The fiscal year 2008 budget request provides for $2 million of additional funds for testing compounds and increasing the efficiency of the medications development infrastructure. Whereas it is cost effective to concurrently test multiple compounds, the fiscal year 2008 budget permits sequential testing of a few promising new compounds.

NATIONAL INSTITUTE ON DRUG ABUSE

Question. If the President's budget were to be adopted by Congress and research funding were frozen or cut below existing levels, what specific research priorities at your institutes would be delayed or have to be set aside?

Answer. With the resources requested in the fiscal year 2008 President's Budget, NIDA will be able to support its highest priority research. While the President's request did not propose to decrease NIDA's budget, if additional resources became available to NIDA beyond these priorities, NIDA would likely seek to pursue additional clinical trials and development of new addiction medications; develop a specialized NeuroChip for substance abuse to put in place a single standardized platform for researchers to rapidly screen thousands of an individual's relevant gene variants; support a Genes, Environment, and Development Initiative (GEDI)—a cross-disciplinary initiative designed to increase knowledge of the interactions between genes, environment, and developmental stage in relation to drug abuse risk; and expand NIDA's services research programs operating at the community level, such as its large research collaborations to improve drug abuse treatment for criminal justice populations.

ECONOMIC BENEFITS OF NINDS RESEARCH

Question. Dr. Landis, I am particularly interested cost-savings resulting from NIH research. I understand that NINDS has analyzed the economic benefit of NINDS-supported clinical trials. Could you highlight the results of this study for the Committee?

Answer. At the request of the National Advisory Neurological Disorders and Stroke Council, the institute contracted for an independent evaluation of the costs and benefits of all NINDS phase III clinical trials conducted from 1977 to 2000. The total cost of the clinical trials in the study was $335 million (adjusted to 2004 dollars). Over 10 years, the benefits from these trials exceeded $15 billion and added 470,000 healthy years of life to people in the United States. For the entire period of the study, the benefits surpassed $50 billion, which was greater than the total NINDS budget over that period ($29.5 billion).

Advances in neuroscience are yielding more clinical trial opportunities than ever before, but trials are expensive and can take years to complete. So, NINDS is now developing computer models to do this kind of analysis prospectively, that is to estimate in advance which trials would have the most impact on public health.

DUCHENNE MUSCULAR DYSTROPHY

Question. Dr. Landis, I understand that NINDS recently funded a large-scale project in translational research for Duchenne muscular dystrophy. Can you tell me about this project, and how it fits into the bigger picture of finding cures for this disease?

Answer. NINDS will soon fund a large-scale project to an investigator at the University of Pennsylvania to develop new small molecule drugs for the treatment of

Duchenne muscular dystrophy (DMD) and potentially other forms of muscular dystrophy as well. DMD is a disease caused by mutations in the dystrophin gene, resulting in a lack of the dystrophin protein. Dystrophin is part of a complex structure involving several other protein components that is required for maintaining proper skeletal muscle structure and function. In the absence of the dystrophin protein, muscle weakening and wasting, and ultimately death, occurs.

The project will pursue a number of strategies for therapy development, including stimulating muscle growth by modulating growth factor pathways, and upregulating proteins that may structurally and functionally substitute for dystrophin or that contribute to the dystrophin protein complex in normal muscle cells. The researchers have already completed a high-throughput screening process on each of these strategies in order to identify small molecules that are candidate therapies. The project will focus on improving the properties of these small molecules as drug candidates and carry out research that will help support further clinical studies using these compounds. One exciting aspect of this project is the fact that a patient voluntary organization (Parent Project MD) as well as a company (PTC Therapeutics) are contributing funds to this project, thereby creating a public-private partnership to leverage funds for this project.

This project is one important component of the larger NIH effort to find cures for DMD and other forms of muscular dystrophy. The Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers also fund translational research aimed at developing therapies for muscular dystrophy. In addition, a few years ago, NIH released a number of initiatives to stimulate translational research in muscular dystrophy, and grants are being funded through these initiatives, as well as through other mechanisms at NIH. A number of strategies for therapy development are being pursued in these studies including gene therapy, cell replacement therapy, enhancing muscle regeneration, and genetic modification strategies. In addition to these translational projects, it is important to note that the mechanistic knowledge obtained through NIH-funded basic research studies has yielded a range of therapeutic targets that NIH-funded research is now pursuing.

SPINAL MUSCULAR ATROPHY

Question. Dr. Landis, can you tell us if any progress has been made toward a treatment for spinal muscular trophy? What continuing efforts is your institute making in this area? Also please describe the SMA Project, explain what makes it different than the traditional way of doing translational research at NIH, and comment on how it might serve as a model for research on other diseases.

Answer. The goal of the SMA Project is to bring at least one new drug for SMA to readiness for clinical testing as quickly as possible. The project uses a performance-based contract. It is quite different from the usual way we do research because of the central direction and the way it is organized. A project steering committee, with extensive expertise in drug development from industry and the FDA, as well as from the NIH, put together a detailed drug development plan and is heavily engaged in guiding progress. The project is implementing the plan via a "virtual pharma organization" that develops and brings together all of the necessary resources through subcontracts to companies that serve the drug development industry.

The Project has put more than 800 compounds through repeated cycles of modification and evaluation in laboratory tests and is making encouraging progress. Some of these potential drugs show dramatically improved potency and efficacy in simple laboratory tests, and NINDS gathered sufficient data to file a patent application in March 2007. In 2007 and 2008, the most promising compounds will advance through more definitive tests of effectiveness in mice that have been genetically engineered to mimic human SMA. By June of 2007, the project intends to select a clinical candidate and begin the preclinical safety studies that will support clinical testing. We are already applying lessons from the SMA Project for other disorders through a similar contract mechanism planned for this year that will address a major barrier to drug development by providing access to medicinal chemistry services.

We are also continuing other lines of SMA research in both the extramural and intramural programs. This year, for example, intramural researchers collaborating with Italian scientists showed for the first time that a drug treatment could be effective in an animal model of SMA when treatment is begun after the symptoms of disease have already appeared, which is an encouraging finding.

STEM CELLS

Question. Dr. Landis, you serve as the Chair of the NIH Stem Cell Task Force. What steps would NIH take to implement S. 5, the Stem Cell Research Enhancement Act of 2007?

Answer. If the bill were to be passed, a panel of experts would need to be immediately convened to develop and issue guidelines for implementation. NIH's experience in implementing human embryonic stem cell (hESC) research the past years would be vital in developing these new guidelines. In addition, NIH would develop a format for reporting requirements mandated within sections 2 and 3 of the act.

CLINICAL TRIALS

Question. Dr. Insel, when Dr. Zerhouni was here last week, he noted that to continue to support ongoing research projects and allow for new investigators to successfully apply for support, it has been necessary to reduce support for clinical trials research. Has this also affected your institute? Will you be able to continue important clinical trials?

Answer. NIMH is providing infrastructure support to maintain three large networks of investigative clinical teams that have evolved from the recent NIMH practical clinical trials on major depressive disorder, schizophrenia, and bipolar disorder. The networks comprise over 60 sites throughout the United States with continual outreach and engagement to diverse groups of patients and families with mental illnesses. NIMH plans to support research studies that utilize the resources established by these networks; these studies must be of significant public mental health importance, provide value to individuals living with mental illnesses and to practitioners, and incorporate input from broad scientific and public domains. Under the President's Budget request, NIMH would be able to support a few studies on these clinical trial networks.

Other recent NIMH-funded research has led to several promising new pharmacological treatment approaches for mental disorders. For example, a recent study uncovered a new mechanism of action to target for the fast relief of depression. In addition, NIMH has supported a large research effort focused on identifying novel compounds for treating the cognitive deficits associated with schizophrenia. NIMH hopes to build on these research findings to develop new compounds as fast-acting treatments for depression and as cognitive enhancers for those diagnosed with schizophrenia. Under the President's Budget request, NIMH would support a limited number of trials to test the efficacy of these promising new compounds.

ECONOMIC BENEFITS OF MENTAL HEALTH RESEARCH

Question. Dr. Insel, can you tell us about the economic benefits that have resulted from investment in mental health research?

Answer. Mental disorders are associated with enormous economic burdens. The President's New Freedom Commission on Mental Health estimated that these economic costs are on the order of $150 billion each year in the United States alone.[4] Much of this cost is due to the lost work productivity that results from mental illness. A large body of NIMH-supported research indicates that much of this economic cost, including that derived from impaired work performance, could be alleviated by standard treatments for mental disorders. Yet, the cost of mental illness persists in part because of widespread underuse and the poor quality of implementation of treatments that have been shown to be efficacious and tolerable. Recent effectiveness trials supported by NIMH have shown that a variety of models that enhance the care of mental disorders through aggressive outreach and improved quality of treatments are highly effective at improving clinical outcomes, and in some cases, on work performance outcomes as well. Economic analyses accompanying these effectiveness trials have also shown that these quality improvement interventions are cost-efficient. Unfortunately, widespread uptake of these enhanced mental health treatment programs has not occurred due to barriers at the level of providers, health care systems, and purchasers of health care. Additional ongoing research supported by NIMH is examining how to most effectively overcome these barriers to high-quality mental health care and to ultimately reduce the enormous adverse economic impact from mental disorders.

[4] New Freedom Commission on Mental Health, Achieving the Promise: Transforming Mental Health Care in America. Final Report. DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

HEARING LOSS

Question. What recent progress has been made toward better treatments for partial and full hearing loss? Has there been any specific progress in better hearing aid technology?

Answer. Approximately 28 million Americans have a hearing impairment. Hearing loss is one of the most prevalent chronic health conditions in the United States, affecting people of all ages, in all segments of the population, and across all socioeconomic levels. It affects approximately 17 in 1,000 children under age 18. Incidence increases with age: approximately 314 in 1,000 people over age 65 have hearing loss. Because of the immense public health need, for over 30 years, the NIH has played a significant and important role in sponsoring the development of cochlear implant technology. The cochlear implant is the only sensory neural prosthesis in widespread clinical use and according to the Food and Drug Administration's 2005 data; nearly 100,000 people worldwide have received implants. In the United States approximately 22,000 adults and nearly 15,000 children have received them. Continued research on ways to assess how well current users benefit from their cochlear implants will enable scientists to design implants that will be more effective for all future implant users. Some individuals with severe to profound hearing loss are receiving a cochlear implant for each ear. Research is demonstrating that these dual implant users are significantly better at localizing sounds and hearing speech in a noisy room, when compared to individuals with a single implant. Scientists also are developing a new cochlear implant electrode designed to provide electrical stimulation of the auditory nerve for high-frequency sounds while preserving useful, residual hearing at low frequencies. Scientists can now study the large groups of newborns who are identified for hearing loss and use this knowledge to document how cochlear implants can lead to improved speech acquisition, academic performance, and economic outcomes for these children.

While cochlear implants bypass damaged portions of the inner ear and directly stimulate the auditory nerve, hearing aids amplify sounds. Scientists are determining which individuals can most benefit from hearing aids and the best ways to select and fit hearing aids in children and other people whose hearing ability is difficult to test. One of the most exciting advancements in hearing aid technology resulted from NIH-supported research. The discovered technology is based on the ears of a parasitic fly, Ormia ochracea. Despite their small size and the short distance between them, Ormia's ears are able to rapidly pinpoint the location from which the sound of a potential host—a cricket—is coming, even in a noisy environment. The intriguing mechanism that enables Ormia to accomplish this feat has provided a model for scientists and engineers to use in developing miniature directional microphones for hearing aids that can better focus on speech in a single conversation, even when surrounded by other voices. This finding has revolutionized the technology used for directional microphones and will improve the quality of life for the million of individuals with hearing impairment.

Scientists are continuing to develop treatments for hearing loss that can be tailored to individuals' unique needs. The combined use of a hearing aid and a variation of the cochlear implant is another treatment being explored. A hearing aid in one ear combined with a shortened electrode array inserted into a portion of the cochlea of the other ear have proven to be effective in allowing individuals with hearing loss in the high frequencies to improve hearing. More research needs to be done to determine which individuals should receive these combined devices and which devices yield the most benefit. Researchers continue to conduct studies to determine the age at which hearing aids provide maximum success in early language development.

BASIC RESEARCH AND HEARING

Question. Please give us an example of how basic research into the mechanics of hearing has led to better patient outcomes. Why is basic research important in the areas covered by your institute?

Answer. Hearing aid users want devices that enable them to better understand speech. Two recent surveys demonstrate this desire. Poor benefit in noisy situations was listed among the top 20 reasons why hearing aid owners don't use their hearing aids. Another survey of 2,428 hearing aid owners found that improved understanding of speech in noise was among the top 10 desired changes. Of all the available technologies, directional microphones for hearing aids have shown the most promise for addressing this problem, as demonstrated by clinical studies of individuals with hearing loss.

Because of basic research, NIH-supported scientists successfully completed a fabrication process to miniaturize the prototype of a low-power, highly directional hear-

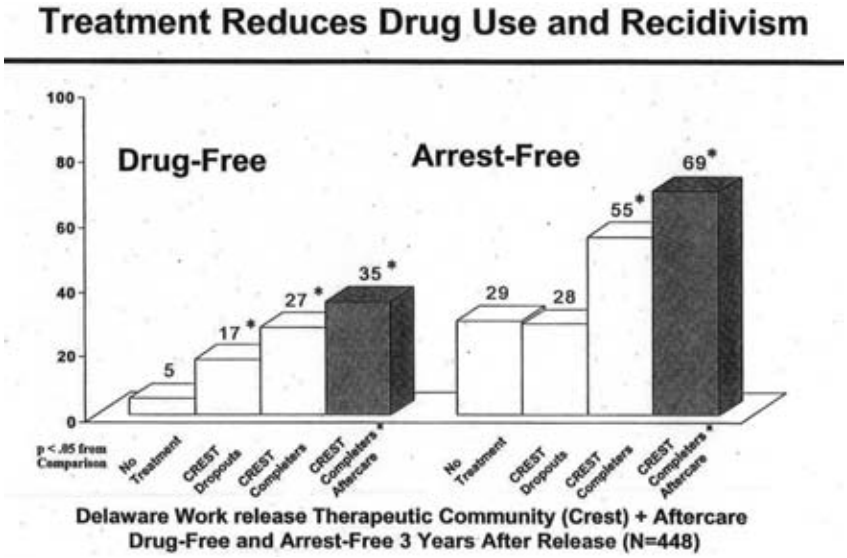
ing aid microphone so that it will fit into a hearing aid. This directional microphone mimics the auditory system of the parasitic fly, *Ormia ochracea.* The fly's system is an excellent model to imitate because its mechanically coupled ears enable it to detect the direction of sound and because it suggested a way to miniaturize a microphone for use in hearing aids. The scientists used silicon microfabrication technology to make a directional microphone that is small enough to be incorporated into a hearing aid. The directional microphone developed in fiscal year 2006 will ultimately help hearing aid users to better understand speech in a noisy background, such as in a crowded room. The microphone is able to do this by giving more weight to sound originating closest to the ear.

This is an excellent example of why basic research is so important. Basic research often relies on studies in "model organisms," such as mice, fruit flies, or bacteria. Because human cells contain the same molecular building blocks and pathways as those of most other living things, researchers can learn much about the way our cells work by studying these simpler organisms. These models allow scientists to design and control their experiments tightly and to select the type of organism best suited for examining a specific problem or process. The ability to conduct basic research on the ears of *Ormia*, has revolutionized the technology used for directional microphones and will improve the quality of life for millions of individuals with hearing impairment. This is one of the many examples of advances that grew out of basic research. In conclusion, while basic research studies do not always have an immediate impact on our health, such research often leads to new medicines, technologies, and research tools.

DRUG ABUSE TREATMENT

Question. Dr. Volkow, I understand that your Institute has released principles of drug abuse treatment for criminal justice populations. Could you please summarize for us how you recommend dealing with drug abuse treatment for criminal populations?

Answer. NIDA's recently released booklet, Principles of Drug Abuse Treatment for Criminal Justice Populations: A Research Based Guide, reflects NIDA-supported research aimed at improving outcomes for offenders with substance abuse problems. The principles emphasize the need for customized strategies, which can include behavioral therapies, medication, and consideration of other mental and physical illnesses. The key message is that drug abuse treatment works, especially with community involvement and support, and brings about reduced drug abuse, criminal recidivism, and relapse to addiction.



For that reason, treatment is cost-effective: for every dollar spent on drug abuse treatment an estimated $4–$7 in benefits ensues from avoided criminal justice costs—benefits that grow as addiction treatment continues over time. Data also

show that treatment can work even when it is entered involuntarily. NIDA therefore recommends that treatment for criminal justice offenders be part of a continuum of care that begins in prison and continues throughout the difficult periods during and following re-entry into the community.

To help ensure better outcomes for offender populations, NIDA recommends an integrated approach that cuts across multiple public health and public safety systems. In this vein, NIDA launched a Criminal Justice-Drug Abuse Treatment Studies (CJ–DATS) Initiative, a multisite and multiagency research initiative to focus on implementing new research-based drug abuse treatment models in the criminal justice system. And because effective interventions may include pharmacotherapies, or medicines for drug abuse and addiction, NIDA recommends their use in criminal justice settings as part of a comprehensive treatment regimen—which will necessitate a culture change.

Another tenet of effective drug abuse treatment is a proper balance of rewards and sanctions to encourage prosocial behavior and treatment participation. It is important to reinforce positive behavior for those participating in drug abuse treatment, with sanctions applied gradually, in line with degree or persistence of noncompliance.

To effect needed changes, NIDA will continue to reach out to judges and others in the criminal justice system to educate them about the behavioral and biological aspects of addiction through intensive training workshops. We will also continue to support studies examining ways to make quality treatment options available through drug courts and other alternatives to incarceration for substance abusers.

ADDICTION AS A BRAIN DISEASE

Question. Dr. Volkow, I understand that many in the field of drug abuse research strongly argue that addiction is a brain disease. Do you agree with this assessment, and if so, why?

Answer. Yes, I wholeheartedly agree that addiction is a brain disease. Decades of scientific research by NIDA and others have affirmed drug addiction as a disease that alters the brain in ways that affect behavior. The compulsive craving, seeking, and use of drugs, even in the face of dire life consequences, happens because addiction affects the same brain circuits that are also involved in reward, motivation, memory, and control over behavior. And when these are usurped by drugs, so is a person's capacity to freely choose not to use drugs, even when it means losing everything they used to value. In fact, the inability to stop is the essence of addiction.

Brain imaging and basic neuroscience research have helped us to understand how drugs of abuse alter brain function. We depend on our brain's ability to release dopamine in order to experience pleasure and to motivate responses to the natural rewards of everyday life, such as the sight or smell of food. Drugs of abuse produce very large and rapid dopamine surges and over time the brain responds by reducing normal dopamine activity. Eventually, the disrupted dopamine system renders the addict much less sensitive to pleasure—even to the drugs they seek to feed their addiction. Drugs of abuse also affect the regions of the brain that help people control desires and emotions, as evidenced by brain imaging research in humans revealing changes in the functions of these circuits. Thus, drug addiction affects the very brain areas that people need to "think straight," apply good judgment, and make good decisions for their lives. The resulting lack of control leads addicted people to compulsively pursue drugs, even after the drugs have lost their effectiveness in producing pleasure; for now even the memories that are linked to the drug motivate behaviors to seek the drug. Behavior becomes reflexive and much less amenable to cognitive interference. Just as the damaged heart can no longer propel the blood to our bodies, the damaged brain can no longer propel the nerve impulses to control desires and emotions.

Like any other medical disorder that impairs the function of vital organs, repair and recovery of the addicted brain depends upon targeted and effective treatments that address the complexity of the disease. Brain imaging shows recovery as well. Research is proving new insights on how this can be done. NIDA is engaged in studying new scenarios for what constitutes effective treatment: pharmacological treatments to mitigate stress and prevent relapse, cognitive treatments that strengthen the frontal (thinking) part of the brain, and strategies that diminish conditioned responses, promote new learning, inhibit stress-induced relapse, and restore the rewarding experiences from natural reinforcers.

UNDERAGE DRINKING

Question. Dr. Li, how is your institute addressing the growing problem of underage drinking? Is progress being made?

Answer. Although the problem of underage drinking persists progress is being made:

(1) Based on converging evidence from multiple fields we now know that underage drinking is best addressed and understood within a developmental framework because this behavior is directly related to processes that occur during adolescence. Using such a framework will make us more effective in preventing and reducing underage alcohol use and its associated problems.

(2) This paradigm shift along with recent advances in the fields of epidemiology, developmental psychopathology, human brain development, and behavioral genetics provided the scientific foundation for the Surgeon General's recently released Call to Action to Prevent and Reduce Underage Drinking, the work of the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) and the work of its member federal agencies and departments.

(3) The release of the first ever Surgeon General's Call to Action on underage drinking is a landmark event which will heighten awareness of the problem in all sectors of society.

(4) Federal surveys indicate some modest declines on certain measures of underage drinking. While this progress is encouraging, the prevalence of underage drinking, and especially binge drinking, remain high.

(5) In order to better characterize trends in underage drinking in America, information beyond that previously available from national surveys is needed. Based on NIAAA's recommendations, new questions on patterns of drinking (e.g. very high level consumption, sources of alcohol, and drinking venues) are now being included in national surveys.

(6) A key research question is the extent to which adolescent drinking impacts the developing human brain. Research with rodents and studies with alcohol dependent youth suggest that alcohol use during adolescence, particularly heavy use can have deleterious short- and long-term effects on the developing brain. To further address this central scientific question, NIAAA has released a Funding Opportunity Announcement for two-year pilot studies in this area entitled The Impact of Adolescent Drinking on the Developing Brain. Successful applications in response to this announcement will be funded in fiscal year 2007. These studies are expected to inform a larger longitudinal initiative.

ALCOHOL AND CANCER

Question. Dr. Li, I understand that drinking alcoholic beverages has been linked to an increased risk of several types of cancer. Could you please tell us if this link has been confirmed, and if so do we know what the mechanism for the link might be?

Answer. Chronic alcohol consumption is a well-established risk factor for cancer of the oral cavity, pharynx, esophagus, and larynx. For example, for those individuals who average 100 grams of alcohol consumed per day (about 7 standard drinks) the relative risk for cancer of the oral cavity and pharynx increases 6.5 times compared to non-drinkers. Consuming this same level of alcohol increases the relative risk for cancers of the larynx, esophagus, breast and liver 3.9, 3.6, 2.4, 1.8 fold respectively. While not as high, there are also significant elevated risks for each of these cancers associated with consumption of 25 grams of alcohol per day (about 2 standard drinks). Concurrent smoking and drinking, which is common, synergistically increases the risk of cancer. For example, one study reported an 18-fold increase in the relative risk for esophageal cancer due to the consumption of more than 6 drinks/day, a 5-fold increase due to smoking more than 20 cigarettes/day, and 44-fold greater risk for combined heavy alcohol consumption and cigarette smoking.

Alcohol is metabolized primarily by alcohol dehydrogenase in the liver to form acetaldehyde, a highly reactive and carcinogenic compound which is further metabolized by aldehyde dehydrogenase (ALDH2) to acetate. A variant of this enzyme (ALDH2*2) is virtually inactive (leading to higher concentrations of acetaldehyde) and occurs in 28–45 percent of Asian populations. As a result of the accumulation of acetaldehyde, homozygous carriers of this allele (ALDH2*2/*2) experience aversive reactions to alcohol including strong facial flushing and toxic reactions. Therefore most homozygous individuals either abstain or drink infrequently. In contrast, heterozygous carriers (ALDH2*1/*2, which has about 10 percent residual ALDH2 activity) who consume alcohol are at a high risk for developing esophageal cancer. Thus, acetaldehyde is implicated as a carcinogen, and is included in the list of "IARC Group 2B Carcinogens." Several mechanisms have been implicated in alcohol-induced cancer, including: (1) formation of acetaldehyde which forms adducts with DNA; (2) production of reactive oxygen species (ROS) and lipid peroxidation

products; (3) changes in folate and methionine metabolism; (4) alcohol-induced increase in estrogen formation in breast cancer; (5) suppressed immune function; and (6) alcohol's solvent action enhancing the bioavailability of carcinogens from tobacco and other sources. The induction of microsomal cytochrome P450 enzymes by alcohol increases the metabolism of procarcinogens, such as nitrosamines, present in tobacco smoke, and likely plays an important role in the greater risk for cancer due to heavy alcohol consumption and smoking.

SUBCOMMITTEE RECESS

Senator HARKIN. So with that, thank you very much.

The subcommittee will stand in recess to reconvene at 9:30 a.m., Wednesday, March 28, in room SD–124. At that time we will hear testimony from the Honorable Elaine L. Chao, Secretary, Department of Labor.

[Whereupon, at 5:24 p.m., Monday, March 26, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, March 28.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

WEDNESDAY, MARCH 28, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:46 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin and Specter.

DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

STATEMENT OF HON. ELAINE L. CHAO, SECRETARY

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. This Appropriations Subcommittee on Labor, Health and Human Services and Education will come to order for this hearing on the funding for the Department of Labor.

JIM SOURWINE TRIBUTE

But before we begin, I would like to have us take a moment here to pay tribute to someone who has meant a great deal to me, to this committee, the Senate, and the mission of the Department of Labor. That is Jim Sourwine.

Jim has been an essential part of the committee's work since 1972, when he was detailed to this committee from the Department of Labor. So this morning I want to recognize him on his retirement from the committee staff.

For more than 30 years, Jim did his best to keep a low profile and stay out of the limelight. But I am sorry, Jim. It is time you get the public credit you deserve.

Jim's outstanding service has made a real difference for the American people. When Jim started working at the Department of Labor in 1967, the Job Corps program was in its infancy—just 3-years-old. Today it is a $1.6 billion enterprise, widely touted for its performance standards and student outcomes, helping more than 60,000 youths each year. Well, it was Jim's skill, and expertise, and doggedness that helped make that happen.

He has organized and staffed countless hearings on important topics, such as ergonomics and overtime. And whenever this subcommittee has faced some sticky legislative problems, he has always known just how to solve them. You might say he is our default guy. He is our go-to person.

For example, Jim is the one who figured out how to create a stable funding system to handle the fluctuating workloads of unemployment insurance claims. So Jim will be missed not just for his outstanding work for the committee, we will also miss him for how he has treated each of us. Senators and staffers alike. Always courteous. Always helpful. He is an appropriator's appropriator.

He has worked for Republicans and he has worked for Democrats, back and forth for all these years. He has done it with equal diligence and faithfulness to both.

Now he deserves a chance in retirement to do all the things he had less time to do while he slaved here late into the night and on weekends, and everything else for all those years. I suspect and hope that many of the things he will be doing involve golf clubs.

So, Jim, the committee thanks you for your service, as do I personally. We wish you all the best in your retirement.

I would yield to my esteemed colleague, Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Well, thank you, Mr. Chairman. Thank you for scheduling this well-deserved tribute to Jim Sourwine. When you go back to 1972, when Senator Warren Magnuson was the chairman of this subcommittee, that establishes Jim Sourwine with a lot of seniority. More seniority than either the chairman or the ranking member have at the present time.

The staff work that Jim has undertaken has been really very, very difficult. Our staffs on the Appropriation Committee are called upon to draft, and redraft, and amend, and supplement legislation. It is a job which requires a lot of overnights, when they have to read out the bill. A lot of weekends, when we are into that stage in September, October. It is very, very intense work. I think unusually so. Jim has undertaken a wide share, focusing on the very difficult issues, which the Department of Labor has had.

I suspect that the golf courses will be seeing a lot more of Jim Sourwine in the future than they have in the past. But this will give him an opportunity to spend more time with his wife, Annette, children, Molly, Matt, and Billy. We will miss you, Jim, but we wish you the very best.

Mr. SOURWINE. Thank you.

Senator HARKIN. That is great.

Madam Secretary.

Secretary CHAO. Yes. Please.

Senator HARKIN. No. Wait, Jim. We are not done, yet.

Secretary CHAO. No. We are not finished yet.

JIM SOURWINE TRIBUTE

On behalf of the Department of Labor, let me also thank Jim Sourwine for his 40 years of service to America's workers. As the chairman and Senator Specter mentioned, Jim began his career at

the Job Corps, at the Department of Labor. In 1972, he was detailed on a temporary basis. What a detail it has been.

While he may have moved up to the Hill 35 years ago, before even the Department's Francis Perkins Building opened in 1974, he has dedicated his entire career to the Senate, to working on some of the most difficult and significant budgets, appropriations issues, facing several very significant departments. That is a tremendous accomplishment.

I have been told that today is the thirty-fifth Labor Appropriations hearing that Jim has attended. As you know, Chairman Harkin and Senator Specter, Jim has been the Senate's institutional knowledge, not only for the Senate, but also for the Department of Labor as well.

He understands these issues. He has always been an honest broker. We have valued his judgment, and also, many times, his advice. He knows how much this committee has spent on the Department's programs and which states they operate. All these kinds of details.

Most of all, I think we all know that at the Department, he really appreciates the staff at the Department of Labor, the tremendous work that the Department does to advance the interest and the concerns of working men and women. So thank you, Jim, so much.

You obviously have had a wonderful time up here. We want to wish you the best. We hope that you will take it easy, really enjoy yourself, and also get the time that your family so richly deserves, and your loved ones as well. Thank you.

Mr. SOURWINE. Thank you all so much.

I will have to get a copy of the transcript now.

Senator HARKIN. Thank you, Jim. It will never be the same without you.

Well, Madam Secretary, thank you very much. We will now turn to our hearing, as soon as I find my right page here.

OPENING STATEMENT

First of all, Madam Chairman, I would like to welcome you again to the committee, and return to the subject of today's hearing, the budget of the Department of Labor. First and foremost, I would be remiss if I did not thank you for the great work you did on the Job Corps Center in Ottumwa, Iowa. Also in Wyoming and New Hampshire.

As we just said about the Job Corps, it is interesting that this was Jim's deal when he first started. To this day, and today, we are still opening new Job Corps centers around the country. These three, I think, will be a welcome addition to all the other Job Corps centers around the country. So I thank you for that. We will see what we do to work together to make sure we move these along as rapidly as possible. Whatever else we need to do up here.

Madam Secretary, your Department has several critical responsibilities. One is administering Federal labor laws that guarantee workers' rights to safe and healthful working conditions. Another is helping workers find and prepare for work, such as a worker displaced by an employer that is relocating overseas and other things.

MINE COMMUNICATIONS TECHNOLOGIES

Now, Madam Secretary, I am a little disturbed by some of the progress, or I should say lack of progress being made on some of these objectives. Now we had hearings here last month on MSHA; the assistant secretary of Mine and Safety Health Administration was here. I expressed my disappointment with the small number of communications technologies approved by MSHA to date.

We had had that hearing a year ago or so. That was under Chairman Specter's reign at that time. We had those hearings. We were talking to MSHA about moving ahead on some of these technologies. But it does not seem like we are making much progress on that.

Earlier this month, United Mine Workers Association reporting on the Sago Mine disaster, found significant shortcomings in MSHA's actions that could have prevented the deaths of the 12 miners who perished in that tragedy.

OIL REFINING INDUSTRY INSPECTIONS

Last week, the Chemical, Safety, and Hazard Investigation Board released a report on the BP Texas City Refinery explosion in 2005 that resulted in the deaths of 15 workers and more than 100 injuries. The Board found that on your watch the Occupational Safety and Health Administration has not conducted one planned comprehensive inspection in the oil refining industry.

INTERNATIONAL CHILD LABOR

I am also concerned, as you might guess, Madam Secretary, about the proposed—once again, the fight against international child labor. Now this is something that this committee has focused on, oh, for 12, 13, 14, years. Something like that. Last year, the International Labor Organization's global report, "The End of Child Labor Within Reach," stated that for the first time, child labor, especially in its worst forms, is in decline across the globe.

Between the years 2000 and 2004, the number of child laborers worldwide fell by 11 percent. So we are making real progress that could be reversed by the proposed cuts in this budget on that.

So I do not think this is the time to rest on our laurels. We are making headway. This Department has been a partner with us, as I said, going back a dozen years maybe or so in the efforts on child labor. I hope we are not going to be backing off on that now.

DOL BUDGET REQUEST

We may get into talking about ergonomic standards, enforcing the requirements for protective equipment. Effective enforcement under the Family Medical Leave Act. But it is not just worker protection program. Your budget proposes a cut of $1 billion in job training programs.

Earlier this month, Bill Gates testified before the HELP Committee, on which I also sit, the authorizing committee, and he said, and I quote, "Workforce enhancement should be treated as a matter of national competitive survival." He went on to say, "It is a down payment on our future. An extremely vital step to secure American competitiveness for future generations and to honor the

American ideal that every single one of us deserves the opportunity to participate in America's success." So I wonder what kind of a future can we expect if we are going to be cutting our budget by $1 billion.

So Madam Secretary, that is what we are here to talk about, is the budget. Obviously, we are going to have some disagreements in that budget, because these values and policies, I think, this committee has supported strongly in the past under both Democratic and Republican chairmen.

We just cannot turn a blind eye towards employers who are denying their workers a safe place to work. Our continued success, I believe, in this country depends on investments that we make in workforce. Workforce training.

So again, we will get into more of that later and talk about these proposed cuts and stuff. But first, I would recognize my ranking member, Senator Specter, for any comments.

Senator SPECTER. Thank you. Thank you, Mr. Chairman. Madam Secretary, I join the chairman in welcoming you to this hearing. I compliment you, on your seventh year of service to the administration of President Bush. If you are not the longest serving secretary, you are certainly tied, because you have been here for the entire tenure of the President.

At the outset, I want to thank you for the Department's prompt response and your prompt response to the inclusion of $25 million in the continuing resolution—directed at at-risk youth and tremendous problems in juvenile crime across this country.

It takes very prompt action to get those funds moving, so that they will be available for the start of the school year, and perhaps even sooner.

I share the concern about the budget. I know we live in an era of severe budget constraints. I know we made a large—or we are in the process of making a large appropriation on an emergency basis for the administration's programs, including the funding in Iraq.

But it seems to me that with the very heavy responsibilities which your Department has, that a decrease in the budget of $1.1 billion, almost 10 percent from the fiscal year 2007 level, is hard to sustain.

If there is going to be this kind of a cut, there are going to have to be some very important programs affected. The $1 billion decrease in job training and employment services, is a real problem. It impacts directly upon juvenile crime. As does the $55 million cut in the Job Corps.

You have the prisoner reentry initiative and the reintegration of ex-offenders, with a decrease of $25.4 million. These cuts will be very, very difficult to sustain, given the issues which that funding addresses.

We will, obviously, be taking a very, very close look at these recommendations. On our constitutional responsibility to appropriate, we will be putting our own imprint on the budget, as we always do. But we thank you for your hard work and your diligence, and look forward to your testimony.

Senator HARKIN. Thank you very much. Secretary Elaine Chao was sworn in as the twenty-fourth Secretary of Labor on January

31, 2001. She is the first Asian-American woman appointed to the President's cabinet in U.S. history.

Secretary Chao was president and CEO of the United Way Foundation from 1992 to 1996, and served as Director of the Peace Corps and Deputy Secretary of the Department of Transportation under former President Bush.

Most recently, she was a distinguished fellow at the Heritage Foundation. Secretary Chao received her MBA from Harvard Business School and her undergraduate degree from Mount Holyoke College. She also studied at M.I.T., Dartmouth, and Columbia University.

Madam Secretary, my first question for you—are you the longest-serving Labor secretary?

Secretary CHAO. No. I am not.

Senator HARKIN. Oh.

Secretary CHAO. Frances Perkins was Secretary of Labor for 12 years, under Franklin Delano Roosevelt. There was also Mr. Wilson.

Senator HARKIN. Has anyone served longer as a secretary in the administration of George W. Bush?

Secretary CHAO. I am probably the longest serving. Since the 1960s, I am probably the longest-serving Secretary of Labor.

Senator HARKIN. Very good. Welcome, Madam Secretary. And please proceed.

SUMMARY STATEMENT OF HON. ELAINE L. CHAO

Secretary CHAO. Thank you. Mr. Chairman, I have got a longer statement, which I will leave for the record. And then I have a shorter statement. I will go through it very quickly.

Senator HARKIN. That will be great.

Secretary CHAO. I will just go through some of the numbers, which we know already. But just also emphasize some of the priorities.

Chairman Harkin, Senator Specter, thank you for the opportunity to present the administration's fiscal year 2008 budget for the Department of Labor. The total budget for the Department is $50.4 billion, of which $10.6 billion is for discretionary spending. The Department's fiscal year 2008 budget focuses on four overall priorities: Protecting workers' health and safety; protecting workers' pay, benefits, pensions, and union dues; securing the employment rights of America's veterans; and increasing the competitiveness of America's workforce.

In fiscal year 2008, $1.5 billion is requested for the Department's worker protection programs. The fiscal year 2008 budget request for MSHA is $313.5 million, and 2,306 FTEs. The request will allow MSHA to continue implementing the historic MINER Act. This request also includes $16.6 million specifically targeted to retain the 170 mine and safety enforcement personnel that were added in 2006 and 2007.

The budget would support MSHA's efforts to provide for the following: approval of emergency response plans; strengthening compliance for increased civil penalties; improving the safety of abandoned areas of mines and increasing the effectiveness of mine rescue teams.

This request will also enable MSHA to continue testing and evaluating promising new technologies that could be deployed in support of mine rescue operations.

The fiscal year 2008 request also includes $490.3 million and 2,186 FTEs for OSHA. This request will enable OSHA to focus its enforcement efforts on high hazard industries that typically employ disproportionate numbers of low-wage, vulnerable workers.

The fiscal year 2008 budget request before this committee for the Employment Standards Administration is $699.6 million and an FTE of 4,082. The request for ESA includes $182.4 million, and 1,336 FTEs for the wage and hour division. The request for wage and hour includes funding for additional inspectors, enhanced enforcement in low waging industries, and a legislative proposal to increase civil monetary policies associated with the violation of child labor laws.

The ESA request also includes $84.2 million and 625 FTEs for the Office of Federal and Contract Compliance Programs, OFCCP, to protect workers from discrimination by, obviously, Federal contractors. Another $106.6 million and 867 FTEs are requested for the Office of Workers' Compensation Programs. ESA also requests an additional $56.9 million and 369 FTEs for the Office of Labor-Management Standards.

For the Employee Benefits Security Administration, EBSA, which protects the health and retirement benefits of 150 million workers, the fiscal year 2008 budget request is $147.4 million, and 855 FTE.

This request will enable EBSA to implement important regulations required under the Pension Protection Act, including making it easy for Americans to save for retirement, ensuring that the pension promises made to workers are kept, and that retirement security for workers is, indeed, maintained.

Then on your point, Mr. Chairman, as we all know, the United States is transitioning to a knowledge-based economy, closely intertwined with the worldwide economy. Our country's worker training programs need to keep pace with these developments. We need to equip workers with the skills needed to succeed in this new economic environment.

The fiscal year 2008 budget request includes $8.3 billion and 1,196 FTEs for the Department's Employment and Training Administration, ETA. This request includes proposals for innovative reforms that will increase the quality of the training offered, as well as the number of workers trained.

The next priority is this Nation's commitment to our veterans must be honored. The Department is committed to providing returning veterans with the support needed to make the transition back to the non-military workforce a smooth and successful one.

So for the Department's Veterans' Employment and Training Service, the fiscal year 2008 budget request is $228.1 million and 244 FTEs. This will enable VETS to maximize employment opportunities for veterans and protect their employment and re-employment rights.

PREPARED STATEMENT

So, Mr. Chairman, the Department's fiscal year 2008 budget request will enable us to meet our key priorities. That is protecting workers, preparing workers for the 21st century workforce and economy, ensuring veterans' employment and re-employment rights, and maintaining fiscal discipline.

I will be happy to answer any questions.

Senator HARKIN. Yes, your statement, full statement will be made part of the record in its entirety.

Secretary CHAO. Thank you.

[The statement follows:]

PREPARED STATEMENT OF HON. ELAINE L. CHAO

Good morning Mr. Chairman, Ranking Member Specter, distinguished Members of the Subcommittee, ladies and gentlemen. Thank you for the opportunity to appear before you today to present the fiscal year 2008 budget for the Department of Labor.

The total request for the Department in fiscal year 2008 is $50.4 billion and 16,869 FTE, of which $15.4 billion is before the Committee. Of that amount, $10.6 billion is requested for discretionary budget authority. Our budget request will allow us to build on the accomplishments achieved in recent years and enable the Department to meet its critical priorities for fiscal year 2008, while helping to achieve the President's deficit reduction goals by reforming programs and reducing or eliminating ineffective or duplicative activities.

As the President has noted, our country's economy is strong and growing. We have seen:

—42 months of uninterrupted job growth;
—7.6 million new jobs created since August 2003;
—An unemployment rate that has fallen to 4.5 percent since June 2003;
—An increase in average hourly earnings of 4.1 percent over the past 12 months (before adjustment for inflation); and
—GDP growth of 3.1 percent in 2006.

These achievements are a tribute to the flexibility of our workforce and the dynamism of our economy. The Department's fiscal year 2008 budget will promote continued economic growth by strengthening the health, safety, and competitiveness of our Nation's vibrant workforce.

RECENT ACCOMPLISHMENTS

As an introduction to the fiscal year 2008 budget, I would like to highlight some of the Department's recent accomplishments, which reflect the strong enforcement of worker protection laws and efforts to assist American workers. For example:

—In 2006, the Employee Benefits Security Administration achieved monetary results in the protection of workers' pension and health benefits that were 94 percent higher than in 2001.
—Since 2001, there has been a nearly 7 percent reduction in the fatality rate, an achievement that can be partially attributed to the Occupational Safety and Health Administration's enforcement and cooperative programs. The fatality rate among Hispanic workers has fallen by 18 percent during the same period. There has been a more than 13 percent reduction in the overall injury and illness rate since 2002.
—In 2006, as a result of the Wage and Hour Division's enforcement, more than 246,000 workers received $172 million in back wages, including overtime. This is a 30 percent increase over the amount of back wages recovered in 2001.
—The Office of Federal Contract Compliance Programs has posted record results in enforcing equal opportunity rights for employees of Federal contractors, with an increase in financial recoveries of nearly 80 percent between 2001 and 2006. In 2006, OFCCP recovered $52 million in back pay, salaries, and benefits for over 15,000 employees.
—The Employment and Training Administration has enhanced its services to American workers through innovative initiatives designed to link economic development, education and workforce development.

FISCAL YEAR 2008 PRIORITIES

The Department's fiscal year 2008 budget seeks to build on the success of previous years. The budget features three overall priorities: protecting workers' safety and health; protecting workers' pay, benefits, pensions, and union dues; and increasing the competitiveness of America's workforce.

PROTECTING WORKERS' SAFETY AND HEALTH

The 2008 budget includes $1.5 billion in discretionary funds for DOL's worker protection activities. This funding level will enable the Department to continue its record-setting protection of workers' health, safety, pay, benefits and union dues.

Mine Safety and Health Administration (MSHA)

The fiscal year 2008 budget request for MSHA is $313.5 million and 2,306 FTE. The request will allow MSHA to continue implementing the historic Mine Improvement and New Emergency Response (MINER) Act, the most sweeping mine safety legislation in 30 years.

Since the President signed the MINER Act of 2006, the Department has taken aggressive action to implement and enforce the Act. For example, we have:

—Established new policies regarding the approval of Emergency Response Plans and the creation of a Family Liaison program;
—Proposed regulations to increase the Civil Penalties for violations of safety and health standards;
—Issued information bulletins regarding the provision of post-accident breathable air to trapped miners and guidance for sealing abandoned areas of mines;
—Initiated rulemaking to develop new standards for Mine Rescue Teams;
—Coordinated the first meeting of the Belt Air and Conveyor Belt Materials technical study panel to review the use of belt air to ventilate the mine production area;
—Begun to aggressively hire and train 170 new mine safety enforcement personnel; and
—Issued an Emergency Mine Evacuation Final Rule (ETS).

The fiscal year 2008 budget will allow the Department to continue these efforts and improve the health and safety of all miners. The request includes $16.6 million specifically targeted to retain the 170 coal enforcement personnel that were added in 2006 and 2007 in response to the increase in coal mine fatalities. The budget will support MSHA's efforts to provide for approval of Emergency Response Plans; strengthen compliance through increased civil penalties; improve the safety of abandoned areas of mines; and increase the effectiveness of mine rescue teams. The request allows MSHA to continue testing and evaluating promising new technologies that could be deployed in support of mine rescue operations.

Occupational Safety and Health Administration (OSHA)

The fiscal year 2008 budget request for OSHA is $490.3 million and 2,186 FTE. The request provides resources to support 89,700 Federal and State safety and health inspections.

With an emphasis on enforcement, complemented by compliance assistance, OSHA will focus on those high-hazard industries where we typically find large numbers of non-English speaking workers. In fiscal year 2008, all elements of OSHA's intervention strategies—enforcement, training, compliance assistance, outreach, cooperative programs and guidelines—will be brought to bear to protect this vulnerable population. The request for OSHA includes $4.6 million and 13 FTE to expand OSHA's Voluntary Protection Programs (VPP), a cooperative health and safety recognition program that has been very effective in reducing illness and injury rates. Employers participating in VPP achieve lost-time injury and illness rates that are 50 percent lower than their industry average.

PROTECTING WORKERS' PAY, BENEFITS, AND UNION DUES

The Department will also continue its high priority programs to protect workers' pay, benefits, and union dues.

Employment Standards Administration

The Department's Employment Standards Administration (ESA) administers and enforces a variety of laws designed to enhance the welfare and protect the rights of American workers. The fiscal year 2008 budget request for administrative expenses for ESA is $699.6 million and 4,082 FTE.

Wage and Hour Division

The Wage and Hour Division is responsible for the administration and enforcement of a wide range of worker protection laws, including the Fair Labor Standards Act, Family and Medical Leave Act, Migrant and Seasonal Agricultural Worker Protection Act, worker protections provided in several temporary non-immigrant visa programs, and prevailing wage requirements of the Davis-Bacon Act and the Service Contract Act. These laws collectively cover virtually all private sector workers, as well as State and local government employees.

The fiscal year 2008 budget also includes resources to hire additional Wage and Hour investigators to strengthen enforcement resources for industries and workplaces that employ low-wage, immigrant workers. The budget also re-proposes legislation to increase civil monetary penalties associated with violation of child labor laws, raising the penalties from $11,000 to $50,000 for violations that result in the death or serious injury of youth in the workplace, and increasing the penalty to $100,000 for willful or repeat violations that result in death or serious injury. The administration expects to transmit legislation to the 110th Congress shortly, and urges Congress to act swiftly to pass it.

The fiscal year 2008 budget request for the Wage and Hour Division totals $182.4 million and 1,336 FTE, which excludes $31.0 million in estimated fee revenue from DOL's portion of the H–1B visa fraud prevention fee authorized by the 2004 H–1B Visa Reform Act. Given strict statutory limits on the use of these funds DOL has been unable to spend more than $5 million in any single year and entered 2007 with more than $60 million in unspent balances. The fiscal year 2008 budget cancels $50 million of these balances and amends the Immigration and Nationality Act to permit a more effective use of the fraud prevention fees collected under this provision going forward.

Office of Federal Contract Compliance

The fiscal year 2008 budget request for the Office of Federal Contract Compliance Programs (OFCCP) totals $84.2 million and 625 FTE. OFCCP is responsible for ensuring equal employment opportunity and non-discrimination in employment for businesses contracting with the Federal Government. OFCCP carries out this mandate by conducting compliance evaluations to identify instances of systemic discrimination in the workplace, taking appropriate enforcement action, and providing relevant and effective compliance assistance programs. During fiscal year 2008, OFCCP will use its Active Case Management and Functional Affirmative Action Programs to target non-compliant contractors and continue to improve the effectiveness of OFCCP's enforcement activities, meaning more workers will be protected.

Office of Workers' Compensation Programs

The fiscal year 2008 discretionary budget request for administration of the Office of Workers' Compensation Programs (OWCP) totals $106.6 million and 867 FTE to support the Federal Employees' Compensation Act (FECA) ($93.4 million) and the Longshore and Harbor Workers' Compensation program ($13.2 million).

The OWCP budget also includes mandatory funding totaling $104.7 million (including $55.4 million for HHS/NIOSH) and 275 FTE to administer Part B of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), and $56.9 million and 189 FTE for Part E of the act. EEOICPA provides compensation and medical benefits to employees or survivors of employees of the Department of Energy and certain of its contractors and subcontractors, who suffer from a radiation-related cancer, beryllium-related disease, chronic silicosis or other covered illness as a result of work at covered Department of Energy or DOE contractor facilities.

Lastly, OWCP's fiscal year 2008 budget includes $37.6 million in mandatory funding and 201 FTE for its administration of Parts B and C of the Black Lung Benefits Act, and $52.3 million and 127 FTE in FECA Fair Share administrative funding.

The 2008 budget includes two legislative proposals affecting OWCP programs that play a critical role in protecting workers' economic security, by providing monetary and medical benefits to Federal employees and coal miners whose ability to work has been diminished by an occupational injury or illness. The first re-proposes reforms to the Federal Employees Compensation Act to update its benefit structure, adopt best practices of State workers' compensation systems, and strengthen return-to-work incentives. This proposal is expected to generate Government-wide savings of $608 million over 10 years. The second is a proposal to restructure, and eventually retire, the mounting debt of the Black Lung Disability Trust Fund—a debt that now approaches $10 billion.

Office of Labor-Management Standards

The fiscal year 2008 budget request for the Office of Labor-Management Standards (OLMS) totals $56.9 million and 369 FTE. OLMS enforces provisions of Federal law that establish standards for union democracy and financial integrity. OLMS conducts investigative audits and criminal investigations for embezzlement and other financial mismanagement; conducts civil investigations of union officer elections and supervises remedial elections where required; administers statutory union financial reporting requirements; and provides for public disclosure of filed reports. OLMS also administers employee protective provisions created under Federal transit legislation.

The resources requested will allow OLMS to continue to further the goals of financial integrity, union democracy, and transparency. The budget also supports legislation that would authorize OLMS to impose civil money penalties on unions and others that fail to file required financial reports on a timely basis.

Employee Benefits Security Administration

The Department's Employee Benefits Security Administration (EBSA) protects the integrity of pensions, health plans, and other employee benefits for more than 150 million workers. The fiscal year 2008 budget request for EBSA is $147.4 million and 855 FTE. The request includes a $5.5 million increase to be supplemented with $2.5 million of agency-absorbed costs to complete the replacement of EBSA's outdated, paper-based ERISA Filing and Acceptance System, known as EFAST. I note that the amount of the fiscal year 2008 EFAST2 funding request may be reduced pending the final resolution of EFAST2 funding in fiscal year 2007, and we appreciate the opportunity to continue working with the committee on this important project. The new electronic filing system for Form 5500 reports will strengthen the protection of employee benefits by greatly reducing processing times for Form 5500 filings and improving the reliability of Form 5500 data. By making data on the funding of pension and other benefit plans more transparent and accessible, this new system will support the President's efforts to strengthen retirement security for the Nation's workers and retirees.

Pension Benefit Guaranty Corporation

The Pension Protection Act of 2006 made important structural reforms to the defined benefit pension system, but further premium changes are needed to restore long-term solvency to the pension insurance program. The President's fiscal year 2008 budget proposes to adjust insurance premiums paid by underfunded pension plans to address the nearly $19 billion gap between the liabilities and assets of the Pension Benefit Guaranty Corporation (PBGC). Although PBGC will be able to pay benefits for some years to come, it is projected to be unable to meet its long-term obligations under current law. The proposed reforms would improve PBGC's financial condition and safeguard the future benefits of workers and retirees.

PREPARING WORKERS FOR NEW OPPORTUNITIES

Reforming the Workforce Investment System

The fiscal year 2008 budget request for the Department's Employment and Training Administration (ETA) is $8.3 billion in discretionary funds and 1,196 FTE, not including the 120 FTE associated with the PERM fee legislative proposal. Through innovative reforms, the budget request for ETA will allow the Department to increase the competitiveness of the American workforce in a knowledge-based economy.

The United States competes in a global economy that is far different from the international markets of the past. As our Nation's economy and businesses transform to meet the challenges of the 21st century, so too must the government systems and structures that support our economic growth and job creation.

The President has sought to transform worker training programs into a demand-driven system that prepares workers for jobs in growth sectors of the economy. The workforce investment system should recognize and strengthen workers' ownership of their careers, and provide more flexible resources and services designed to meet their changing needs.

American workers will need higher levels of education and skills than at any time in our history, as evidenced by the fact that almost 90 percent of new jobs in high-growth, high-wage occupations are expected to be filled by workers with at least some post-secondary education. However, the current workforce investment system does not provide the necessary educational and training opportunities for workers. Too much money is spent on competing bureaucracies, overhead costs, and unneces-

sary infrastructure, and not enough on meaningful skills training that leads to employment opportunities and advancement for workers.

To increase the quality of training offered, as well as the number of workers trained, the Department proposes legislative reforms to consolidate funds for the following programs into a single funding stream:

—Workforce Investment Act (WIA) Adult Program;
—WIA Dislocated Worker Program;
—WIA Youth Program; and
—Employment Service programs (including Employment Service formula grants, labor market information grants, and grants for administration of the Work Opportunity Tax Credit and the Welfare-to-Work Tax Credit).

States would use these funds primarily to provide Career Advancement Accounts (CAAs) to individuals who need employment assistance. CAAs are self-directed accounts of up to $3,000, an amount sufficient to finance approximately 1 year's study at a community college. The accounts could be renewed for one additional year, for a total 2-year account amount of up to $6,000 per worker. CAAs would be used to pay for expenses directly related to education and training. The accounts would be available to both adults and out-of-school youth entering the workforce or transitioning between jobs, and incumbent workers in need of new skills to remain employed. The funds would also be used by States to provide basic employment services such as career assessment, workforce information, and job search assistance to job seekers. By removing bureaucratic restrictions that can prevent workers from being trained, increasing the flexibility of State and local officials to shift funding to where it is most needed, and requiring the majority of dollars in the system to be spent on training instead of infrastructure, these reforms will significantly increase the number of individuals who receive job training and attain new and higher-level job skills.

Community-Based Job Training Initiative

The fiscal year 2008 budget provides $150 million for the fourth year of grants under the President's Community-Based Job Training Initiative. This competitive grant program leverages the expertise of America's community colleges and takes advantage of the strong natural links between community colleges, local labor markets and employers to train workers for jobs in high-demand industries. In October 2005, the Department awarded the first grants totaling $125 million to 70 community colleges in 40 States. A second competition for Community-Based Job Training Grants was held in the summer of 2006, and in December 2006, the Department awarded $125 million in grants to 72 entities in 34 States. These grants will be used to increase the capacity of community colleges to provide training in local high growth, high demand industries and train new and experienced workers for jobs in these industries. The Department plans to hold the competition for the fiscal year 2007 Community-Based Job Training Grants in the summer of 2007.

YouthBuild

In the summer of 2006, Congress unanimously passed the YouthBuild Transfer Act to transfer the YouthBuild program from the Department of Housing and Urban Development to the Department of Labor, as recommended by the White House Task Force on Disadvantaged Youth. The fiscal year 2008 budget includes $50 million for YouthBuild to provide competitive grants to local organizations for the education and training of disadvantaged youth age 16–24. Under these grants, youth will participate in classroom training as well as learn construction skills by helping to build affordable housing. Within DOL, YouthBuild will take advantage of better connections to the workforce investment system, closer association with occupational safety and health and youth employment protection programs, stronger ties to Job Corps and apprenticeship programs, new links to the President's High Growth Job Training Initiative, improved access to the postsecondary and community college system, and stronger connections to employers and local labor markets.

Reintegration of Ex-Offenders

The fiscal year 2008 budget requests $39.6 million for a program that brings together the President's Prisoner Re-entry Initiative (PRI) and the Responsible Reintegration of Youthful Offenders (RRYO) program. This new consolidated program would avoid the duplication of efforts that currently exists between PRI and RRYO and adopt the practices of these two efforts that have shown great promise in boosting employment and reducing recidivism among ex-offenders. Through competitively awarded, employment-centered grants that holistically address the multiple challenges facing offenders upon their release, the Reintegration of Ex-Offenders program would tap the unique strength, networks, and relationships of faith-based and

community organizations to reach out to ex-offenders to help them find jobs and build new lives.

Strengthening Unemployment Insurance Integrity and Promoting Re-Employment

The fiscal year 2008 budget continues the administration's efforts to ensure the financial integrity of the Unemployment Insurance (UI) system, and help unemployed workers return to work promptly. Our three-pronged approach includes:

—A package of legislative changes that would prevent, identify, and collect UI overpayments and delinquent employer taxes. These changes include: allowing States to use a small amount of recovered overpayments and collected delinquent taxes to support additional integrity efforts; authorizing the U.S. Treasury to recover UI benefit overpayments and certain delinquent employer taxes from Federal income tax refunds; requiring States to impose a penalty on UI benefits that individuals obtain through fraud and using those funds for integrity activities; and requiring employers to include a "start work" date on New Hire reports to help identify persons who have returned to work but continue to receive UI benefits. We estimate that these legislative proposals would reduce overpayments and increase recoveries and delinquent tax collections by a total of $2.3 billion over 5 years.

—A $40 million discretionary funding increase to expand Reemployment and Eligibility Assessments (REAs), which review UI beneficiaries' need for reemployment services and their continuing eligibility for benefits through in-person interviews in One-Stop Career Centers. This initiative already has yielded quicker returns to work for UI beneficiaries. We estimate that annual benefit savings of $205 million could result from this investment.

—A legislative proposal to permit waivers of certain Federal requirements to allow States to experiment with innovative projects aimed at improving administration of the UI program, and speeding the reemployment of UI beneficiaries.

We urge the Congress to act on these important proposals to strengthen the financial integrity of the UI system and help unemployed workers return to work.

Senior Community Service Employment Program

The fiscal year 2008 budget requests $350 million for the Senior Community Service Employment Program (SCSEP). The Department is pleased that the recently reauthorized Older Americans Act includes many of the administration's reform proposals to streamline SCSEP and increase the number of persons who may enjoy the benefits of unsubsidized employment. The Department expects that legislative reforms will improve program efficiency and reduce costs compared to the previous program design. We are optimistic that the important reforms included in SCSEP reauthorization—including the elimination of inappropriate fringe benefits, caps on the duration of program participation, additional flexibility to provide training, and increased emphasis on placement in unsubsidized employment—will allow SCSEP to use funds more efficiently, serve more participants per dollar, and allow participants to achieve greater economic self-sufficiency than ever before.

Job Corps Transfer

The budget includes $1.5 billion to operate a nationwide network of 123 Job Corps centers in fiscal year 2008. Job Corps provides training to address the individual needs of at-risk youth and ultimately equip them to become qualified candidates for the world of work. In the fiscal year 2006 appropriation act, the Congress directed the Department to transfer the Job Corps program out of the Employment and Training Administration (ETA) into the Office of the Secretary. The 2008 budget proposes to return the program to ETA, where it had been administered for more than 30 years, to ensure close coordination with the other job training and employment programs administered by ETA, including the YouthBuild program. Moving the program back to ETA will ensure these young people have access to the principal experts on labor markets as well as other youth employment programs.

OTHER PROGRAMS

Veterans' Employment and Training Service

This Nation's commitment to our veterans must be honored. No veteran should return home without the support that is needed to make the transition back to private life a smooth and successful one. For the Department's Veterans' Employment and Training Service (VETS), the fiscal year 2008 budget request is $228.1 million and 244 FTE. This will enable VETS to maximize employment opportunities for veterans and protect their employment and reemployment rights.

The $161.9 million requested for State grants will help over approximately 700,000 veterans seeking reemployment services. The fiscal year 2008 budget in-

cludes $23.6 million for the Homeless Veterans Reintegration Program (HVRP), allowing the program to provide employment and training assistance to an estimated 15,100 homeless veterans. In addition, the budget requests an additional $2.5 million to meet the increased demand for Transition Assistance Program (TAP) services. It is projected that the number of departing service members receiving TAP Employment Workshops will increase from 160,000 in fiscal year 2007 to 170,000 in fiscal year 2008. TAP Workshops play a key role in reducing jobless spells and helping service members transition successfully to civilian employment. The fiscal year 2008 request will also enable VETS staff to carefully monitor our performance in administering the Uniformed Services Employment and Reemployment Rights Act (USERRA) to protect the civilian job rights and benefits of veterans and members of the armed forces, including members of the Guard and Reserve and others.

Bureau of Labor Statistics

In order to maintain the development of timely and accurate statistics on major labor market indicators, the fiscal year 2008 budget provides the Bureau of Labor Statistics (BLS) with $574.4 million and 2,431 FTE. This funding level provides BLS with the necessary resources to continue producing sensitive and critical economic data, including the Consumer Price Index (CPI) and the monthly Employment Situation report. The CPI is a key measure of the Nation's economic well-being that directly affects the income of millions of Americans. To ensure that the CPI is accurate and up-to-date, the budget includes funding of $10.4 million to continually update the housing and geographic samples that underlie the index to ensure that these samples fully incorporate the most recent demographic and geographic trends and changes. The current sample was derived from the 1990 Census and has not been updated since the late 1990s.

Office of Disability Employment Policy

The fiscal year 2008 budget request provides the Office of Disability Employment Policy (ODEP) with a total of $18.6 million and 40 FTE. The fiscal year 2008 budget reflects a decrease in ODEP's grantmaking function, which duplicates those of other Federal agencies like the Department of Education. The fiscal year 2008 budget focuses ODEP on its core and critical mission of providing national leadership in developing disability employment policy and influencing its implementation to increase employment opportunities and the recruitment, retention and promotion of people with disabilities.

Bureau of International Labor Affairs

The request for the Bureau of International Labor Affairs (ILAB) in fiscal year 2008 is $14.1 million and 58 FTE. In recent years, ILAB has had a very large grantmaking function, duplicating activities that are carried out by State, USAID, and other agencies with a larger role in international affairs. The budget returns ILAB to its core mission of developing international labor policy and performing research, analysis, and advocacy. It also includes $1.5 million to allow ILAB to monitor the use of forced labor and child labor in violation of international standards, as required in the Trafficking Victims Protection Reauthorization Act (TVPRA) of 2005.

The requested funding levels would allow ILAB to implement the labor supplementary agreement to NAFTA and the labor provisions of trade agreements negotiated under the Trade Act of 2002, participate in the formulation of U.S. trade policy and negotiation of trade agreements, conduct research and report on global working conditions, assess the impact on U.S. employment of trade agreements, and represent the U.S. Government before international labor organizations, including the International Labor Organization.

ILAB will continue to implement ongoing efforts in more than 70 countries funded in previous years to eliminate the worst forms of child labor and promote the application of core labor standards.

Office of the Solicitor

The fiscal year 2008 budget includes $103.1 million and 643 FTE for the Office of the Solicitor (SOL). This amount includes $95.5 million in discretionary resources and $7.7 million in mandatory funding. The Solicitor's Office provides the legal services that support the Department, including the Department's enforcement programs. This appropriation level will allow SOL to provide legal services for the nearly 200 laws the Department must enforce, including new legislation that Congress recently passed to strengthen mine safety and retirement security. The fiscal year 2008 budget includes $3.5 million and 23 FTE to provide additional legal support for DOL client agencies, and $4.4 million to support 30 FTE who are currently providing certain auxiliary administrative services to client agencies that are closely re-

lated to legal services provided by SOL. The requested appropriation level is essential to allow SOL to fulfill its primary mission of ensuring that the Nation's labor laws are forcefully and fairly applied.

Women's Bureau

The fiscal year 2008 budget includes $9.8 million and 60 FTE for the Women's Bureau. This budget will allow the Women's Bureau to continue its mission of designing innovative projects addressing issues of importance to working women and providing information about programs and polices that help women succeed in the 21st century workplace.

President's Management Agenda and Department-wide Management Initiatives

Before I close today, Mr. Chairman, I also want to highlight the Department's ongoing efforts to implement the President's Management Agenda. In August 2001, President Bush sent to Congress his President's Management Agenda (PMA), a strategy for improving the management and performance of the Federal government. The agenda called for focused efforts in the following five government-wide initiatives aimed at improving results for citizens: Strategic Management of Human Capital; Competitive Sourcing, Improved Financial Performance; Expanded Electronic Government; and budget and Performance Integration. DOL is also responsible for three of the PMA initiatives that are found only in selected departments: Faith-Based and Community Initiatives; Real Property Asset Management; and Eliminating Improper Payments.

I am proud to say that the Department was the first Cabinet agency to earn "green" ratings in all five government-wide PMA scorecards. By the close of fiscal year 2006, the Department had achieved two additional "green" ratings, for its efforts to Eliminate Improper Payments and support the President's Faith-Based and Community Initiative. In December 2006, DOL was honored with the President's Quality Award for excellence in Expanded Electronic Government, in addition to previous presidential honors received for management excellence.

The Program Assessment Rating Tool, or PART, is central to our efforts at the Department of Labor to improve the performance of our programs. To date, 32 DOL programs have been assessed through the PART. The PART assessments have not only been useful to informing the public and policy makers of our programs' strengths and weaknesses, but they have provided our programs and their managers a systematic method of self-assessment. A PART review helps inform both funding and management decisions aimed at making programs more effective. The Department is actively implementing program improvements identified through PART assessments and its 5-year plan to conduct re-assessments of programs that have previously undergone a PART review.

CONCLUSION

With the resources we have requested for fiscal year 2008, the Department will continue its strong enforcement of worker protection laws, provide innovative programs to increase the competitiveness of our Nation's workers, secure the employment rights of veterans, and maintain fiscal discipline.

Mr. Chairman, this is an overview of the programs we have planned at the Department of Labor for fiscal year 2008.

I am happy to respond to any questions that you may have.

Thank you.

OTTUMWA JOB CORPS CENTER

Senator HARKIN. We will start with a round of questions.

First of all, Madam Secretary, I started out by congratulating you and thanking you for your work on getting these three Job Corps things designated in New Hampshire, Wyoming, and in Iowa; Ottumwa, Iowa. But we hear things from different sources, and just the other day I heard from a source that said that maybe the Ottumwa Job Corps center is going to be delayed.

Secretary CHAO. Oh, we hope not.

Senator HARKIN. Oh, okay. I just want reassurance. I hear it might be delayed perhaps up to 8 years.

Secretary CHAO. Oh. I hope not. That is not our intent. We are going ahead with the design and construction.

Senator HARKIN. Okay.

Secretary CHAO. Each Job Corps center costs about $40 million.

Senator HARKIN. Right.

Secretary CHAO. There are different phases. So I do not see any delays in that.

Senator HARKIN. In all three of them?

Secretary CHAO. We do not anticipate delays. Unless there are funding issues. But it is never the practice to fund 100 percent up front anyway.

Senator HARKIN. Okay. But when are you going to——

Secretary CHAO. I think that——

Senator HARKIN. When are you going to finalize the Ottumwa center? I do not know about the other two, but——

Secretary CHAO. There are design—there are planning, feasibility studies, design, construction. So it is a multi-year project. We do not anticipate delaying it. It is on target, as far as I know.

Senator HARKIN. Okay.

Secretary CHAO. We are proceeding with planning——

Senator HARKIN. Yes.

Secretary CHAO [continuing]. The satellite facility in Iowa. We know, also, the priorities of this committee on these issues.

Senator HARKIN. Yes. Well, I appreciate that. I was told, correct me if I am wrong, that the Ottumwa is to be looking at opening sometime by 2010. Is that——

Secretary CHAO. That might be possible. It takes about 4 years to go through the planning. Because there is—you have to go—it takes about a year for the planning. It takes another year for the design. It takes a couple of years for construction. But those are usual planning——

Senator HARKIN. Okay. But there is nothing——

Secretary CHAO [continuing]. Time lines, so——

Senator HARKIN [continuing]. That you know of that is going to be delaying this at all.

Secretary CHAO. No, Mr. Chairman. I would also assure you that, again, we know how important this——

Senator HARKIN. Okay. Thank you.

Secretary CHAO [continuing]. Issue is.

FMLA ENFORCEMENT

Senator HARKIN. Thank you very much. There was one—oh, yes. I have been contacted by a number of Iowans who have told me that Wage and Hour in Iowa is telling them that if they belong to a union, they cannot ask Wage and Hour to intervene on their behalf in resolving Family Medical Leave Act enforcement. Rather, it is up to them to go through the labor management grievance process instead. Then even if they cannot resolve the situation satisfactorily, they still cannot even appeal that decision to Wage and Hour.

My question is: Is this action by Wage and Hour in Iowa coming from some DOL directive that I do not know about, and that we have not seen?

Secretary CHAO. I am not aware of that complaint. I will be more than glad to look into it.

Senator HARKIN. Would you, please?

Secretary CHAO. There is a lot of—Family Medical Leave was, obviously, passed in 1993. Regulations are promulgated. There have been a number of court challenges. It has been very confusing. But I have not heard that one. So I will be more than glad to take a look at that.

Senator HARKIN. I wish you would. I would like to resolve this. Do you feel that DOL is doing what it can to proactively improve overall FMLA compliance and employee understanding of their rights?

Secretary CHAO. Enforcement of the law is always our priority. So we are always very concerned when there are any lapses or any non-compliance. We enforce the law.

Senator HARKIN. Well, let us look at that one in Iowa and see what is happening there.

Secretary CHAO. I will do so.

FUNDING FOR INTERNATIONAL CHILD LABOR

Senator HARKIN. I would appreciate that. International child labor. One of my priorities as you know. Has been for a long time. The fiscal year 2008 budget requests $14 million for international labor affairs. A decrease of $58.4 million from last year. An 80 percent cut.

Well, that is just like tearing it out. This would cause reduction of 27 FTEs, and significant reduction in grants for technical assistance on ending international child labor. Madam Secretary, could you, again, just tell us why you are proposing to cut funds for fighting international child labor? What is the reasoning behind this?

Secretary CHAO. We care about this issue. Mr. Chairman, I think we have talked about this before. We are just going to have to respectfully disagree.

ILAB was an organization that was fairly small. I know that in 1996, this committee gave ILAB about $76 million, $74 million. In 2000, it increased the budget further to about $147 million.

Senator HARKIN. That was under his chairmanship.

Secretary CHAO. We know this is a priority, but the administration respectfully disagrees with the mission of this organization. We believe that it should be pared back to its original mission of providing technical assistance, providing participation at the ILO, working on advocacy and increasing core labor standards. That grant making is not really a function that was the original intent of this organization. But we care about this issue. Obviously, when given the money, we have used it wisely.

Senator HARKIN. But it is all right to care about it.

Secretary CHAO. Yes.

Senator HARKIN. We all care about it. But we are trying to do something about it. Quite frankly, the Department of Labor has done some really good things in the past, both before you and in your earlier time—I mean in your first few years. But lately, it seems like we are just totally backing off of this. At a time when the ILO and others, they are making—they are saying, "Things are—you know, things are happening. These things take time."

Once we started on this back in the 1990s, and we kept at it, as I said, we have actually seen some discernible progress. Also, in the past couple of years, the Department of State has come to the De-

partment of Labor to carry out projects and workers' rights, in relation to CAFTA, the Central American Free Trade Agreement.

So when I see something like that, obviously, the Department of State is saying, "You have the expertise. You know how to do it." They come to you to ask you to handle it. So it is not that somebody else is going to pick this up someplace. It is the Department of Labor. I just do not think that it is befitting a great Nation like ours, that has put so much stock in human rights and the value of children, to make sure that children are not abused, and make sure that they get a decent education, and that they are not exploited.

I think it is one of the best faces that America can give the rest of the world. That is to help try to end this exploitative labor of children in other countries. I visited some of these things around the world. The reverberations are great.

When we work on that and—and I am just telling you, it has been one of the best, I think, reflections of America anywhere in the world. We may respectfully disagree on it, but this is something that this committee has charged the Department of Labor to do, and we will again.

Secretary CHAO. Yes, I understand.

Senator HARKIN. I am just sorry to see that we are having this conflict on it. Because I just do not think we want to back down on that one and back off of what we have been doing around the world.

CAFTA FUNDING

Secretary CHAO. We agree with you on the goals. I think the disagreement, perhaps, may be that we are just not quite sure this is the right agency or the organization with which to channel these funds.

On the State Department, the CAFTA, we got additional funding for that. The money was——

Senator HARKIN. They transferred money over.

Secretary CHAO. Yes. It was given to us. Yes.

Senator HARKIN. They gave you money——

Secretary CHAO. Right.

Senator HARKIN [continuing]. To do it.

Secretary CHAO. But it was given to State. No. I agree with you. So the State Department gave it to us.

Senator HARKIN. Yes.

Secretary CHAO. We will do the same thing.

Senator HARKIN. You seem to indicate——

Secretary CHAO. We will do the same thing. We were given the money. We will do the same thing.

Senator HARKIN. We are going to give you money, and we are going to ask you to enforce it.

Secretary CHAO. We will do so.

Senator HARKIN. All right, Madam Secretary. Well, you know that we are going to be tough on it. Well, my time has run out. I am going to yield this round and I will yield to Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman.

Secretary Chao, at the outset, I would associate myself with the remarks that Senator Harkin made about the international child

labor issue. He has emphasized it sufficiently. But I just want you to know that he has my concurrence.

JOB TRAINING FUNDING

On the issue of the cuts which are made for job training and Job Corps, and the prisoner reentry initiative, and reintegration of ex-offenders, Madam Secretary, I would emphasize that the increase in crime across the country, and especially juvenile crime, really underscores the need for those programs.

I think that our budget recommendations will reflect that, but I want you to know how deeply at least I feel about it. As you know, I have had a lot of experience in the field of being a district attorney of a city like Philadelphia, and seeing the kind of crime problems. It is characteristic of cities across the country.

When you have job training, you are trying to provide the background to take these at-risk youth off the streets. When you are talking about reentry, it has been a problem that I have been intimately concerned with for decades. The recidivism rates are extremely high because of the lack of job training, and releasing functional illiterates from jail without a trade or skill—so they go back to a life of crime. It would be surprising if they did not. So these reentry programs and the legislation that is pending now on second chance, these, I think, are of the highest priority.

PANDEMIC FLU

Let me ask you now about the issue of pandemic flu. It could be a catastrophe of phenomenal proportions. We have had a series of hearings on the subject and, to date, this subcommittee has included $5.4 billion for pandemic flu.

There was a petition filed in December 2005 for the Department of Labor to issue standards for public health care workers in the event of such a pandemic. On February 26, your Department denied the petition on the grounds that no human influenza virus exists at this time.

Shouldn't there be protections in place to protect workers, in case there is a pandemic? Shouldn't we be prepared. Every day you see an article on the H5N1 virus, though regrettably, they are in the back pages of the papers. I believe yesterday Pakistan was going to submit information on the virus, but in a limited extent. I would ask you to take another look at this regulation.

Secretary CHAO. I will do so. There is a government-wide task force on pandemic flu. So we, through, OSHA, have participated in this government-wide interagency workforce, and have been a very active participant. We have issued five significant guidance documents. I will take a look at that.

Senator SPECTER. Well, it looks to me as if the rejection of that petition may have been decided by someone at a lesser level than the Secretary.

Secretary CHAO. The emergency—I did not quite understand the question.

EMERGENCY STANDARD FOR HEALTH CARE WORKERS

Senator SPECTER. The petition was for an emergency standard to protect health care workers in the event of a pandemic. So take another look at it.

Secretary CHAO. I will take another look, but I think the original premise was that it was not—there are very strict guidelines as to what constitutes an emergency standard. Based on our review of the situation, it was not deemed to fit those quite—I mean it has to be a—well, I am not being very eloquent. But it has to be—there are emergency standards, there are rules and criteria to when that should be issued. It has to be like a pandemic.

I do not want to defend that without looking——

Senator SPECTER. Do we have to be in the middle of the pandemic before the rules are issued?

Secretary CHAO. Pretty near it. But as ridiculous as that sounds, I do not want to talk any further. I will take a look at——

Senator SPECTER. Now we have finally found something we agree upon. That is as ridiculous as it sounds.

Secretary CHAO. Yes. I will take another look at that.

OSHA'S SUSAN HARWOOD GRANTS

Senator SPECTER. Okay. Speaking of OSHA, why is the administration proposing to eliminate the $10 million OSHA program for worker training and education? Have these programs been unsuccessful?

Secretary CHAO. I suppose you mean the Susan Harwood grants. That was a very narrow, a very—a targeted—it was a very narrow set of grants given out to a very narrow constituency. We are concerned about worker training. We thought that with a wider approach through more—a web-based educational approach, more outreach, and efforts to other groups, to a larger array of groups, would be a more effective way to use those education grants.

Senator SPECTER. Well, we may have a disagreement there, too.

Mr. Chairman, I know my red light is on, but I have two more questions, and that will eliminate the need for a second round. If I may?

Senator HARKIN. I have some that I want to follow-up on, but go ahead.

FUNDING FOR MIGRANT JOB TRAINING

Senator SPECTER. Okay. Well, I will proceed here. The funding for the migrant and seasonal farm workers program has been eliminated. Almost $80 million. We are right in the middle of our new immigration bill, which is a very high priority for the President. Migrant job training is a big part of that. We are dealing with gigantic costs on employer verification and border patrol.

Why the repeated effort to eliminate that program when every time you do, both the House and Senate come back and insist on it?

Secretary CHAO. The whole issue of trying to integrate migrant workers into the work force is one that we both share. The question is how best to do that. This administration's philosophy has always been to take specific programs that are segregating workers into

separate funding streams and finding that that is not a very effective way of helping workers, when there is a whole nationwide publicly funded network of one-stop career centers, with all its full array of services that will be much better to help workers access the professionals that are in this system as well as the full array of funding programs. So the intent is to integrate more fully the migrant workers into the workforce development system.

Senator SPECTER. Well, do not the migrant farm workers have very unique needs, contrasted with the rest of the work force?

Secretary CHAO. Well, the program—we understand how important this is to members of this committee and to others on this committee. But there does seem to be some disagreement as well. We have found that this program, aside from the reason that I just gave previously, has been very often used as an income support program. We want to be able to use these funds to help migrant workers find better jobs, be able to transition into other opportunities on a seasonal basis, if they—if that were to occur.

Senator SPECTER. Well, I do not think it should be an income support program. But I think you could eliminate that and still have the training.

H–2B LABOR CERTIFICATION

The final question I have for you, Madam Secretary, relates to the H–2B labor certification. We are in the middle of a great human cry from some of the leading entrepreneurs of the world. Bill Gates is leading the charge on this.

The current regulations permit employers to file applications only 120 days in advance of their seasonal needs. Your Department's regulations call for an adjudication, a decision, within 30 days. Now the processing takes more than 100 days.

Two questions. Can you reduce or eliminate that delay in applications? Should we allow employers to file their applications more than 120 days in advance of their seasonal needs, in light of the delays in your Department's decisions on the applications?

Secretary CHAO. You are referring to the H–2A, H–2B program or to the H–1——

Senator SPECTER. To the H–2B labor certification——

Secretary CHAO. Okay. The H–2B.

Senator SPECTER [continuing]. Program.

Secretary CHAO. Right. Unfortunately, we have had an increase in backlog in the H–2B program this year. As background, let me say that when we first came into this Department, we had tremendous backlogs in the PERM and in other visa programs.

We have worked diligently to work down the backlog. This particular year, there has been a 40 percent increase in the number of H–2B visas. We do have a backlog in Georgia, in that processing center.

We have diverted additional personnel and additional resources to that region in an effort to work down the backlog. But the real problem is the cap that occurs on this visa and the time line that is involved, of which we are not in control. We play a very small part in this whole visa/immigration issue. Most of it is over at the Department of Homeland Security.

Where it is possible, where we have control, we have been able to decrease the backlog from over 100 days to process to—to be a little bit under 30.

Senator SPECTER. Well, Madam Secretary, I can understand the problem of the backlog, especially when the funding for your Department is cut.

Secretary CHAO. Well, this comes out of a different fund. That is not—it does not come out of—in fact, we have requested funding every year for the last 5 years, and the Congress has not given us additional funding. We have been underfunded for about $8 million.

Senator SPECTER. It does not come out of your overall budget?

Secretary CHAO. Some of that is—we have asked for, like, $37 million and $46 million, and we have been given about $37 million.

Senator SPECTER. Well, is it not a part of your $10 billion-plus appropriations?

Secretary CHAO. Yes. It is.

Senator SPECTER. Well, if you would submit a bigger budget request to OMB, or if you could get OMB to give you more money, you would have more money.

Secretary CHAO. It is the President's request. The President has traditionally asked for about $46 million. We have gotten about $37 million for the last 5 years.

Senator SPECTER. Well, you make the request, but it is a question of how we slice up the pie. If the pie were a little bigger, we would be able to give more to your requests. That means you have to come in here and bang the table. Before that, you have to have practice at OMB banging the table.

Secretary CHAO. Well, we went over there——

Senator SPECTER. You might even go from banging the table to banging heads. You are a strong secretary.

Secretary CHAO. Well, we have succeeded at OMB. We have requested about $45 million, $47 million for the last 3 years. The enacted was about $37 million.

Senator SPECTER. Well, we will continue to work with you, Madam Secretary. We have been for a long time. These are big, big problems. We want to do our best to try to solve them.

Secretary CHAO. Thank you very much.

Senator SPECTER. Thank you very much. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter. Madam Secretary, I just have a few areas I would like to also go through with you. You just mentioned something I wrote down about narrow grants to narrow constituencies. I want to get into an area——

Secretary CHAO. I did not——

CONGRESSIONAL EARMARKS

Senator HARKIN [continuing]. That has gotten a lot of publicity lately, as it concerns Congress. I am not going to single you out, Madam Secretary. I am going to bring this up with every secretary that appears here. Secretary of Health and Human Services. Secretary of Education. Those are the three under our jurisdiction. That has to do with earmarks. Earmarks.

In President Bush's State of the Union address this year, he stated, and I quote, "Next, there is the matter of earmarks. These special-interest items are often slipped into bills at the last hour, when not even C–SPAN is watching. The time has come to end the practice."

Now for the record, I do not think that more than 1 percent—almost all the earmarks are less than 1 percent. One-third to two-thirds of 1 percent of all that we appropriate here, but they have really gotten hit by the President.

HIGH-GROWTH JOB TRAINING GRANTS

On the other hand, a recent Congressional Research Service report found that 90 percent of the funds under DOL's high-growth job training initiative were awarded non-competitively. Ninety percent. In other words, over the past 5 years, DOL earmarked more than $250 million without any competition and without any transparency.

Now I understand that Federal regulations allow for the awarding of sole-source contracts in certain situations. However, earmarking 90 percent of these funds raises some very serious questions.

Now I just drafted a letter for the inspector general, Mr. Heddell, of the Department of Labor. I said, "Dear Mr. Heddell, I am writing today to request that you look into the Department's practices of awarding non-competitive awards under its high-growth job training initiative." As I said, "As you may know, the Congressional Research Service recently analyzed the Department's funding practices under this initiative, and found that 90 percent of the funds were awarded through non-competitive awards. These actions resulted in more than $250 million in funding being awarded without full and open competition."

"I understand"—and this is my letter—"I understand it is sometimes maybe in the public's best interest to award funds on a non-competitive basis. For example, if the services are available from only one responsible source and no substitute will suffice."

"The Federal Grant and Cooperative Agreement Act identifies other exceptions to the general rule of competition. However, I believe such extensive use of non-competitive grant making raises serious questions."

"I encourage you to look into these matters on an expedited basis. I ask that you audit a sufficient number of non-competitive awards to understand whether relevant statutes and regulations were adhered to, and to evaluate the extent to which these awards are meeting their specific performance objectives and contributing to the Department's missions."

So Madam Secretary, that is a lot of money. Ninety percent raises a lot of questions. Could you explain the criteria that you used when making the decision to earmark a quarter-of-a-billion dollars under this initiative?

What are the specific performance measures, the evaluation criteria, and operational requirements of grantees? I would like to know what the results of these grants are thus far. So, again, help me understand, what is your criteria in sole sourcing 90 percent of this money?

COMPETITION FOR HIGH-GROWTH JOB TRAINING GRANTS

Secretary CHAO. First of all, let me say that it is a philosophy—it is, in fact, the tendency of the Department to engage in competitive bidding. All high-growth grants are now competitive. The initial grants in the sectors were—in the high-growth job training program were initially directly responsive to worker shortage sectors. So that was just the first round.

All single-source contracts have to go through what is called a procurement review board. They were all approved by the procurement review board.

Having said that, our preference is always to competitively bid. So I think the particular instance that you mention—I wonder about the 90 percent. Because it depends on what you use as a base. But it is our preference to always competitively bid.

There are single-source contracts that do have to go through the procurement review board. As for the specific criteria, it is done by a group of—by the Employment Training Administration, which was trying, again, to meet the tremendous deficits in worker shortages in some of the high-growth industries.

Senator HARKIN. Madam Secretary, you said they are all competitive now. Not because of what you did. But because Congress required it.

Secretary CHAO. I do not think so. I think it was always the intent to competitively bid these.

Senator HARKIN. Intent? When 90 percent went uncompetitively?

Secretary CHAO. That was the only first round, to my understanding. That was to get the program off to a rapid start, because we were receiving a great deal of concerns.

Senator HARKIN. So you are saying that that did not happen over 5 years. It just happened in 1 year?

Secretary CHAO. I do not—I do not believe that is true. I do not believe that is the case. Whether it was 5 years or 1 year, it was—it was the first round. I will look more into it, but it was never our—our preference always is to competitively bid. And it was part of an overall effort to get—you know, we also—you asked about the performance measures, and——

RECIPIENTS OF HIGH-GROWTH JOB TRAINING GRANTS

Senator HARKIN. Okay. Well, I am looking at some of these, and I asked the IG to look at them. One went to the National Retail Federation Foundation. $2.25 million.

Secretary CHAO. I was not involved in that. But I would suspect that that, again, was to address the tremendous need for retail workers. We were trying to match workers' skill sets with high-growth industries that needed particular workers. There are many others as well. Construction workers are at a premium. Skilled trade workers are at a premium. We needed workers in financial and professional services.

I mean these were dire requirements in our economy. We actually can have a larger discussion about how training occurs through the Employment Training Administration and the workforce development system. I think it is actually quite valuable to have a discussion like that. Because right now there is a disconnect

between the workers—between the skill sets that are needed, and what workers are being trained in. How many workers are being trained.

Senator HARKIN. Well, some of these—I do not know. There is one in 2004 to the Manufacturing Institute of the National Association of Manufacturers.

Secretary CHAO. Again, I was not involved in that. But that is probably involving advanced manufacturing workers. Traditional manufacturing is declining as we all know. It has been declining worldwide for the last 40 years. Yet, manufacturing is evolving.

There is a new phenomenon now called advanced manufacturing, in which workers with higher technological and information technology skills are desperately needed. So what we are seeing, and this is precisely what the issue is facing our workforce, it is a skills gap. We have—at any one time, about 4 million jobs are vacant. We have high-growth industries that are desperately seeking workers. Yet, we do not have workers with the right skills.

So we have to train workers, help to train workers for relevant skills, so that they can get a job when they graduate.

Senator HARKIN. Madam Secretary, you are right.

Secretary CHAO. Okay.

Senator HARKIN. So then why is your budget cutting a billion dollars out of workforce training and all of that?

WORKFORCE INVESTMENT SYSTEM

Secretary CHAO. Well, it is an excellent question. I am pleased to answer it. It is, primarily, because—and I am grateful for this dialogue, because it is so important.

I agree with Bill Gates. We need to prepare our workforce. But what is happening is that of the workforce—I love the system. We all support and treasure the system. But even people who work in the system are frustrated by the bureaucracy, the overlaying, duplicative infrastructure.

Most of the funding goes to salaries and infrastructure. We are training 200,000 people at a budget of $6.8 billion. We have employment services offices that reside right next to one-stop career systems. They do the same thing. Yet they cannot talk to one another or they do not coordinate.

We have $1.1 billion to $1.7 billion in excess carryover funds every year. So in terms of just good cash management, that is not a very good practice. Over $3.4 billion goes to infrastructure.

We need to—all of us who work in the system need to challenge ourselves more to do more to ensure that workers are being trained for the relevant skills. We have this wonderful system. Yet we also have high-growth industries, where they cannot find enough workers. So something is wrong. Again, we need to challenge ourselves to do more and take a look at the system.

How can we use this money better? How can we train more workers? That is an issue——

Senator HARKIN. So you are saying you do not need any more—you can use—you can do all of this with a lot less money. That is what you are saying.

Secretary CHAO. We need to carry out reforms. We need to carry out reforms that will enable——

Senator HARKIN. Have you suggested any reforms to this committee and to the Congress?

Secretary CHAO. We have. That is part of the overall debate and discussion that we need to have.

Senator HARKIN. All right.

Secretary CHAO. It takes 10 years—7 to 10 years for the whole system and for these national debates to occur. It happened with——

Senator HARKIN. Well, we have been there——

Secretary CHAO [continuing]. JPTA and, you know, in 1998 with WIA. So we are in the process of discussing further enhancements and reforms to this workforce investment program.

WIA CARRYOVER BALANCES

But the reality is, there is $1.1 billion in carryover funds that are not used. Every State has excess funds.

Senator HARKIN. Well, I am going to have to look at that, too. But I wanted to follow up on just one thing. You mentioned that there were 200,000 being trained annually. GAO has consistently refuted the data that you have presented to us. GAO found that your Department's calculation of carryover, what you just mentioned, has created a mistaken impression of excess unspent balances. Now this is GAO.

GAO found in their June 2005 report that GAO's estimates represent a more complete and accurate picture than Department of Labor's. Because they are based on information obtained directly from the local workforce areas. Include all funds spent or obligated for training. Count all adults who received training in program year 2003, not just those who exited the program.

So your Department's justification for a $335 million cancellation of job training funds rests on your claim of excess unspent carryover, which you just mentioned. Overestimates, according to the GAO. The GAO found that most unspent balances in states had already been obligated or committed.

So I hear you. I hear what you are saying. But GAO does not agree with you and we rely on GAO. That is our investigative arm. So we have to rely on GAO to give us accurate information. So are you telling me that GAO is not giving us accurate information?

Secretary CHAO. Unfortunately, we respectfully disagree with GAO's findings. We are also disturbed—and just from that passage that you just read—we are very results oriented. If we ask—if we help a person go through training, we owe it to that person to ensure that they get relevant training, so they can access a real job when they graduate.

So we have performance measurements. So graduation rates do make a difference. Placement rates do make a difference. We are looking at employment upon graduation, retention, and also earnings. We want to know how long that person stays on the job after they graduate. After they get a job. Also what the earnings are.

So we are concerned about, again, the outcome. The graduation rate is important.

Senator HARKIN. I never said it was not.

Secretary CHAO. I thought that GAO said that they were looking at not only those who exit the program.

Senator HARKIN. That is right. But GAO—but they are looking—what they are talking about is the actual picture. Because they said their information is obtained directly from local workforce areas, directly. They include all the funds spent or obligated for training. Count all adults who receive training in program year 2003. Not just those who graduated.

Secretary CHAO. Yes.

Senator HARKIN. So to get a whole picture of what is happening, obviously, graduation rates are important. But you have to look at the whole pool that is out there.

Secretary CHAO. Absolutely. But we do—we do not—I want to just—I want to be respectful. So we disagree with that.

If you look at the unspent balances in each of the states, there are unspent balances. Every year, there are carryovers. Every year. They range from $1.7 million to $1.1 billion.

Senator HARKIN. Let me put it this way. Let us say that I have a contract in 2006 to do certain things in 2007, to meet certain obligations. I have a contract to do that. That contract is $1,000.

Let us say in December 2006, I have $1,000 in my pocket. Well, you can say in December 2006, I have $1,000 of unspent money. But if you really calculate it on a balance sheet, like GAO would look at it, they would say, "Well, no, because that is obligated." You really do not have any unspent —you have not spent it yet, but you are obligated to it.

That is what they are looking at here. So I respectfully also say, are we playing some word games here? I am looking at obligated—what they have. You say unspent. GAO says obligated to spend. When you look at it that way, you do not have that much carryover money.

Secretary CHAO. Well, that brings us, unfortunately, to another area of discussion. Related, of course. That is the whole issue of when you—if you have $1,000, and let us say someone buys 3 years of training slots, because, first of all, WIA does not train. We purchase the training slots from a training provider.

Senator HARKIN. Right.

Secretary CHAO. So whether the training slots are actually used or not is another story. So you can obligate it for 3 years or 330 slots, or 2 years, and then 334, for another. But whether workers are actually filling those slots is another question.

So there are a lot of—not only is there the issue of excess balances, or in your words, obligated funds, but there is also the tremendous need for reforms in this program. When we talk about the money, that is just part of it. We need to reform this program so that it is relevant.

WIA REFORMS

Senator HARKIN. What is the most significant reform that comes to your mind that we need to do?

Secretary CHAO. I think we need to give the States more flexibility. Right now, I keep—the Federal Government keeps 5 percent. The rest of the money goes down to the State. Depending on the 17 different revenue funding streams, the State keeps about 15 to 35 percent, and the remainder goes into the municipalities.

What we have sometimes are adjoining districts. When they have a surplus, when they have a deficit. Yet, the State will not have any flexibility in shifting those funds around. We do not want to shift those funds around. We are not proposing that we be given the authority. But we think that these funds, at least, should be more flexible. So that at the State level, they can shift them around. Right now, that cannot be done. Also, we have——

Senator HARKIN. But you can.

Secretary CHAO. Not really. It is very strict. It is very strict.

Senator HARKIN. Well, I will have to look into that. I mean, obviously, I do not know it as well as you do. But it has been my information that DOL can do that, if you have——

Secretary CHAO. Not really. If you have employment services. Adult. Youth. Dislocated. These are very strict funding——

Senator HARKIN. You are saying your hands are tied. If you have a deficit area right next to a surplus area, you cannot take it from the surplus area and put it in the deficit area if that is needed?

Secretary CHAO. No. Because it is their money. It has already been given out, by statute.

Senator HARKIN. Okay.

Secretary CHAO. So what we are asking for is just more flexibility. Again, we are not asking for the authority ourselves. We are just asking that the State level be given more flexibility.

Senator HARKIN. Why will you not ask for the authority? Why not give it to the DOL? Why give it to the States?

Secretary CHAO. Because I think probably——

Senator HARKIN. You have a better handle on the national picture.

Secretary CHAO. Well, number one, it is by statute. So there has to be a statutory change. And number two, probably the States would——

Senator HARKIN. Well, there would have to be a statute change for the States to do it, too.

Secretary CHAO. Yes.

Senator HARKIN. Well, I am just saying, I do not know—I mean it would seem to me that if you are talking about flexibility to do that—and I will look at that and consider that.

Secretary CHAO. There are workforce investment boards. I think that the thought was that probably the States know better. They are more direct to the grassroots and to the ground. They would know at a faster rate—they would know faster what the needs are.

Then another thing is incumbent workers. I will give you another example. Right now, we have major companies in our country that have said that in 2 or 3 years they are going to close a plant. With all the money that we have in this fund, we do not have any money for incumbent workers. So we have to wait until the workers are laid off before we can offer them transition employment services assistance.

These days, companies are getting further and further in advance notice of when they plan to shift facilities around. Yet, we cannot do anything to help these incumbent workers while they are waiting for this transitional period. So we—and so this is a big issue, too.

There are reforms such as this that we believe that would really make the system better, more responsive.

Senator HARKIN. That is interesting.

Secretary CHAO. More helpful to workers. Because we support the system. But there has got to be a better way to do all this.

Senator HARKIN. Well, I will look at that, too. I mean if you have some suggestions on changes in that, we will look at that. Let me just consult with my staff on that.

Well, now I am getting different information.

Secretary CHAO. Okay.

Senator HARKIN. I am told for the last 5 years we have given you the authority for flexibility to train incumbent workers. I have just been told that for the last 5 years we have given you that authority. So——

Secretary CHAO. Okay. I hate to give you piecemeal answers. So I apologize. I have been told that it is only at the State level, but not at the local level.

Senator HARKIN. What? The State level?

Secretary CHAO. Because all the funds, if you recall, go directly to the local—most of the funds go directly to the local WIB boards.

WIA FUNDING FLEXIBILITY

Senator HARKIN. My brains over here just told me that we have provided for an authority for 30 percent to shift between the adult block grant and the other block grant. So you have a 30 percent authority there. Is that right?

Second, you say it is at the State level, not the local level. But I am also told that when the State takes the block grant and gives it to the local level, they can provide the flexibility to the local level. States can do that.

So you are saying they do not have the flexibility at the local level. That has more to do with the State than us. If you want to give more money to the States, then—but they are not providing the flexibility at the local area. Not us. The States are not doing it.

Secretary CHAO. I guess what we are saying is that we need flexibility, not only at the State level, but at the local level as well. The whole system is very important.

Senator HARKIN. Well then we are going to have to tell the States that—obviously, we are going to have to tell the States they have to do certain things. So it is not just a block grant. We are going to have to tie some strings to it, to tell the States that they have to give the flexibility at the local level.

Secretary CHAO. We would agree with that as well. Because a lot of times the funding goes directly to the local, and it is used for deficit reduction purposes as well sometimes.

I would really welcome a discussion with your staff about this. We would welcome that.

Senator HARKIN. Well, because—and the reason I am caught up in this is because we really have a difference here between what GAO is telling us and what you are telling us. We have a real difference here.

Secretary CHAO. Inflexibility in the system and the different silos, in terms of funding streams, makes it very difficult to shift

money around. We are not trying to decrease the money. We are just trying to shift it around, so that it is more responsive to local conditions.

Senator HARKIN. But is it 30—as I have just been told by counsel, you have 30—up to 30 percent to shift around.

Secretary CHAO. I was told it was an insignificant amount, not as large an amount as that. Is it 30 percent?

Let me correct it. It is 30 percent. But apparently the local boards do not think that that is significant or large enough.

Senator HARKIN. Well, are they even utilizing the 30 percent?

Secretary CHAO. It is on—I believe so. We get a lot of waivers. We get a lot of requests. That is very burdensome. It is very—it is done only under extraordinary circumstances.

Senator HARKIN. Well, we will get to the bottom of it. We will, and I will have my staff get a hold of your staff and start working some of this stuff out here.

Secretary CHAO. Thank you.

HIGH-GROWTH JOB TRAINING GRANTS

Senator HARKIN. I still just repeat for emphasis sake, and I am going to have the IG look at this earmarking, the 90 percent. We changed it. We stopped it, in law. Did I just read to you the public law that we just passed, that said you cannot do that any more. That is why, because——

Again, Madam Secretary, I do not think anyone would have minded if it were 10 percent or 4 percent. I mean we, in Congress, our congressionally directed funding is less than 1 percent.

Secretary CHAO. Yes.

Senator HARKIN. All the newspapers and all the press are out there going after Congress. It is less then 1 percent.

Secretary CHAO. It is a bigger budget, too.

Senator HARKIN. I agree that sometimes you have—what?

Secretary CHAO. It is a bigger budget, too.

Senator HARKIN. But it is still less than 1 percent. If you look at it percentage wise.

Secretary CHAO. I do not want to dispute on the 90 percent. We have to take a look at that, because that is a surprising number to me. I think, again, it depends on what you—it was that one particular year, when it was starting up. That was an effort to jumpstart some worker training programs in high-growth industries that were desperately seeking workers. But I will take a look at that.

Senator HARKIN. Well, like I said, I think there is a need for you as a secretary, me as a senator, Senator Specter as a Senator, and others, to respond to certain needs that may not be applicable on a competitive basis. But we have guidelines for that.

Secretary CHAO. Absolutely.

Senator HARKIN. We have guidelines for that. But when it comes out to 90 percent, that sort of—is pretty startling. I think that is one of the reasons we put that in the law this year. Just this year. Well, last year. Pertaining to this year.

WORKFORCE INVESTMENT SYSTEM

Secretary CHAO. Mr. Chairman, may I also suggest—request one other thing. As we talk about some of these issues with the overhang and the excess balance, may we also talk about some of the—may our staffs also discuss some of the need for how to handle the duplicative structure? Because right now——

Senator HARKIN. Duplicative——

Secretary CHAO [continuing]. We have dual structures within the workforce investment system. Again, I believe that everyone wants to do the right thing. The issue is: How do we break down some of these silos that are preventing a full focus on the worker?

All of these services should be arrayed with the worker in the center. Nowadays, the workforce investment system is so complicated that a worker almost needs an advanced degree to be able to access the various different types of programs. It is very confusing, so——

Senator HARKIN. Back in the nineties, then Secretary of Labor—I do not remember who, which one it was. We started these—I remember they had a big deal about this one-stop shop. This one-stop thing. What has happened to all that?

Secretary CHAO. Well, it was an improvement over the previous years. But the idea is not complete. So more needs to be done to bring that about.

Senator HARKIN. Legislatively? Or administratively? You are the administrator.

Secretary CHAO. I think we—we have tried to do as much as we can, administratively. Then some of it has to be legislatively done as well.

Senator HARKIN. Have you——

Secretary CHAO. We would hope that——

Senator HARKIN. Have you suggested legislative language to us?

Secretary CHAO. We have.

Senator HARKIN. I mean, if you have, I am sorry.

Secretary CHAO. I——

Senator HARKIN. In fact, that is the other committee, but I am on that committee, also.

Secretary CHAO. Right. Again, we have. It is part of the national discussion that we need to be having.

Senator HARKIN. Because, obviously, my concern here is budget-wise, money-wise, but that has to do with the issues, and how the programs are carried out. Then, of course—then the other committee I serve on the—the HELP Committee, in terms of the——

Secretary CHAO. So you are ideally positioned, Mr. Chairman.

Senator HARKIN. Say what?

Secretary CHAO. You are ideally positioned, Mr. Chairman.

Senator HARKIN. Well, maybe if I was chairman of that other committee, too, maybe.

Let me—a couple of other things, Madam Secretary. I do not mean to drag it out too—but there are some issues here that I want to cover with you.

ERGONOMICS

One of your four stated goals is protecting worker safety. I am going to get into an issue that has sort of been a sore point between us for a long time. Not between you and me, but just between the Department and Congress. Ergonomics.

Secretary CHAO. Yes.

Senator HARKIN. Approximately one-third of all injuries and illnesses with days away from work are musculoskeletal disorders that result from exposure to ergonomic hazards on the job. In 2005, the last year we have data for, there were 375,540 serious ergonomic injuries, resulting in time off the job, reported by employers.

In 2002, after the repeal of OSHA ergonomics standard, you, Madam Secretary, announced a comprehensive plan to address ergonomic injuries, including, and I quote, "Industry-targeted guidelines and tough enforcement measures." You stated, "Our goal is to help workers by reducing ergonomic injuries in the shortest possible timeframe."

Well, let us look at the tough enforcement measures. OSHA has only issued 17 ergonomic citations since 2001. Twelve were issued in 2003. Four in 2004. One in 2005. None in 2006. So Madam Secretary, when are you going to practice this tough enforcement that you have committed to?

One citation, I think, over the past 2 years does not sound like tough enforcement, when we see there were 375,000-plus serious injuries reported by employers, resulting in time off.

So I want to ask you about, where is the tough—where is this tough enforcement?

ERGONOMIC ENFORCEMENT

Secretary CHAO. Well, as you mentioned, the approach that we have taken is strong enforcement, outreach, research based on sound science, and, of course, industry-specific guidelines. So we have issued the final ergonomic guidelines for nursing homes, retail grocery stores, poultry processing. They are obviously all industries of high rates of MSDs.

Then a fourth guideline on shipyards was delayed, because of some information quality challenges. OSHA is in the process of updating that, and we hope to have a draft for public comment shortly, soon.

We have conducted over—OSHA has conducted over 850 ergonomic inspections per year and sent out about 408 hazard alert letters.

Senator HARKIN. Well, why one citation in the last 2 years, when you have all these injuries? Why only one citation? How come it has gone from 17—or 12 in 2003, down to none? I mean that is just——

Secretary CHAO. I will take a look at that.

Senator HARKIN. That just does not sound right, you know, when no citations are being issued. So someone at OSHA is just not—I do not know—I am trying to figure this out. Why? What is happening at OSHA?

I hope that you will provide us with some plans to step up these enforcement efforts. Now that is enforcement of the guidelines. You mentioned the guidelines.

ERGONOMIC GUIDELINES

You appointed members to a national advisory committee on ergonomics, which recommended 16 industries—you mentioned some of them there—for the development of guidelines. But only three guidelines have been issued, and none since 2004. So when are the other 13 guidelines going to be provided or completed?

Secretary CHAO. If you—I will just bring this up. If you recall, we did not have an OSHA Administrator for almost 18 months. So it does—leadership does count. When we do not have leadership at the agency level, it does make a difference.

We now have a new Administrator. He is committed to ensuring the worker's safety and health of our workforce. I will take a look at that.

Senator HARKIN. Well, please take a look at it, because these guidelines are just dead. Nothing is happening. Can you provide us with a specific time—not today. But can you provide us with a specific time line for the number of guidelines issued this fiscal year and next? Looking at those 13.

Secretary CHAO. Yes. May I also just mention that we take, of course, these issues seriously. But the musculoskeletal disorders involving days away from work declined 13.7 percent. So they have been declining.

Now the total number of cases evolving and days away from work declined both in 2003 to 2005. So the decline in the MSD is twice that of other cases. But your point is well taken. I will take a look at it.

[The information follows:]

OSHA has carefully considered the recommendations offered by the National Advisory Committee on Ergonomics (NACE) which was established to advise the Secretary of Labor on ergonomics guidelines, research, and outreach and assistance. We have updated the NACE analysis using more recent injury statistics. The agency is using the results of this updated analysis as one source of information as it considers candidates for future ergonomics guidelines. It should be noted that NACE recommended that OSHA consider "Other Criteria" (e.g., injury trends, absence of available guidelines) established by the Guidelines Workgroup when making specific industry selections from the NACE list.

Our past experience with guideline development is the best indicator of future timelines. The Guidelines for Nursing Homes were completed in about a year. The Guidelines for Poultry Processing and the Guidelines for Retail Grocery Stores were completed simultaneously in a 2-year period. We plan to publish draft Guidelines for Shipyards in fiscal year 2007, and anticipate finalizing them in late fiscal year 2007 or early fiscal year 2008.

Senator HARKIN. All right. Thank you. One last question about this.

Secretary CHAO. Sure.

MUSCULOSKELETAL DISORDER REPORTING FORM

Senator HARKIN. You talk about decreases. I have been told that you changed the reporting form and eliminated the column that had been used to report musculoskeletal disorders. Is that so?

Secretary CHAO. I seem to recall——

Senator HARKIN. I was told that you changed the reporting form and eliminated the column that had been used to report musculoskeletal disorders. So then it would make it look like there is less.

Secretary CHAO. I do not think that was the intent. I do remember something to that effect, but I do not have the answer at hand.

Senator HARKIN. Can you provide the committee——

Secretary CHAO. I will look into—sure.

Senator HARKIN [continuing]. With that information, too, on this? Also, any analysis that you have done concerning the effect that the elimination of this column may have had on the accuracy of reporting. I am not here saying it has or it has not.

Secretary CHAO. Okay.

Senator HARKIN. I am just asking if you had done any looking at getting rid of that column—I do not know why it was gotten rid of. I am not an expert in that area. But why it was gotten rid of. Analyzing if it has had any effect on the accuracy of reporting.

Secretary CHAO. We will do so.

Senator HARKIN. If you can provide that to us, I would appreciate that.

[The information follows:]

Each year, the Bureau of Labor Statistics (BLS) produces statistics of Musculoskeletal Disorders (MSDs) as part of its annual survey of occupational injuries and illnesses. The BLS is able to calculate and publish both the number and rate of MSDs involving days away from work, using individual case data collected from the detailed OSHA injury and illness 301 form. MSD statistics are available by industry and occupation, along with various estimates of MSD characteristics (such as median days away from work), and demographics (such as the age and sex of the injured employee). The BLS statistics on MSDs are generated by including cases with a defined combination of nature of the injury or illness and event or exposure, and a specific MSD column on the OSHA form is not needed to generate them. The BLS MSD statistics enable OSHA and the general public to accurately evaluate the scope and trend of MSDs in America's workplaces.

OSHA has never implemented a specific column for recording MSDs on its injury and illness forms. OSHA's old 200 Log contained a column for "repeated trauma" cases, which captured some, but not all MSDs, but also included other conditions, such as occupational hearing loss. Since the column did not provide an accurate tally of all MSDs, it caused confusion regarding MSD statistics and was removed in 2001 as part of a comprehensive injury and illness recordkeeping revision.

An MSD case is recorded on the OSHA Log 300 using the same process as for any other type of injury or illness. If an MSD is work-related, and is a new case, and meets one or more of the general recording criteria, the case must be recorded on the OSHA forms. Inclusion of a specific MSD column would have no bearing on the recordability of an MSD case. However, requirements for entering MSD cases in a specified MSD column would have relied on the same MSD definition used in the ergonomics standard repealed by the Congress. The requirements for the MSD column were delayed while the agency reconsidered the issue, and in 2003, following public comment and extensive deliberation, OSHA decided not to include an MSD column on the form. The agency decision was based on several factors, including: (1) the column would not impact employer, employee and OSHA MSD analyses at the establishment level; (2) the column had no impact on OSHA's ability to carry out ergonomics enforcement under Section 5(a)(1) of the OSH Act; (3) different definitions of MSD may be appropriate depending upon the context in which they are used; and (4) accurate MSD statistics were already available from BLS.

Senator HARKIN. I do not know why we are having so much trouble with ergonomics. I just do not know why. You know. We know it is happening. We see people every day. We hear the reports. We see the data. Yet nothing ever seems to get done about it. It is—it is a health problem in America.

I mean if we had workers exposed to asbestos or dangerous substances, we would be taking action. Yet, they are exposed to repetitive motion injuries that many times will plague them for the rest of their lives. Yet we just seem to just do nothing about it.

Secretary CHAO. I do want to correct one perception. When we inspect workplaces, it is not that we do not inspect for ergonomic infractions. When we talk about some of this, this is specifically ergonomics—specific ergonomics investigations or inspections. When our inspectors go into a workplace, they will take a look at the whole array of non-compliance activities and behaviors, which include many times, but it is not specifically targeted out as ergonomics.

MSHA'S REVIEW OF MINE ACCIDENTS

Senator HARKIN. Senator Byrd cannot be here today, and wanted me to just ask a couple of questions on MSHA. It has been more than 16 months since the mining tragedies at Sago and Alma. The United Mineworkers Association, as I said in my opening statement, issued a report recently stating that if MSHA had followed their legislative mandates, all 12 Sago miners would have survived. That was according to the United Mineworkers Association.

MSHA's internal reviews of these accidents will be released shortly. I do not know when. Sometime soon. Could you provide for the record: One, a plan and time line for taking the corrective actions necessary to prevent tragedies, like those that occurred last year. Number two, the specific steps MSHA will take to get better communication and tracking technology into mines as soon as possible, until wireless systems are available. Third, provide for the record quarterly reports on MSHA funds being used to and outcomes achieved related to the specific requirements of the MINER Act.

So if you could provide that to the committee. I will have these——

Secretary CHAO. I will do so.

[The information follows:]

MSHA is currently conducting exhaustive internal reviews of its own enforcement activities at the Aracoma, Darby, and Sago mines. These will evaluate the actions of MSHA prior to the accidents and provide appropriate recommendations to improve the quality and effectiveness of MSHA's enforcement program at the field offices, district offices and the headquarters levels of MSHA. MSHA will assess any deficiencies in its enforcement program and take corrective actions as soon as possible to address all identified shortcomings and issues.

MSHA Technical Support has conducted an exhaustive review of communication and tracking technologies available in other industries globally and solicited interest from providers of this technology. We have received suggested technology improvements from more than 138 interested parties, met with 52 of these parties and witnessed 20 underground demonstrations of these improved technologies. MSHA's focus has shifted from evaluating and encouraging new technology manufacturers into the mining industry (as was done last year) to testing and evaluating for MSHA approval of this new technology. MSHA has received a total of 51 applications for approval of new communications and/or tracking technology since January 2006, and 25 of these were received in 2007. This represents a very significant increase from the typical number of communications systems approval applications. MSHA's Approval and Certification Center has prioritized all communications and tracking approval applications and has shifted internal resources towards evaluation of these applications. Six new communications or tracking products and 15 revised products have already been approved as of May 24, 2007, and it is anticipated that a significant number of improved technology products will be approved in the near future.

Under the MINER Act, MSHA is ensuring that each mine's accident response plan provides for a redundant means of communication with the surface, such as secondary telephone or equivalent 2-way communication, and provides for pre-accident tracking as an interim step to wireless 2-way communication and electronic tracking systems.

MSHA does not directly track expenditures of funds to the MINER Act. However, MSHA has implemented, or is in the process of implementing, all mandated MINER Act provisions. The following table summarizes MSHA's actions to date to implement the MINER Act:

MINER ACT—IMPLEMENTATION DATES AND STATUS

Description of task	Status
SEC. 2. EMERGENCY RESPONSE	
Develop and adopt an Emergency Response Plan (ERP) that contains provisions for post-accident communications and tracking; post-accident breathable air; lifelines; training; and local coordination.	MSHA issued Program Policy Letters P06–V–8 on 07/21/06; P06–V–9 on 08/04/06; P06–V–10 on 10/24/06 implementing the Emergency Response Plan (ERP) provisions in section 2 of the MINER Act.
Update plans periodically	MSHA issued breathable air guidance on 2/8/07 in Program Information Bulletin (PIB) No. P07–03. ERPs submitted to MSHA by 08/14/06 or citations were issued to operators. MSHA has partially approved 100 percent of ERPs and fully approved 66 percent of ERPs for active, producing underground coal mines. Once the breathable air provisions and other deficiencies are addressed, ERPs can be fully approved.
Post-accident communications and tracking	MSHA issued a Request for Information (RFI) on 01/25/06 soliciting proposals for new communication and tracking technology. MSHA is sharing results of evaluations and testing with NIOSH. MSHA is evaluating submitted proposals, assisting in arranging demonstrations, observing testing at various mine sites, meeting with communication and tracking system company representatives, and communicating with parties interested in developing a mine communication and/or tracking system. MSHA approved four communication systems in 2006 that are commercially available now. MSHA issued PIB P07–01 on 01/18/07 addressing the use of Global Positioning Systems during storms.
Post-accident breathable air for maintenance of individuals trapped underground.	MSHA published an RFI on 8/30/06; comments received 10/16/06. MSHA issued PIB P07–03 and associated compliance materials containing options for providing post-accident breathable air to underground coal miners on 02/08/07. Mine operators were required to submit a portion of the ERP addressing breathable air by 3/12/07. Mine operators have resubmitted ERPs with provisions for breathable air. As of May 31, 2007, 306 of these ERPs have been fully approved while the remaining are currently being reviewed by the districts for breathable air and other deficiencies. The National Mining Association has challenged MSHA's breathable air guidance in the Court of Appeals for the District of Columbia. Mine operators must implement breathable air provisions 60 days after MSHA approval of ERP.
Post-accident, flame resistant, directional lifelines	Emergency mine evacuation final rule was published 12/08/06. The final rule requires that lifelines be made of flame-resistant material upon replacement, and that all lifelines be flame-resistant no later than June 15, 2009
Training program for emergency procedures	Required in emergency mine evacuation final rule published 12/08/06.
Local coordination and communication between the operators, mine rescue teams, and local emergency response personnel.	Required in ERPs
Emergency Response Plan approval and review	Required to be submitted to MSHA by 8/14/06 and every 6 months thereafter

MINER ACT—IMPLEMENTATION DATES AND STATUS—Continued

Description of task	Status
SEC. 4. MINE RESCUE TEAMS	
Provides certification, composition, and training requirements for underground coal mine rescue teams.	MSHA drafting proposed rule expected. The final rule is due under the MINER Act on 12/14/07.
SEC. 5. PROMPT INCIDENT NOTIFICATION	
Requires operator to notify MSHA within 15 minutes of a death or an injury or entrapment, which has a reasonable potential to cause death.	Included in Emergency Mine Evacuation final rule (published on 12/08/06).
	Minimum civil penalties under the MINER Act are in effect (see penalties, below).
SEC. 7. REQUIREMENT CONCERNING FAMILY LIAISONS	
MSHA to be liaison and primary communicator with families of victims and primary communicator with mine operators, the press, and the public.	Assistant Secretary for MSHA was assigned responsibility for developing Family Liaison Program on 11/02/06.
	MSHA issued PPL P06–V–11 on family liaison and primary communicator on 12/22/06. MSHA is developing policy to be implemented as a part of accident investigation handbook. Training completed for 14 designated MSHA personnel.
SEC. 8. PENALTIES	
Revise existing rule to increase minimum penalties for unwarrantable failure citations and orders; and ''flagrant'' violations.	MSHA immediately implemented new minimum civil penalties after passage of the MINER Act for unwarrantable failure and failure to notify violations. MSHA established procedures for evaluating ''flagrant'' violations in October 2006. MSHA's final rule on civil penalties was published on 03/22/07 and is now in effect.
SEC. 10. SEALING OF ABANDONED AREAS	
Requires increase of 20 psi standard for sealing of abandoned areas in underground coal mines.	MSHA issued PIBs establishing a temporary moratorium on new seal construction until the agency issued subsequent guidance for addressing alternative seals: PIB–06–11 issued 06/01/06; PIB–06–12 issued 06/12/06; PIB–06–14 issued 06/21/06; PIB–06–16 issued 07/19/06. Seal strength for alternative seals was increased to 50 psi under this PIB. MSHA issued Procedure Instruction Letter (PIL) I06–V–09 on 08/21/06 establishing procedures for agency approval of ventilation plans that include alternative seals. MSHA has approved one plan that included alternative seals and has approved a number of others provisionally. MSHA will continue to work with NIOSH on research and testing of seals, pa articularly full-scale testing of seals at higher explosion pressures. NIOSH draft report issued 02/09/07. Emergency Temporary Standard (ETS) issued on May 22, 2007. The ETS, effective May 22, 2007, addresses the design, construction, maintenance and repair of seals, as well as requirements for sampling and controlling atmospheres behind seals. It requires training for persons who conduct sampling, and who construct and repair seals. Mine operators must submit design and installation applications for MSHA approval. In accordance with the Mine Act, the ETS must be finalized by February 22, 2008.
SEC. 11. TECHNICAL STUDY PANEL	
Establish Belt Air Technical Study Panel to provide review and recommendations on the use of belt air and the composition and fire retardant properties of belt materials in underground coal mining.	Belt Air Technical Study Panel established 12/20/06.
	1st meeting held on January 9–10, 2007. 2nd meeting held on March 28–30, 2007. 3rd meeting held on May 16–18, 2007.

MINER ACT—IMPLEMENTATION DATES AND STATUS—Continued

Description of task	Status
	Procedures and timetable established. Relevant documents posted on MSHA's website.
	4th meeting will be June 20–22, 2007 in Birmingham, AL.
	5th meeting will be scheduled to summarize all the Panel's activities.
Submit a report to the Secretaries of Labor and HHS and to the Congress.	Panel report due 12/20/07.
Provide a response to Congress describing the actions that the Secretary intends to take based on the report and the reasons for such actions.	Secretary of Labor's response due 6/20/08.
SEC. 13. RESEARCH CONCERNING REFUGE ALTERNATIVES	
Conduct research, including field tests, on the utility, practicality, survivability, and cost of refuge alternatives in an underground coal mine environment.	MSHA will share with NIOSH data collected as a result of MSH's Request for Information (RFI), published 01/25/06, and other MSHA/NIOSH public meetings, including 03/13/06 meeting on mine rescue communication and tracking technology and 4/18/06 meeting on Mine Escape Planning and Emergency Shelters.
Issue report to Congress concerning its research results.	NIOSH report due 12/15/07.
Provide response to Congress describing the actions that the Secretary intends to take based on the report, including proposing regulatory changes.	MSHA response due 6/15/07.
EMERGENCY MINE EVACUATION RULE	
MSHA issued final rule, effective immediately, on 12/08/06 finalizing emergency temporary standard providing improved protections for emergency mine evacuation.	National Mining Association has challenged the final rule in the Court of Appeals for the District of Columbia.
	On 03/30/07, MSHA issued notice on availability of SCSR training units which must be used within 60 days after receipt of the units.

Senator HARKIN [continuing]. Submitted——

Secretary CHAO. Did you want me to answer some of that or——

Senator HARKIN. What?

Secretary CHAO. Did you want me to answer some of that?

Senator HARKIN. Do you want to answer that? I just——

Secretary CHAO. We will provide more for the record as well. Obviously, we have been very, very focused——

Senator HARKIN. Okay.

Secretary CHAO [continuing]. On all of this in the aftermath of the tragedy of 2006.

Senator HARKIN. Do you know when this review is going to be issued? Do you have any idea on MSHA's review?

Secretary CHAO. Yes.

Senator HARKIN. Shortly?

MSHA'S ARACOMA MINE REPORT

Secretary CHAO. Yes. In fact, the Aracoma Mine report will be coming out tomorrow. I respectfully ask that we debrief—we brief the family members first before doing so to the committee.

Senator HARKIN. Okay.

Secretary CHAO. That has always been the procedure. But we are—it takes a long time to file these reports. Please know that we are diligently working away to find out the causes. We do not want

to prejudge. There is an internal review process that occurs. Then that report is usually released about a month after the accident report.

PERSONAL PROTECTIVE EQUIPMENT

Senator HARKIN. One last thing and then we will, I think—one or two last things here. Personal protective equipment.

Secretary CHAO. Yes.

Senator HARKIN. OSHA's own estimates indicate that requiring employers to pay for basic personal protective equipment such as safety goggles and earplugs could prevent workers from suffering nearly 50,000 workplace injuries per year. These are OSHA's estimates.

It has now been 8 years since a standard was first proposed. Despite repeated assurances, OSHA has let this fundamental worker safety requirement languish. In response to a recent lawsuit, OSHA, again, is promising to issue a standard. This time by November. OSHA has offered no assurances about what kind of standard it will issue.

So my question, Madam Secretary, is: When will you issue the standard that OSHA first proposed in 1999? Given the opposition to this proposal by special industry interests, what assurances can you give us that you will not weaken the final standard in comparison to the 1999 proposal?

Secretary CHAO. We have been, actually, working on this issue for quite a while. The issue as to who should pay for personal protective equipment, you know, appears pretty straightforward on the surface. But, in fact, it is a very complicated issue. It requires careful deliberation to address a lot of the complex issues that have been raised in the rulemaking record.

We are currently considering the issues raised in the rulemaking. We reopened it for comment in 2004. We do—we know that this is important. So the Department does intend to issue a final rule, absent, again, unforseen circumstances, by November of this year. We think that we can probably do it. It is our intent to do it by that time.

Now regardless as to who pays for PPEs, our standards require employers to determine and ensure that workers use PPEs appropriately, so they can be protected. That is very firm.

Senator HARKIN. All right. Thank you very much.

Let me loop back to something that I talked about earlier. Because in between time, I talked about these earmarks and stuff. These special non-competitive awards.

INTERNATIONAL LABOR ORGANIZATION

Again, back to international child labor. Which has been an interest of this Subcommittee—mine, but also Senator Specter's too, when he was chair.

We—you, the Department of Labor, had a relationship with the International Labor Organization for a long time. What I am hearing—what I am hearing is that you are now thinking of putting that out for other recipients.

As I said earlier, a small amount of non-competitive grants is reasonable. We have guidelines for that. Considering certain fac-

tors, such as the unique qualifications of a grant recipient. The continuance of an existing relationship that has allowed for the maintenance of services are of particular significance to the agency on a long-term basis.

So I am concerned that you are undergoing efforts to discontinue the relationship that Labor has had with the International Labor Organization. I am wondering what that is all about.

Secretary CHAO. Well, that certainly is not true. I mean I, myself, have gone to every single International Labor Organization's annual meeting. I think I have gone more frequently than any other secretary. I think that is pretty accurate.

As I mentioned, the stance of the Department is that we try to competitively bid these grants. Because we want to ensure that the best services are available to the recipients and beneficiaries of these grants.

The 90 percent that you mentioned, I will look at that.

Senator HARKIN. Okay. Well, we do not need to go over ——

Secretary CHAO. I do not think that is quite correct.

Senator HARKIN [continuing]. That ground any more.

PERFORMANCE REVIEW BOARD

Secretary CHAO. Then where there are instances for sole-source, which, again, we try not to do, it has to go through a performance review board. As you mentioned, there has to be some pretty extraordinary circumstances.

Senator HARKIN. Who makes up that performance review board anyway? How are they appointed? How are they picked? Who picks? How many are there?

Secretary CHAO. I think I—I think I choose them, but I think I sign off on the candidates who are nominated for this board, and it goes—you know, goes through clearance. It is primarily——

Senator HARKIN. Could you find out for me?

Secretary CHAO [continuing]. Professionals——

Senator HARKIN. I want to find out who this performance review board is, and how they are picked, and how many. I do not have any idea whatsoever.

Secretary CHAO. They are primarily career people.

Senator HARKIN. Yes.

Secretary CHAO. It has been there before we—you know, it has been there for a very long time.

Senator HARKIN. I think so. I just do not know anything about it.

ILO FUNDING THROUGH ILAB

Secretary CHAO. We hope that the ILO will compete in this grant-making process. ILO is very competent. They should be able to do very well in the grant competition.

We have over 30 other organizations, however, that do work in child labor. We have AED. Catholic Relief Services. International Rescue Committee. Save the Children. Winrock International. International Youth Foundation. UNICEF, even.

So absent, again, a hard earmark within the legislation, there are many other organizations that have this capability to provide the services. So—

Senator HARKIN. Well, I would respectfully disagree with you on that. In terms of this—I mean they do good stuff. Do not get me wrong. But this is something I have tracked down for a long time. The ILO has been involved in this. They have the structures. They work with these other agencies. They coordinate with these other agencies to do certain things in the field on child labor.

Secretary CHAO. Then if they fund——

Senator HARKIN. Gathering data, for example. That type of thing. Pardon?

Secretary CHAO. If they fund these other organizations then, they of course, take a fee, you know, for the management. There is an overhead—excess overhead charge. Again, we are not against ILO for doing this. We just say—we are just saying that in the current situation—as you well know, throughout the administration, there is this emphasis on earmarks. Unless—in the language of the bill, which, of course, could not happen in this last go-around. But nevertheless, anything short of that, we basically are opening it up for competitive bidding.

So we hope the ILO will compete.

Senator HARKIN. Well——

Secretary CHAO. I mean with their particular expertise, they should do very well.

Senator HARKIN. Again, as I said, there is a—there is an exception made for unique qualifications, continuance of an existing relationship for maintenance and services, on a long-term basis, that allow for non-competitive grants.

The problem I see with this is that—obviously, everybody wants some money. So if you throw it out there, sure, you may—I do not want to see this parceled out. I do not want to see a little bit going to Catholic Relief Services, and a little bit—Lutheran Relief Services. A little bit to Red Cross, or whoever, out there. They are all good organizations. They do great work in a lot of ways.

We have had a focus on international child labor from this Department through ILO, for about, if I am not mistaken, 12 years now. I think that has been about right. Maybe a little bit longer.

As I said, we are making great progress. It is something that I monitor closely personally, and my staff. I am concerned about parceling things out and sort of taking the focus off. You have just got to—you have a good focus on it. I think ILO has been uniquely qualified to do that. Only because they—well, they have been doing it for a long time.

All of the things I have seen in the field indicates that they are doing a good job. If you have other information other than that, I would be more than happy to see it. But I am concerned about that aspect of it. So we will leave it at that, I guess.

Secretary CHAO. I take your advice on not fragmenting or parceling out——

Senator HARKIN. Yes.

Secretary CHAO [continuing]. These——

Senator HARKIN. Because it is not that much money anyway.

Secretary CHAO. It is a lot of money.

Senator HARKIN. Well, you are trying to cut it. You are trying to cut it. I know that. But I am not trying to cut it.

Secretary CHAO. I understand your point about not parceling it out. But I think that is still separate from competitive bidding. So——

Senator HARKIN. I do not know about that.

Secretary CHAO. Okay.

Senator HARKIN. We will have to take a look at it——

Secretary CHAO. I will.

Senator HARKIN [continuing]. And see. See who else—see if there is anyone else out there qualified. Only because I said that we have—unless you have information and data that can show me that ILO is not doing its job, and that it has been falling down on it, and that, then that is different. That is quite different.

Secretary CHAO. Yes. I do not think that is the case either. I think it has always been—we just try to—more and more we are just trying to competitively bid these contracts, again, with——

Senator HARKIN. I do not have anything wrong with competitive bidding, unless that would lead to a derogation——

Secretary CHAO. I understand.

Senator HARKIN [continuing]. Of the efforts that we have ongoing. Well, Madam Secretary, first, before I—this is really all I wanted to cover, that I had. The only other thing I would just say is that a 9.4 percent cut in this budget is—it is not good. Especially, just the whole area of Job Corps cut, $55 million. A 3.5 percent cut.

OFFICE OF DISABILITY EMPLOYMENT POLICY

The other one—oh. Yes. There is one other area I just want to bring to your attention. There is a proposed cut in funds for the Office of Disability Employment Policy by $9 million. That is a 32 percent cut.

Madam Secretary, we passed the American Disabilities Act in 1990. President Bush, the first Bush, signed it into law. It was bipartisan. We have had 17—and my name is on that, by the way. We have had 17 years of experience under ADA. One of the goals of ADA was self-sufficiency, that people with disabilities would become self-sufficient.

Yet, 17 years later, the unemployment rate among people with disabilities is over 60 percent.

Secretary CHAO. Right.

Senator HARKIN. It is over 60 percent.

Secretary CHAO. I agree with you, yes.

Senator HARKIN. So, you know, this is one where we just have to start focusing more attention. Now that is why, and this is not in your area, but—I am making sure we have reasonable accommodations for people with disabilities. Transportation. All those other things. But that is outside of your bailiwick.

But one thing that is in there is this disability employment policy. I do not know why—what is the reason for a 32 percent cut when we have over 60 percent unemployment among people with disabilities.

Secretary CHAO. We share your concern about the high rate of unemployment among Americans with disabilities. But I think we disagree on what ODEP should be doing. By having ODEP give out grants, we do not feel it is the best way to tackle this problem ei-

ther. ODEP should be a catalyst. It should be a facilitator. It should be a—you know, a convener. It should be sharing best practices. It should be doing the kind of—advocacy. Promotion work. Rather than give out grants. We are very limited on——

ODEP GRANTS

Senator HARKIN. What do those grants do?

Secretary CHAO [continuing]. What people——

Senator HARKIN. What do those grants do, Madam Secretary?

Secretary CHAO. With not very much results, I am afraid.

Senator HARKIN. But what do they do? What do those grants do?

Secretary CHAO. They give them out—sometimes they are direct grants to increase employment. A very small amount. $20 million, basically.

Senator HARKIN. Is that $20 million just given out in grants?

Secretary CHAO. Actually, the budget is about $40 million. So we have asked for $20 million. So there is a difference of about $20 million. But we do not think that, again, ODEP should be involved in grant making.

Senator HARKIN. Well, can your staff give us some idea of what those grants are?

Secretary CHAO. Sure.

Senator HARKIN. I have been told that some of those grants actually go out to show employers how they can employ people with disabilities by making modest, small accommodations that do not cost a lot of money.

I have heard all kinds of stories of these grants going out and showing an employer that by just a small amount of investment, they can hire people with disabilities, and have good workers who are very productive.

But a lot of times, they do not think about things. It is not that they are bad. The employers do not think about things like that. They have businesses to run, and they are trying to move ahead and stuff. But sometimes these grants go out to really show what can be done. Then others can see it.

So if I am wrong in that, let me know. I would like to know what some of these——

Secretary CHAO. I will take a look.

Senator HARKIN [continuing]. Grants look like.

Secretary CHAO. I will do so.

Senator HARKIN. I am not sure if I agree with you that we should not be giving grants. It depends on what the grants are for. If the grants are just busy work and studying something to death, well, you are right. I would agree with you that that would not be—but if it is actually going out to provide information and support to employers, especially small employers, to show what they can do to enhance the workplace for people with disabilities, well, I would not think those would be bad things to do. But if you would just give me some information on it, I would sure appreciate it.

Well, actually, I have kept you long enough, Madam Secretary. There are some others, but—well, we may have some questions for the record we will submit to you.

One last thing. Madam Secretary, I am concerned that the Department is not responding to requests from the subcommittee. We

are still waiting for responses to questions for the mine and safety hearing record, which were due last week, and the State tables on the impact of your proposed $335 million cancellation of Job Training funds.

Again, will you assure me that your Department will provide this subcommittee, our staffs, both sides, with timely and accurate responses to requests for information?

Secretary CHAO. I am sorry that that has been delayed. I thought they were—I am sorry that you have to bring it up. It will not happen again.

Senator HARKIN. I appreciate that very much. Then we also have some questions for the record.

Secretary CHAO. I would be more than glad——

Senator HARKIN. Anything else?

Secretary CHAO [continuing]. To answer them.

Senator HARKIN. All right. Anything else, Madam Secretary, you would like to request of us, or bring our attention to, or anything? I mean——

Secretary CHAO. I think we are okay. We have a good relationship with your staff. We look forward to working with them on some of these——

Senator HARKIN. Very good. Yes.

Secretary CHAO [continuing]. Tough issues.

Senator HARKIN. Okay. Well, thank you very much. You have been generous—oh, wait. Just a moment.

Secretary CHAO. I will submit a document on the balances per the State. I thought you might be interested in this.

Senator HARKIN. Oh. Yes. Yes. Yes. We would like to see that.

Secretary CHAO. All right.

Senator HARKIN. I will get my staff to take a little bit more look at that. On the balances. This is the carryovers that we were talking about earlier.

Secretary CHAO. Right.

Senator HARKIN. Yes.

Secretary CHAO. Because this comes up every year.

Senator HARKIN. I know. I would like to get a handle on it.

Secretary CHAO. Yes.

Senator HARKIN. I have one kind of view, or something, or one way that I think about it. I do not know if that is the right way or not, because—well, I mentioned about the contractual obligations. That type of thing.

You had a different way of looking at it, as to whether or not that money is actually spent or not. Well, I do not know the answer to that question.

Secretary CHAO. We look forward to working with you on this.

Senator HARKIN. I appreciate it very much.

Secretary CHAO. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. Well, you have been very generous with your time, and your answers and responses.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

NUMBER TRAINED UNDER CAREER ADVANCEMENT ACCOUNTS

Question. Please provide a chart displaying for the past 5 program years, the number of individuals trained under the proposed consolidated programs versus the number trained under the proposed Career Advancement Accounts. Please provide a quantitative analysis of how this proposal, which reduces funding sources for consolidated programs by more than $600 million, or 16 percent, can result in an increase of the number of trained individuals from 200,000 under current law to 600,000 under your proposal.

Answer. The Career Advancement Account proposal for Workforce Investment Act (WIA) reauthorization proposes the consolidation of four programs—the WIA Adult, Dislocated Worker, and Youth programs and the Employment Service. The following table shows the number of individuals trained in each of the past 5 years in the WIA Adult and Dislocated Worker programs. A minimal number of youth receive training under the WIA Youth program, and training is not provided under the Employment Service.

Program	Number of Individuals Trained				
	Program year				
	2001	2002	2003	2004	2005
WIA Adult	75,963	107,671	102,950	109,492	105,457
WIA Dislocated Worker	66,192	98,540	102,415	95,113	83,669

Source: Workforce Investment Act Standardized Record Data file.

The President's proposal for WIA Reauthorization would result in over 600,000 individuals trained through Career Advancement Accounts each year. Under the proposal, the amount of WIA funding dedicated to training would be substantially increased. This would be accomplished by (1) eliminating the current inefficient "silo" business model whereby programs are duplicative and create inefficient and parallel service delivery structures and (2) implementing a customer-focused model that enhances access to postsecondary education and training.

At the President's request level in the fiscal year 2008 budget, local areas would be required to spend a total of $1,899,000,000 on training. A Career Advancement Account would provide up to $3,000 each year for a worker to obtain training, resulting in an estimated 633,000 individuals trained each year. Additional funds are provided to States for Employment Services, to be used by local areas for the provision of intensive services and discretionary One-Stop Career Center services in addition to the provision of core services. More detail on the proposed funding structure is provided in the following table.

WIA REAUTHORIZATION PROPOSAL FUNDING STRUCTURE PRESIDENT'S FISCAL YEAR 2008 BUDGET REQUEST

	Amount
Total Appropriation	$3,413,000,000
National Reserve (7.5 percent of Total Appropriation)	255,975,000
Total Funding to States	3,157,025,000
Set Aside for Outlying Areas (.025 percent)	7,892,563
State Administration (5 percent of Total Funding to States)	157,456,622
33 percent to State Level	1,039,213,704
State Administration (5 percent of the Total Funding to States)	157,456,622
Employment Services (67 percent of State Level funds)	696,273,182
State-wide Activities (Remaining State Level funds)	185,483,901
67 percent to Local Areas	2,109,918,733
Local Administration (10 percent of Local Area funds)	210,991,873
Career Advancement Accounts (90 percent of Local Area funds)	1,898,926,860
Average Account	3,000
Number of Accounts	632,976

FUNDS SPENT ON ADMINISTRATION

Question. The budget justification States that "too many resources are being used to pay for administrative functions, overhead costs, and multiple layers of staff." What is the specific evidence for these conclusions? Please provide more detailed information about the amounts of resources that DOL believes is spent inappropriately on administrative functions.

Answer. The Department's belief that too much workforce investment funding is used for administration and overhead costs comes from a number of sources. First, while the Employment Service is intended to be a cornerstone of the One-Stop Career Center system under the Workforce Investment Act (WIA), many States continue to have separate Employment Service offices offering the same core services that are available in the same communities at the One-Stop Career Centers under WIA. The lack of integration in the delivery of core services by different programs has continued duplicative bureaucracies that divert funds that could be spent on services, including education and training.

Second, the current WIA regulation at 20 CFR 667.220(b) enumerates the specific functions defined as administrative costs. As required by WIA, this definition of administrative costs was developed in consultation with Governors and other stakeholder groups in 1999, and was more narrow than the definition in use before 1999. However, instead of reducing the level of administrative activity when the caps were lowered, some States and local areas charge some activities considered administrative costs under earlier programs as program costs. Activities such as performing oversight and monitoring of the program, the costs of facilities used for programmatic activities, the provision of technical assistance, the activities of State and local boards, professional organization membership dues, and the evaluation of program results, which have traditionally been classified as administrative costs, are currently classified as programmatic costs. As a result, there is no effective administrative cost ceiling.

Finally, based on expenditure data submitted by the States, the Department estimates that the proportion of WIA and Employment Service funding that has been spent on infrastructure is about one-quarter for the last 4 program years. For this estimate, the Department looks at the costs of infrastructure, including both physical and organizational costs, at the State and local levels that support the delivery of services to participants by the One-Stop system such as local administration and other infrastructure costs. While the Department does not question whether some of these costs are necessary or appropriate, taken in total, too large a proportion of WIA funds is spent on infrastructure and overhead rather than direct services.

COMMUNITY-BASED JOB TRAINING GRANTS

Question. The budget request proposes to continue a fourth year of investments in two related initiatives that according to the Department are critical to the "transformation of the workforce system and talent development"—the High Growth Job Training Initiative and the Community-Based Job Training Initiative, better known as the Community College Initiative.

To improve the training capacity in many communities, the budget request also includes the Community College Initiative. How does the Department plan to evaluate the impact of this investment—$250 million in the first two rounds alone—on increased community college capacity, better skilled workers, and community economic growth? How does the Department plan to identify and share promising practices with the education, workforce and economic development networks to further advance these improvements? How will the Department determine what is a "promising or best" practice?

Answer. The Department of Labor's Employment and Training Administration (ETA) is launching a full evaluation of the Community-Based Job Training Grant (CBJTG) program, also known as the Community-College Initiative, in Program Year (PY) 2007. It is focused on all grants awarded under the first two competitive Solicitations for Grant Applications. The evaluation will be composed of two parts. The first part is an implementation study that explores the effectiveness of capacity building efforts. The second part of the CBJTG evaluation is a net-impact study. This study, using non-experimental matching methodologies, will assess the net impacts of CBJTG training against a comparison group of like individuals. Additionally, grantees report their progress towards meeting their capacity building goals and the impact of their capacity building activities to ETA on a quarterly basis. ETA is in the process of compiling and validating the impact data reported to date.

Grantees are taking a variety of approaches to help bridge the gap between the workforce needs of industry, and the training and education provided to individuals who need jobs. As a result of these new approaches, grantees are producing a vari-

ety of products including best practice case studies, curriculum, competency models, distance learning tools, career awareness and outreach materials, research, career lattices, creation of industry skill centers, and Web sites.

CBJTGs were funded because they met an identified high growth or high demand industry need by implementing a capacity building and training strategy. Therefore, ETA believes all products developed under these grants may provide useful resources to the workforce system and many are potential promising or best practices. ETA is currently implementing a comprehensive dissemination plan to distribute the approaches, products, models, and tools from both the CBJTG and High Growth Job Training Initiative grantees to the public workforce investment system and educators from across the country. To do this, ETA utilizes a network of national, regional, State, and local stakeholders including industry, education, and the workforce investment system. ETA makes all of these grantee tools, models, and products available through the Workforce3One Web site (www.workforce3one.org), a site designed for sharing innovative resources, tools and learning events with workforce and education professionals. ETA routinely features products and promising practices through Webinars and monthly electronic newsletters distributed through Workforce^{3}One. In addition, ETA is developing a series of industry product CDs in order to share all Workforce^{3}One materials with 1,900 community colleges, 3,200 local One-Stop Career Centers, State and Local Workforce Investment Boards, Governors, and a wide variety of industry associations.

WIA REALLOCATION AND RESCISSION

Question. The budget proposes to cancel $335,000,000 of unexpended balances from various State formula grant programs authorized under the Workforce Investment Act. Since this proposal will cancel unexpended balances in State WIA funds, how will the Department know whether these funds are obligated already for authorized activities, including training?

Answer. States submit quarterly financial status reports to the Department which include data on Workforce Investment Act (WIA) title I formula fund obligations as well as expenditures. By using data reported at the end of Program Year (PY) 2005 (the most recent completed program year) as a guideline, approximately $555 million in WIA formula funds not obligated by the State and local areas were carried over into PY 2006. Since these unobligated funds greatly exceed the proposed $335 million cancellation, and make up only part of the total unexpended carryover balance that reaches over $1.1 billion, the Department does not expect obligated balances to be impacted significantly. Furthermore, the proposal would provide flexibility for the Secretary, at the request of the State, to allow a portion of the cancellation to be applied to a State's current-year funds, which are less likely to be fully obligated.

Question. The budget proposes to allow the Secretary to reallocate among the States for program year 2007 any amount that a State had unexpended for certain WIA program in excess of 30 percent and provide those funds to any State that did not have a balance greater than this amount. In addition, bill language is proposed that would allow Governors to reallocate funds in the same manner at the local level.

For each of the last 3 program years, please provide information on the extent to which reallocations at the local level take place currently, by State. Is there good enough data available to the Secretary and governors for making the reallocations, under the authority requested in the fiscal year 2008 budget?

Answer. The fiscal year 2008 budget proposes that the Secretary for States, and the Governor for local areas, have the authority to recapture and reallocate unexpended funds in excess of 30 percent of available funds. This would expand the current law recapture and reallocation authority that only applies to unobligated funds. The Department currently receives certified reports on expenditures from States providing the information needed to calculate which States would be affected by the proposed recapture and reallocation. Because of early concerns about the quality of accounting and financial reporting, the Department has conducted extensive financial training sessions with State and local staff to ensure that financial data is accurately gathered, recorded and reported. For instance, the Department developed and offered across the Nation a course on accrual accounting.

Individual local area financial data is reported to the State, but only aggregate local information is reported by the State to the Department of Labor. The State determines the recapture and reallocation of local funds and the Department does not collect reallocation data from the States; therefore, the Department cannot provide that information.

FINANCIAL REPORTING GUIDANCE

Question. Has DOL provided more financial reporting guidance, technical assistance and promising practices, as recommended by the Government Accountability Report, GAO–03–239? Please describe the actions taken and/or planned (including a timeline) to address the recommendations in this report.

Answer. Yes, the Department has provided financial reporting guidance and technical assistance. Between fiscal year 2004 and fiscal year 2006, the Department provided a number of States considerable technical assistance through Accrual Accounting and Financial Reporting training sessions. During these sessions, the Department provided 23 States with guidance and technical assistance on accrual accounting and financial reporting requirements, such as in-depth training on the reporting requirements for WIA funds as well how to account for, define, and report consistently on obligations, unliquidated obligations, and accrued expenditures.

The Department conducted Accrual Accounting and Financial Reporting training sessions for State and local employees on the following dates:

—January 23–27, 2006—Two sessions in Washington
—April 11–12, 2006—One session in Maryland
—April 18–19, 2006—One session each in Wisconsin and Arkansas
—April 25–26, 2006—One session each in Minnesota and Oklahoma
—May 9–10, 2006—One session in New Mexico
—May 17–18, 2006—One session in Michigan
—May 23–24, 2006—One session in Oregon
—June 27–28, 2006—One session in Ohio
—June 20–21, 2006—One session in Pennsylvania
—July 17–18, 2006—One session in Nebraska

Additionally, the Department has held three major national conferences around the country during the most recent year to train State, local and other financial and administrative staff on WIA and other Federal requirements that must be followed, including those relating to financial reporting.

MIGRANT AND SEASONAL FARMWORKER PROGRAM

Question. The budget proposes to eliminate funding for this program, inpart, because the Department believes the program does not focus enough on providing employment and training services. Over the last 5 years, about 5 percent of grant funds have been spent on related assistance, of which some is for gas and car repairs and some for emergency food, housing and medical care. Over 80 percent of the funds have been spent on job training and placement activities. About 90 percent of the jobs farmworkers were placed into were outside of agriculture and came with benefits and significant wage gains. Are these figures consistent with Department of Labor records? If not, why not? If the data is accurate, what's wrong with spending patterns and outcomes achieved by grantees under this program?

Answer. The Department does not collect data on whether jobs into which farmworkers are placed are outside of the agricultural industry. However, the goal of the program, and of all job placements, is economic self-sufficiency.

The expenditure rates cited are largely consistent with what grantees have reported to us. The Department of Labor's Employment and Training Administration (ETA) has been concerned that, historically, a majority of participants have been receiving only low cost related assistance services, which are available through other Federal programs and do not promote self-sufficiency, compared to those receiving employment and training services. This concern led ETA to implement three new approaches during the 2005 Program Year (PY):

(1) refocusing the Solicitation for Grant Applications by highlighting that the National Farmworkers Jobs Program (NFJP) is a job training program;

(2) establishing a cap on the number of participants who could receive related assistance services only; and

(3) changing the reporting system so that, for the first time, ETA could collect both participant and financial data on related assistance services only. Therefore, the PY 2005 expenditures for related assistance, accounting for 5.4 percent of the total, reflect, for the first time, the expenditures for those participants receiving these services and no others.

Currently, the NFJP provides services to about 20,250 of an estimated 2 million farmworkers, which demonstrates the need for a wider system approach. The One-Stop Career Center system can provide a full array of employment and training services, as well as supportive services and other related assistance, available from 17 Federal programs. Those being served by the NFJP have similar types of barriers to full-time employment that other workers do, and the relatively small NFJP does

not provide its participants with the full array of benefits they would derive from the workforce investment system.

COMMUNITY SERVICE EMPLOYMENT FOR OLDER AMERICANS

Question. The budget proposes a reduction of $133.6 million for the Community Service Employment for Older Americans program, based in part by efficiencies that could be realized under the reauthorization of the program. Specifically, what are the efficiencies that DOL believes will be achieved for administration of this program? What factors and assumptions did DOL use to calculate the proposed reduction of $133.6 million?

Answer. Improvements to the program as a result of the changes made by the 2006 amendments to title V of the Older Americans Act (OAA), which authorizes the program, allow the Department to more efficiently use funds to serve workers than is possible under current law. Reforms that will contribute to increased efficiency in the program include the following:

—A new time limit on participation of eligible individuals in the program is a key reform of the program. This ensures that more people can access the program by rotating individuals more promptly through available slots, and helps grantees focus on the end goal of the program—helping seniors find unsubsidized employment.

—Performance measures have been streamlined and strengthened, holding grantees accountable for results, and promoting efficient and effective use of program funds.

—The newly reauthorized program provides more training options for participants. While community service can provide valuable work experience, many seniors need additional education and training in order for their skills to be viable in regional labor markets.

—The reauthorized OAA requires that an open competition for national grants be conducted every 4 years, ensuring that the best grantees operate the program and provide a stimulus for new ideas, innovation, and high-quality service.

The Department examined a number of factors in determining its fiscal year 2008 request. These include excessive recaptured funds, which have steadily increased over the past few years and topped $13 million in PY 2004. The Department also considered the high number of unfilled slots among program grantees, which totaled over 1,500 in Program Year 2005. These factors indicate that program improvements are still needed in order to provide the most efficient and responsive services to low income seniors.

Question. What is the cost of maintaining the participant level at the 2007 program year level as adjusted by the higher minimum wage provided by H.R. 2, which was passed by the Senate on February 1, 2007?

Answer. Program Year (PY) 2007 has not yet begun, but will begin on July 1, 2007. In PY 2006 (July 1, 2006-June 30, 2007), the Department allocated 60,438 SCSEP authorized positions. The higher minimum wage provided by H.R. 2 would increase the unit cost. The unit cost represents how much each authorized position costs, and its calculation is set by the Older Americans Act section 506(g). The current unit cost is $7,153. The minimum wage increase was signed into law May 25, and will become effective 60 days later on July 24, 1 month into PY 2007. The new unit cost for PY 2007 will be $7,949. To support 60,438 positions at the PY 2007 unit cost of $7,949 requires $480,421,662 ($7,949 unit cost times 60,438 authorized positions). To support 60,438 positions at the $6.55 minimum wage and a unit cost of $8,850 requires $534,876,300 ($8,850 unit cost times 60,438 authorized positions). The actual unit cost of SCSEP authorized positions will depend on whether a minimum wage bill is passed by the Congress, and the effective date of the minimum wage increase.

Question. How does the Department analyze and interpret the data that it has collected from all SCSEP grantees since July 2004 as well as the SCSEP evaluation completed by DAH Consulting for DOL in 2006? Both provide a very positive report on SCSEP's effectiveness. For example, SCSEP is given a higher customer satisfaction score than WIA by participating seniors and employers, according to a national survey published by the Charter Oak Group, a DOL contractor.

Answer. The Department regularly analyzes Senior Community Service Employment Program (SCSEP) data using the following sources: (1) grantee data in the SCSEP Performance and Results Quarterly Progress Report (SPARQ) system and (2) customer satisfaction surveys returned by SCSEP participants, host agencies, and employers. Although the customer satisfaction scores from participants, host agencies and employers are quite high, an analysis of performance data and financial data raises concerns about program effectiveness and indicates that some grant-

ees have not provided services at the full level for which they receive funds, resulting in a significant amount of funds being recaptured and a significant number of authorized training positions or "slots" being unfilled. Improvements to the SPARQ system will result in increasingly accurate data and will allow the Department to provide better guidance and technical assistance to grantees in efforts to perform more efficiently.

The Department also has analyzed results from a draft of the SCSEP evaluation by DAH Consulting. Although the DAH evaluation was positive overall, it also pointed to some areas where the SCSEP needs improvement. Specifically, the program could be more effective at moving participants into unsubsidized employment. As the report points out, this involves improving collaboration between SCSEP and the One-Stop Career Center system and improving access to training for good jobs. Two specific aspects of the newly reauthorized SCSEP—providing more training options for participants and placing a time limit on participation—should begin to address this challenge, ultimately enabling more individuals to secure unsubsidized employment. Finally, although the evaluation included some analysis of outcomes, it did not look at a critical aspect of the program's effectiveness: its impact on the longer-term self-sufficiency of its participants. The Department will begin a study of that aspect of SCSEP this summer.

JOB CORPS OFFICE

Question. The fiscal year 2008 budget proposes to transfer the Job Corps office back to ETA on the basis of better integration of Job Corps within the workforce system and greater efficiencies. Please provide a more detailed justification for this proposal.

Answer. We continue to believe that the unique services of the Job Corps program are maximized when leveraged with the other job training and employment programs administered by ETA. The transfer back to ETA will maximize coordination and strategic planning efforts, and achieve efficiencies in overhead and administrative costs.

ETA already has an accountability structure in place. The Office of the Secretary, by contrast, is not structured to directly administer over $1 billion in contracts. Doing so would require creating new bureaucracy in the Office of the Secretary to coordinate many functions, including:

1. National contracting support from the Office of Administration and Management.
2. Policy guidance from the Office of Policy.
3. Approval of media campaigns by the Office of Public Affairs.
4. Technology support from the Office of Administration and Management.
5. Administrative support for human resources, payroll, staff training, etc. from Administration and Management.

TEACHER SALARY INITIATIVE

Question. How will funds be allocated for the teacher salary initiative identified in the fiscal year 2008 budget? Which occupations will be covered and will it apply to all individuals in those occupations? How many individuals will receive an increase under the proposal and by how much?

Answer. Funding will be provided to each center operating contractor based upon the differential between their existing salary structure at that time and the salaries indicated by the comparability study for the positions in their area. The occupations covered are the Academic and Vocational Instructors (teachers). There are 2,051 teachers eligible to receive a pay increase under this proposal. However, the actual salary increase will be based on their salary comparability at that time, as indicated in the study, and by the center operator's determination of qualifications (certifications received, experience).

EFFICIENCIES IN JOB CORPS OPERATIONS

Question. What are the efficiencies identified in the budget that will be achieved in Job Corps operations? How did the Department calculate the $57 million in savings that could be achieved without any programmatic impact?

Answer. By identifying the number and location of student training slots that have remained consistently unfilled, we are able to reduce the slot levels at centers at the beginning of their contract or option year and thus reduce the fixed costs associated with providing services for more students than are on the center. Currently, we recover cost underruns from the contractors at approximately 15 percent of the per student cost because they must maintain fixed costs in anticipation that those training slots might be filled. It is far more efficient to price the contract at

what is actually needed based upon consistent trends in on board strength. The services to those students who are at the center are retained and thus, there is no impact on the program.

The savings were calculated by determining the per student training slot cost multiplied by the number of training slots identified for reduction. Some of the savings were offset by increases for pay and FECA, rent, inflation for all other categories resulting in an overall savings of approximately $57 million.

JOB CORPS MARKETING CAMPAIGN

Question. DOL has announced a "major national marketing campaign to try to attract and to get more young people interested in attending the Job Corps program." Can you describe this campaign, including the amounts budgeted in fiscal year 2007 and fiscal year 2008 for related activities?

Answer. On a national level, Job Corps' National Recruitment and Outreach Campaign consists of program recruitment on television, radio, and specific print publications. Television spots remain the largest component of the campaign and are the most successful referral source in driving calls to Job Corps' National Call Center, the first step of the admissions process. For Program Year 2006, we funded the campaign at $5 million; for Program Years 2007 and 2008, Job Corps intends to fund it at $6 million (which is the same level of funding from PY 1999 thru PY 2005).

Additionally, in October 2006, we launched Job Corps' Consolidated Outreach Plan, which combined the program recruitment efforts of the National Office and its six Regional Offices into a single recruitment contract, which allows Job Corps to take advantage of economies of scale and ensures that a single message and unified brand is communicated to our target audience. With this consolidated plan, we are rolling out new Job Corps recruitment materials and television spots beginning May 1, 2007. All OA contractors, Regional Offices, and the Job Corps National Call Center will be provided with these national materials.

JOB CORPS RECRUITMENT

Question. Historically, Job Corps' student enrollment levels have been cyclical and dependent on various factors including the economy, retention and recruitment. In the past, Job Corps has quickly devised plans to increase enrollment on Job Corps centers across the country. What is your national recruitment plan? What amounts are planned to be spent in fiscal year 2007 and fiscal year 2008 to implement the plan? When do you expect to see results?

Answer. Recruitment is a priority at all levels of the program and is independent from the decision to reallocate student slots. We do not believe that it makes economic sense to funnel additional recruitment funds to centers that have historically not been able to maintain full capacity. Instead, we would prefer to set more realistic slot levels at these centers and move the unfilled slots to other centers where they can be filled.

It is important to note that the number of students enrolled in the program is not solely a function of recruitment and admissions. In addition to student arrivals, the number of student separations and students' average length of stay also factor into the OBS count. Even if student arrivals increase, students' length of stay must not decrease (just as the student separation rate must not increase) if centers are to be filled. A vital component of increasing Job Corps' OBS is student commitment, or the willingness and readiness of a student to remain in the program through graduation. To improve performance in this area, Job Corps has implemented the Speakers, Tutors, Achievement, Retention, and Success program (STARS), offering structured tutoring and mentoring to provide those students at risk of leaving early the encouragement and support necessary to remain longer in the program, thereby increasing the number of program graduates. Furthermore, we have implemented Career Success Skills (CSS) which permeates employability and social skills development into all aspects of the program, leading to a more personalized relationship between staff and students, improving center culture, and students' willingness to remain in Job Corps. Additionally, we are piloting a drug screening program in which applicants are tested for drug use prior to admissions to further ensure that we are enrolling students who are committed to their education and ready for the rigor and demands of the program.

Job Corps monitors the programs' arrivals, separations, weekly termination rates, average length of stays, and reasons for separation, at the center, regional and national levels, to ensure that any unexpected fluctuations in these areas are identified and reviewed, and to evaluate the effect new programs and programmatic changes may have on the OBS.

On a national level, Job Corps' National Recruitment and Outreach Campaign consists of program recruitment on television, radio, and specific print publications. Television spots remain the largest component of the campaign and are the most successful referral source in driving calls to Job Corps' National Call Center, the first step of the admissions process. For PY 2006, we funded the campaign at $5 million; for PYs 2007 and 2008, Job Corps intends to fund it at $6 million (which is the same level of funding from PY 1999 thru PY 2005).

Thus, Job Corps is addressing challenges with recruitment and retention throughout the program in order to implement a more holistic solution.

WIA ADULT PROGRAM

Question. ETA is developing and disseminating policy guidance and practical technical assistance to assist the WF system to increase education opportunities for adults and eliminate duplicative administrative and service delivery structures. What specifically has been provided in fiscal year 2006 and fiscal year 2007?

Answer. The Department of Labor's Employment and Training Administration (ETA) has issued a number of policy guidance documents designed to support the State and local workforce investment system in increasing adults' access to education opportunities and to ensure that the majority of workforce investment system resources are invested strategically in training and education, rather than in administrative expenditures and duplicative infrastructure. Examples of such policy guidance include the following:

—In March 2006, ETA issued policy guidance entitled, "Using Workforce Investment Act Funds to Serve Incumbent Workers and Employed Workers" (Training and Employment Guidance Letter (TEGL) No. 18–05). This guidance encourages the workforce investment system to take advantage of existing flexibilities under the Workforce Investment Act (WIA) to provide education and training to employed workers in order to support their career advancement and mobility.

—In November 2006, ETA issued Training and Employment Notice (TEN) No. 17–06, "Vision for 21st Century Apprenticeship." The TEN encourages the workforce investment system to adopt innovative apprenticeship models as a critical post-secondary education and training approach for adults.

—In January 2007, ETA issued policy guidance on the development and submission of States' strategic State Plans (TEGL No. 13–06, "Instructions for Workforce Investment Act and Wagner-Peyser Act State Planning and Waiver Requests for Years Three and Four of the Strategic Five-Year State Plan (Program Years 2007 and 2008)"). The TEGL explicitly requires that States discuss in detail their strategies for reducing duplicative administrative expenditures and structures, in support of increasing adults' access to education and training.

In addition to these policy issuances, ETA is currently developing guidance documents that, when published, will support the workforce system in increasing access to education for adults, while eliminating duplicative spending and service delivery structures. ETA expects to publish all of these draft policy guidance documents this year. Examples of policy currently in development include:

—Policy guidance on enhancing the integration of reemployment services for unemployed workers identified as most likely to exhaust their unemployment insurance benefits, within the broader continuum of education and training services provided through the public workforce investment system.

—Policy guidance that builds off of TEN No. 17–06 and provides the workforce investment system and the Registered Apprenticeship system with additional guidance on strategies for using the apprenticeship model as an innovative competency-building and education approach for adults, which could result in greater access for women in this program, as recommended by the PART assessment.

—Policy guidance that encourages the workforce investment system to implement innovative approaches to providing adults with access to entrepreneurship training and education.

—A TEN that communicates to the workforce investment system ETA's vision for the critical role of talent development and education as the key drivers of competitiveness and growth in regional economies.

—Policy guidance that provides the workforce investment system with guidance on accessing supportive service resources and support for adults through programs other than those funded under WIA, to ensure that the maximum amount of WIA resources are devoted to education and training, rather than to duplicative supportive service expenditures.

—Policy guidance encouraging the use of technology-based learning to increase access to learning opportunities for workforce investment system customers within existing statutory and regulatory flexibilities.

In addition to policy guidance currently in development, ETA is pursuing a number of cross-cutting initiatives and approaches aimed at enhancing adults' access to education and lifelong learning opportunities and improving the provision of training for adults under WIA. Examples of these efforts follow.

—The Workforce Innovation in Regional Economic Development (WIRED) initiative is focused on developing and replicating innovative talent development strategies that create high skill, high wage jobs for workers. Increasing education and training opportunities is a strong component of the WIRED initiative. In each region, the workforce investment system is collaborating with the continuum of education, industry, and economic development partners to ensure that workers are becoming educated and trained for high growth occupations and sectors. Promising practices from the WIRED Initiative will be highlighted at Workforce Innovations 2007 and shared widely on Workforce^{3}One, a knowledge network for the workforce system, industry, and economic development stakeholders.

—Both ETA's High Growth Job Training Initiative and Community-Based Job Training Grants seek to develop, implement, and support the dissemination and replication of innovative models for providing adults with education and training in high growth, high demand, and emerging industries and sectors.

—Through the Technology-Based Learning (TBL) Initiative, ETA seeks to increase the number of people trained in high growth jobs through the broadening of opportunities for skill and competency development made available timely and conveniently through the use of technology-based learning methodologies.

—Our Performance Enhancement Project (PEP), a dynamic technical assistance contractual resource that assists ETA in improving the performance of WIA program operators, has provided a varied array of customized technical assistance to under-performing State and local areas over the past 4 years. One topic PEP addresses for the benefit of the workforce investment system as a whole is service integration. Through PEP, ETA is providing States and local areas with promising practice examples and simple training tools to help them better integrate programs.

—Workforce^{3}One is an interactive learning tool designed to build the capacity of the workforce investment system to develop strategies that enable individuals to be successful in the 21st century economy by fully understanding the skills and competencies needed of business and industry and working collaboratively with a wide range of strategic partners to develop innovative workforce solutions. Workforce3One carries out this mission through a variety of strategies:

  —Allowing the workforce system, educators, business and industry, and others to share their innovative approaches, products, and tools;

  —Hosting online learning events as Webinars that highlight promising practices and provide a forum for policy discussions;

  —Providing a vehicle for ETA to share information and products developed at the national level;

  —Serving as a key point of dissemination for the approaches, products, and tools of the High Growth Job Training Initiative, Community-Based Job Training Grants, and WIRED; and

  —Offering a searchable database of over 3,500 learning objects, including tools, data, Webinars, and self-paced learning events.

Question. What guidance and tools have been disseminated to assist in working with veterans?

Answer. It is the Employment and Training Administration's (ETA) specific mission to ensure that the public workforce investment system is positioned to provide priority of service to veterans and to help veterans maximize their employment opportunities in civilian life by providing them access to education and training opportunities they need to obtain good jobs with career pathways. This requires understanding the full array of services and resources that are available to veterans and collaborating across organizations and programs to ensure leveraging of those resources for the benefit of veterans.

In response to the unique career and job placement assistance needs of transitioning military personnel and veterans, ETA has collaborated with the Department of Defense (DOD) and the Department of Labor's Veterans Employment and Training Service (VETS) on multiple efforts to create integrated and substantive employment, training, and support services. These efforts include providing guidance to the workforce investment system, including State workforce agencies, grantees, and One-Stop system leads, on priority of service for veterans; promoting awareness among veterans of One-Stop Career Center assistance; and exploring ways to ease the transition into civilian employment.

ETA has focused efforts on ensuring that veterans are provided with priority of service at One-Stop Career Centers. Training and Employment Guidance Letter (TEGL) No. 5–03, "Implementing the Veterans Priority Provisions of the Jobs for Veterans Act (Public Law 107–288)" was issued on September 16, 2003. This guidance was followed with the development of the Jobs for Veterans Act Web site, www.doleta.gov/programs/vets, and the posting of a series of questions and answers on this site for 15 programs administered by ETA.

With a policy of priority of service to veterans and an extensive array of programs and services in place, the Department has turned its focus to increasing veterans' awareness of, access to, and use of these employment and training services. The Key to Career Success campaign is designed to connect veterans and separating military personnel to services and resources available from One-Stop Career Centers nationwide. Announced by Secretary Elaine L. Chao on November 10, 2005, the centerpiece of the Key to Career Success campaign is a special wallet card issued worldwide to military personnel and others transitioning to civilian life. Information on the card guides veterans to their nearest One-Stop Career Center. To date, over 300,000 Key to Career Success cards and brochures have been distributed to over 300 DOD and DOL–VETS locations in the United States and abroad, mainly through Transition Assistance Program (TAP) workshops worldwide. The TAP is a partnership among the Departments of Defense, Veterans Affairs, Transportation and the Department of Labor's Veterans' Employment and Training Service (VETS) to give employment and training information to armed forces members within 180 days of separation or retirement through comprehensive 3-day workshops at selected military installations nationwide.

In November 2006, a Key to Career Success Military Transition Portal was launched at www.careeronestop.org/militarytransition. The portal provides career information and links to services that help veterans and military service members successfully transition to civilian careers and functions as a landing page for accessing the resources that are currently available on the suite of CareerOneStop Web sites. The Key to Career Success portal will continue to be upgraded and will provide key components to the DOD TurboTAP Web site under development by the DOD in cooperation with DOL–VETS and ETA. The TurboTAP Web site provides information for service members on transitioning from military service and is a supplement to the services offered by the Transition Assistance Offices and other groups. The site is supported by DOL–VETS and ETA.

ETA will work with One-Stop Career Center staff to further implement the Key to Career Success campaign by documenting best practices and success stories at local One-Stop Career Centers. During the next few months, a 60-minute Web conference will be available through ETA's Workforce3One Website targeted at service providers with the goal of sharing best practices. Also, at Workforce Innovations, ETA's annual workforce conference, a workshop will focus on developing and connecting a local HireVetsFirst campaign to the Key to Career Success campaign.

In addition to connecting veterans with One-Stop Career Centers through the Key to Career Success campaign, ETA is examining ways to ease the transition into civilian employment for returning veterans. DOD and ETA have established a "Credentialing Working Group" to help remove credentialing barriers that some veterans and transitioning service members face. Translation of qualifications from the context of the military mission to the civilian setting still presents challenges for individual transitioning military members. In many cases, this is due to the range of civilian occupational licensing and certification requirements, which vary from State to State. The group will target high-value occupations that are both significant to the military and are sought by civilian employers. In those areas, the group will sponsor work to: (1) map career pathways between military occupations and civilian occupational employment, (2) promote uniformity/reciprocity across States with regard to occupational licensing, and (3) promote efforts to maximize the transferability of military education and training for purposes of credit toward licensure and certification requirements. To support this effort, ETA has established the Workforce Credentials Information Center, on the Careeronestop.org Web site. The Center provides information on licenses, certifications, apprenticeship programs, educational degrees, and training, and includes information on matching military experience with civilian opportunities.

ADULT TRAINING OPPORTUNITIES

Question. The budget proposal would result in more than 50,000 fewer training opportunities under the Adult program. What's the impact of this proposal?

Answer. The budget proposal would not result in more than 50,000 fewer training opportunities under the Adult program. Under the President's Career Advancement

Account proposal for Workforce Investment Act (WIA) reauthorization that is part of the fiscal year 2008 budget, the WIA Adult, Dislocated Worker, and Youth programs and the Employment Service would be integrated into a single funding stream and, thus, a separate Adult program would no longer exist. The integrated funds would be used for Career Advancement Accounts and employment services for job seekers and employers. This proposal would result in significantly more individuals being trained in comparison with the number who now receive training under the current system. The Department estimates that over 600,000 individuals would receive Career Advancement Accounts at our fiscal year 2008 budget request level versus the roughly 189,000 adults who exit training under the current system. Under the Department's proposal, these individuals would include adults and out-of-school youth entering or re-entering the workforce or transitioning between jobs, and incumbent workers in need of new skills to remain employed or move up the career ladder.

MONEY SPENT ON BUREAUCRACIES AND OVERHEAD COSTS

Question. The budget claims that too much money is spent on competing bureaucracies, overhead costs, and unnecessary infrastructure. Please cite specifically the evidence for this conclusion.

Answer. The Department's belief that too much workforce investment funding is used for administration and overhead costs comes from a number of sources. First, while the Employment Service is intended to be a cornerstone of the One-Stop Career Center system under the Workforce Investment Act (WIA), many States continue to have separate Employment Service offices offering the same core services that are available in the same communities at One-Stop Career Centers under WIA. The lack of integration in the delivery of core services by different programs has continued duplicative bureaucracies that divert funds that could be spent on services, including education and training.

Second, the current WIA regulation, at 20 CFR 667.220(b) enumerates the specific functions defined as administrative costs. As required by WIA, this definition of administrative costs was developed in consultation with Governors and other stakeholder groups in 1999, and was more narrow than the definition in use before 1999. However, instead of reducing the level of administrative activity when the caps were lowered, some States and local areas charge some activities considered administrative costs under earlier programs as program costs. Activities such as performing oversight and monitoring of the program, the costs of facilities used for programmatic activities, the provision of technical assistance, the activities of State and local boards, professional organization membership dues, and the evaluation of program results, which have traditionally been classified as administrative costs, are currently classified as programmatic costs. As a result, there is no effective administrative cost ceiling.

Finally, based on expenditure data submitted by the States, the Department estimates that the proportion of WIA and Employment Service funding that has been spent on infrastructure is about one-quarter for the last 4 program years. For this estimate, the Department looks at the costs of infrastructure, including both physical and organizational costs, at the State and local levels that support the delivery of services to participants by the One-Stop system, such as local administration and other infrastructure costs. While the Department does not question whether some of these costs are necessary or appropriate, taken in total, too large a proportion of WIA funds is spent on infrastructure and overhead rather than direct services.

REFOCUSING THE WORKFORCE SYSTEM

Question. According to the budget justification, ETA is increasing its focus on postsecondary and training resources to help the workforce system be more responsive to changing labor market needs and regional economies. Please provide examples of what is being done and how the fiscal year 2008 budget supports this focus.

Answer. There are two ways the Department is helping the workforce investment system be more responsive to regional economic needs: (1) by implementing initiatives designed to promote regional competitiveness and greater access to education and training, and (2) by working with the Congress to substantially reform the workforce investment system.

Through the President's High Growth Job Training Initiative, ETA has invested over $285 million in 150 partnerships among employers, education programs, and the workforce investment system. Each project targets the skill and talent needs of high-growth, high-demand and transformational industries in our Nation's economy and provides the resources necessary to train workers in the skills demanded by the 21st century economy.

Community-Based Job Training Grants, also known as the Community College Initiative, seek to address a critical shortcoming in the workforce development capacity of many regions by supporting community colleges to train workers for jobs in high-growth, high-demand industries. Due to their close connection to local labor markets, community colleges are well positioned to understand the intricacies of local economies and better prepare workers for occupations in these industries. The Department has provided $250 million to 142 community colleges and other entities under this initiative.

The Department launched the Workforce Innovation in Regional Economic Development (WIRED) Initiative in February 2006 to emphasize the critical linkage between workforce development and economic development in regional economies. WIRED focuses on the role of talent development in driving regional economic competitiveness, job growth and prosperity for workers. Under the WIRED Initiative, the Department has invested $260 million and provided expert assistance to 26 regions across the Nation to implement strategies that will create high-skill and high-wage opportunities for American workers.

The administration has also recently submitted to Congress legislation that will improve the ability of the workforce investment system to support our Nation's competitiveness by providing States and local communities more flexibility to design streamlined workforce systems that best fit the unique needs of their economies. Our proposal would also better serve the needs of American workers and employers by making more money directly available for education and training. Under the proposal, four separate funding streams would be consolidated and allocated to States—and through States to local areas—to provide Career Advancement Accounts and employment services to job seekers and employers. Most of these funds would be spent on education and training.

Career Advancement Accounts would enable current and future workers to gain the skills needed to successfully enter, navigate, and advance in the 21st century labor market. Accounts would be available to both adults and out-of-school youth entering or re-entering the workforce or transitioning between jobs, and to incumbent workers in need of new skills to remain employed or move up the career ladder.

DISLOCATED WORKER PROGRAM

Question. Under DWAC pilot programs—for career advancement accounts and other automotive industry layoffs—will help inform broader efforts for dislocated workers for fiscal year 2007 and beyond. What are these activities and specifically what is being learned that will shape future activities? What is proposed in the fiscal year 2008 budget under pilot programs and based on lessons learned?

Answer. Five States impacted by the announced General Motors and Ford plant closures (Georgia, Michigan, Minnesota, Missouri, and Ohio) have volunteered to pilot Career Advancement Accounts (CAAs) to serve the dislocated workers impacted by the closures as well as those workers who are displaced as a result of impacts on supplier companies and the community. This demonstration will focus on the use of CAAs for transitioning workers in need of tuition assistance for education, enabling them to either build on transferable skills or gain skills for new careers. Each State has received $1.5 million from the Department and is expected to leverage a like amount in Federal, State, and local resources.

The CAA automotive demonstration is being evaluated to establish empirical knowledge and understanding of the provision of customer-driven training vouchers to dislocated workers impacted by the Ford and GM plant closures, as well as impacted employees of supplier companies and in communities. The evaluation involves four steps—technical assistance, data collection, an implementation study, and a net-impact evaluation, which together will lead to evaluation results that will inform future proposals and activities.

—*Technical Assistance*.—Technical assistance is currently being provided to the five automotive States. The overall objective of the technical assistance strategy is to support the CAA demonstration States with information and training that will help them to successfully implement their CAA projects.

—*Data Collection*.—To evaluate the overall effectiveness of the CAA demonstration, a standardized participant reporting system to collect data on services received through the CAA demonstration will be established and maintained.

—*Implementation Study*.—An implementation study of the CAA demonstration will examine the extent to which both individual project objectives and the overall grant program objectives were achieved; document project activities undertaken for possible replication in other States; and measure changes in outcomes

relative to a baseline period prior to the funding of the grantees projects. Work on the implementation evaluation will begin in June 2007.

—*Net-Impact Evaluation.*—A net-impact evaluation will provide statistically valid and reliable estimates of the effects of CAAs on key outcomes. A non-experimental net-impact evaluation of the five automotive States using either comparison group or comparison site methodologies will be conducted. The purpose of the net-impact evaluation is to determine the effects of the CAA training model on the employment and earnings of the dislocated workers participating in the demonstration. The CAA evaluation will also include two types of cost analyses—an administrative cost analysis and a benefit-cost analysis. The administrative cost study examines the extent to which the workforce investment system realized savings in bureaucratic and administrative costs from conducting the CAA model. The benefit-cost analysis looks at the overall CAA model to determine the cost effectiveness of the initiative to the government, the taxpayers, and society.

YOUTH ACTIVITIES: YOUTH PILOT PROJECT

Question. Youth Pilot Project—Have any States submitted the required reports to DOL? What is known about the changes and performance that have been achieved under the Pilot Projects? If DOL has yet to receive information, what is the timeline for the receipt of such reports? Please provide information about the amount of funds currently being spent on technical assistance to States related to furthering collaborative approaches for youth activities.

Answer. In February 2007, the Department of Labor issued the "Shared Youth Vision Pilot Project" application to the 16 State Teams that attended the 2006 Shared Youth Vision Forums. The State Teams submitted their completed applications to the Department on or before April 6, 2007. Funds will be awarded to the State Teams in two phases between now and June 30, 2007, based on the States' readiness as demonstrated by their proposals. The Shared Youth Vision Federal Partnership is currently reviewing these proposals to determine how well the State Teams responded to the criteria in the pilot application that States demonstrate how their collaborative strategy will support integrated systems development and collaboration at the local service delivery level.

Because the pilot projects will not begin implementation until July 1, 2007, it is too early to assess changes and performance that have been achieved under the projects. States will operate the pilot projects over the course of Program Year 2007 (July 1, 2007-June 30, 2008), reporting quarterly on their progress. Also, the Department is funding a Shared Youth Vision Pilot Project Study to document the success of the shared youth vision collaborative efforts at the Federal, State, and local levels. This study will be completed by the fall of 2008. As part of this study, the Department will conduct the following analysis of the Shared Youth Vision Federal Partnership and the State Teams:

—Documenting the work of the Federal Partnership from 2004 to 2007 in support of system transformation, as recommended by the White House Task Force for Disadvantaged Youth.

—Documenting the work of the State Teams in a usable and transferable fashion in the following areas: (1) coordination and integration of services for the targeted populations; (2) multiple partner agencies working together at the service delivery level to serve targeted youth population(s) that reflects the State's overall shared youth vision; (3) policies and practices identified and implemented based on gap analysis; (4) challenges associated with higher-level strategic planning and implementation among the State Teams; (5) interagency State Teams definition, collection and validation of measurable outcomes for neediest youth; (6) methods for engaging business and industry; and (7) implementation of replication and sustainability strategies.

—Developing a "Blueprint" model that can be used by States and local levels to assist them in their collaborative efforts around a shared youth vision.

The total amount of funding to be provided to the State Teams through the Shared Youth Vision Pilot Projects is $1,720,000. In addition, the Department is funding $100,000 of technical assistance for the pilot projects.

YOUTH ACTIVITIES: ALTERNATIVE EDUCATION

Question. In working with the Department of Education on identifying and bringing to scale systemic alternative education approaches for creating multiple pathways to graduations, how did DOL and the Department of Education factor in evidence of effectiveness? What was the standard adopted and what role did the Education's Institute of Education Sciences play in this collaboration? How will this

focus on the alternative education be continued under the current law budget request?

Answer. The Departments of Labor and Education promote alternative education through unique yet complementary initiatives, and collaborate in sharing evidence of effective practices and productive strategies. Through its implementation of the No Child Left Behind Act, the Department of Education is focusing its efforts on reducing the number of drop-outs and holding school districts accountable for low graduation rates. In the Department of Labor, the Employment and Training Administration's (ETA's) Youth Vision, developed over 2 years ago, augments this work by addressing the large number of youth leaving high school without a diploma and unprepared for the demands of the 21st century workplace. Through the Youth Vision, ETA uses the Workforce Investment Act (WIA) Youth program as a catalyst for increasing both the quality and quantity of alternative learning environments and re-connecting out-of-school youth with secondary and post-secondary educational opportunities and high growth employment.

ETA studied different alternative education interventions for evidence of effectiveness. In a report funded by ETA on alternative education programs that re-engage out-of-school youth with learning, the Urban Institute found that there are few scientifically-based rigorous evaluations on the effectiveness of alternative education approaches. However, the study points to programs that have a clear focus on academic learning and address the education and career interests of students as promising interventions.

In an effort to build upon that research, ETA gathers evidence of effective practices not only from its own research and demonstrations, but also from the Department of Education's efforts, such as the Office of Vocational and Adult Education's (OVAE's) Disconnected Youth project and related research. Further, in an effort to comprehensively factor evidence of effectiveness into program planning and to learn more about the factors that contribute to strong, vibrant academic alternative learning environments, ETA has held three Alternative Education Listening Sessions. These sessions were attended by experts from around the country well-versed in alternative education including Department of Education representatives who shared expertise from all of Department of Education's sub-agencies, practitioners, policy makers, and individuals from various educational think tanks and affinity groups.

The Listening Sessions provided invaluable input from a range of experts on the effectiveness of different alternative education models. The consensus of experts revealed an urgent need to take existing models that have been proven successful to scale, as well as a need to support the development of new models that address the rapidly changing skill sets needed for the workplace and post-secondary education. Listening Session experts concluded that in order to be effective, new models should:

—Align with the No Child Left Behind legislation;
—Focus on helping participants meet State standards in the core subjects;
—Include alternative learning strategies such as applied and/or contextual learning;
—Acknowledge the need for interdisciplinary learning;
—Support portable credentialing;
—Provide extensive career exploration, guidance, and planning; and
—Provide multiple pathways for both learning and career growth.

ETA integrated these elements in several grant competitions recently launched which provide support for alternative education, including:

—A $47 million YouthBuild competition that will fund approximately 95 programs that provide an integrated academic and occupational skill training model for at-risk youth;
—A $3 million competition which will support towns with populations between 75,000 and 300,000 to develop blueprints for multiple education system pathways; and
—A $6 million competition to improve alternative educational pathways for youth recently released from juvenile corrections or on probation.

The Department's fiscal year 2008 current law budget request continues to support ETA's focus on alternative education through the YouthBuild program, pilot and demonstration funding, the proposed Reintegration of Ex-Offenders program which will serve both adults and youth, and the WIA Youth program which will continue its focus on out-of-school youth by addressing alternative education. The Department will also address alternative education in fiscal year 2008 through the Workforce Innovation in Regional Economic Development (WIRED) initiative, through which several regions are using WIRED grant funds to examine their existing education infrastructure. In all of these efforts, the Department will continue to collaborate not only with the Department of Education but also with other private foundations and organizations that are addressing the Nation's drop-out crisis.

DISABILITY PROGRAM NAVIGATORS

Question. The Disability Program Navigators have been a major benefit to improved services and service delivery coordination with the One-Stops for job seekers with disabilities. Why are you recommending no funding for this activity? Does DOL have a plan for serving individuals with disabilities and others with multiple barriers to employment through the Workforce Development System in the future? What is the plan?

Answer. The Disability Program Navigator (DPN) program has been successful. However, from the outset, it has been the Department's intent for States to ultimately assume responsibility for this activity. The Department has been actively working with grantees on developing sustainability plans. These plans provided strategies by which the States could continue to provide these services through integration within the One-Stop Career Centers. The Department is also working with the Social Security Administration on the pending regulatory revisions to the Ticket to Work program which will make it much easier for One-Stop Career Centers to become Employment Networks, providing an additional funding source to sustain these activities.

The DPN grants have provided effective strategies to improve the accessibility of One-Stop Career Center services for job seekers with disabilities. Effective State practices are being shared broadly through a variety of mediums—such as the Employment and Training Administration's interactive knowledge Web site, Workforce^{3}One, grantee meetings, and conferences—in order to expand the capacity of the One-Stop system to serve people with disabilities and increase service levels to this population.

PRISONER REENTRY INITIATIVE

Question. Please provide a copy of the evaluation of this initiative, which is expected by the end of program year 2007. Also, please provide information on the number of grants awarded under the beneficiary choice model. What is the evidence base for funding this model of service delivery?

Answer. The Prisoner Reentry Initiative (PRI) evaluation will be completed in November 2008, with a final report submitted at that time. An interim report presenting early observations and findings is in development, a copy of which will be provided following DOL/ETA review, which is anticipated to be completed by November 2007.

With regard to the Beneficiary Choice Initiative (BCI), a substantial body of research on ex-offenders has documented high levels of unemployment, substance abuse and mental illness following release from incarceration, in conjunction with low levels of educational attainment, engagement with family members, and healthy ties to the community. These factors contribute to renewed criminal behavior, reduced public safety, and a host of poor outcomes for future generations, all of which contributed to development of the BCI.

Faith-based and community institutions are among the most trusted institutions in the urban neighborhoods to which the majority of released inmates will return. They have a rich tradition of outreach and service to those most in need of assistance and a proven ability to work collaboratively with other service providers and justice agencies for the delivery of social services. In addition, research has shown that ex-offenders with strong family and community ties have greater success in reintegrating into the community and avoiding future incarceration.

Consistent with the administration's emphasis on individual choice and personal responsibility, the PRI provides flexibility and freedom to both participants and providers in developing a strategy that best fits the unique needs of each individual for developing his or her own talents. Assisting ex-offenders to develop their own service strategy will increase their personal investment in their training decisions with a resultant increase in engagement and, it is hoped, completion of program services.

PRISONER REENTRY INITIATIVE AND RESPONSIBLE REINTEGRATION OF YOUTHFUL OFFENDERS

Question. According to the fiscal year 2008 budget justification, this proposed initiative is based on the lessons learned from the Responsible Reintegration of Youthful Offender Community College Initiative: To date, what outcome data provided by grantees has been used to assess whether this program is meeting stated objectives? What changes, if any?

Answer. The proposed Reintegration of Ex-Offenders initiative would capitalize on lessons learned from both the Prisoner Reentry Initiative (PRI) and the Responsible

Reintegration of Youthful Offenders (RRYO). Outcome data on both efforts are provided below.

The PRI performance measures include enrollment, entered employment, employment retention, employment earnings, and recidivism. During the first year of the project, the Department of Labor collected baseline information on which to base the goals for these performance measures.

As of the first year of data, with four full reporting quarters, the enrollment rate exceeded the first year goal of 6,250 participants across all 30 sites. The entered employment rate was 47 percent; however, this measure is based on program "exiters" of which there are few in the program's first year. The initiative achieved 3,420 initial job placements, indicating success placing participants into employment. The recidivism rate was at 11 percent. It is too early to report data on earnings and retention given that these are also "exit-based" outcomes.

For RRYO, outcome data provides information on: enrollment, placement (including job, military, post-secondary education, or long-term occupational training placements), diploma/GED attainment, participation, career pathways, high growth employer engagement, retention, community service, and service-centered mentoring.

The Ready4Work demonstration, which was funded through the RRYO appropriation and which piloted the PRI program, enrolled 4,482 former prisoners over a 3-year period, placed 2,543 of these persons into employment, and showed a recidivism rate of 6.9 percent over 1 year and a participant cost of $4,500.

Other grants provided under the RRYO appropriation are serving large numbers of youth each year in high-crime communities. Over 9,000 youth and young adults are served by these grants each year, with participants experiencing a recidivism rate of roughly 10 percent.

EBSA FTE AND FUNDING LEVELS

Question. For the past 5 years (including fiscal year 2007, based on the enacted appropriation), please provide a table identifying FTEs and dollars allocated by budget activity.

Answer. The following table depicts enacted funding and FTE levels by budget activity from fiscal year 2003 through fiscal year 2007.

EMPLOYEE BENEFITS SECURITY ADMINISTRATION

[Dollars in thousands]

Budget activity	Fiscal year									
	2003		2004		2005		2006		2007	
	Funding	FTE	Funding	FTE	Funding	FTE	Funding	FTE	Funding	FTE
Enforcement & Participant Assistance	$91,526	696	$102,730	800	$109,374	764	$111,239	753	$118,718	738
Policy & Compliance Assistance	20,441	143	16,907	108	17,357	101	$17,283	96	$17,585	92
Executive Leadership & Program Oversight	4,316	22	4,403	22	4,482	22	5,029	26	5,270	25
Totals	116,283	861	124,040	930	131,213	887	133,551	875	141,573	855

Note.—The fiscal year 2004 FTE level for the Policy and Compliance Assistance budget activity reflects a comparative transfer of 40 FTE for the EBSA participant assistance function into the Enforcement and Participant Assistance budget activity.

PENSION PROTECTION ACT OF 2006

Question. Please provide a timeline for the issuance of regulations required by the Pension Protection Act of 2006.

Answer.

PENSION PROTECTION ACT OF 2006 (PPA) REGULATIONS

PROJECT	PAST ACTION	NEXT ACTION
PPA Annual Report Form Changes (including simple report for under 25 participant plans, pension funding info & e-file for actuarial schedule).	Supplemental Proposal 71 FR 71562 (Dec. 11, 2006) related to larger proposed Forms Revisions 71 FR 41359; 41392; 41616 (July 21, 2006).	Final Forms and Related Rule changes—Summer 2007

PENSION PROTECTION ACT OF 2006 (PPA) REGULATIONS—Continued

PROJECT	PAST ACTION	NEXT ACTION
Default Investments—Safe Harbor	Proposed Rule 71 FR 56806 (Sept. 27, 2006).	Final Rule—Summer 2007
Cross Trading Exemption	Interim Final Rule 72 FR 6473 (Feb. 12, 2007).	Final Rule—Fall 2007
Revocation of Election Re: Multiemployer Plan Status.	Model Notice 71 FR 69594 (Dec. 1, 2006)	Completed
Investment Advice—plans	Issued interpretive guidance—Field Assistance Bulletin 2007–01 (February 2, 2007) RFI 71 FR 70429 (Dec. 4, 2006).	Proposed Rule—Fall 2007
Investment Advice—IRAs Feasibility Determination.	RFI 71 FR 70427 (Dec. 4, 2006)	Report to Congress by December 31, 2007
Plan Assets Regulation		Proposed Rule—Fall 2007
Rollovers for Non-spouse Beneficiaries—Amendment to Abandoned Plan Regulation.	Interim Final Rule 72 FR 7516 (Feb. 15, 2007).	Final Rule—Fall 2007
DB Plan Annual Funding Notice		Interim Final Rule and Model—Fall 2007
Periodic Benefit Statements	Issued interpretive guidance to facilitate administration in the absence of regulations—Field Assistance Bulletin 2006–03 (December 20, 2006).	Proposed Rule and Model—Fall 2007
Access to Multiemployer Pension Plan Information.		Interim Final Rule—Summer 2007
Civil Penalty 502(c)(7)—Failure to Provide Notice of Freedom to Divest ERISA 101(m) (Treasury Model 180 days).		Final Rule—Summer 2007
QDRO Timing	Interim Final 72 FR 10070 (March 7, 2007)	Final Rule—Early 2008
Notification of Endangered or Critical Status.	Requires coordination with Treasury	Model—Early 2008
Civil Penalty 502(c)(4):		
(1) Failure to Respond to 101(k) Request.		
(2) Failure to Provide 514(e) Notice of Auto Contributions.		
(3) Failure to Provide 101(l) Notice of Withdrawal Liability.		
(4) Failure to Provide 101(j) Notice of Funding-Based Limitation.		Proposed Rule—Early 2008
Summary Report of Multiemployer Plan Information to Employers and Unions.		Interim Final Rule and Model—Early 2008
Notice of Funding-Based Limitation	Requires coordination with Treasury	Proposed Rule—2008
Notice of Potential Withdrawal Liability	Requires coordination with Treasury and PBGC.	Proposed Rule—2008
Notice of Reduction to Adjustable Benefits		Proposed Rule and Model –2008
Civil Penalty 502(c)(8)—Failure to Adopt Funding Improvement Plan.		Proposed Rule—2008
Civil Penalty 502(c)(2)—Failure to Provide Notice of Election of Multiemployer Status.		Proposed Rule—2008
Civil Penalty 502(c)(2)—Failure of Multiemployer Plan to Secure Timely Actuarial Certification.		Proposed Rule—2008

Question. What level of resources and FTEs will be devoted to this activity in fiscal year 2007 and under the budget request for fiscal year 2008?

Answer. EBSA's Policy and Compliance Assistance budget activity has primary responsibility for the development and issuance of the regulations required by the Pension Protection Act of 2006 (PPA). Within this activity, approximately 19 FTE and $3.6 million will be devoted to PPA regulatory activity during fiscal year 2007. In fiscal year 2008, EBSA estimates approximately 19 FTE and $3.8 million will be needed for PPA implementation. In addition, the Plan Benefits Security Division of the Office of the Solicitor estimates that it will devote approximately 2.5 FTE and $412,500 in both fiscal year 2007 and fiscal year 2008. These estimates exclude the resources expended by other organizations outside EBSA such as Departmental Management, and other oversight/clearance activities.

EMPLOYMENT STANDARDS ADMINISTRAITON

Question. For the past 5 years (including fiscal year 2007, based on the enacted appropriation), please provide a table identifying FTEs and dollars allocated by budget activity.

Answer. The requested information is included in chart Employment Standards Administration, Budget Activity by fiscal year.

[The information follows:]

EMPLOYMENT STANDARDS ADMINISTRATION BUDGET ACTIVITY BY FISCAL YEAR

Program	Fiscal year									
	2003		2004		2005		2006		2007 [1]	
	FTE	Funding	FTE	Funding	FTE	Funding	FTE	Funding	FTE	Funding
Wage and Hour Division	1,392	$155,626,000	1,442	$160,095,829	1,346	$164,494,758	1,300	$165,685,410	1,200	$170,219,521
Federal Contractor and EEO Standards Enforcement	742	78,033,000	749	79,441,000	691	80,059,000	670	81,285,000	625	82,441,456
Office of Workers' Compensation Programs:										
Federal Employees' Compensation	839	86,392,000	839	86,260,000	801	86,819,000	801	88,446,000	760	90,137,213
Longhsore and Harbor Workers' Compensation—General	96	10,232,000	96	10,490,000	93	10,511,000	93	10,682,000	90	10,752,158
Longhsore and Harbor Workers' Compensation—Trust Fund	11	1,958,000	11	2,016,000	11	2,012,000	11	2,028,000	9	2,041,885
Division of Coal Mine Workers' Compensation	214	31,632,000	214	31,628,000	214	32,232,000	205	32,659,000	191	33,171,000
Office of Labor-Management Standards	297	34,279,000	347	38,580,000	336	41,681,000	384	45,737,000	313	47,753,357
Program Direction and Support	107	14,591,000	107	15,499,000	103	15,635,000	93	17,592,000	93	17,933,000
Federal Employees Compensation Act Benefits	.....	160,000,000	.....	160,000,000	.....	230,000,000	.....	237,000,000	.....	227,000,000
Federal Employees Compensation Act—Fair Share	133	37,657,000	133	39,261,000	128	39,668,000	127	53,695,000	127	51,034,000
Disabled Coal Miners	17	5,564,000	17	6,143,000	17	5,191,000	17	5,250,000	17	5,373,000
Energy Employees Occupational Illness Compensation Program Act, Part B	380	104,867,000	300	51,651,000	275	40,321,000	275	96,081,000	275	102,307,000
Energy Employees Occupational Illness Compensation Program Act, Part E	.....	.....	.....	.....	105	49,975,000	189	59,950,000	189	59,531,000

[1] Fiscal year 2007 reflects full-year continuing resolution apportionment approved by OMB.

WAGE AND HOUR DIVISION

Question. For the past 5 years (including fiscal year 2007, based on the enacted appropriation), please provide a table identifying FTEs and dollars allocated by budget activity.

Answer.

Fiscal year	FTE used	Actual obligations
2003	1,396	$155,673,000
2004	1,333	160,084,000
2005	1,266	164,616,000
2006	1,238	165,706,000
2007	[1] 1,212	[2] 101,253,000

[1] Estimated.
[2] Through May 9, 2007.

Question. According to the February 26, 2007 Daily Labor Report, Wage and Hour Administrator said that "he understands the concerns of attorneys who believe opinion letters were being used as a tool in ongoing litigation and that it is an issue that needs to be reviewed inside DOL." What is the status of the review of this alleged practice? Have you reached any conclusions, and, if necessary, identified steps for corrective action?

Answer. That portion of the Daily Labor Report article is an imprecise and potentially confusing paraphrasing of the Administrator's remarks. The Wage and Hour Division (WHD) has long had a policy of not issuing an opinion letter to a party to either an ongoing WHD investigation or private litigation involving the issue or issues raised in the request for an opinion letter. During a presentation that the Administrator made to a section of the American Bar Association, some audience members suggested that this policy is unfair to workers. Their concern was that WHD's policy would not preclude DOL from issuing an opinion letter to a trade association or other entity that was not a party to a WHD investigation or private litigation, who in turn would provide that opinion letter to a member of the organization that was involved in an investigation or ongoing litigation. They argued that workers who might like to obtain an opinion letter lack a similar option. The Administrator acknowledged that concern and stated that it merited further consideration. This matter is currently under review.

FAMILY AND MEDICAL LEAVE ACT

Question. In response to questions for the record for the fiscal year 2007 Department of Labor budget, the Department indicated that the possibility of revisions to the Family and Medical Leave Act remains an item on the Department's regulatory agenda. It has been more than 2 years since that statement. Please provide details on the types of changes the Department is considering and a timeline? Will the Department commit to not take any action that would lessen the rights of workers to leave under the Act?

Answer. WHD invited interested parties having knowledge of, or experience with, the Family and Medical Leave Act to submit comments and pertinent information related to the effectiveness of the current implementing regulations and the Department's administration of the statute. WHD received more than 15,500 submissions from a broad cross-section of commenters including employer associations, unions, interest groups, and individuals. These comments are currently being reviewed, and no final decisions have yet been reached as to what, if any, changes might actually be proposed.

Question. Misclassification of employees as independent contractors is a growing problem. Studies have found that up to 30 percent of companies misclassify workers. In all of these industries low-wage workers predominate, and misclassification is often a particular problem for immigrant workers. Please provide an analysis of the expenditures you make and FTEs you devote to enforcing FLSA requirements against misclassification of workers.

Answer. All WHD investigators examine the employment relationship during the conduct of an investigation. Employees who are misclassified as "independent contractors" are identified during the course of investigations that cover many provisions enforced by WHD, and it is not possible to segregate expenditures or FTE used to enforce FLSA minimum wage and overtime requirements on behalf of misclassified workers. However, in its 2006 audit on the contingent workforce, the Government Accountability Office suggests that misclassified employees are more

prevalent in low-wage industries, and WHD spends approximately 60 percent of its enforcement hours in industries that employ low-wage workers.

Question. Please provide a detailed description of your enforcement efforts and results in this area.

Answer. As the Government Accountability Office notes in its 2006 audit, WHD addresses the misclassification of employees as independent contractors through its investigations, primarily those involving the FLSA. All WHD investigators first establish the employment relationship between the worker and the company during the conduct of investigations to determine whether workers are covered under the FLSA.

In its 2006 audit on the contingent workforce, the Government Accountability Office suggests that misclassified employee are more prevalent in low-wage industries, and WHD spends approximately 60 percent of its enforcement hours in industries that employ low-wage workers. Moreover, WHD devotes 20 percent to 25 percent of its resources to directed enforcement in low-wage industries—including construction, agriculture, and landscaping.

In addition to enforcement, WHD has been increasing its appearances on Spanish-language radio and television programs, reaching out to Spanish-language press, distributing worker rights cards, and participating in community events, in an effort to inform workers of their rights and prevent misclassification from happening in the first place. WHD is also in the process of revising its workplace poster to add the agency's toll-free number and web site address, which can be used to report alleged violations of the laws that WHD enforces, including those that may be related to employee misclassification issues.

Question. Please provide a breakdown of what percentage of all cases (e.g., all overtime cases, all janitorial services investigations, etc.) and outcomes involve misclassification of employees as independent contractors by the company.

Answer. The requested information is not available. Misclassified workers are identified during the course of investigations that cover many provisions enforced by WHD, and it is not possible to segregate cases that involve misclassification of employees as independent contractors.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Question. For the past 5 years (including fiscal year 2007, based on the enacted appropriation), please provide a table identifying FTEs and dollars allocated by budget activity.

Answer. The information on budgeted resources follows.

[Dollars in thousands]

	Fiscal year									
	2003		2004		2005		2006		2007	
	Approp.	FTE	Approp.	FTE	pprop.	FTE	Approp.	FTE	Approp.	FTE
Safety & Health Standards	$16,014	95	$15,920	85	$16,003	84	$16,462	83	$16,893	83
Enforcement Programs	162,973	1,612	166,015	1,581	169,651	1,570	172,575	1,542	176,973	1,542
State Programs	90,547	.....	91,959	.....	91,013	.....	91,093	.....	91,093	.....
Technical Support	20,102	107	21,593	109	20,742	107	21,435	105	22,392	105
Compliance Assistance	61,321	357	67,049	356	70,859	352	72,545	348	72,658	348
Consultation	53,204	.....	52,211	.....	53,362	.....	53,357	.....	53,357	.....
Training Grants	11,102	.....	10,509	.....	10,217	.....	10,116	.....	10,116	.....
Safety & Health Statistics	25,894	39	22,237	39	22,203	38	24,253	38	32,274	38
Executive Direction	9,153	50	10,047	50	10,106	49	10,591	49	11,169	49
Totals	450,310	2,260	457,540	2,220	464,156	2,200	472,427	2,165	486,925	2,165

TARGETED INSPECTIONS

Question. OSHA announced in March 2007 that approximately 14,000 employers have been notified that injury and illness rates at their worksites are higher than average. Approximately 4,500 of these will be initially targeted for inspection under OSHA's Site Specific Targeting program. What is the rationale for identifying 4,500 for inspection of these 14,000? What level of resources in FTEs and dollars would be required to inspect adequately all of these worksites in fiscal year 2008?

Answer. OSHA collects occupational injury and illness data from employers each year through the OSHA Data Initiative. Approximately 14,000 employers each year report a Days Away, Restricted, or Transferred (DART) rate that is more than twice the national private sector DART rate. These employers are contacted by letter in an outreach initiative, and are encouraged to take advantage of OSHA's Consultation Program, a free and confidential service in each State that assists employers in reducing injuries and illnesses.

Federal OSHA conducts about 37,700 inspections each year. Slightly less than half of these are "unprogrammed" inspections: responses to fatalities and catastrophes, reports of imminent danger situations, employee complaints, and referrals. The other half are "programmed" or targeted inspections, which do not include inspections in the construction industry. The Site-Specific Targeting (SST) program is OSHA's primary national targeting system for inspecting the specific general industry workplaces that have reported the highest injury and illness rates.

Out of the 14,000 employers with a high DART rate, OSHA then selects approximately 4,500 worksites with the highest self-reported injury/illness rates—approximately four times the national private sector DART rate—to be included for inspection under OSHA's SST. In order to verify generally the reliability of claims by establishments that they have achieved low DART rates, analysts in OSHA's Office of Statistical Analysis in Washington, DC, will select—by applying a random number table to all establishments that have reported a low rate—approximately 100 low-rate establishments in high-rate industries. Some employers who did not respond to the mandatory data collection are also included for inspection. This data effectively targets OSHA's inspection resources towards establishments that are experiencing the highest rates of injuries and illnesses under our jurisdiction.

OSHA believes it is prudent to continue to include those worksites with approximately four times the national private sector DART rate in its inspections, and to use other inspection resources for other SST program sites and to respond to fatalities and catastrophes, reports of imminent danger situations, employee complaints, and referrals.

The rest of OSHA's targeted inspections currently fall under National Emphasis Programs (such as refineries, lead exposure, amputations, and trenching fatalities), construction inspections, and a wide variety of Local Emphasis Programs designed to address hazards and industries of concern, depending on local needs.

NATIONAL EMPHASIS PROGRAM FOR REFINERIES

Question. In response to the Chemical Safety and Hazard Investigation Board's report into the BP Texas City refinery explosion recommendation, OSHA announced a new National Emphasis Program (NEP) to ensure that every refinery under OSHA's jurisdiction is inspected. What is the timeline for carrying out all of the inspections under this new National Emphasis program? Will these planned inspections be Program Quality Verification (PQV) inspections or of a lesser standard? If the inspections will be of a lower standard, please explain why.

Answer. OSHA began developing the National Emphasis Program for refineries prior to the CSB report and includes the agency's plans to inspect every refinery under Federal jurisdiction by the end of 2008.

The planned NEP inspections will not be program-quality-verification (PQV) inspections as described in OSHA's 1992 directive outlining compliance guidelines for the Process Safety Management (PSM) standard. The PQV approach employs a broad, open-ended inspection strategy and uses a more global approach to identify compliance deficiencies. The new refinery NEP provides a more focused and effective protocol for evaluating compliance with the PSM standard by directing OSHA compliance officers (CSHOs) to review documents, interview employees, and verify implementation for specific processes, equipment and procedures.

This NEP is designed to facilitate inspections at all refineries within its scope. In contrast to the PQV approach, this NEP addresses a number of priority items which CSHOs are to evaluate for compliance. OSHA's compliance officers, using the list of inspection priority items, will focus on the conditions most likely to be catastrophic fire/explosion and toxic release hazards to workers in the facility. We be-

lieve the NEP's new inspection strategy will yield more effective results than the current approach to enforcing PSM.

PROCESS SAFETY MANAGEMENT

Question. The Board's report also recommended that OSHA hire or develop new, specialized inspectors and expand the PSM training curriculum at its National Training Institute. What level of resources will be spent in fiscal year 2007 or is planned to be spent in fiscal year 2008 on these activities? How do these spending levels compare to fiscal year 2005 and fiscal year 2006?

Answer. OSHA began the process of expanding the number of Compliance Officers trained in PSM prior to CSB's report. PSM training has been offered annually by the OSHA Training Institute for the past several years. The OSHA Training Institute conducts a sequence of three different courses that qualifies OSHA personnel to participate in inspections conducted in accordance with the NEP on the process safety management standard for petroleum refineries.

OSHA personnel with experience in the chemical processing or refinery industries qualify as Level 1 Refinery NEP Inspection Team Members by completing the required OSHA Training Institute course or by completing other equivalent specialized seminars in process safety management. Employees who have at least 2 years of OSHA inspection experience qualify as Level 2 refinery NEP inspection team members by completing two OSHA Training Institute PSM courses.

Between fiscal year 2000 and fiscal year 2006 the OSHA Training Institute trained 194 OSHA staff on PSM. The Institute is projecting that approximately 250 OSHA staff will attend PSM training courses in fiscal year 2007.

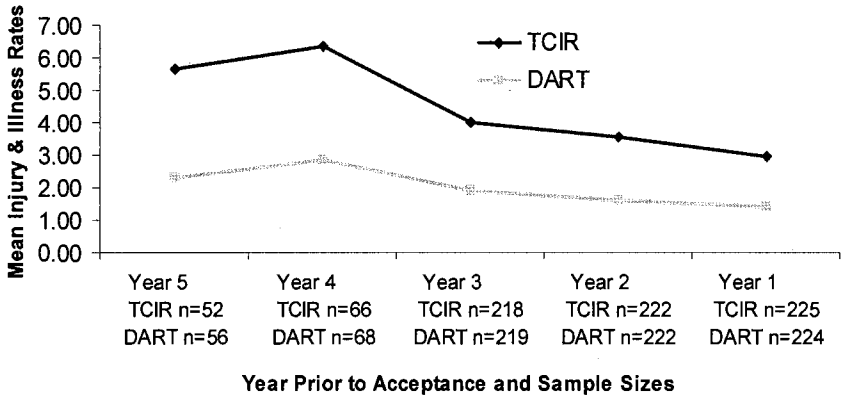
VOLUNTARY PROTECTION PROGRAMS

Question. According to OSHA data provided for a Gallup study of this program, injury rates remain unchanged before and after participation in the VPP. Why does the budget propose additional resources for an activity that, according to OSHA's own data, does not improve workplace safety and health?

Answer. To the contrary, the data collected and analyzed by the Gallup Organization clearly indicates that injury and illness rates dramatically improve for Voluntary Protection Programs (VPP) participants in the years prior to and working toward VPP acceptance. Additionally, once a worksite is accepted into VPP, injury and illness rates remain fairly constant with further improvement in rates for most sites over time

VPP provides a systematic approach for improving workplace safety and health performance. The VPP program allows employers, employees, and OSHA to work together to implement an effective workplace safety and health management system that ensures safety is efficiently integrated into the management of day-to-day workplace operations. In November 2003, Gallup was contracted by the Department of Labor to design and conduct an independent evaluation of the VPP. Gallup collected data from approximately 300 worksites for the 5 years prior to acceptance into VPP. Gallup also looked at how these same worksites performed once they were accepted into the VPP. As the chart below shows, VPP participants achieved dramatic reductions in worker injury and illness rates with the most dramatic change in all 5 years occurs between year 4 and year 3.

TCIR AND DART RATES FOR THE FIVE YEARS PRIOR TO ACCEPTANCE INTO VPP



The Gallup study found that VPP participants not only enhance safety and health at their worksites, but also conduct mentoring and outreach to other worksites within and outside of their company. For example, Gallup found that in 2004, VPP participants mentored over 1,500 other worksites. This impacted over 500,000 employees. It is this very beneficial impact on workplace safety and health that support the agency's proposal to increase resources for VPP.

ERGONOMICS

Question. DOL has issued 408 hazard alert letters on ergonomics. Please provide for the record an example of the hazard alert letter issued by OSHA to an individual company.

Answer. Example is Northwest Airlines, Tampa facility, baggage handling, attached.

U.S. Department of Labor

Occupational Safety and Health Administration
Concord Area Office
279 Pleasant Street, Suite 201
Concord, NH 03301
(603) 225-1629
(603) 225-1580 FAX

December 20, 2002

Reply to the attention of: 304558653

Northwest Airlines
1 Airport Rd., Suite 220
Manchester, NH, NH 03109

Dear Ms Catalina J. Shea:

Section 21 of the Occupational Safety and Health Act authorizes OSHA to train employers and employees about workplace hazards and appropriate abatement methods. During an inspection conducted at your facility located at 1 Airport Rd., Suite 220, Manchester, NH, on 11/14/2002, some conditions were identified which, although not violative of the standards, are considered significant enough to be brought to your attention with the intent of encouraging your efforts to reduce exposure or to eliminate it completely.

OSHA's observations are summarized below:

Employees handling baggage at various locations including the ticket counter, bag room, belt loaders, jetway, and baggage compartment, appear to be experiencing a significant number of injuries/illnesses related to baggage handling risk factors, that have caused and/or are likely to cause back and muscle disorders. These disorders include back pain and over-exertion injuries such as sprains and strains.

Our review of your OSHA 200/300 Injury/Illness logs show that from January 1, 2000 through November 14, 2002, that 10 of the 15 lost work-day and restricted work activity injury/illnesses were the result of baggage handling. Lifting, repetition of lifting and awkward body positions were involved in the lost work-day/restricted work activity accidents.

To aid you in your efforts to control these exposures, the following measures may be feasible for your operations:

To eliminate awkward body positions in the Baggage Room a possible solution is to raise the height of the conveyor line to reduce bending and lifting. However, it should not be so high that the employee(s) must use an elevated and extended reach with arms above the shoulder while performing the task.

A slide attached to the Jetway will reduce injury exposure. Customer Support Agents (CSAs) would not have to attempt to carry

awkward sized baggage/strollers and other last minute checked items down the narrow Jetway stairs.

A recommendation at the ticket counter is to install and use a short collection conveyor to move checked baggage from the scale to the main conveyor that leads to the Baggage Room. This would preclude the ticket agents from lifting and placing their bodies in a twisting position while turning to hand place checked baggage onto the main conveyor.

Baggage should be tagged with colored indicators that alert the Baggage Room handlers as to weights. As an example baggage in the range of 35 - 49 pounds could be tagged yellow and baggage 50 + pounds could be tagged with a red indicator (Note: example weights and colors given are just examples and are not intended to be recommendations in any way).

An additional useful and available tool for the public can be found on OSHAs's web page, **www.osha.gov**. There is an e-CAT (electronic Compliance Assistance Tool) specifically designed for baggage handling, which provides possible solutions and abatement ideas for the potential hazards encountered with each of the tasks associated with baggage handling. The specific web address for the baggage handling e-CAT is:
www.osha.gov/SLTC/baggagehandling_ecat/index.html

These methods are not meant to be the only ones available or feasible. OSHA makes available an on-site consultation service which may identify other measures or you may consider hiring outside consultants. The on-site consultants are free and do not in any way affect the enforcement activities of OSHA. On-site consultants may be contacted at the New Hampshire Department of Labor, phone 271-2024 for Safety, and the New Hampshire Division of Public Health Services, phone 271-4676 for Health.

OSHA welcomes and requests a report of any of your efforts to reduce the above-mentioned exposures and the results of your efforts.

Sincerely,

George L. Kilens

for DAVID C. MAY
Area Director

ERGONOMICS

Question. Please provide for the record a detailed explanation of the types of follow-up actions OSHA undertakes after the issuance of a hazard alert letter to determine if ergonomic hazards have been addressed.

Answer. Follow-ups of ergonomic hazard alert letters are generally conducted under OSHA Instruction CPL 02–00–144—Ergonomic Hazard Alert Letter Follow-up Policy (copy included). This policy is similar to OSHA Instruction CPL 02–00–140—Complaint Policies and Procedures, in that an employer is first contacted by telephone and then faxed a copy of the original ergonomic hazard alert letter. The employer is given 20 working days to respond as to what steps have been taken to address the hazards identified in the original letter. The response is then evaluated and a determination made as to what progress the employer has made. The outcome of the evaluation can range from the case being closed to scheduling the employer for a second inspection.

The directive CPL 02–00–144 Ergonomic Hazard Alert Letter Follow-up Policy, is attached.

OSHA INSTRUCTIONS

DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION

DIRECTIVE NUMBER: CPL 02–00–144 EFFECTIVE DATE: APRIL 11, 2007

SUBJECT: ERGONOMIC HAZARD ALERT LETTER FOLLOW-UP POLICY

ABSTRACT

Purpose.—The purpose of this directive is to outline a process for contacting employers who received an ergonomic hazard alert letter (EHAL).

Scope.—This directive applies to any inspection coded N–03, or other IMIS code for ergonomic inspections, for which an ergonomic hazard alert letter has been issued. This directive is intended to apply only to ergonomic hazard alert letters (EHALs).

References.—Ergonomics Enforcement Policy, found on the web at: (http://www.osha.gov/SLTC/ergonomics/enforcement_plan.html); Field Inspection Reference Manual, OSHA Instruction CPL 02–00–103.

Cancellations.—None.

State Impact.—State adoption not required.

Action Offices.—Regional Offices, Area Offices

Originating Office.—Directorate of Enforcement Programs

Contacts.—Office of Health Enforcement, 200 Constitution Avenue NW, Room N–3119, Washington, DC 20210

By and Under the Authority of

EDWIN G. FOULKE, JR.,
Assistant Secretary.

EXECUTIVE SUMMARY

Employers who have received ergonomic hazard alert letters (EHALs) will be asked to provide information on progress in addressing the hazards outlined in the EHAL. This Notice outlines a process for contacting employers to determine whether hazards and deficiencies identified in the letter have been addressed. This directive applies to any inspection coded N–03 for which an ergonomic hazard alert letter has been issued, regardless of whether the inspection was initiated under an emphasis program, the Site Specific Targeting (SST) program, or was unprogrammed. This directive is intended to apply only to EHALs.

SIGNIFICANT CHANGES

No significant changes to previous policy.

I. *Purpose*.—The purpose of this directive is to outline a process for contacting employers who have received an ergonomic hazard alert letter (EHAL) since April 2002. This contact is a continuation of the inspection that led to the EHAL, and is intended to determine whether hazards and deficiencies identified in the letter have been addressed.

II. *Scope*.—This directive applies to any inspection coded N–03, or other Integrated Management Information System (IMIS) code for ergonomic inspections, for which an ergonomic hazard alert letter has been issued, regardless of whether the inspection was initiated under an emphasis program, the SST program, or was unprogrammed. This directive is intended to apply only to EHALs.

III. References.

A. Ergonomics Enforcement Policy, found on the web at: (http://www.osha.gov/SLTC/ergonomics/enforcement_plan.html);

B. Field Inspection Reference Manual, OSHA Instruction CPL 02–00–103.

IV. *Cancellations*.—None.

V. Action Offices.

A. *Responsible Office*.—Directorate of Enforcement Programs, Office of Health Enforcement.

B. *Action Offices*.—Regional Offices. Each Region will be responsible for ensuring that this process is implemented.

C. *Information Offices*.—The Region may determine who will implement this directive (e.g., the Compliance Safety & Health Officer [CSHO], the Regional Ergonomic Coordinator [REC], etc.) based upon the most effective use of resources.

VI. *Federal Program Change*.—This Notice describes a Federal program change which does not require State adoption or response.

VII. *Significant Changes*.—Not applicable.

VIII. Initial Contact with Employer.

A. Using the current phone/fax process, contact will be made with all employers who received an EHAL issued on or after April 1, 2002 and have been in receipt of an EHAL for at least one year (this will allow employers time to implement changes). Employers who voluntarily supplied a progress report to the Area Office (AO) need not be contacted again, unless the AO determines that the response was inadequate.

B. During the initial phone/fax contact, OSHA staff will explain that the employer is being contacted as a follow-up to the original inspection. OSHA staff is to determine what specific measures were taken by the employer in response to the EHAL. It is suggested that in order to maintain consistency, OSHA staff should ask to speak, if possible, with the management contact(s) at the establishment who was (were) originally involved in the inspection.

C. Following the initial phone/fax-type telephone call, the employer will be faxed a copy of the original EHAL and a letter (OSHA staff are to use the template provided in Appendix A) requesting: (1) the employer's response regarding measures taken to address the hazard(s) noted in the EHAL; (2) copies of the employer's Log of Work-Related Injuries and Illnesses (OSHA Form 300) since the close of the original inspection; and (3) the estimated number of full-time employees (FTE) or work hours for the exposed employees for the time period corresponding to the injury and illness reports. The employer should be asked about all ergonomic control measures implemented, including those recommended in the EHAL.

D. A response from the employer is due within twenty (20) working days of the initial phone/fax-type telephone call. The employer may provide the response via fax, e-mail or U.S. Postal Service mail, or common carrier (i.e., FedEx, UPS, etc.).

E. An evaluation of the employer's response will be made and the employer's efforts will be categorized, as indicated below. The RECs will be available to assist in reviewing the response, if necessary. The response categories are:

1. *No response (NR)*.—The employer did not provide any e-mail, fax or mail response to the EHAL or telephone/fax inquiry.

2. *Inadequate response (IR)*.—The employer's response did not establish that it had taken useful steps, such as those identified in the EHAL, to reduce the hazard identified in the EHAL.

3. *On-the-right-track response (RT)*.—The employer has undertaken measures to address the hazards identified in the EHAL, but the efforts may have either stalled or have not been sufficient to address the hazards. Injury and/or severity rates are not improving.

4. *Successful response (SR)*.—The employer has implemented measures which address the hazards in the EHAL.

IX. Second Contact with the Employer.

A. No response (NR) or Inadequate response (IR)

1. If no response is received from the employer within the allotted twenty (20) working days, or if an inadequate response is received, additional contact with the employer should be made to obtain the desired information. The AO may determine whether this second contact should be made by phone, letter, or inspection (see section X. for inspection procedures).

2. If the second contact with the employer is by phone call or letter, the response shall be evaluated. The AO will have discretion regarding whether additional follow-up phone calls or additional letters are still warranted. This judgment will be based on the extent to which the employer implemented measures to address the hazard.

3. Upon completion of any additional contact(s) if the employer still has not responded or has responded inadequately, an inspection shall be scheduled to

determine if the ergonomic hazards are being addressed (see section X. for inspection procedures)

B. On-the-right-track response

For all responses deemed to be "on-the-right-track," the AO will have discretion regarding whether a follow-up phone call, an additional letter, or an on-site inspection is warranted (see section X. for inspection procedures). This judgment will be based on the extent to which the employer implemented measures to address the hazard.

C. Successful response

No further action is required.

X. Inspection Procedures.

A. All inspections shall be unannounced. The scope of the inspection will be limited to the ergonomic hazards identified in the original EHAL, any conditions cited in the original inspection, and any hazards in plain view.

B. Inspection findings shall be handled in accordance with the FIRM and any other enforcement guidelines. Conditions which are re-inspected may be considered as apparent potential violations, and citations may be issued based on the findings of the reinspection.

C. Where ergonomic hazards remain and citations are not issued, the employer should be sent a letter (additional EHAL) suggesting relevant hazard abatement measures (Appendix B).

XI. Data.

A. A spreadsheet listing ergonomic hazard alert letters will be provided to the Area Offices by the RECs. The results of the follow-up contact with each employer shall be entered into the spreadsheet and be forward the RECs twice a year (June and December) or as otherwise requested by the RECs. The information submitted by the AO will be limited to the date of the initial contact under section VIII., the date the follow-up is finalized and the final outcome for each employer. Possible results are given below and the outcome for each employer may have more than one result. For example, if an employer is contacted and provides an inadequate response resulting in an inspection which leads to a second EHAL, the spreadsheet would contain codes IR, FI and LT in addition to the appropriate dates. The EHAL follow-up will be considered final if the site is no longer in business, when a successful response is received, when an on-the-right-track response has been received and the AO determines no further action is required, or when an inspection is initiated.

NR No response
IR Inadequate response
RT On-the-right-track
SR Successful response
OB Out of Business
FI Follow-up inspection
LT Second Letter
CI Citation

B. The RECs will be responsible for submitting the results to the NO. The NO will summarize the results.

XII. IMIS.

A. When a second inspection is not conducted:

The time spent on the evaluation is to be recorded on the CSHO's OSHA 31 under Activity Details. Mark line 5a I (Inspection), then enter the inspection number of the original case on line 6 along with the time spent on the contact.

B. When a second inspection is conducted:

This will be considered a new inspection, and normal coding procedures are to be used.

XIII. *Expiration*.—This directive will be effective for three (3) years from the date signed.

APPENDIX A—TEMPLATE LETTER FOR EHAL FOLLOW-UP

DEAR EMPLOYER:

On _____ (date) _____, the _____ Area Office of the Occupational Safety and Health Administration (OSHA) conducted an inspection of your work-

place, including an evaluation of risk factors which may contribute to injuries of the musculoskeletal system. As a result of this inspection, a letter addressing these hazards (copy enclosed) was forwarded to you on _____ (date) _____.

To evaluate your progress in addressing the hazards identified, we are seeking the following information:

—Any controls you may have implemented to address these hazards, including adding mechanical devices, redesigning workstations, modifications to employee workloads, changes to the way injuries are addressed, or any other changes which you feel may have impacted the hazard identified in OSHA's letter. This includes any controls recommended by OSHA or other controls implemented.

—A list of the types of training provided to your employees to address these hazards.

—Copies of OSHA's Form 300, Log of Work-Related Injuries and Illnesses, beginning with the year of the original inspection.

—An estimate of the number of hours worked or full-time employees for each employee whose job title(s) is (are) _____ or are in at-risk job(s) _____, by year beginning with the year of the original inspection.

Please provide your response to the _____ Area Office within twenty days of receipt of this request by fax, e-mail, regular mail, or common carrier. A brief evaluation of the effectiveness of the controls may be included if you believe this will help OSHA in evaluating your efforts. The lack of a response to this letter will result in further action by OSHA, possibly including another inspection of your facility.

Sincerely,

AREA DIRECTOR.

Enclosure.

APPENDIX B—TEMPLATE LETTER FOR SECOND CONTACT

DEAR EMPLOYER:

An evaluation of your efforts to address ergonomic hazards related to an Occupational Safety and Health Administration (OSHA) inspection has been conducted. As you know, the original inspection took place on _____. We initiated a second contact with your organization to determine your success in addressing the hazards in your workplace.

OSHA has determined that your efforts in addressing ergonomic risk factors are (unlikely to address the hazard/on-the-right-track) and that further measures, as detailed below, would contribute to resolution of the hazard:

—List relevant Engineering Controls

—Administrative/Work Practice Controls

—Training Needed

OSHA offers various forms of cooperative assistance to employers, some focused on specific hazards, others aimed at helping employers develop and implement safety and health management systems that provide more comprehensive protection for workers. These include:

—The OSHA Consultation Program, administered by the States and funded largely by OSHA, which offers free consultation services to qualifying small businesses, primarily in high hazard industries. Consultants help employers identify and correct workplace hazards and develop more comprehensive safety and health management systems.

—The Voluntary Protection Programs (VPP), which recognize companies where managers and employees are working together to establish comprehensive safety and health management systems. The VPP Mentoring Program, offered by the independent VPP Participants' Association, offers mentoring to any employer seeking assistance.

—OSHA Strategic Partnerships, which often address specific safety and health issues such as ergonomics.

—OSHA Alliances with trade or professional organizations, employers, labor organizations, and educational institutions, which provide training and other services to help employers reduce injuries and illnesses. Many OSHA Alliances focus on ergonomic issues.

You can find information about these programs, plus an array of electronic tools (e-tools), publications, and other information at www.osha.gov. Any further assistance needed in this matter may be obtained by contacting our offices.

Sincerely,

AREA DIRECTOR

ERGONOMICS

Question. Please provide for the record a list of follow-up inspections conducted after the issuance of an ergonomic hazard alert letter.

Answer. Because the Ergonomic Hazard Alert Letter Follow-up Policy was recently signed (April 11, 2007), only three sites have received follow-up inspections thus far. All three of those inspection sites were Transportation Security Administration locations (Anchorage and Fairbanks Alaska, and Portland Oregon). The original and the follow-up inspections were conducted under a Federal agency targeting program in effect for OSHA's Seattle Region.

Question. Please provide for the record the number of ergonomic hazard alert letters issued by year for the years 2001 to 2006.

Answer. The information follows.

	Year					
	2001	2002	2003	2004	2005	2006
Letters	NA	30	224	109	52	31

Note.—OSHA did not begin tracking ergonomic hazard alert letters until after the announcement of Secretary's Four-Pronged Approach to Ergonomics in April 2002.

Question. Please provide for the record the number of follow-up inspections conducted after the issuance of an ergonomic hazard alert letter by year for the years 2001 to 2006.

Answer. Because the Ergonomic Hazard Alert Letter Follow-up Policy was recently signed (April 11, 2007), only three Transportation Security Administration sites have received follow-up inspections, one each in 2004, 2006, and 2007.

Question. In 2004, the National Advisory Committee on Ergonomics (NACE) recommended 16 industries for developing ergonomic guidelines. To date, only 3 industry ergonomic guidelines have been developed—for nursing homes, poultry processing and retail grocery. What other ergonomic guidelines is OSHA working on? Which ergonomic guidelines will OSHA finalize in fiscal year 2007 and in fiscal year 2008?

Answer. OSHA has completed work on guidelines for three industries (nursing homes, retail grocery and poultry). The approaches to addressing ergonomics in these guidelines are also applicable to hospitals and department stores, two industries that NACE recommended for future guidelines.

Since 2004, OSHA has updated the NACE analysis with more recent injury and illness statistics and is considering industries for future ergonomics guidelines. OSHA is working on the ergonomics Guidelines for Shipyards. Once completed we anticipate a 60-day comment period and, if requested by interested parties, a stakeholder meeting shortly following the end of the comment period. We anticipate publishing the final Guidelines for Shipyards late in fiscal year 2007 or early fiscal year 2008.

Question. Overall, how long will it take for OSHA to issue guidelines on the 16 industries recommended by your National Advisory Committee?

Answer. OSHA has carefully considered the recommendations offered by NACE, which was established to advise the Secretary of Labor on ergonomics guidelines, research, and outreach and assistance. We have updated the NACE analysis using more recent injury statistics. The agency is using the results of this updated analysis as one source of information as it considers candidates for future ergonomics guidelines. It should be noted that NACE recommended that OSHA also consider the "Other Criteria" (e.g., injury trends, absence of available guidelines) established by the Guidelines Workgroup when making specific industry selections from the NACE list.

Our past experience with guidelines development is the best indicator of future timelines. The Guidelines for Nursing Homes were completed in about a year. The Guidelines for Poultry processing and the Guidelines for Retail Grocery Stores were completed simultaneously in a 2-year period. We plan to publish draft Guidelines for Shipyards in fiscal year 2007, and anticipate finalizing them in late fiscal year 2007 or early fiscal year 2008.

PERSONAL PROTECTIVE EQUIPMENT

Question. In litigation regarding the OSHA Employer Payment for Personal Protective Equipment standard, DOL informed the U.S. Court of Appeals for the District of Columbia that it will issue a final standard by the end of November 2007, barring unforeseen circumstances. Please provide the committee with a written timetable indicating the remaining steps in the process for issuing the final rule and

the timetable for completing those steps and bi-monthly reports on the progress that has been made in meeting that timetable.

Answer. As you note, OSHA is moving forward with the PPE payment rulemaking. The regulatory team assigned to work on the project is currently developing the regulatory text and preamble discussion explaining the rule, as well as the legal discussions and economic analyses required by the various laws and executive orders that affect the rulemaking process. We have agreed to provide the court with updates on the rule's progress every 60 days, with the first report to be made on June 4, 2007.

When the team has completed its work and I have approved the rulemaking documents, we will submit them to OMB for review. When that process is completed, we will publish the final rule in the Federal Register and submit it to Congress per the Congressional Review Act. Barring unforeseen circumstances, we expect to complete that process in November 2007.

PANDEMIC INFLUENZA PREPAREDNESS

Question. On February 26, 2007, the Department of Labor denied a petition from AFSCME and other labor organizations to issue an OSHA emergency temporary standard (ETS) to protect health care workers and other emergency responders. During the hearing on March 28, Secretary Chao indicated that the Department did not believe that OSHA had the legal authority to issue an ETS for pandemic flu under the Occupational Safety and Health Act because a pandemic had not yet occurred. Has the Department re-evaluated its authority on this issue? If so, does the Department still believe that the United States needs to be in the middle of a flu pandemic to be able to issue an emergency standard?

Answer. After careful consideration of the provisions of the Occupational Safety and Health Act of 1970, OSHA determined that it had to deny the petition because it could not legally support an ETS for a hazard that does not technically exist at this point. The rulemaking process can be complex, but has evolved in such a manner as to ensure, as much as possible, that a final rule is not only effective, but can also stand up to legal challenges.

We clearly recognize and agree with the petitioner's concerns about the need to be prepared for the possibility of an influenza pandemic. To this end, OSHA recently issued guidance to assist employers and employees in preparing for a pandemic, entitled "Guidance on Preparing Workplaces for an Influenza Pandemic." This guidance outlines steps employers and employees can take to prepare for and respond to an influenza pandemic. On May 21, 2007, OSHA also issued guidance for hospital-based health care providers, entitled "Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers."

Question. When will the Department of Labor issue guidelines for protecting health care workers and emergency responders in the event of a pandemic?

Answer. In addition to its recently published general guidance for workplace preparations for an influenza pandemic, OSHA, in close consultation with the Centers for Disease Control and NIOSH, has just issued a detailed guidance document for healthcare facilities entitled "Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers." OSHA also ensured that this critical subject was addressed at a conference co-sponsored with the Joint Commission for the Accreditation of Healthcare Organizations in the fall of 2006. Now that the healthcare guidance has been issued, OSHA plans to seek opportunities for outreach in the healthcare industry.

Question. Does the Department intend to enforce these guidelines under the general duty clause (section 5(a)(1)) of the Occupational Safety and Health Act?

Answer. No. As a matter of policy, OSHA does not issue general duty clause citations based on guidelines that the agency has issued.

Question. Please provide information or data on the percentage of hospitals that have implemented the infection control procedures and respiratory protection measures for health care settings recommended by the Department of Health and Human Services in order to prepare for a pandemic.

Answer. OSHA has no information on the percentage of hospitals/healthcare facilities that have implemented infection control procedures and respiratory protection measures. We are not aware of a source for this information.

PERM FEE

Question. The fiscal year 2008 budget proposes legislation to authorize a cost-based user fee on new applications for the Permanent Labor Certification (PERM) program. What is the fee structure for the PERM proposal?

Answer. The Department's proposal sets an initial filing fee of $650 per application. This fee amount was calculated based on the Department's analysis of the funds necessary to recover the processing costs of administering this service, which helps employers to lawfully hire non-immigrant workers to fill labor shortages. Employers, not alien beneficiaries, would pay the fee. Under the Department's proposal, the Department would review and adjust the fee amount annually to ensure it remains a cost-based fee.

A–76 CIRCULAR, COMPETITIVE SOURCING

Question. From fiscal year 2004 through fiscal year 2006, please indicate at DOL how many standard OMB Circular A–76 competitions have been completed and how many of those standard competitions were won by in-house workforce? For the same period at DoL, please indicate how many streamlined OMB Circular A–76 competitions have been completed and how many of those streamlined competitions were won by the in-house workforce?

Answer. DOL completed 3 standard competitions that were all won by the in-house workforce. DOL completed 18 streamlined competitions that resulted in 2 converting to contract performance and 16 being won by the in-house workforce.

Question. From fiscal year 2004 through fiscal year 2006, please indicate at DOL how many times in-house workforces have been allowed to compete to perform new work? For the same time period, please indicate how many times in-house workforces have been allowed to compete to perform outsourced work. Please indicate whether OMB has ever directed or encouraged the Department of Labor to allow in-house workforces to compete to perform new work or outsourced work. Please identify those instances as well as the numbers of FTEs involved.

Answer. New work is typically staffed by Federal employees using OPM and DOL personnel rules and procedures. Where appropriate, contractor support may be procured using the Federal Acquisition Regulation procedures to perform work that is commercial in nature.

OMB has neither encouraged nor discouraged the use of the A–76 competition process by in-house workforces to perform new work or work currently performed by contractors. The opportunity to recompete work previously competed under the A–76 process has not presented itself because contracts awarded for previous competitions have not yet expired.

Question. From fiscal year 2004 through fiscal year 2006, please indicate whether DoL has ever sought to use alternatives (e.g., high performing organization, business process reengineering, etc.) to OMB Circular A–76 to reach its competitive sourcing goals. Has OMB encouraged or allowed for the use of alternatives to achieve the goals? Please identify those instances as well as the numbers of FTEs involved.

Answer. Between the years fiscal year 2004 through fiscal year 2006, DOL focused its attention on a relatively narrow set of activities (less than 5 percent of its commercial workforce and less than 3 percent of its entire workforce) that were good candidates for competitive sourcing—e.g., common recurring support services, performed competently and cost-effectively in the marketplace, suitable for performance by either a contractor or an in-house team. DOL also identified commercial activities for which competitive sourcing is not the best management tool and will not be considered for competition, largely because the activities are core to the agency's mission and best performed with Federal employees. Of the 26 competitions completed to date, Federal staff have been successful retaining the work in-house in 23 cases. However, none of the competitions have reached the conclusion of their full performance period—generally 3 to 5 years following the competition. Therefore, DOL has not yet had an opportunity to consider the high performing organization (HPO) alternative. In general, OMB has indicated that they are receptive to allowing agencies to use HPO as an alternative to conducting A–76 competitions.

Question. How many OMB Circular A–76 privatization reviews has DOL scheduled for fiscal year 2010, fiscal year 2011, fiscal year 2012, and fiscal year 2013, and how many FTEs would be involved during each of those years?

Answer. DOL's current fiscal year 2010 Competition Plan identifies approximately 1,500 FTEs for possible competition. However, the final management decision to pursue competition and the size and scope of a competition will be contingent on the results of a feasibility study. DOL has not yet developed a competition plan for fiscal years 2011–2013.

OFFICE OF DISABILITY EMPLOYMENT POLICY (ODEP) WORKING TO ELIMINATE BARRIERS TO EMPLOYMENT

Question. Based on findings and results of ODEP's grants, what policy to reduce barriers to employment for people with disabilities has ODEP developed and seen implemented?

Answer. ODEP has developed policy in several disability-related employment policy areas for implementation at the national, State and local levels. Examples include:

—*Disability-related Amendments to the Workforce Investment Act (WIA).*—Based on issues identified through ODEP's pilot project and technical assistance grants, ODEP developed a set of policy recommendations for and proposed amendments to the WIA. These recommendations and proposed amendments targeted the needs of persons with disabilities, and included a description of problems with current law, justification for change, the proposed amendment, and an explanation of its intent. As a result of ODEP's efforts, the State plan requirements for WIA implementation were amended in several ways; first, to ensure that the description of how the State will meet the needs of persons with disabilities is tied to WIA section 188 (which ensures non-discrimination and equal opportunity) and Executive Order 13217 (relating to community-based alternatives for individuals with disabilities); and second, that the State should be required to specifically describe how it will ensure physical and programmatic accessibility for persons with disabilities. ODEP also recommended that the WIA youth program elements be expanded to include instruction in basic economic literacy, which while necessary for all youth, is particularly important for youth with disabilities in planning for a solid financial future and working toward self-sufficiency. The administration's bill for reauthorization of the WIA contained many additional recommendations from ODEP's, and a number of ODEP's recommendations are in the House and Senate bills for reauthorization of WIA.

—*Improving Transition Results for Youth with Disabilities.*—Special education students are more than twice as likely to drop out of high school as their peers in general education, are half as likely to participate in post secondary education, and are much more likely to be unemployed and live in poverty as adults than their non-disabled peers. To help steer families, institutions, and youth themselves through the difficult transition form youth to adulthood, ODEP developed Guideposts for Success, reflecting what research has identified as key educational and career development interventions that can make a positive difference in the lives of all youth, including youth with disabilities.

The dissemination of Guideposts for Success has increased access to coordinated, comprehensive transition services that youth with disabilities need to successfully enter employment and/or post-secondary education. Examples of how the Guideposts have been implemented at the State and local levels include:

—In Iowa, a State team of nonprofit and State government agencies working to strengthen employment services for Iowans with disabilities, is developing a State Report Card looking at indicators specific to youth with disabilities and transition from secondary school to employment and/or postsecondary education based on the Guideposts. The State Report Card will be used to measure how Iowan youth with disabilities are transitioning to adulthood compared to their peers. A draft report card can be found at http://www.iowaemploymentpartners.com/tools/draft_report_card92205.xls

—To date, South Carolina, Indiana, Wisconsin, and Texas are at various stages of implementing High School/High Tech projects using the Guideposts for Success model. Oklahoma's HS/HT program has received a $300,000 grant from the National Science Foundation to develop a new program using the HS/HT model for middle school students with disabilities.

—In Maryland, the State Superintendent for the Maryland Department of Education signed a Statewide Transitioning Cooperative Agreement, which provides for statewide implementation of the Guideposts framework and is finalizing agreements with 24 local school districts to provide for incorporation of the Guideposts at the local level. Five of those agreements also include a voluntary addendum for provision of assistive technology before students leave high school. These agreements will ensure that all students with disabilities, not just those participating in the High School/High Tech program, have access to the type of comprehensive transition programming that research indicates leads to transition success.

—ODEP worked with the National Alliance for Secondary Education and Transition to develop a framework identifying what schools need to do to ensure that

youth have access to the services and supports articulated in the Guideposts. Forty-six States are now using the framework to develop their transition improvement plans, helping students in thousands of school districts prepare to enter employment and/or post-secondary education.

Question. What ODEP grants have lead to what policy, and where is it implemented?

Answer. ODEP pilot project, research, and technical assistance grants have lead to policy developed and implemented on the Federal, State, and local level. These grant efforts have supported ODEP's development of disability employment policy in the areas of:

—Universal access and design to improve the workforce development system's operational practices, services, and physical environments so they benefit the greatest number of people, including people with disabilities, and enhance the workforce development system's overall cost-effectiveness and quality;

—Youth in transition to ensure that the transition-related needs of youth with disabilities between the ages of 14 to 24 are viewed holistically with their non-disabled peers and are effectively prepared for entering employment or post-secondary education;

—Employment strategies and incentives to expand the implementation of creative strategies such as customized employment, telework, and utilization of tax and work incentives to maximize employment opportunities for people with disabilities; and

—State and local infrastructure leadership to increase leadership, collaboration and foster the development of needed infrastructure at the State and local levels where policy implementation ultimately occurs.

Forty-six States—including Alaska, Florida, Wisconsin, Georgia, New York, and California—have adopted evidence-based policies and practices that ODEP has developed based on the findings of the grants that the agency has funded.

We have included a chart for the record that provides specific examples of policy developed by ODEP that the agency has since seen implemented. None of these examples of policy adaptation, adoption, and implementation would have happened without ODEP's ongoing efforts to improve employment opportunities for people with disabilities.

Question. Has ODEP developed and implemented policy that ODEP developed from efforts other than grants? If so, what policy and where has it been implemented?

Answer. While awarding pilot project, research, and technical assistance grants is one strategy that ODEP has successfully used to develop policy and foster its implementation, ODEP also employs other critical non-grant strategies, each of which relies on its staff of disability experts and their policy analysis and development and research skills. ODEP's mandate—to eliminate barriers to employment for people with disabilities—requires an approach that utilizes multiple strategies. Policies that ODEP has developed from efforts other than grants include:

—*Expanding Employment-related Transportation Options.*—Since research supports the lack of available and accessible transportation as the most often cited barrier to employment, ODEP's policy staff established new working relationships with the Department of Transportation (DOT) and other Federal partner agencies that provide transportation supports and services. The policy staff also worked with DOT on the creation of DOT's technical assistance and grant programs that assist States in their efforts to better coordinate their employment-related transportation activities. This initiative eventually resulted in the following:

  —ODEP's co-sponsorship with DOT of a National Summit on Employment and Transportation for People with Disabilities.

  —ODEP's draft of Executive Order13330, Human Service Transportation Coordination (EO), was signed and announced by the White House at a second, larger conference that included the Departments of Education and Health and Human Services. The EO established the Coordinating Council on Access and Mobility, which implemented the United We Ride initiative. The United We Ride initiative, led by DOT, includes the participation of ten Federal agencies working together to simplify, coordinate, and enhance customer access to transportation, and to reduce duplicative laws, ensure comprehensive planning, standardize cost allocation processes, and document successful strategies for human service transportation.

  —ODEP's work with DOT ensured that the reauthorization of SAFETEA–LU included $80 million in new funding for employment-related transportation for people with disabilities. These funds will be provided to each State to be

used to establish new transportation options for people with disabilities to gain or maintain employment.

—*Documenting the Unemployment Rate of People with Disabilities*.—A credible unemployment rate is fundamental to research and policy development across government and the private sector to increase workforce participation for people with disabilities. A multi-year collaborative effort between ODEP research staff and the Bureau of Labor Statistics (BLS) is ongoing to develop a valid and reliable method of measuring the unemployment rate of people with disabilities.

Seven disability questions are being tested and validated for use in the Current Population Survey (CPS), which is jointly conducted by BLS and the Bureau of the Census. BLS is working to launch these questions in the monthly CPS in June of 2008, and for the first time, the Department of Labor will be able to publish an official unemployment rate for people with disabilities.

In addition to the examples given here, we have included a chart for the record that provides more examples of policy developed by ODEP that the agency has since seen implemented. None of these examples of policy adaptation, adoption, and implementation would have happened without ODEP's ongoing efforts to improve employment opportunities for people with disabilities.

Strategy /Activity	Issue Addressed	Policy Implemented	Location /System
		Workforce Systems Policy	
Pilot Project Grants.—Customized Employment	Promoting Self-Employment as a Valid Employment Outcome for People with Disabilities.	One-Stop Career Centers—Self-Employment Training for Workforce Investment Act Clients TEGL#16–04 http://wdr.doleta.gov/directives/corr__doc.cfm?DOCN=1684.	States and State workforce agencies
Technical Assistance and Pilot Project Grants.—National Center on Workforce and Disability for Adults (NCWD–A); Working for Freedom, Opportunity and Real Choice Through Community Employment (WorkFORCE) Action; and Customized Employment.	Ensuring Access to One-Stop Career Centers for People with Disabilities.	WIA section 188 Disability Checklist http://www.dol.gov/oasam/programs/crc/WIASection188DisabilityChecklist.htm; Strategies and Practices for Effectively Serving all One-Stop Customers—A Framework for Systems Change.	One-Stop Career Centers
Technical Assistance and Pilot Project Grants.—National Collaborative on Workforce and Disability for Youth (NCWD–Y) and Innovative State Alignment Grants for Improving Transition Outcomes for Youth with Disabilities through the Use of Intermediaries (Intermediaries).	Increasing Access to Youth Services for Youth with Disabilities.	Youth Vision Training and Employment Guidance Letter No. 28–05 (TEGL) http://wdr.doleta.gov/directives/corr__doc.cfm?DOCN=2224.	Workforce Investment Act (WIA)-funded programs
Pilot Project Grants Activity.—Customized Employment grant and (Intermediaries)	Increasing Participation in WIA Programs for People with Disabilities through Reauthorization of the WIA.	ODEP recommendations in the administration's bill for reauthorization of the WIA; ODEP recommendations in the House and Senate bills for reauthorization of WIA..	Federal WIA legislation
Grant Activity.—High School/High Tech (HS/HT) State Development and Implementation Grants and NCWD–Y.	Improving Transition Results for Youth with Disabilities.	Guideposts for Success http://www.dol.gov/odep/categories/youth/	46 State education systems
Pilot Project Grant.—Customized Employment	Improving the Workforce Investment System's Effectiveness with ''hard to serve'' Customers.	Customized employment policy for the WIA system	Workforce Investment system
Research Project Grant.—Telework/Telecommuting Pilot Research.	Validating Telework as a Strategy to Reduce Employment Barriers for People with Disabilities.	Telework strategies that promote employment, impact employer policies, and integrate telework into the services of the Nation's One-Stop Career Centers. www.teleworkusa.net.	Employers; One-Stop Career Centers

		Employers and the Workplace Policy	
Technical Assistance and Pilot Project Grants.—NCWD–Y and Innovative State Alignment Grants for Improving Transition Outcomes for Youth with Disabilities through the Use of Intermediaries.	Improving Professional Development of Youth Service Practitioners.	Knowledge, Skills, and Abilities of Youth Service Practitioners: The Centerpiece of a Successful Workforce Development System http://www.ncwd-youth.info/assets/background/ksa.doc; National Association of Workforce Development Professionals use: http://www.nawdp.org/certification.htm; National Partnership for Juvenile Services use: http://www.npjs.org/Training/default1.html.	National Association of Workforce Development Professionals: 4,500 members; National Partnership for Juvenile Services: 900 member organizations
Non-Grant Activity.—ODEP Staff work	Promoting Workplace Safety and Security for Federal Employees with Disabilities.	Preparing the Workplace for Everyone: Accounting for the Needs of People with Disabilities—A Framework of Emergency Preparedness Guidelines for Federal Agencies (Framework): http://www.dol.gov/odep/pubs/ep/preparing2.htm.	National, regional, and field levels in GSA; HR and disability program managers in OPM; Federal safety and health officials in OSHA
Non-Grant Activity.—ODEP Staff work	Influencing Employer Policies and Practices.	Valid, credible workplace accommodations information: http://www.jan.wvu.edu/ Society for Human Resource Management (SHRM)/ODEP Alliance Agreement: http://www.dol.gov/odep/alliances/directive.htm.	Society for Human Resource Management (SHRM): 217,000 members; Employers
Non-Grant Activity.—ODEP Staff work	Increasing Awareness about Persons with Disabilities and Employment.	Secretary of Labor's New Freedom Initiative Award (NFI): http://www.whitehouse.gov/news/freedominitiative/freedominitiative.html.	Employers
		Employment-Related Supports Policy	
Non-Grant Activity.—ODEP Staff work	Employment and Mental Health.	Customized employment and Guideposts influencing the design of service delivery methods of OASVETS training curriculum and REALifelines; Draft guidance by ETA for front-line staff in the One-Stop Career Centers nationwide.	Department of Labor /VETS & ETA
Non-Grant Activity.—ODEP Staff work	Expanding Employment-related Transportation Options.	Executive Order (13330): Human Service Transportation Coordination; The reauthorization of SAFETEA–LU included $80 million in new funding for employment-related transportation for people with disabilities: http://www.unitedweride.gov/.	Department of Transportation
Non-Grant Activity.—ODEP Staff	Documenting the Unemployment Rate of People with Disabilities.	In June 2008, BLS will launch seven (7) disability questions in the Current Population Survey (CPS), which is jointly conducted by BLS and the Bureau of the Census; The results will, for the first time, document the actual unemployment rate of people with disabilities: http://www.dol.gov/odep/categories/research/rate.htm.	DOL/Bureau of Labor Statistics; Department of Commerce

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

TECHNOLOGY TRAINING FOR WOMEN

Question. In your testimony, you discussed the preparation of workers for jobs in growth sectors of the economy. The Maui Economic Development Board introduced the Women in Technology program in Hawaii to encourage young women and underrepresented minorities to pursue educational opportunities in fields such as science, technology, engineering, and math. Madame Secretary, would you comment on programs to provide technology training for women, such as the Women in Technology Program introduced by the Maui Economic Board?

Answer. The Department of Labor applauds State and local efforts to promote opportunities for women in the fields of science, technology, engineering and math (STEM). The national STEM workforce agenda of the Department's Employment and Training Administration (ETA) ensures that all workers, including women, can take advantage of the opportunities presented in the STEM fields and can develop the skills that employers demand. ETA's national STEM workforce agenda is focused on (1) building an educated and prepared STEM workforce in the context of regional economies; (2) developing national, State, and regional strategies for talent development in support of economic growth; and (3) implementing STEM workforce education strategies across the continuum of education with a focus on post secondary opportunities for workers. In the Fall of 2007, ETA anticipates a grant competition for approximately $10 million for STEM talent development strategies that attract and prepare workers for STEM careers, including creating an alternative pathway for out-of-school youth.

ETA's national STEM initiative is underpinned by the flagship initiatives of the agency. The President's High Growth Job Training Initiative builds partnerships among employers, education programs, and the workforce investment system to balance the skills of America's workers with the demands of employers in high growth, high demand industries that include STEM fields, such as Aerospace, Biotechnology, Health Care, and Information Technology. In order to build the pipeline of STEM workers to meet the current and future demand for their talents, the Community-Based Job Training Grants strengthen the capacity of community colleges and increase the training opportunities in the STEM fields.

Within the Workforce Innovation in Regional Economic Development (WIRED) initiative, regions are bringing together the workforce investment system, the continuum of education, industry, economic development, and other regional partners to ensure that workers are becoming educated and trained for high growth occupations and sectors in their regional economy. Many of these regions are targeting high-tech industries that require strong foundational skills in STEM education. The WIRED regions are pursuing strategies to open the door to STEM fields for a broader range of individuals, including developing 2+2+2 and accelerated math/science programs, supporting teacher development through summer camps and internships, and establishing apprenticeship programs.

Building on WIRED, Community-Based Job Training Grants, and the High Growth Job Training Initiative, ETA is committed to working collaboratively with community colleges, agencies across the Federal government, the State and local workforce investment system, and a wide array of strategic partners in the public and private sectors to help coordinate regional assets and to drive a national workforce agenda for promoting STEM education and workforce preparation.

MAUI COMMUNITY COLLEGE NURSING DISTANCE EDUCATION

Question. The nursing shortage in the United States is particularly problematic in rural communities. I appreciate your interest in pursuing proper labor support to train health professionals for rural Hawaii. In particular, distance education seems to be an effective strategy to train nurses in rural areas. The Department of Labor recently funded a streamed video delivery of the nursing curriculum at the Maui Community College. I am interested in your impressions of this nurse training program at the Maui Community College.

Answer. The distance education program at Maui Community College significantly increases the geographical reach of the nursing program while expanding health care training capacity in Hawaii by making training offered at the campus available statewide through streamed video technology. For instance, in the spring semester pharmacology class, only 20 of the 130 registered students live on Maui. The remaining students live elsewhere in the State and accessed the course content remotely. This type of training delivery offers a low-cost means of expanding training capacity in that only one instructor is needed rather than a separate instructor at each campus. This is a promising practice in addressing the nationwide health

care faculty shortage. Further, the fact that the training can be accessed around the clock from any location helps to attract more individuals to the profession by providing more flexible training options.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

OFFICE OF WORKERS' COMPENSATION PROGRAMS

Question. It has taken DOL 2.5 years to post the site exposure matrices, which lists the toxins present at some facilities, to your website. Over 14,000 claims were denied under Part E before the claimants had access to this information. It appears that these claimants did not have the necessary evidence to develop their claim. Does DOL plan to reopen these denied claims and if so, can you elaborate on how long it will take and how much money will need to be expended?

Answer. There are a number reasons why Part E claims have been denied, including the submission of claims by ineligible survivors, claims for non-covered employment, claims for the death of an employee that is not related to a covered condition, insufficient medical evidence to support a claimed condition, and no relationship between toxic exposures and the claimed conditions.

Although the public Site Exposure Matrices (SEM) website was just recently launched, a SEM database has been available for claim adjudication purposes by claims examiners and the Final Adjudication Branch since April 2006. Moreover, the SEM is one of many tools available to DOL in making decisions on causation. Claims staff routinely obtains exposure information from the Department of Energy and former worker programs, and resource center staff conduct an occupational health survey with the claimant. In addition, claims staff may request a review of the case by an industrial hygienist or a physician. Utilizing the SEM database in conjunction with other causation development methods afforded equitable decision-making on claims adjudicated prior to the deployment of the public SEM website.

As a matter of policy, the SEM is not used as the sole basis for a decision. Additional tools are used by the Division of Energy Employees Occupational Illness Compensation (DEEOIC) in causation evaluation and every effort is made to assist the claimant in meeting his or her burden of proof, regardless of what information is available in SEM.

Further, although the SEM database is a valuable tool, it does not represent 100 percent of the toxic substances potentially present at a given facility and it is updated as new information becomes available. Interested stakeholders are encouraged to submit evidence to the SEM project team for evaluation and possible inclusion into the SEM. The status of site-specific comments will be available for viewing on the public site.

If an individual whose claim was previously denied now finds information in the public SEM website concerning the toxic substances that are linked to his or her particular illness, and believes that this information is relevant to the claim and was not previously considered, then he or she may submit this information with a written request to reopen the claim to the DEEOIC.

DEEOIC also engages in an ongoing review of the quality of decisions throughout the decision-making process. Recommended decisions are written by claims examiners and reviewed and signed by senior claims examiners. The claimant has the opportunity to object to the recommended decision through a review of the record or hearing, and the Final Adjudication Branch reviews and issues the final decision. Even after the final decision, a claimant may request a reconsideration within 30 days. In addition, the program conducts accountability reviews of a sample of cases. During these reviews, all aspects of the case are reviewed by a National Office team. Any errors discovered in the decision would result in reopening the claim.

REQUEST FOR PHILADELPHIA SHIPYARD FUNDING

Question. On September 7, 2006, Senator Santorum and I sent you a letter that identified the core concept of a project to revitalize the Philadelphia Shipyard. The concept is that in a global economy, companies focus their efforts on a limited set of core competencies and procure all other necessary goods and services through a highly competitive global sourcing process. If the procurement requirements of major companies are intensely analyzed, business that can potentially be done locally at competitive prices can be identified and strategically targeted.

It is my understanding that on October 26, Assistant Secretary Emily DeRocco subsequently met with Philadelphia Shipyard Development Corporations (PSDC). PSDC explained that its goal was to have small and medium sized companies in the Philadelphia region reclaim supplier jobs now being done by foreign workers for the Aker Philadelphia Shipyard and to start a pilot program to prove it could be

done. At that point, the Department of Labor was very excited about the project. The WIRED Region in Philadelphia was mentioned as a possibility for funding. At that meeting, the Department also recommended that PSDC apply for the WIRED 3rd Generation funding. However, as you know, the Governor is able to only submit two applications in this round and the Commonwealth has already endorsed projects for WIRED Generation 3 for Central PA and Western PA.

It is more than 5 months later and the PSDC is still looking for funding through the Department of Labor. My constituents in Southeast Pennsylvania are very frustrated with this process and the progress with possible funding opportunities within the DoL. The innovative supplier network training program would return jobs to the tri-State region. The cost of the project is $1.6 million over 18 months. It will immediately result in $16 million in sales for deckhouses to be built here with an increasing number of local workers. It includes both classroom and on the job training. It will create 60 jobs which will pay about $55,000, including benefits, vacation and holidays.

Once PSDC provides this turnkey process, they would like to move on to other supplier contracts involved in Aker's contract for 13 tankers, with options for more that now goes overseas.

Where does the Department suggest PSDC go to secure the Department of Labor funding for this important project? This has been ongoing since early September 2006.

Answer. The U.S. Government, specifically the Department of Labor and the Department of Defense, has devoted significant funding during the past 9 years to the employees of the Philadelphia Shipyard. In particular, the Department of Labor's Employment and Training Administration (ETA) has provided approximately $35,205,600 since 1997 in the following grants:

—A dislocated worker demonstration grant of $11,880,000 between 1999 and 2003;

—A Defense Conversion Adjustment grant of $5,505,600 between 2001 and 2002; and

—National Emergency Grant funds totaling $17,820,000 between 1997 and 2005 to serve employees of the shipyard.

The Commonwealth of Pennsylvania has also provided considerable funding to support the shipyard and its employees in the form of State and local Workforce Investment Act funds since 1998, and previously, under the Job Training Partnership Act.

ETA has worked with the Philadelphia Shipyard Development Corporation (PSDC) to assess the economic development opportunities for the shipyard and the surrounding community. Recently, Assistant Secretary Emily S. DeRocco convened a meeting of Federal, State, and local government, workforce development, economic development, and business leaders to examine the opportunities and challenges in developing the region's comprehensive economic strategy, and to strategically align and leverage the Federal, State, and local public and private resources available to transform the local economy. ETA has also supported collaboration between PSDC and the Mid-Atlantic Innovation Network and Innovation Philadelphia, which has received an ETA WIRED Initiative grant.

ETA aims to award its grants through competitive processes as requested by Congress. ETA is facilitating a connection between Aker Philadelphia Shipyard and a broader audience of stakeholders and fund sources to determine the best methods of support for the supplier development proposal. ETA is hopeful that the PSDC proposal can be supported and that the shipyard can become self-sustaining, providing meaningful jobs to the many workers in the Philadelphia area.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

PROPOSALS TO STREAMLINE AND STRENGTHEN WIA

Question. Secretary Chao, I understand that the Department of Labor has recently proposed policy changes to the Workforce Investment Act to streamline and strengthen the Nation's workforce development system. Can you comment on how these changes will affect States and their ability to meet the needs being met by the current framework?

Answer. The administration's most recent legislative proposal for Workforce Investment Act (WIA) reauthorization, which was transmitted to the Congress in April, would improve the ability of the workforce investment system to support our Nation's competitiveness by providing States and local communities more flexibility to design streamlined workforce systems that best fit the unique needs of their

economies. The proposal would also better serve the needs of American workers and employers by making more money directly available for education and training.

Under the proposal, four separate funding streams through which funds are currently allotted to States to support the workforce investment system—the WIA Adult, Dislocated Worker, and Youth programs and the Employment Service—would be integrated into a single funding stream. This consolidated funding would be allocated to States—and through States to local areas—to provide Career Advancement Accounts and employment services to job seekers and employers. Career Advancement Accounts would be available to both adults and out-of-school youth entering or re-entering the workforce or transitioning between jobs, and to incumbent workers in need of new skills to remain employed or move up the career ladder.

The proposal would further enhance the workforce investment system by strengthening One-Stop Career Centers, providing for more effective governance arrangements, promoting access to a more comprehensive array of employment and training services, and improving performance accountability. We believe our proposal will give States the tools they need to enable current and future workers to gain the skills needed to successfully enter, navigate and advance in the 21st century labor market.

HIGHER EDUCATION AND ADVANCED SKILL TRAINING INITIATIVES

Question. Secretary Chao, as we prepare workers for the new challenges of competing in a global economy, can you comment on specific initiatives that will provide opportunities for higher education and advanced skill training?

Answer. Today's globally competitive economy has heightened the demand for a skilled workforce. Aligning the workforce system with the new economic realities of the 21st century is critical to ensuring that American workers and businesses are competitive in the global marketplace. The Department of Labor has strived to transform the workforce investment system into a demand-driven system that catalyzes and leverages all available resources to respond to regional businesses' need for a skilled workforce and create employment and advancement opportunities for workers. The Department has undertaken three key initiatives to create a demand-driven workforce investment system and increase opportunities for education and skills training:

—Through the President's High Growth Job Training Initiative, ETA has invested over $285 million in 150 partnerships among employers, education programs, and the workforce investment system. Each project targets the skill and talent needs of high-growth, high-demand and transformational industries in our Nation's economy and provides the resources necessary to train workers in the skills demanded by the 21st century economy.

—Community-Based Job Training Grants, also known as the Community College Initiative, seek to address a critical shortcoming in the workforce development capacity of many regions by supporting community colleges to train workers for jobs in high-growth, high-demand industries. Due to their close connection to local labor markets, community colleges are well positioned to understand the intricacies of local economies and better prepare workers for occupations in these industries. The Department has provided $250 million to 142 community colleges and other entities under this initiative.

—The Department launched the Workforce Innovation in Regional Economic Development (WIRED) Initiative in February 2006 to emphasize the critical linkage between workforce development and economic development in regional economies. WIRED focuses on the role of talent development in driving regional economic competitiveness, job growth and prosperity for workers. Under the WIRED Initiative, the Department has invested $260 million and provided expert assistance to 26 regions across the Nation to implement strategies that will create high-skill and high-wage opportunities for American workers.

In addition, the administration has recently submitted Workforce Investment Act (WIA) reauthorization legislation to Congress that would improve the ability of the workforce investment system to support our Nation's competitiveness. The proposal would provide State and local communities with more flexibility to design streamlined workforce systems that best fit the unique needs of their economies. The WIA reauthorization proposal would also better serve the needs of American workers and employers by making more money directly available for education and training.

QUESTIONS SUBMITTED BY SENATOR KAY BAILEY HUTCHISON

ADMINISTRATIVE FUNDING FOR STATE UNEMPLOYMENT COMPENSATION PROGRAMS

Question. It is my understanding that the Resource Justification Model, currently being utilized to allot funds to the States to administer the State unemployment compensation program, is under review by DOL.

—Could you explain how DOL is planning to comply with the current Federal statutory requirements (i.e., to properly allocate funding to States based on(1) determinations necessary for the proper and efficient administration of the UI program, (2) the population of the States, and (3) the estimated number of persons covered by each State's law)?; or

—Does DOL currently allocate State administration grants according to these certain enumerated Federal requirements and appropriately account for State populations and their administrative efficiencies?

—If you believe that DOL is properly allocating the UI administrative grants, then could you explain how DOL, and its current methodology, is in compliance with Federal law in its administration of the grants to the States equitably?

Answer. The Department of Labor has completed its review of the long-standing method by which the Department of Labor allocates funds to States to administer the unemployment compensation program. The Department determined that the method takes into account the statutory requirements of section 302(a) of the Social Security Act (SSA).

Section 302(a) requires the Secretary to grant each State "such amounts as the Secretary of Labor determines to be necessary for the proper and efficient administration . . ." of the State's unemployment compensation law. In making this determination, the Department collects data through the Resource Justification Model (RJM) reflecting actual expenditures by States each year in administering their unemployment compensation laws. The Department uses these data along with its projections of the level of claims and employers in each State for the upcoming budget year to determine the amount allocated to each State. These allocations in total are constrained by the total amount appropriated for State Unemployment Insurance administration.

The Department believes that all of the enumerated Federal requirements cited in section 302(a), including population, are appropriately accounted for in the allocation methodology. The statute does not assign weights to the various factors cited, thereby allowing the Secretary broad discretion. A key component of the allocation methodology is a State's claims workload level which is influenced by factors including the population of the State, its economic situation, and its unemployment compensation laws. In addition, a State's population is reflected in the number of wage records reported quarterly by employers and processed by States as a workload item funded in the allocation methodology. Wage records are also an excellent "estimate of the number of persons covered by the State law" cited in section 302(a).

"The cost of proper and efficient administration" upon which the Secretary is to determine the allocation begins with the actual cost data collected by RJM. However, the allocation process takes into consideration each State's operating costs vis-à-vis other States, and adjusts downward (through an iterative mathematical process) the subsequent year allocations of States whose costs are comparatively higher, thus encouraging efficiency in program administration. Finally, the statute allows the Secretary to use other relevant factors which, for example, include the cost of space rental and maintenance, utilities costs, and personnel salaries and benefits.

Each State's administrative funding allocation is based on State submitted data and a methodology which treats each State equally using the factors cited in section 302(a). Hence, the Department believes administrative funding for the unemployment compensation program is allocated equitably among States and in compliance with Federal requirements.

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you very much, Madam Secretary. I hope that our subcommittee here will do you a favor and give you more money than what you requested.

The subcommittee will stand in recess to reconvene at 2 p.m. on Tuesday, April 17, in room SD–124. At that time we will hear from Dr. Julie Gerberding, Director, Centers for Disease Control and Prevention and Dr. Thomas R. Insel, Director, National Institute of Mental Health.

[Whereupon, at 11:28 a.m., Wednesday, March 28, the subcommittee was recessed, to reconvene at 2 p.m. Tuesday, April 17.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

TUESDAY, APRIL 17, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 2:05 p.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Durbin, Reed, and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION

STATEMENT OF DR. JULIE GERBERDING, DIRECTOR

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Good afternoon, the Subcommittee on Labor, Health, Human Services, Education, and Related Agencies of the Appropriations Committee will come to order.

The subcommittee has invited a number of distinguished witnesses to appear before this hearing and this subcommittee, to tell us more about a very important issue, autism.

The Centers for Disease Control and Prevention estimates that 1 of every 157 children born this year will be diagnosed with autism. Millions of families across the country are facing the very real difficulties in coping with this disease.

It's tough on parents who would do anything to help their children at home, while at the same time, fighting to find the supportive services that their children so badly need. We hear the heartbreaking stories, day after day, about families just trying to get the best treatments for the children, and wondering why it's their family that faces this ordeal.

I know we have heard from several families and groups, and I want to thank them for sharing their stories.

This hearing will address a number of questions. First, is the prevalence of autism on the rise, both in the United States and other countries? If so, why is that? Is there really an increase in children of autism, or is the disease being better diagnosed? I keep hearing both sides of that debate.

Second, of course, what causes autism? Is it environmental, is it genetic? Is it a combination of both? Imagine my surprise, when I

read the last issue of Discover magazine. It had a big story in there about understanding autism, and the subtitle is, The Answer May Lie in the Gut, Not in the Head, saying that there may be a direct link between physical illness—physical illness—and the onset of autism. So, again, I'll be asking questions about that article. [Discover magazine, April 2007, "Autism: Its Not Just in the Head," by Jill Neimark.]

Third, what therapies work best for children with autism? Are parents able to find the services they need for their kids, and at what cost?

As Dr. Favell will point out, and also Marguerite Colston in her testimony, that in looking for a cure and putting more research dollars out there, and trying to find how we have a cure, or a good intervention, we can't forget the families need help now. Now—not 10 years from now, they need help right now—in finding the best possible support for their children.

So, we have two panels of witnesses today. The first panel will be, of course, Dr. Julie Gerberding, the Director of the Centers for Disease Control and Prevention, who will talk about the incidents, and prevalence, of autism. Dr. Thomas Insel, the Director of the National Institute of Mental Health, will bring us up to date on some of the science.

PREPARED STATEMENT

Our second panel will include Dr. Judy Favell, who has done great work with young children with autism; Marguerite Colston, a parent of a child with autism who can speak to the issue from the perspective of a parent; Mr. Bob Wright, the Co-Founder of Autism Speaks; and, Bradley Whitford, actor; as well as, former Deputy Chief of Staff to President Jed Bartlett (on TV, of course) and foremost an advocate for children with autism.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Good Afternoon. The subcommittee has invited a number of distinguished witnesses, this afternoon, to bring us up to date on a very important topic: the status of autism, and of autism research, in the United States. The Centers for Disease Control and Prevention estimates that one of every 157 children born in the United States this year will be diagnosed with autism. Millions of families are grappling with the profound difficulties of understanding and coping with this disease. My heart goes out, in particular, to parents who go to heroic lengths to assist their autistic children at home, and who fight the daily fight to secure the support services that their children so badly need.

This hearing will look at several key questions:

First, the number of diagnosed cases of autism is on rise, both in the U.S. and in other countries. Why is this? Are we simply doing a better job of diagnosing autism, or has there been a real increase in the incidence of this disease?

Second, what causes autism? Are the causes environmental? Are they genetic? My guess is that it is a combination of the two, but I am eager to hear the views of our witnesses.

Third, which therapies work best for children with autism? And are parents able to find the services they need for their children, and at what cost? As Dr. Favell points out in her testimony: while doing research on causes and cures is important, people need help now to overcome or lessen the effects of autism.

Last, what is the outlook for finding a cure for autism? And what more can the federal government do to help?

We will have two panels of witnesses today. The first panel includes Dr. Julie Gerberding, the Director of the Centers for Disease Control and Prevention, who will talk about the incidence of autism; and Dr. Thomas Insel, Director of the Na-

tional Institute of Mental Health, who will bring us up-to-date on the science and research.

Our second panel includes Dr. Judy Favell, who has done great work with young children with autism; Marquerite Colston, a parent of a child with autism, who will speak to this issue from the perspective of a parent; Bob Wright, the co-founder of Autism Speaks; and Bradley Whitford, former deputy chief of staff to President Jed Bartlett—actually, a very accomplished actor—and an outspoken advocate for children with autism.

Senator HARKIN. With that, I will turn to my colleague, Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Senator Harkin, for convening this very important hearing on this very debilitating disorder. We have seen a significant increase in the funding by the National Institute of Health for autism research from $27 million in 1998, to the current funding of $108 million. CDC funding for autism has grown from $281,000 in 1998, to $15.1 million today.

My view is that the funding through the NIH is insufficient. As is generally known, Senator Harkin and I have taken the lead on increasing the funding for the National Institutes of Health from $12 billion to $29 billion. During the course of the past decade, we have re-allocated priorities within this subcommittee—as we frequently say, the gavel has changed seamlessly between the two of us over the course of the past decade and a half—and in some years, have increased NIH's funding by as much as $3.5 billion.

This year, with a lot of pressure, the budget resolution came forward with an additional $1.5 billion, and Senator Harkin and I added an amendment to add $2.2 billion more to the National Institutes for Health.

Candidly, a budget resolution is only Confederate money, it doesn't really count until there is an allocation. Senator Harkin and I are working our way up the seniority route, and we're getting to be closer to the coveted status of chairman of the Appropriations Committee. Only Senator Cochran is ahead of me on the Republican side, and it's a great position to have to be able to deal in real dollars when those allocations are made.

But, we hear parents across the country tell us about their children with autism, and it's an ailment, a malady, which I think could be, could be solved if we had sufficient research intensity.

For a moment, on a purely personal note, one of the leading national advocates on this subject is John Shestack, who is the son of a very prominent lawyer, Jerome Shestack in Philadelphia—longstanding friend of mine—and, his mother Marcia Rose is a noted television personality. John and his wife, Portia, have established a foundation, one of the largest non-governmental funding resources for autism, and they have recently joined with Bob and Suzanne Wright for the February merger of their two leading autism organizations.

So, it is very heartening to see this in the private sector, and Senator Harkin and I, and this committee—and I think, really, the whole Congress—are determined to increase funding so we can find an answer to autism.

Regrettably, I'm not going to be able to stay for the entire hearing today, we are very deeply involved in the issue with the De-

partment of Justice and the resignation of the U.S. Attorneys which is taking a great deal of time, and I'm going to have to excuse myself partway through this hearing to attend there, but I will stay for as long as I can.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Specter. Again, thank you for our close working relationship over all these years, and for your continued commitment to bio-medical research and especially to this very important issue of autism.

I had dinner Sunday night with a couple whose child is autistic, and all I can say is that we've got to get the families some help. People are looking to us for answers and some help. Hopefully this hearing today will point us in the right direction.

So, let's get started, and I'll just make it clear that all of your statements will be made part of the record in their entirety. I'm going to ask each of our witnesses to try to sum it up in about 5 minutes. But if you get around 7 minutes or so, I might start motioning for you to quit.

So, if you could just sum it up for us, and then I'm going to ask both you, Dr. Gerberding and Dr. Insel, at the end of your presentations, to maybe take a seat on either end, and we'll bring up the other witnesses. It's not my intent to question you at that time—but to question everyone all at once.

Okay? So, we'll kick it off first with Dr. Julie Gerberding, the Director of the Centers for Disease Control and Prevention. Dr. Gerberding, welcome back.

SUMMARY STATEMENT OF DR. JULIE L. GERBERDING

Dr. GERBERDING. Thank you, it's good to be back. We really appreciate the committee's interest in this topic. Is my microphone on, can you hear me okay?

Senator HARKIN. Yes.

Dr. GERBERDING. We are very grateful for all of the support that the committee has given us, and particularly for our ability to expand our autism activities significantly.

Senator Harkin, I also know that you walk your talk on this issue, having had a chance to be with you at the summer Olympics—the Special Olympics last summer—and knowing your commitment to developmental disabilities, and disabilities of all nature. So we really appreciate your championing this issue.

I'd like to share with you the CDC perspective on autism and the work that we're doing. It's important to appreciate that we recognize that we're talking about a spectrum of diseases here, not a single disease. We're talking about autism, per se, about pervasive developmental disorders, and some other conditions that have characteristics in common with autism—Asperger's disorder and some other conditions—and these are diseases that are not diagnosed by a test. They're diseases that are diagnosed by observing behaviors, and watching behaviors change and develop over time. So, there's a lot of difficulty in making a distinction between who has what, and where one of these conditions leaves off and the other one begins.

We know that autism has a tremendous impact on children who are affected as well as their families and the people who care for

them. The diseases are characterized primarily by difficulties in forming relationships, and engaging in the kind of social interactions and communications that enrich life, and allow people to effectively communicate with one another.

Many of these children also have differences in the way they respond to stimuli in the environment; the way they learn, the way they play, and the way they experience their life overall.

The bottom line is, there is no cure for autism now, and these effects can last a lifetime. We also know that the sooner we make the diagnosis of autism spectrum disorders, the more likely children are to benefit from interventions, and so it's imperative that we not wait until the full-blown syndrome has evolved, but that we have early detection and characterization.

Under the Combating Autism Act, CDC has three main responsibilities. One is, to answer your first question, what is the prevalence of autism in our communities, and is it changing over time, and who is at risk, why and when?

Our second priority is research. We are engaged in several kinds of epidemiologic research that will help us look at a variety of the hypotheses about causality, and try to make some determinations about which are the most promising associations, and what can we learn about cause that could help us lead to intervention, or even treatment.

Last, and importantly, is our responsibility for awareness. We need to be able to inform parents and caregivers, as well as teachers and clinicians about the full spectrum of these conditions so that earlier diagnosis is possible. We also need to improve community awareness so that children can live more comfortably in their communities, and overall public awareness so that we have the kind of support we need to solve these problems.

Just recently, CDC published information about the rate of autism in communities around our country. I'm going to focus on the communities that were reporting data in 2002, we also have a report from 2000, and there will be an upcoming report on information from 2004. But the information from 2002, probably is the largest sample, and so I'm going to focus on that—this represents about 10 percent of 8-year-old children in our country, so it's not everyone, it's not every community, but it's a significant proportion.

What was found in this study is that about 1 in 150 children have autism. Boys, in general, were more likely than girls, and at least some of the sites showed that white children were more likely to have autism than non-white children. So, this is a healthy—a helpful—perspective, but we can't yet say anything about trends over time, until these studies go on for a longer period of time.

We also have initiated a set of studies in a group of sites called CADRE, Centers for Autism and Development Disabilities Research and Epidemiology. And this is a study that will allow us to look at causes. We're going to compare children who have these disorders, with children who have other disabilities, and children who are normal, and look for the frequency of a variety of factors, including infections, as you mentioned in the Discover magazine, their parents' health status, their family health status, their genes and so on and so forth. We will be able to tease out of that leading hypothesis about why are children with autism different from chil-

dren who have other conditions, or who don't have a developmental disability. This is a project we're starting this spring, and we will probably have information from the study over the next couple of years.

The last point I wanted to make very quickly, was the importance of awareness. We know that at least half of children with autism have obvious symptoms and signs before they're age three, but most children with autism are not diagnosed until they are 4 or 5 years old, so there's a gap between when it should be completely clear what is going on, and the gap when they come to attention.

So, we initiated this "Learn the Signs, Act Early" campaign to target parents, health professionals and caregivers in pre-school and daycare to be able to recognize the child who is at risk, or who may have early signs. Of course, we're doing this with a number of our partners.

This has been an incredibly effective campaign already. Pediatricians now indicate that they have the tools to be able to diagnose autism at least two-thirds of the time, parents understand that this disease can be detected through developmental screening, and an increasing proportion of doctors recognize that you can diagnose autism as early as 18 months, and that you need to initiate the screening much earlier than when the child enters school, which is often when these conditions are initially detected.

PREPARED STATEMENT

So, we're going to continue this awareness campaign, we hope that will create a platform so that the work that we're doing on research, on causality and interventions will have a better chance to really make a difference.

So, I—again, I thank you for your attention, and I look forward to being able to answer some specific questions that you mentioned at the beginning of this hearing.

[The statement follows:]

PREPARED STATEMENT OF DR. JULIE L. GERBERDING

Good afternoon, Senator Harkin and distinguished members of the subcommittee. Thank you for the opportunity to appear before you on behalf of the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services, to discuss our agency's research and prevention activities addressing autism spectrum disorders. Thank you also for your continued support of CDC's goals in support of healthy people throughout all stages of their lives and facets of living. Good health is essential to a good life, and the health and well-being of a Nation's people are essential for its continued strength and growth.

Today, our Nation and the world are focused on urgent threats such as pandemic influenza, natural disasters, and terrorism. While these threats require and deserve our immediate attention, we cannot lose sight of the pressing realities of public health issues that we face every day, such as autism and other developmental disabilities. Autism spectrum disorders include autistic disorder, pervasive developmental disorder—not otherwise specified (PDD–NOS, including atypical autism), and Asperger's syndrome.

Autism spectrum disorders cause considerable impairments in social interaction and communication that show up early in a child's life—before the family celebrates the child's third birthday—and can dramatically affect a child's ability to participate in activities with loved ones, caregivers, and peers. It is often difficult for a child with an autism spectrum disorder to communicate and interact with others, and they can retreat from group activities. An affected child may also have unusual ways of learning, paying attention, or reacting to different sensations, and can show unusual behaviors and interests. There's no cure at this time, and the effects of these disorders can last a lifetime. The profound lifelong impact of autism spectrum

disorders, tremendous costs to the affected individuals and their families, the lack of known causes or cures, and concerns about the increased rates of diagnosis all make autism spectrum disorders one of our urgent realities, and a top concern for many families, health professionals, educators, and local and national organizations.

CDC's efforts on autism spectrum disorders are led largely by our National Center on Birth Defects and Developmental Disabilities (NCBDDD), which was created following the Children's Health Act of 2000. The Center takes a life-span approach by working to identify and prevent birth defects and developmental disabilities—including autism spectrum disorders—and by promoting the health of children and adults with disabling or potentially disabling conditions. The Center's top priorities are improving health and wellness for people with disabilities, preventing birth defects, and addressing autism and related conditions.

As reauthorized by the Combating Autism Act of 2006 (Public Law 109–416), NCBDDD's work in autism spectrum disorders focuses on three broad areas—understanding rates and trends, advancing public health research in the search for causes or a possible cure, and improving early detection and diagnosis so that affected children can begin receiving intervention as soon as possible. Early intervention that provides structure, direction, and organization can often help a child with an autism spectrum disorder. Today, I will provide an update on the prevalence of autism spectrum disorders, discuss the launch of CDC's epidemiologic study of potential causes and correlates, and share with you some of our successes in promoting early identification of autism spectrum disorders and other developmental disabilities.

CDC'S WORK IN AUTISM SPECTRUM DISORDERS PREVALENCE

Parents, policy makers, and the public want to better understand how many people are affected by autism spectrum disorders—and whether the higher rates are due to better identification or a true increase in the occurrence. In order to address these questions about rates and trends, we have focused our efforts on developing prevalence estimates of autism spectrum disorders in multiple communities over time. "Prevalence" is the number of existing disease cases in a defined group of people during a specific time period, and it should be differentiated from "incidence," which is the number of new cases for a given period of time.

Previous efforts to understand the prevalence of these conditions have varied widely in their methods and findings—making it difficult to accurately answer critical questions about trends. For example, studies published before 1985 indicated that the prevalence of autism and related conditions was 0.4—0.5 per 1,000 children. However, later studies using updated diagnostic criteria and differing methods from multiple countries have identified rates ranging from 2.0 to 12.0 per 1,000 children with "best estimate" rates ranging from 2.0 to 6.0 per 1,000 children. Two previous CDC studies specific to U.S. communities from the mid-1990s found rates of 3.4 and 6.7 per 1,000 children 3–10 years of age and have identified the urgent need for population-based autism spectrum disorder prevalence monitoring in the United States.

CDC has been monitoring the prevalence of developmental disabilities since the 1980s and autism spectrum disorders specifically since 1996. Since 1999, CDC and its partners in 14 States have been building the Autism and Developmental Disabilities Monitoring (ADDM) Network to better understand the size and characteristics of the population of children with autism spectrum disorders, and to provide consistent and reliable estimates over time. This network, the only one of its kind, provides multiple-site, multiple-source, population-based prevalence data on the number of children with an autism spectrum disorder. CDC began with six sites (Arizona, Georgia, Maryland, New Jersey, South Carolina, and West Virginia) in 2000 and in 2002 expanded to include eight additional sites (Alabama, Arkansas, Colorado, Missouri, North Carolina, Pennsylvania, Utah, and Wisconsin). Today, we are continuing our surveillance efforts in 10 of these sites. While this method does not provide a nationally representative sample, the network represents the largest effort to monitor prevalence to date, capturing up to 10 percent of the U.S. population of 8-year-old children. The network aims to provide accurate information and a strong basis for bringing autism and developmental disabilities surveillance to scale, similar to our national efforts in monitoring other urgent realities.

RECENT PREVALENCE ESTIMATES

Together with our partners in the ADDM network, CDC is beginning to answer one of the critical concerns that I discussed earlier—are rates of autism spectrum disorders truly increasing? In February of this year, the CDC released the largest summary of prevalence data from multiple U.S. communities ever reported. The results showed an average of 6.7 children out of 1,000 with an autism spectrum dis-

order in the six communities assessed in 2000, and an average of 6.6 children out of 1,000 with an autism spectrum disorder in the 14 communities included in the 2002 study. The average finding of 6.6 and 6.7 per 1,000 eight-year-olds translates to approximately 1 in 150 children in these communities. This estimate is consistent with the upper end of prevalence estimates from previously published studies, with some of the communities having an estimate higher than those previously reported in U.S. studies. Reported rates ranged from about 1 in 100 to 1 in 300 children in the 2002 study year.

Six of the participating sites (Arizona, Georgia, Maryland, New Jersey, South Carolina, and West Virginia) reported data in both 2000 and 2002. Autism spectrum disorder prevalence was similar across the 2 years in four of the six sites. New Jersey's prevalence estimates are higher than all other sites in both years, but did not increase significantly between 2000 and 2002. In West Virginia, the prevalence estimate is significantly higher in 2002 than in 2000; the prevalence in Georgia appears to have increased, but not significantly. While the stability of autism spectrum disorders in four of the six sites is fairly consistent, the increase in two sites is a concern.

As anticipated, the findings from both study years confirmed a higher prevalence for boys than girls; this finding is consistent with past studies. Also, the data show some differences in rates among children by race or ethnicity. Similar to past reports, prevalence rates in most sites were similar for white and black children; however, five of the 14 sites found a higher prevalence among white children compared to estimates for black children.

In addition to measuring prevalence and demographic differences, the studies looked at when parents and others first noted signs of developmental concerns in their children. We know that autism and related conditions can be diagnosed as early as 18 months. However, these studies showed that up to 88 percent of children with an autism spectrum disorder had documented developmental concerns before the age of three, but half of these were diagnosed between 4½ and 5½ years. It is of critical importance to diagnose the child as early as possible, as early intervention services hold the most promise to improve the quality of life for these children and their families.

The 2000 and 2002 data points do not constitute a trend, but they do provide important baseline information on the prevalence of autism spectrum disorders in multiple areas of the United States. As I mentioned earlier, we are continuing to work with our network partners on prevalence estimates for 10 of these same sites for 2004 and 2006. Since the system has now been established, I expect information for these new data points will come more quickly, hopefully by the end of 2008.

I want to stress that CDC and many of our public and private partners see these numbers as an important step in understanding autism spectrum disorders, but more importantly, we recognize that "1 in 150 children" represents the lives of the hundreds of thousands of children and parents touched by autism and related conditions. Because of this, we are committed to the search for answers. We are also working to ensure that parents, health care and child care professionals, and everyone who cares for children, are able to recognize the early signs of autism spectrum disorders. In the absence of a cure, early identification and action hold the most promise for affected children and families.

EPIDEMIOLOGIC RESEARCH

We all want to know the causes of autism and related conditions. In addition to building a public health surveillance network for developmental disabilities, CDC has also been researching potential causes. Following the passage of the Children's Health Act of 2000, CDC has been working closely with partners in five sites to develop the Centers for Autism and Developmental Disabilities Research and Epidemiology, or CADDRE. This multi-state collaborative study will help to identify factors that may put children at risk for autism spectrum disorders and other developmental disabilities.

CADDRE is a collaborative effort from which we expect to build a large pooled data set that will be used to examine priority research questions. As the largest epidemiologic study of its kind, it holds the potential to be an important complement to the array of other work occurring at the National Institutes of Health and in academia. It is important to note that what CDC brings to autism spectrum disorder research is a unique perspective of studying health issues in large populations—not just among individuals or families who self-refer for intervention or study. To date, CADDRE sites have studied conditions that often occur with autism spectrum disorders, screening and management, and associations with immune system and genetic and environmental factors.

Later this spring, CADDRE will begin data collection to study a number of factors for their potential association with autism spectrum disorders. Known as the Study to Explore Early Development (SEED), the factors include: infections or abnormal responses to infections in the child, mother, or father; genetic factors in the child, mother and father; mother's reproductive history; abnormal hormone function in the child, mother or father; gastrointestinal problems in the child; family history of medical and developmental problems; select environmental exposures; behaviors during pregnancy; and parents' occupations and other socio-demographic factors. The information will be obtained by conducting interviews and exams, reviewing medical records, and by collecting cheek swabs and blood and hair samples.

Several steps in the development of SEED have already been completed. The protocol has been written, and Institutional Review Board approval has been obtained. In addition, site-specific advisory boards have been established to review the study materials and the study design. Focus groups with parents of children—with and without developmental disabilities—were conducted to obtain additional feedback on the study design and feasibility of the study. The implementation and quality control protocols for all aspects of SEED field work have been developed and "train-the-trainer" sessions for field implementation procedures have been completed. Data sharing protocols and general analysis plans have been developed, and the CADDRE Information System (web-based subject tracking and data collection application) has been established. We expect data collection to take 3 to 4 years, and preliminary results would be available shortly thereafter.

Study participants will include approximately 3,000 children ages 2–5 years and their parents. All study children will be drawn from the cohort of children born and currently residing in the study areas of each CADDRE site in select birth years. Three groups of children will be selected: children identified with autism spectrum disorders, children identified with other developmental problems, and a random sample of all children in each area born in the selected birth years (most of them typically developing).

LEARN THE SIGNS. ACT EARLY

Recent studies have shown that developmental disabilities such as autism spectrum disorders can be diagnosed as early as 18 months; however, we know that about half of all children are not diagnosed until much later. Early intervention is a child's best hope for learning to communicate and connect with his or her parents and friends and to be able to learn in a classroom with his or her peers.

CDC, in collaboration with a number of national partners—the American Academy of Pediatrics (AAP), Autism Speaks (Cure Autism Now and the National Alliance for Autism Research, which have both recently merged with Autism Speaks), the Autism Society of America (ASA), First Signs, the Interagency Autism Coordinating Committee (IACC), and the Organization for Autism Research (OAR)—launched a national public awareness campaign in 2004 called Learn the Signs. Act Early. The campaign aims to educate parents, health care professionals, and child care providers about child development, including the early signs of autism spectrum disorders and other developmental disabilities, and to encourage developmental screening and intervention. Learn the Signs. Act Early. builds on familiar experiences of parents, such as monitoring their children's physical growth, and expands to social and emotional milestones such as how children speak, learn, act, and play. Just as taking a first step is a developmental milestone, so are smiling, pointing, and waving goodbye.

We know that when developmental delays are not recognized early, children cannot get the help they need. By increasing the awareness of autism spectrum disorders and other developmental disabilities and their signs and symptoms, we can increase early developmental screening, diagnosis and intervention. This means affected children can receive the help they need to enhance their development and improve the quality of life for them and their families.

To date, the campaign has reached more than 11 million health care professionals, parents, partners, campaign champions, and it is achieving its first goal—to encourage target audiences to "Learn the Signs" of autism spectrum disorders and other developmental disabilities. Outcome data show significant improvements in the percentage of parents who are aware of early warning signs of developmental delays, as well as increases in the number of pediatricians who agree that a child with an autism spectrum disorder can be diagnosed as early as the age of 18 months. Since the launch of the campaign, more pediatricians report that they regularly screen pediatric patients for developmental delays.

In November 2006, Learn the Signs. Act Early launched the childcare provider segment, targeting the more than 407,000 childcare facilities in the United States.

This new phase will provide free materials to help childcare providers and preschool teachers educate parents about child development and autism spectrum disorders.

FUTURE OPPORTUNITIES

CDC recognizes that parents want answers. If a child has an autism spectrum disorder, his or her parents want to know what caused it, the most effective intervention, and how they can lower their risks if they plan to have other children. We share their frustration at not having more answers about the causes and possible cure for the debilitating symptoms of autism and related conditions. That is why CDC continues to track the rates of autism spectrum disorders, research possible causes, and provide accurate information about identifying developmental concerns and seeking help during a child's early years of development.

CDC is positioned to bring surveillance, research, awareness and intervention activities to scale. Building on the encouraging success in these areas, CDC can continue answering important questions about prevalence and trends and can bring to bear population-based research tools in the effort to find answers about potential causes of autism spectrum disorders. The CDC can encourage the best known timely interventions for children and their families. Enhancing our programs would allow us to maintain surveillance in key sites and evaluate prevalence for different age groups, research potential causes more aggressively, and answer prevalence and trend questions faster. We can build on successes in educating the public about early intervention and education in our Learn the Signs campaign by continuing to develop and implement strategies to support parents, healthcare professionals and childcare providers in their efforts to Act Early when concerns are raised about autism spectrum disorders and other developmental disabilities.

Thank you for the opportunity to appear here today to discuss this important public health issue. Thank you also for your continued interest in, and support of, our activities on autism spectrum disorders. Together we hope to find answers for this very complex disorder.

I appreciate your longstanding support for our vision of healthy people throughout all stages of their lives and all facets of living. I will be happy to answer any questions you may have.

Senator HARKIN. Thank you, Dr. Gerberding, and I just mentioned, I am going to change the format since Senator Specter has to leave, I will go with Dr. Insel, then we will have some questions for the two of you before we bring the other people up.

Dr. GERBERDING. Thank you.

Senator HARKIN. Now, we turn to Dr. Thomas Insel, Director of the National Institute of Mental Health since September 2002. Dr. Insel received his B.A. and M.D. degrees from Boston University. Dr. Insel, welcome back to the committee.

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF MENTAL HEALTH

STATEMENT OF DR. THOMAS R. INSEL DIRECTOR

Dr. INSEL. Thank you, Senator Harkin and Senator Specter.

It's a real pleasure to be here, and I too would like to express my gratitude for the support that we've gotten from both of you, and your leadership positions over the years.

As you mentioned, the NIH budget has increased very significantly, in the case of autism, it's gone up, actually, almost five-fold since 1997, and that's only possible with your leadership and with your advocacy for bio-medical research.

I think in view of the time and the number of the things that we want to cover, you already have my written testimony, I think I will make my comments rather brief.

What I thought I would do is speak to what we actually know, that we're confident about at this point in time, and unfortunately, I can do that in less than 5 minutes, because it's a fairly short list.

So, what you have before you are what, I think, are the four most important points that we can use as a baseline for the knowledge-base. We can talk more about some of the specifics and some of the actual research, as we get further into the hearing.

The first point to make, and it may seem obvious, but it's actually a fairly complicated point, is that autism is a developmental brain disorder. Yes, it involves other organs of the body, and the gut is one that has been implicated, as you mentioned Senator Harkin, but it's important for us to focus on this as a brain disorder that evolves through development.

The reason I stress that is, because when you think about developmental brain disorders, it's not simply what happened, or where it happened, it's when it happened that may be really critical. So, much of what we need to understand is when the train goes off the tracks in brain development to result in the kinds of deficits that Dr. Gerberding mentioned—the difficulties in social reciprocity, the difficulties in language, the abnormal behaviors that are really key to autism.

It changes the way we think about this a little bit because it suggests also that there could be multiple causes that if they occur at the same point in time—and many of us think that that point may be prenatal—it sets up a trajectory that's abnormal, that leads to this very, as you mentioned, devastating disorder.

Point number two, you'll hear from constituents and you'll read in the press—is this really genetic? Is this really environmental? The answer is, it's both. That, with this disorder, as with so many of these developmental disorders that we study now, we've—in the scientific world—have gotten beyond the point of arguing between genes and environment, it's like the old nature/nurture debate. The debate now is about how genes and the environment interact to result in this disorder.

We do know there's an important genetic component, no question about that, from what we have from twin studies, but we also know that that doesn't explain the entire disorder. And it certainly wouldn't explain any potential increase in the prevalence—or increase, even, in the incidents—over the last decade.

So, lots of interest in what the environmental factors might be. But, to understand those, we will need to drill down, and get a very good understanding of who has the genetic risk to be responsive to that environmental factor. So, much interest now, in trying to understand the complicated interaction of those two factors.

Third, this is—as Dr. Gerberding mentioned—important to have early detection, early interventions. There are treatments that work—they don't work for all children. Perhaps 25 to 30 percent of children respond beautifully to behavioral interventions, but they respond best with early detection and early intervention, particularly before age 3. As Dr. Gerberding mentioned, many of these children aren't even diagnosed until sometime thereafter.

PREPARED STATEMENT

Finally, current science more and more is telling us that this is not one illness. This is a group of disorders—much the way we think about hypertension, much the way we think about other classes of disorders in medicine. This is one—in the way that we perhaps once talked about mental retardation—it's likely we're going to find many, many disorders within this overall rubric. Increasingly, at NIH, we talk about "autisms" instead of "autism." That is probably an important perspective to remember, as we begin to think about causes, and also about treatments.

Thank you, I look forward to your questions, and I look forward to the discussion, as well.

[The statement follows:]

PREPARED STATEMENT OF DR. THOMAS R. INSEL

Good afternoon, Senator Harkin and members of the subcommittee, I am pleased to present a brief review of the research activities and accomplishments in autism research of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). I deeply appreciate your continued support for our mission: making medical discoveries to improve health and save lives. In focusing today's hearing on autism we will be discussing an urgent, critical public health challenge affecting many families.

WHAT IS AUTISM?

Autism is a developmental brain disorder, with onset by 3 years of age. We now believe that autism includes a large number of disorders that share deficits in social behavior, abnormal communication, and repetitive behaviors. Autism in turn is part of a broader continuum of syndromes called pervasive developmental disorders, now more commonly known as autism spectrum disorders (ASDs). ASDs range in severity, with "classic" autism being the most disabling, while others, such as Asperger's syndrome, produce milder symptoms. Among children at the more severe end of this spectrum, mental retardation, seizures, and self-injurious behaviors are common.

Current Centers for Disease Control and Prevention (CDC) estimates of the prevalence of ASDs are as high as 6.7 children per 1,000.[1] "Prevalence" refers to the number of affected individuals at a given point in time, essentially a snapshot. While prevalence estimates have increased many-fold since the early 1990s, it is unclear if there also exists an increase in "incidence", which measures the number of new cases across time in the same population. It is unclear whether the rise in prevalence is due to a rise in incidence, better identification and awareness of the disorder, or both. A similar increase in prevalence has been observed in many countries outside of the United States, and in virtually every study, boys are three to four times as likely to have ASDs compared to girls.[2]

WHAT CAUSES AUTISM?

There is much that remains unknown about the causes of autism. Scientific research has demonstrated that autism is highly heritable, as measured by concordance rates in twins. If one identical twin has autism, there is a 60–91 percent chance the other will also have it. For fraternal twins, the concordance for autism drops significantly, to 0–10 percent.[3] While higher concordance in identical twins is not proof of a genetic cause, approximately 10 percent of autism cases with a family history of ASDs are associated with genetic mutations.[4] Recently, a study of people with autism who did not have another family member also affected found approxi-

[1] Centers for Disease Control and Prevention. Prevalence of Autism Spectrum Disorders' Autism and Developmental Disabilities Monitoring Network, 14 Sites, United States, 2002. Surveillance Summaries, February 9. MMWR 2007;56 (No. SS–1).

[2] Fombonne E. Epidemiology of autistic disorder and other pervasive developmental disorders. J Clin Psychiatry. 2005;66 Suppl 10:3–8.

[3] Veenstra-VanderWeele, J, Christian, SL, Cook, EH (2004) Autism as a paradigmatic complex genetic disorder. Annu. Rev. Genomics Hum. Genet. 5:379–405.

[4] Barton M, Volkmar F, J Autism Dev Disord., 1998, 28(4):273–8.

mately 10 percent associated with spontaneous genetic mutations.[5] In addition, autism is frequent in children with several known genetic neurodevelopmental disorders, such as Fragile X, Rett Syndrome, or Tuberous Sclerosis Complex.

Identifying both the environmental and the genetic underpinnings of autism are critical first steps in bringing the full scientific power of modern neuroscience to bear on this complex set of disorders. We now have the genetic sequencing and neuroimaging tools that will permit a more thorough understanding of the neural substrates of autism. Indeed, what these scientific tools may tell us is that ASDs are illnesses with multiple causes and, much like hypertension or cancer, may be treated and possibly prevented through interventions on multiple fronts. Importantly, these new scientific approaches will enable us to develop new diagnostic tests and rational therapies based on the biology of the illness that will permit us to detect and treat ASDs in much the same way was as other medical conditions.

HOW IS RESEARCH COMBATING AUTISM?

Combating autism is a collaborative effort, involving several NIH Institutes, the CDC, and public-private partnerships with advocacy organizations. NIH has increased funding for autism nearly five-fold since 1997, to support broad research efforts across genetic, neuroscience, environmental, and treatment studies. Already, this investment is bearing important results for better understanding the brain abnormalities in autism, improved methods for early detection, and refining interventions for optimizing daily functioning. NIH continues to fuel this research momentum, most recently with program announcements encouraging research on the characterization, genetics, pathophysiology, and treatment of autism and related neurodevelopmental disorders, as well as requests for applications to collect data and biomaterials from autistic individuals and their relatives for use in genomic, basic, translational neuroscience research, and clinical trials. Here I will note just a few of the recent developments that offer hope for families struggling with autism.

The recently established NIH National Database for Autism Research (NDAR) for the first time provides an open-access platform to facilitate sharing of raw research materials, foster collaborations and public-private partnerships, and enhance rapid dissemination of research findings into clinical practice. It is envisioned as a dynamic, federated system, with improvements and updates being added routinely to meet the most critical and valuable needs of the research community.

Early detection is important for improving outcomes. The National Institute of Child Health and Human Development (NICHD) and the National Institute on Deafness and Other Communication Disorders (NIIDCD) continue to partner with Autism Speaks to support the High Risk/Baby Sibling Research Consortium, an effort to improve early detection and diagnosis. The Consortium?s primary project is to identify factors that may influence recurrence rates of ASDs and broader developmental outcomes in infant siblings of individuals with ASD. Recruitment of sibling and comparison groups is on target and database development and data analysis have begun.

Responding to the urgent need for an amplified autism effort, the National Institute of Mental Health (NIMH) created a new, integrated autism research program in its intramural laboratories in Bethesda. Several new clinical trials were launched in 2006 that provide opportunities for rapid progress in defining the biological and behavioral characteristics of different subtypes of ASDs and examining effects of innovative treatments for autism. Intramural researchers are also collaborating with M.I.N.D. (Medical Investigation of Neurodevelopmental Disorders) Institute and University of California at Davis scientists in a pilot of the first large-scale effort to provide a comprehensive biomedical and behavioral characterization of 1,500 individuals with autism spectrum disorders. The goal of this Autism Phenome Project is to identify the many subtypes of autism, providing guides for personalized approaches to treatment.

In addition to these efforts, NIH is striving to identify and understand environmental influences as potential causes of ASDs. The National Institute of Environmental Health Sciences (NIEHS), in partnership with the Environmental Protection Agency (EPA), supports research through Centers that focus on this important question. One of the centers, at the University of California at Davis, is conducting the first large population-based, epidemiologic case-control study of children with autism. In addition, the National Institute of Neurological Disorders and Stroke (NINDS) is providing support for a five-year prospective epidemiological study of a large Norwegian birth cohort of 75,000 women and their babies. The study, which

[5] Sebat et al, Strong Association of De Novo Copy Number Mutations with Autism. Science. 2007 Mar 15; [Epub ahead of print].

we expect to include up to 500 children with ASDs, will examine the contribution of genetic and environmental factors to the development of autism and other neurodevelopmental disorders; these factors include infection history, low birth weight, dietary and environmental exposure to methyl-mercury, and vaccination history.

Solving the mysteries of autism will require scientists from many disciplines working together on common problems. To launch a broad, multidisciplinary attack on autism, NIH recently created an ambitious, integrated program in order to maximize coordination and cohesion of NIH-sponsored efforts—the Autism Centers of Excellence (ACE), for which the first grants will soon be issued. Research projects will focus on identifying biological and environmental causes and preventive interventions for autism, as well as improved pharmacological and behavioral treatments. These Centers will be coordinated through NDAR and will represent the first integrated, national research effort for this disorder, with an estimated funding level of $25 million per year.

HOW CAN WE CURE AUTISM?

While there is not a proven biological treatment for the core symptoms of autism, it is generally agreed that early identification and behavioral intervention is beneficial. Thirty years of study have shown the value of employing behavioral methods to enhance social skills, language acquisition, and nonverbal communication. Such gains may be evident in individual responses to particular behavioral techniques in the short term ? in as little as a matter of months.

Yet even in studies where children have received the largest gains, outcomes are variable, with some making significant progress and others advancing quite slowly or not at all. A multi-study analysis of the effect of treatment indicates that behavioral treatments are most successful when they begin early, are intensive, and highly structured. Current NIH-funded research includes studies for toddlers that involve parents in the delivery of interventions at home, immediately after diagnosis, as opposed to waiting for community or other services to begin.

While medications are useful for some of the accessory symptoms of autism, such as self-injurious behaviors, we lack medical treatments for many of the core symptoms, such as social deficits. As we discover more about the causes and the mechanisms of autism, we expect to develop a new generation of medications to help children and adults affected with ASDs. Ultimately, our goal is prevention, based on early detection of risk, understanding environmental factors that increase or decrease symptoms, and development of effective interventions before behavioral and cognitive deficits appear.

THE FUTURE

The Combating Autism Act of 2006 (Public Law 109–416) was signed into law on December 19, 2006. Plans are underway to implement the provisions of this law, which calls for the establishment of a new Interagency Autism Coordinating Committee (IACC) to coordinate all efforts within HHS concerning autism spectrum disorders, including the development of a strategic plan that sets research funding priorities. Thus, broad collaborative partnerships involving government, private industry, public and educational institutions, and families of those with autism will continue to fuel the vital research endeavors that will reveal the mysteries of this disabling disorder and lead to prevention and effective treatments.

Autism is a serious, disabling developmental illness that affects many families in this country. Research is our best hope for making a difference for these families. Given the complexity of the disorder, answers will not be as simple or as quick as we wish, but NIH is committed to bringing the best minds and the best tools to ensure that we get the correct answers that will lead to the best treatments. I therefore appreciate the interest of the members of this Subcommittee on autism research. I look forward to answering your questions.

Senator HARKIN. Thank you very much, Dr. Insel, and Dr. Gerberding.

I'll yield to Senator Specter.

BUDGET ALLOCATIONS

Senator SPECTER. Well, thank you very much, Mr. Chairman for accommodating my schedule.

Dr. Insel, the funding for autism has risen, as I noted, from $27 million in 1998, to a projected budget in 2008 of $107,870,000—that's actually about a $400,000 decrease from last year.

The allocation for autism is substantially less than the allocation for other major research activities, of the National Institutes of Health. It is obviously a very serious disorder, striking 1 children out of 150. With the New Jersey statistics, which are said to be more representative of the national average, being 1 child out of 97.

There is total discretion left within the National Institutes of Health to make the allocation of the $29 billion which is appropriated by Congress, and that is so we do not, so-called "politicize" it—we don't make political decisions, but leave it up to the scientists. But, I think within the range of following that very important principle, it is not inappropriate to raise a question. When you take a look at the budgets for cancer—and I'm all for cancer research—or the budgets for heart disease, they range into, close to $5 billion for cancer. How are the allocations made, to have the $107 million, roughly, which is a very, very small part of the NIH budget, compared with other research budgets?

Dr. INSEL. Well, as you mentioned, much of this is driven by the science, it's investigator-initiated for the largest part of what we're currently doing.

In the area of autism, unlike many of the other areas that you mentioned, and many areas in medicine, in general, we do have an organization in place to begin to think about how best to deploy the funds that we have. That's this Inter-agency Autism Coordinating Committee, that meets twice a year, includes public members as well as members of several Federal——

Senator SPECTER. How about the basic decision as to how much goes to the National Cancer Institute, for heart research, contrasted with $107 million for autism?

Dr. INSEL. So, how is the decision for the envelope, the overall envelope, made for autism, versus other priorities at NIH?

Senator SPECTER. Start there.

Dr. INSEL. Right. So, I would have to again, give you the answer that Dr. Zerhouni has given when you've asked him a similar question, that it's a combination of public health needs and scientific priorities. This case, the public health——

Senator SPECTER. Public health, what?

Dr. INSEL. Public health needs. There, and as you mentioned, the public health urgency here is obvious, to all of us. This is a problem which is increasing in everyone's radar screen, this is, without question, a much bigger issue for us than it was 5 years ago——

Senator SPECTER. I've got to move on to some other questions because of limited time, but you will be here for the entire proceeding today, and maybe when you hear some of the parents, you'll have a little different view of the urgency of a greater allocation. That is a judgment which NIH is going to have to make.

Autism is characterized—as the experts have written—by three distinctive behavior difficulties, with social interaction, display problems with verbal and non-verbal communications, and the exhibition of repetitive behavior, or narrow obsessive interests.

It is well-known, Dr. Gerberding, and you've noted it, that the early detection of these behavioral disorders can produce improvements. What should parents do as soon as they observe some of these behavioral disorders? Your comments here will get some substantial coverage on C-Span—what advice would you give to parents who—well, let's start with something more concrete than the definition I've just given you, which is pretty high-falluting. What should parents look for, specifically, in lay terms?

Dr. GERBERDING. You know, when you have a child, you're used to thinking about, what is its weight, what is his or her height, what is their head circumference—we're used to measuring those physical development milestones. But, there are behavioral milestones just like that.

By early age, a child ought to be able to make eye contact, if you play peek-a-boo with a child, they should engage your attention, they can repeat after you——

Senator SPECTER. Okay, eye contact—eye contact is not made. Give us another easy-to-understand symptom.

Dr. GERBERDING. If a child is unable to repeat simple motions, in other words, if you clap your hands, a young child ought to be able to repeat your pattern—we have these laid out by age, just like you would lay out weight by age——

Senator SPECTER. Laid out where, are they on a website?

Dr. GERBERDING. They are, absolutely, on the CDC website, www.cdc.gov, they are posted prominently in pediatricians' offices around the country——

Senator SPECTER. Can you give us a couple of other simple illustrations?

Dr. GERBERDING. I would be happy to give you a whole little chart, because I have here——

Senator SPECTER. Why don't you repeat them, so people can hear you on C-Span?

Dr. GERBERDING. Okay, I'd be happy to.

I'm quoting from Newsweek magazine, because I thought they did a terrific job in one of the articles here of laying them out.

By 7 months, a normal child ought to be able to turn its head when its name is called and smile at another person. If your children is a year old, usually they can wave "bye-bye" and they can make sounds like "mom" and "dad" or "ma" and "da" and they can clap when you clap.

At 18 months, a child ought to be able to pretend, like pretend to talk on a telephone, or to look at objects when you point to them. By 2 years, a child ought to be able to make simple sentences with several words in a phrase, and follow simple instructions, and, I think most importantly, engage socially with other children, they'll play——

Senator SPECTER. Let me interrupt you, at that point—to ask you what should a parent do to try to deal with the issue of the behavioral disorder as soon as it noted?

Dr. GERBERDING. If a child is—if a parent is concerned about their child's development, the pediatrician or the family doctor is absolutely the first place to go, and we have really been pushing information—about 85,000 kits have gone out to pediatricians around the country. So, parents go in, express their concern when

they're bringing the child in for well-baby care, or for the immunization clinic visit, and the most important thing to the parent is, don't give up. If the doctor says, "Oh, no, maybe your child is just a little slower to catch on," ask for the doctor to do a screen, and if there's any worry, make sure that you get a second opinion, or ask the child to be seen by someone with more expertise.

Senator SPECTER. But, what kind of a screening?

Dr. GERBERDING. It's a developmental screening, and typically the doctor will ask the child to go through some of the same activities that I just mentioned to you, they'll conduct a developmental assessment.

NEW DIRECTIONS FOR RESEARCH

Senator SPECTER. One final question, because I don't want to go too long, and out of sequence.

Dr. Insel, if more funds were available, suppose we're able to increase NIH funding so all the boats would rise, where would those additional research funds be directed to the kinds of problems that Dr. Gerberding has described?

Dr. INSEL. Well, there are at least three very urgent problems that we would like to do more of, and do them faster. One would be very similar to what Dr. Gerberding is describing, looking at the tools for early detection or early diagnosis, early intervention—much of that's going through what we call our "baby sibs" project, looking at children at risk, and studying them in a very comprehensive way.

Second area, very important, is to lay out what we call the "autism phenome" project, the idea of being, the phenome is like phenomenology, understanding the full spectrum of this disorder, and all of the components, so that we can get a sense of, what are the sub-groups? That this is many disorders, if it's 10 disorders, what are they? How do we diagnose them? How do we treat them?

Third area that's very important, it doesn't sound so sexy, perhaps, but is developing a database, which we call the National Database for Autism Research—we have such a database that brings the entire research community, as well as, potentially, families together. It's a federated database, which means it will take other databases that are out there and bring them in for imaging, genetics, and clinical information.

What we'd like to do—we have this now, it went live on April 2, but it's still very restricted—we need to grow that, and we need to make this a sort of electronic meeting place for both families and scientists from across the country, to try to get the best information possible about autism.

Senator SPECTER. Well, in conclusion, let me just make an observation or two.

Dr. Gerberding, I think the website is fine. If people write to you, not having access to the website, or not understanding the website, is CDC in a position to respond to parents by providing this kind of a graphic illustration of symptoms and signs to look for, perhaps even a copy of what appears in Newsweek, under the caption, Babies and Autism?

Dr. GERBERDING. We would be happy to get information to parents and to their doctors, and we can do that by a variety of means, absolutely.

Senator SPECTER. Dr. Insel, when you take a look at your priorities, I know you'll pay attention to all of them, and I know you'll listen carefully to what you hear today.

Senator Harkin and I, and some of the others on the committee are magnets for a lot of comments from parents, because they see what the committee has done. It is accurate to say that I hear a disproportionate comment from parents whose children have the autism disorder. I hear a lot of people—and a lot of my friends are dying of cancer—and I know a lot of people with heart conditions. I've seen a fair amount of that in the mirror. But, on a numerical basis, I hear, just a lot about autism, and maybe that comes because we advertise on this Subcommittee with what we do for NIH, but I'd like to see it get a little more attention.

Senator Harkin, thank you for your courtesy.

Senator HARKIN. Thank you, Senator Specter.

Again, just another little change because the clock is ticking, and I want to hear the testimony of others. I would ask if you two could maybe, give us some bookends here, Dr. Insel on one side, Dr. Gerberding, because I have questions for you, I'm sure other Senators do. But I'd like to ask our second panel to come up, if I could, at this time.

Marguerite Colston, Dr. Judith Favell, Mr. Bob Wright, and Mr. Bradley Whitford.

Again, welcome to the committee, and as I said at the beginning, all of your statements will be made a part of the record in their entirety, and I'd appreciate it if you'd just sort of sum up for us, the essence of your statements, and I'll go in the order in which I had called people up.

First, we'll recognize, Marguerite Colston, Communications Director for the Autism Society of America. More importantly, she's a parent of a child with autism, her 6-year old son, Camden. Welcome to the committee, and please proceed.

STATEMENT OF MARGUERITE COLSTON, DIRECTOR OF COMMUNICATIONS, AUTISM SOCIETY OF AMERICA, BETHESDA, MARYLAND

Mrs. COLSTON. Thank you. I'd like to thank Chairman Harkin, and Senator Specter and the members of the subcommittee for giving me the opportunity today to share my experience of living with a child on the autism spectrum. I also wanted to say thank you very much to you and Senator Specter for those very important questions you asked.

It is truly an honor to be asked to speak to you today, and I hope I can convey some of the needs, hopes and dreams of the more than 1 million families in America who are affected today.

As you mentioned, I am the Director of Communications for the Autism Society of America, and I am the mother of two children, including a 6½ years old son with autism. My son, pictured here, is Camden, this is Camden.

My son has a disorder with no known cause, and no known cure. You have, at your disposal today, the best experts on researching causes and cures. But I am here today to tell you about the very

important space between causation and cure, the space that Camden and I occupy, that is, how we live with autism.

Because that important space is occupied today by 500,000 children, and at least as many adults, families desperately need Federal leadership and funding for autism today.

Camden is on the severely affected end of the spectrum. He cannot talk, has some cognitive delays, major attention deficits, and suffers significant social and behavioral challenges. As you can see, though, he's also adorable, and he has a much larger capacity to learn than any of us imagined.

Like many parents, I was told that autism was not treatable, and that the best thing I could do for Camden was to prepare myself and my family for the idea that he would never be independent. Experts told me that information when he was only 2½ years old.

Today, my little boy, who for years did not turn to his name or react to games, now grabs my hand after dinner, and takes me to the refrigerator for his nightly ice cream. When the school bus comes every morning, he walks on with a grin and he finds his seat. Camden does not make these developments naturally, but through intensive therapy, Individualized Education Plans, high medical costs, and a sizable team of dedicated professionals.

In many respects, my story is typical. Camden was diagnosed with autism when he was 2½. However, I was lucky that Camden was born with other medical ailments, and very low muscle tone, because unlike most children with autism, Camden began receiving Early Intervention services from our county when he was just 6 weeks old. Even though we only received 4 hours per week of Early Intervention, that program was the reason Camden can chew, sit up, and walk onto a school bus today.

Like most families, I had to wait 12 long months to get an appointment with a developmental pediatrician, when my pediatrician expressed concerns about Camden. My wait times for his specialists continue to be 12 to 18 months, so we rely heavily on the public educational services we receive, thanks to the IDEA Act, and thank you for your support of that.

As I think about it, however, I am still very concerned about what would happen to Camden, once the school bus stops coming. Camden, and most children and adults with autism, is going to need a lifetime of supports and services. Even if he is able to speak someday, he will need training to prepare him to enter the workforce, assistance with transportation and housing, access to health care, and a range of other services to allow him to live as independently as he is able.

Unlike most parents, I consider myself to be a very privileged American. I received a great education, I have a good job, I own my own house, and I have a wonderful and supportive family, and several of them are here today. I can afford a small amount of respite care and private therapy. So, I have to wonder, if I couldn't get my son diagnosed before 2½, and if it takes me 18 months to see a doctor, and if I can't afford truly comprehensive services, than what is happening to the average American with a child on the autism spectrum today?

If I accepted that autism was not treatable, and Camden had no hope, what do others do? What happens after Camden turns 22,

and the federally-mandated disability services end? What are we going to do about this?

One of the things we can do for Americans living with autism is fund the Combating Autism Act, and encourage the resulting research to be treatment-guided, not just causation specific. Funding the CAA also means funding the Inter-Agency Autism Coordinating Committee, and they have a wonderful roadmap for services. We can also pass and then fund the Autism Services bill put forth by Senators Clinton and Allard last month, and which the House introduced today.

As a parent, I strongly support those bills. As a staff member for the Autism Society, I can assure you that we, our chapters and our members will work tirelessly to advance legislation that includes research services and supports for individuals with autism.

I love my son, Camden, with every bone in my body. I know there are a million Camden's out there whose needs are not being met, and whose families are in crisis. Regardless of the cost, we need to support coordinated Federal autism solutions today. Only then will we be able to optimize the potential of each child with autism, and provide them opportunities for success in their communities.

PREPARED STATEMENT

Being here today and being heard by the U.S. Senate gives me an enormous sense of hope that I never dared to have. With your help and your leadership, I may start to hope for Camden, the same hopes I have found I have for my neuro-typical daughter, Theresa—that he will be provided the opportunity to be a happy, productive member of his community.

I'd like to thank the committee again, for hearing me, and for support of this legislation.

[The statement follows:]

PREPARED STATEMENT OF MARGUERITE KIRST COLSTON

I would like to thank Senator Harkin and the members of this subcommittee for giving me the opportunity today to share my experience of living with a child with autism. It is truly an honor to be asked to speak to you today, and I hope I can convey some of the needs, hopes and dreams of the more than 1 million families in America today who are affected by autism.

My name is Marguerite Kirst Colston. I am the Director of Communications with the Autism Society of America and I am the mother of two children, including a 6-year-old son with an autism spectrum disorder. My son, pictured here, is named Camden.

As you have heard today from the panelists, my son has a disorder with no known cause and, as I have been told by many doctors, no cure. You have at your disposal the best experts on researching causes and cures, but I am here today to tell you about the very important space between causation and cure—the space Camden and I occupy—that is: how we live with autism. Because that important space is occupied today by 500,000 children, and at least as many adults, families desperately need federal leadership and funding for autism.

Camden is on the more severely affected end of the autism spectrum, by which I mean he cannot talk, has some cognitive delays, major attention deficits and suffers significant social and behavioral challenges. As you can see, he is also adorable and, as I am finding, has a much larger capacity to learn than any of us imagined.

Like many parents, I was told that autism was not treatable, and that the best thing I could do for Camden was to prepare myself and my family for the idea that he would never be independent. Experts told me that when Camden was 2½. Today, my little boy, who for years did not turn to his name or react to games, now grabs my hand after dinner and takes me to the refrigerator for his nightly ice cream.

When the sun sets, he runs to take a bath. When the school bus comes every morning, he walks on with a grin and finds his seat. Camden does not make these developments naturally, but through intensive therapy, individualized education plans, high medical costs, and a sizeable team of dedicated professionals helping us along.

In many respects, my story is typical. Camden was diagnosed with an autism spectrum disorder when he was 2½. This diagnosis came after 2½ years of emerging symptoms, disappearing interaction, specialist referrals, hundreds of doctor's visits, several hospitalizations—and many missed clues. I was "lucky" that Camden was born with other medical ailments and very low muscle tone, because unlike most children with autism, Camden began receiving Early Intervention services from our county when he was just 6 weeks old. Even though we only received 4 hours per week of Early Intervention, that program was the reason Camden can chew, sit up, and walk onto his school bus today.

Like many parents with children with autism, I had to wait 12 long months to get an appointment with a developmental pediatrician when my pediatrician expressed concerns about Camden. My wait times for his specialists continue to be 12 to 18 months in duration, so we rely heavily on the educational services with receive in our public school system thanks to IDEA Act. I want to say a heartfelt thank you to you, Senator Harkin, for your strong support of legislation like this.

As I think about it, however, I am still very concerned about what will happen to Camden once the school bus stops coming. Camden—and most children and adults with autism—is going to need a lifetime of services and supports. Even if he is able to speak one day, he will need training to prepare him to enter the workforce, supports in his job, assistance with transportation and housing, access to health care, and a range of other services to allow him to live as independently as he is able.

Unlike most parents, I consider myself a very privileged American. Like the rest of the panelists here today, I received a great education, have a good job, own my own house, and have a wonderful and supportive network of family. I can afford a small amount of respite care and private therapy. I stand up for my rights and have the confidence to ask questions of the medical and educational communities. But I have to wonder: if I couldn't get my son diagnosed before 2½, and if it takes me 18 months to get into a doctor, and I can't afford truly comprehensive services, then what is happening to the average American with a child with autism today? If I accepted, in a desperate moment, that autism was not treatable and Camden had no hope, what do others do in their sorrow? What happens after he transitions away from the education system? And, what are we going to do about this?

One of the things we can do for Americans living with autism is fund the CAA and encourage the research done here to be treatment-guided, not just causation-specific. Funding the CAA also means funding the Inter-Agency Autism Committee, which could serve parents tremendously by coordinating Federal autism services and research along a road map that will help us now. This is why the Autism Society of America encouraged tens of thousands of members to support CAA and why we also support legislation like the reauthorization of the IDEA act, the Lifespan Respite Act, and S–CHIP funding.

Last month, Senators Clinton and Allard took a historic step toward empowering families and individuals with autism by introducing legislation to build and support a services infrastructure for autism spectrum disorders. Unfortunately, our current system for assisting adults with disabilities is stretched way too thin. Providers do not have the capacity to meet the ever increasing number of individuals with autism. We must do more to identify best practices for serving people with autism spectrum disorders. The House companion bill will be introduced today.

As a parent I strongly support this legislation. As a staff member for the Autism Society of America, I can assure you that we will work tirelessly to advance this bill, and other measures that improve services and supports for individuals with autism. I love my son Camden with every bone in my body, and I know there are a million Camdens out there whose needs are not being met and whose families are in crisis. Regardless of the cost, we need to support coordinated federal autism solutions today. We will then be able to optimize the potential of each child with autism and provide them opportunities to for success in their communities.

Being here today and being heard by the U.S. Senate, gives me an enormous sense of hope that I never dared to have. With your help and your leadership, I may start to hope for Camden the same hopes that I have for my "neurotypical" daughter Theresa—that he will be a happy, productive member of his community in his way, some day. Thank you.

Senator HARKIN. Thank you very much. That is very poignant and heartfelt testimony.

Next, we turn to Dr. Judith Favell, CEO of AdvoServ, a multi-State network of treatment programs for children and adults with developmental challenges. Dr. Favell received her Bachelor's Degree in Psychology from Western University, and her Ph.D. from the University of Kansas, out my way. Dr. Favell, welcome to the committee, please proceed.

STATEMENT OF DR. JUDITH E. FAVELL, CHIEF EXECUTIVE OFFICER, ADVOSERV, EXECUTIVE DIRECTOR, THE CELESTE FOUNDATION, MOUNT DORA, FLORIDA

Dr. FAVELL. Thank you, Mr. Chairman.

I'm also executive director of the Celeste Foundation, and a member of the Professional Advisory Board for the Autism Society of America.

During my nearly 40-years' career as a behavior analyst and as a psychologist, I have devoted myself to the field of autism, and developmental disabilities.

Now, during this period, I've specialized in the treatment of behavior problems such as self-injury and aggression that sometimes associated with these disorders. It is on the delivery of such treatment services that I'm focusing my comments today.

While research on the cause and course of autism continues, while the incidents and prevalence is tracked, while basic research on the underlying mechanisms of the disorder is conducted, we cannot lose sight, as just has been said, of the 1.5 million children and adults today living with autism who need help today. Today they are seeking services that will allow them to gain the skills and resolve the behavioral challenges that will enable them to live and enjoy the fullest life possible.

Fortunately, across the last years, major advancements have been made in the development of educational and behavioral strategies to teach these skills and to treat these problems. These methods have been tested across, literally, decades of scientific research, and confirm that children and adults with autism can indeed be helped in meaningful and substantial ways.

They can learn to communicate, they can learn to care for themselves. They can achieve academic and job goals. They can reciprocate love with friends and family. Likewise, people experiencing autism can engage in behavioral problems that hurt themselves, or harm others. In short, effective treatment and teaching methods designed to help people with autism, notably those based on learning theory, and applied behavior analysis are available today, and each day are becoming more effective with continued research.

So, this picture is a decidedly optimistic one. However, effective methods of instruction and behavioral treatment are clearly not enough. To impact the lives of people with autism, an equally important issue must be addressed, and that is, how to actually make these services available to people who need them. There exists not just a gap, but a chasm, between what we know, and what consumers actually receive.

For example, we know as has been said, that to be optimally effective, services should begin as early in a child's life as possible, and be intensive, that is, encompass as many hours as possible. Yet, as we hear, families lose precious months—years—waiting for

services, and then too often must settle for a fraction of what their child needs.

Too often, then, those very services are not available when and where they are actually needed—at bedtime, during meals, or in the midst of the meltdown during the weekend. Needs of people with autism do not conveniently conform to professional appointments or clinic hours. Support may be needed any time, day or night.

Further, we know that to be effective, and to produce positive outcomes, services need to be provided by qualified caregivers, and yet, despite widespread training of families and service personnel, despite extensive recruitment of professionals to the field of autism, there remains a serious shortfall of qualified professionals to guide the treatment process.

Thus, though we know a great deal about how to help, we must increase the accessibility and availability of these services, to ensure that people with autism actually receive that help.

If we're truly to ensure that services are available early, in sufficient amounts, and targeted when and where needed, traditional solutions, for example, increasing training of professionals—though important—is simply not sufficient. To meet the challenge, new service models must be developed.

Our own work at the Celeste Foundation provides an example of possible new approaches to improving services, both their availability, and potentially their cost-effectiveness. From support from the Department of Education and the States within which we conducted this project, we recently completed a demonstration project, investigating the use of tele-health systems to provide professional services directly into homes.

Now, in this model, after a brief period of on-site training, families were linked to professionals via an interactive video system that enabled live, real-time teaching, consultation and support directly into the home when and where it was needed. Through this tele-health model, families received help teaching their child, coping with their challenges, from professionals who might be located hundreds, even thousands of miles away, ensuring rapid and responsive assistance, regardless of the distance involved.

This demonstration, utilizing technology developed by the CNOW Organization, proved to be an extremely effective and reliable vehicle for aiding families and children with autism.

Children learned and maintained a wide array of skills from communication, to toilet training to eating green beans. Parents reported relief from stress, and an improvement of quality of life as a function of having support available to them on an ongoing basis, and families and professionals alike affirmed the effectiveness of this method of facilitating services, and its ease of use.

The following brief news feature provides a graphic picture of the benefits of the model involved, of using tele-health systems for service delivery, and it features Josh Cobbs and his family, who is with us today.

Work such as this by the Celeste Foundation, demonstrating the efficiency and effectiveness of utilizing tele-health to facilitate services exemplifies the type of innovative approach that we must pursue, if we are truly going to meet the ever-increasing needs of chil-

dren, and adults, and their families with autism, bridging that chasm between knowledge and practice, moving services from the paper to the people.

PREPARED STATEMENT

I ask all in a position of influence, certainly including the distinguished members of this committee, to support efforts to find innovative methods of service delivery for all of those on the spectrum, including my grandson, Alex, so that they may receive the very best we have to offer, and lead the brightest future possible.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. JUDITH E. FAVELL

"SEEKING INNOVATIONS IN SERVICE DELIVERY"

Good afternoon, Mr. Chairman and members of this distinguished committee. My name is Dr. Judith Favell. I am CEO of AdvoServ, Executive Director of the Celeste Foundation, and a member of the Professional Advisory Board of the Autism Society of America. I have devoted my nearly 40-year career as a behavior analyst and psychologist to the field of autism and developmental disabilities. During this period I have specialized in the treatment of problem behaviors such as self-injury and aggression which can be associated with autism. And it is on the delivery of such treatment that I focus my comments this afternoon.

While research on the cause and course of autism continues, while its incidence and prevalence is tracked, while basic research on the underlying mechanisms of the disorder is conducted, we cannot lose site of the one and a half million children and adults who are now living with autism, and who need help now. Today they are seeking services that will help them gain the skills and resolve the behavioral challenges that will enable them to enjoy the fullest life possible.

Fortunately, across the last years, major advancements have been made in developing educational and behavioral methods to teach these skills and treat these problems. These methods, tested through decades of scientific research, confirm that children and adults with autism can be helped in meaningful and substantial ways. They can learn to communicate, to care for themselves, to achieve academic and job goals, to reciprocate love with friends and family. Likewise, people experiencing autism need not engage in behavior problems that hurt themselves or harm other people. In short, the treatment and teaching methods designed to help people with autism, notably those based on learning theory and applied behavior analysis, are available today, and each day are becoming more effective as a result of ongoing research. This picture is an optimistic one. However, improving these methods of instruction and treatment is not enough. To impact the lives of people with autism, an equally important issue must be addressed: how to actually make these services available to people who need them.

There exists not just a gap, but a chasm between what we know and what consumers receive. For example, we know that in order to be optimally effective, services should begin as early in the child's life as possible and be intensive, encompassing as many waking hours as possible. Yet families lose precious months or years waiting for services, and then must settle for a fraction of the help that their child really needs. Too often, these supports are also not available when and where they are needed, for example at bedtime, during meals or in the midst of a weekend meltdown. The needs of people with autism do not conveniently conform to clinic hours or professional appointments. Support may be needed at any time, day or night.

Further, we know that effective services and positive outcomes for people with autism depend on qualified caregivers, and yet despite widespread training of families and service personnel and extensive recruitment of professionals to the field of autism, there remains a serious shortage of qualified professionals to guide the treatment process.

Thus, though we know a great deal about how to help, we must now increase the accessibility and availability of these services, to insure people with autism actually receive that help. If we are to truly meet this ever expanding need, if we are to insure that services are available early, in sufficient amounts, and targeted when and where they are most needed, traditional solutions such as increased training of pro-

fessionals are simply not enough. To meet the challenge, new service delivery models must be explored.

Our own work at the Celeste Foundation serves as an example of possible new approaches to improving the scope and cost-effectiveness of delivering services to people with autism and their families. With support from the Department of Education we have recently completed a demonstration project investigating the use of telehealth systems to provide professional services directly into homes. In this model, after a brief phase of on-site training, families were linked to professionals by an interactive video system that enabled live training, consultation and support directly into the home when and where it was needed.

Through this telehealth model, families received help in teaching their children and coping with their challenges from professionals located hundreds of miles away, insuring rapid and responsive assistance. This demonstration, utilizing technology developed by the Cnow organization proved to be an extremely reliable and effective vehicle for helping families and their children. Children learned and maintained skills ranging from communication to toilet training, parents reported relief from stress due to the availability of support, and families and professionals alike affirmed the effectiveness and ease of using the system. This very brief news feature provides a more graphic picture of the model and benefit of using telehealth to facilitate services.

Work such as this by the Celeste Foundation, demonstrating the efficiency and effectiveness of utilizing telehealth technology in service delivery, exemplifies the type of innovative approach we must pursue if we are to truly meet the ever increasing needs of children and adults with autism, bridging the current chasm between knowledge and actual practice, moving services from the paper to the people. I ask all those in a position of influence, including members of this distinguished committee, to support efforts to find innovative solutions to service delivery, so that those living with autism now will receive the best we have to offer, leading to the brightest futures possible.

Senator HARKIN. Well, thank you very much, as I said in my opening statement, I hear two pleas from families with autistic children. One, find a cure, but help us now. So many people that, they just don't have the ability to have someone come visit them every day to tell them what to do. I'll have more questions about that later, but I just thought—that's really the first time I've seen that clip, I'd heard about it, since it did take place in Iowa, I'd heard about it.

So I'll have more to ask you about that when we get into our formal questioning period.

Dr. FAVELL. Certainly.

Senator HARKIN. Mr. Bob Wright, Chairman of the Board of NBC Universal, the Vice Chairman of the Board and the Executive Officer of the General Electric Company. Mr. Wright, along with his wife, Suzanne, co-founded Autism Speaks.

Mr. Wright is a graduate of the College of the Holy Cross, received his law degree from the University of Virginia School of Law.

Mr. Wright, again, I thank you for your leadership in this area, and for co-founding Autism Speaks, and again, your statement will be made a part of the record in its entirety, and please proceed as you desire.

STATEMENT OF ROBERT C. WRIGHT, CO-FOUNDER, AUTISM SPEAKS, FAIRFIELD, CONNECTICUT

Mr. WRIGHT. Mr. Chairman, thank you very much for having us here.

Our grandson was diagnosed in 2004, at just 2 years and 3 months, and we were helpless. He was potty-trained, he spoke, he was very active, he was apparently a very normally-developing child, and everything slipped away from him. We were helpless as

we watched him slip away into this cruel embrace of a disorder. My wife, Suzanne, likes to call it kidnapping, as if someone had taken Christian who was meant to live, yet he was taken away, and we got nothing back, and there's no way to restore him back to his family—he's a little prisoner.

Since that diagnosis, we embarked on a mission to learn as much as we could about autism. We received, Christian received the best therapies and treatments that were available, but we discovered, however, that there are scarce resources for parents dealing with autism, and how thin the knowledge base is on the whole issue.

We had so many questions, and instead of answers, we were confronted with a bewildering array of theories and guesses.

Here's what we do know about autism. The numbers that Dr. Gerberding talked about, 1 in 150 children in the United States, 1 in 94 boys, that's the ratio. A decade ago, the experts estimated the prevalence in autism to be 1 in 2,500.

This year, more children will be diagnosed with autism than with AIDS, diabetes, and cancer combined. Autism costs the society, American society, approximately $35 billion in direct and indirect expenses each year, according to a Harvard School of Public Health study. Caring for a child with autism can cost over $3 million over a person's lifetime, those are the estimates.

Frankly, Mr. Chairman, we were shocked that a disorder this prevalent commands so little in terms of resources devoted to research and treatment when compared to other, less common, disorders.

For example, leukemia affects 1 in 25,000 people, children, but receives $300-plus million a year of support from the NIH. Pediatric AIDS affects 1 in 8,000, and it's about $400 million a year. And autism affects 1 in 150, and the funding level is approximately $100 million.

To help close this gap, we launched Autism Speaks in February of 2005 to help raise the funds that would quicken the pace of research. We worked—and together we worked with literally thousands of families affected by autism, to introduce, and pass, and have the President sign the Combating Autism Act.

This is an historic act, it is considered by some to be the most comprehensive piece of single-disease legislation ever passed in the U.S. Congress. It authorizes $920 million over 5 years for research and autism surveillance, awareness, early identification, and authorizes a 50 percent increase in the Department of Health and Human Services spending on autism.

For fiscal year 2008, the Combating Autism Act authorizes a spending level of a total of $168,000, to the Health and Human Services Secretary for autism activities, and within that total, provides for three, distinct, autism-specific items. Sixteen and a half million dollars to the Centers for Disease Control and Prevention, to conduct the developmental disability surveillance and research program, which Dr. Gerberding outlined, the $37 million for Health Resources and Services Administration to carry out an autism education, early detection, intervention program; and $144 million for NIH-funded research.

Mr. Chairman, let me elaborate quickly on each of these. First, for the NIH, the funding increases are incremental, in total. Most

important, the act directs the NIH to spend those dollars more wisely, according to a strategic research plan, devised by an Inter-Agency Autism Coordinating Committee with consumers and advocates comprising a third of its membership. The act also directs the NIH to ramp up its investment in research, and potential environmental causes of autism.

With these new funds, CDC can expand its awareness and intervention activities, to reach more parents, health professionals, et cetera. Previous investment in the CDC has produced the largest-ever surveillance study, which established a baseline to measure autism prevalence trends in the United States.

These studied need to continue so that we can measure the true changes in autism prevalence over time. They probably aren't enough, by a long shot, but you know, that's the best we have right now.

It is also critical that funds be appropriated to the CDC to fund the Seed Study, which is the first epidemiological study to search for environmental exposure, and exposure gene immune interactions.

The Combating Autism Act also creates new and innovative State-based programs in autism education, detection, and early intervention. Early intervention, as we've heard here, can lead to improvements in speech relating to learning.

One of the things I would offer as a comment here, that—this is something we do know, that a child that does early intervention, is diagnosed before 3 years old, and is fortunate enough to have active therapy such as behavioral, occupational, or speech therapy, has a 50 percent chance of being able to matriculate to a public school. If you don't do that, you have almost no chance.

What we also know, is that children in the minority community, the average age of diagnosis is 7 years old. So, if you put those two together, there's almost no chance those children are going to be able to matriculate through a public school system. The two largest minorities are African-Americans and Hispanics, which total almost 80 million, in total. A third of our population is in the minority community. So, I mean, this whole thing, the cost involved, the issues involved, it's critically important.

Mr. Chairman, the funding increases recommended by the Combating Autism Act are relatively modest, at only $25 million more than the Congressional Budget Office's baseline estimates for HHS's autism activities. But the impact this subcommittee would have by not just matching those increases, but by dictating how those funds would be spent, would be a start.

By doing so, Mr. Chairman, this subcommittee would take a giant step toward fulfilling the promise offered to hundreds of thousands of children and their families when Congress passed the Combating Autism Act. The public health crisis posed by autism requires an extraordinary response. With every new child diagnosed with autism, we're looking at another $3 million bill over their lifetime—it isn't business-as-usual. I know you understand that, I know everybody sees this.

But we see a response needed that is akin to what happened with AIDS—a crisis in the 1990's. With line-item appropriations for autism intervention, surveillance and research tied to a strategic

plan. This is a leg-up, it's late-coming to recognize the prevalence, if we don't do something special, the funding won't rise at a fast enough level to deal with that.

I'm fully aware that the autism community is asking this subcommittee to do something which many claim to oppose, in principle, namely to appropriate by disease. In fact, Congress already took that extraordinary step when it passed the Combating Autism Act. The act—by authorizing the creation of autism-specific line-item appropriations—recognized that autism deserves, no, requires, this approach, because of the combination of autisms high prevalence, coupled with the historical neglect exemplified by the numbers you heard today on NIH and the inability to prioritize autism within its portfolio, at least at this juncture.

PREPARED STATEMENT

Last year, the House and the Senate unanimously passed the Combating Autism Act and we urge you to make the funding part of the implementation of the act, as it's written, equally bipartisan, and universally a supported effort.

Thank you very much, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF ROBERT C. WRIGHT

Good afternoon, Mr. Chairman. I am Bob Wright, chairman of the board of NBC/Universal and vice chairman of the board of the General Electric Company. But I appear before you today in another capacity, as co-founder of Autism Speaks and as a grandfather of child with autism.

Our grandson, Christian, was diagnosed with autism in 2004. Helpless, we watched him slip away into the cruel embrace of this disorder. My wife, Suzanne, likens it to a kidnapping, as if someone had taken away the life Christian was meant to live. We all want nothing more than to have him back where he belongs, restored to his family.

Since the diagnosis, our family has been on a mission to learn all we could about autism, and to help ensure our grandchild received the best therapy and treatments available. What we discovered, however, was just how scarce the resources are for parents dealing with autism, and how thin the knowledge. We had so many questions, and instead of answers, we confronted a bewildering array of theories and guesses.

Here's what we do know about autism.

—According to a recent CDC report, autism is now diagnosed in 1 in 150 children in the United States, and a shocking 1 in 94 boys.

—A decade ago, experts estimated the prevalence of autism to be 1 in 2,500.

—This year more children will be diagnosed with autism than with AIDS, diabetes and cancer combined.

—Autism costs society the American economy more than $35 billion in direct and indirect expenses each year, according to a Harvard School of Public Health study. And caring for a child with autism can cost over $3 million over the person's lifetime.

Frankly, Mr. Chairman, we were shocked that a disorder as prevalent as autism commands so little in terms of resources devoted to research and treatment, when compared to other, less common disorders.

—For example, leukemia affects 1 in 25,000 people but receives research funding of $310 million per year;

—Pediatric AIDS affects 1 in 8,000 children; its funding, $394 million per year; and

—Then there's autism, which affects 1 in 150 children and yet NIH research funding is a paltry $108 million.

To help close this gap, we launched Autism Speaks in February 2005 to help raise the funds that will quicken the pace of research. Mr. Chairman, we also worked together with thousands of families affected by autism to introduce, pass and have the President sign the Combating Autism Act. This historic act is considered by some to be the most comprehensive piece of single-disease legislation ever passed

by the U.S. Congress. It authorizes appropriations of $920 million over 5 years for autism research, surveillance, awareness and early identification, authorizing a 50 percent increase in the Department of Health and Human Service's spending on autism.

For fiscal 2008, the Combating Autism Act authorizes a total of $168 million to the HHS Secretary for autism activities and within that total provides for three distinct autism-specific line items—

—$16.5 million for the Centers for Disease Control and Prevention to conduct its Developmental Disabilities Surveillance and Research program;

—$37 million for Health Resources and Services Administration to carry out an Autism Education, Early Detection, and Intervention program; and

—$114.5 million for NIH-funded autism research.

Mr. Chairman, let me elaborate on each of these items.

For the NIH, the funding increases are incremental. Most important, the Act directs NIH to spend those dollars more wisely, according to a Strategic Research Plan devised by an Interagency Autism Coordinating Committee, with consumers and advocates comprising a third of its membership. The act also directs NIH to ramp up its investment in research into potential environmental causes of autism.

With these new funds CDC can expand its awareness and intervention activities, to reach new parents, health care professionals and health care providers. Previous investment in CDC has produced the largest-ever surveillance study which established a baseline to measure autism prevalence trends in the United States. These studies need to continue so that we can measure the true changes in autism prevalence over time. It is also critical that funds be appropriated to CDC to fully fund the SEED study, which is the first epidemiological study to search for environmental exposures and exposure-gene-immune interactions.

The Combating Autism Act also creates new and innovative state-based programs in autism education, detection and early intervention. Early intervention can lead to profound improvements in speech, relating and learning. Right now, we consider getting a diagnosis and intervention for a 3-year-old child a success. But we can do better. Through new diagnostic instruments we can reduce the age of diagnosis to within the first year of life. Service provision must keep pace.

Mr. Chairman, the funding increases recommended by the Combating Autism Act are relatively modest at only $25 million more than the Congressional Budget Office's baseline estimates for HHS's autism activities. But the impact this subcommittee would have by not just matching those increases but dictating how those funds would be spent would be historic. And by doing so, Mr. Chairman, this subcommittee would take a giant step toward fulfilling the promise offered to hundreds of thousands of children and their families when Congress passed the Combating Autism Act.

The public health crisis posed by autism requires an extraordinary response. With every new child diagnosed with autism costing an estimated $3 million over his or her lifetime, we cannot afford to rely on standard, "business as usual" practices. The autism crisis demands a focused, coordinated, and accountable response by our public health agencies, similar to the Federal response to the AIDS crisis in the 1990s, with line-item appropriations for autism intervention, surveillance and research tied to a strategic plan.

I am fully aware that the autism community is asking this subcommittee to do something which many claim to oppose in principal—namely, to appropriate by disease. In fact, Congress already took that extraordinary step when it passed the Combating Autism Act. That act, by authorizing the creation of autism-specific line-item appropriations, recognized that autism deserves, no, requires, this approach because of the combination of autism's high prevalence, coupled with historical neglect exemplified by the failure of the NIH to appropriately prioritize autism within its portfolio.

Last year, the House and the Senate unanimously passed the Combating Autism Act. We urge you to make funding the implementation of the CAA an equally bipartisan and universally supported effort.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much for your statement, and thank you for taking your time to be here today, and for all of your involvement in this issue.

Next, we'll turn to Mr. Bradley Whitford, well-known Broadway and TV actor, who is probably best-known for his role, of course, on "West Wing".

Mr. Whitford studied theater and English literature at Wesleyan University. Dr. Favell went to that school.

Dr. FAVELL. Illinois.

Mr. WHITFORD. Oh no, Connecticut.

Dr. FAVELL. He went to the other one.

Senator HARKIN. Different Wesleyan.

Dr. FAVELL. Yes.

Mr. WHITFORD. Different one.

Senator HARKIN. Oh. Where was yours?

Mr. WHITFORD. Connecticut.

Senator HARKIN. Oh, okay. Then earned a Master's Degree in Theater from the Julliard Theater Center, and again, Mr. Whitford, thank you very much for being here, and for your testimony, and please proceed.

STATEMENT OF BRADLEY WHITFORD, VOLUNTEER SPOKESPERSON, AUTISM SPEAKS

Mr. WHITFORD. Well, thank you, Senator Harkin, on behalf of the acting President of Autism Speaks, I want to thank you for your support on this issue.

Autism is not a disease that any beloved celebrity is going to come down with, and I know sometimes it seems as if celebrity has no place in discussions of priorities, but I hope you will forgive it, because these children have no voice, and it seems an appropriate use of the attention that actors get, to bring voice to them.

I came to this cause when my college roommate, movie producer John Shestack, and his wife, Portia Iverson, had their son, Dov, diagnosed with autism, and founded the amazing advocacy group, Cure Autism Now, which is known, lovingly, as CAN.

CAN recently merged with Autism Speaks, founded as you know, by Bob and Suzanne Wright, and I just want to take a moment to say, I know you're aware of the urgency here, but I want you to express to your colleagues the incredibly proactive nature of the autism community. It's the most heroic response to personal devastation that I have seen in John's family, to not only take of their family, but to reach out and help others. I know there is a great return on whatever investment is made in autism research and treatment.

Autism Speaks is going to make sure that all Americans, and certainly all of our elected officials understand the urgency of this problem.

As my friend, John, has said many times, it's as if 1 in 150 American children was being kidnapped. What would this Congress do if that was the case? What must it do to deal with these sad facts as they truly are?

I know the enormous burden of your high office means you must bear a certain stoicism. I also know that most Senators are parents, and grandparents.

Portia has written a book about Dov called Strange Son. Here's how she describes the kidnapping, "It was his mind they came for. They came to steal his mind. Before anyone gave it a name, even before I knew what it was, I knew it was in our house. They were very, very dark things, and there was no way to get rid of them. When I closed my eyes, I felt their shadows passing over me. I

didn't like to think about where they came from, or where they were going. It was too frightening.

Dov was only a baby, and something was trying to steal him away. I knew that that was what they did whenever I accidentally fell asleep. Night after night, I sat beside his crib. I knew he was slipping away from us, away from our world, and there was nothing I could do to stop it from happening, and there was nothing anybody could do, they told me. So, I did the only things I could—I guarded him. Although I knew it would do no good, because I could not guard his mind. Then, one day, it happened. He was gone."

It is even more than just a tragedy for these kids, many of whom, like Dov, we now know to be of extraordinary intelligence, but trapped in bodies which do not allow them to effectively communicate or interact with the rest of us. It's also a tragedy for our families and for our country.

A mother of an autistic child recently told me, through her tears, that she had been forced to abandon her beloved life's work as a nurse, not mainly to give her more time with her autistic child, but rather to purposely make her family poor enough to qualify for the payment of some of the services her child so desperately needs. She said, "The one thing I won't do, even though I have friends who have, is get divorced just to qualify for additional benefits."

Then there are the cases which don't make national news, but which echo loudly among people in the autistic community. About once a month, somewhere in America, the father of an autistic child kills the child, and himself, to end the despair.

Yet, despite all of this, there is some genuinely good news. The unanimous passage at the end of last year of the Combating Autism Act by both Houses of Congress can be an historic turning point. The act contains, for the first time, specific authorizations of appropriations to combat a single disease, including bio-medical research, public awareness, and consolidation and coordination of Federal efforts to ensure the early diagnosis of kids with autism, so they can get—when it matters most—the interventions that can give them the best possible quality of life.

PREPARED STATEMENT

Now the burden falls on you. I know you have many important matters before you. I also know that none is more important than this. In no other case do you have the opportunity and responsibility to fulfill the commitment made by this historic piece of legislation. These are our most vulnerable citizens. It is our obligation to make them realize their potential, and to make their voices heard.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF BRADLEY WHITFORD

Chairman Harkin, ranking member Specter, members of the subcommittee—it's my great honor to be here today in the hope that my years of training as an actor and stomaching countless audition rejections have led me to some degree of celebrity which I can put to use, helping you garner the support you need to fully fund the appropriations authorized in the Combating Autism Act.

One in 10,000 kids will have autism. That's what top scientists would have told you little more than a decade ago. Then, it became clear that number was ridiculous. And the CDC—with the support of this subcommittee—started to really look at the prevalence of autism. 1 in 2,500, then 1 in 500. By the time the Children's Health Act of 2000 became law, the estimate had become 1 in 250. A few short years ago, the CDC said 1 in 166.

Now, just a couple of months ago, the best data ever collected produced the scariest number yet—1 in 150—1 out of 94 American boys.

I came to this cause when my college roommate, movie producer Jon Shestack and his wife, Portia Iverson, had their son, Dov, diagnosed with autism and founded the amazing advocacy group, Cure Autism Now, known lovingly as "CAN".

CAN recently merged with Autism Speaks, founded, as you know, by Bob and Suzanne Wright—on behalf of their grandson. Now this strong national organization is going to make sure that all Americans—and certainly all of our elected officials—understand the urgency of this problem.

As my friend Jon Shestack has said many times—it's as if 1 in 150 American children was being kidnapped. What would this Congress do if that was the case? What must it do to deal with these sad facts, as they truly are?

I know the enormous burden of your high offices means you must bring to bear a certain stoicism. I also know that most Senators are parents and grandparents. Portia has written a book about Dov—Strange Son. Here's how she describes the kidnapping.

"It was his mind they came for. They came to steal his mind.

Before anyone gave it a name. Even before I knew what it was, I knew it was in our house . . . They were very, very dark things. And there was no way to get rid of them . . . When I closed my eyes, I felt their shadows passing over me . . . I didn't like to think about where they came from or where they were going. It was too frightening. Dov was only a baby and something was trying to steal him away. I knew that was what they did whenever I accidentally fell asleep . . . Night after night, I sat beside his crib. I knew he was slipping away from us, away from our world. And there was nothing I could do to stop it from happening. And there was nothing anybody could do, they told me. So I did the only thing I could. I guarded him, although I knew it would do no good, because I could not guard his mind.

And then one day, it had happened. He was gone."

And it is even more than just a tragedy for these kids—many of whom, like Dov, we now know to be of extraordinary intelligence, but trapped in bodies which do not allow them to effectively communicate or interact with the rest of us. It's also a tragedy for families, and for our country.

I recently spoke to one mom who told me—through her tears—that she had been forced to abandon her beloved life's work as a nurse—not mainly to give her more time with her autistic child, but rather to purposely make her family poor enough to qualify for the payment of some of the services her child so desperately needs. She told me: "The one thing I just won't do—even though I have friends who have—is get divorced just to qualify for additional benefits."

Then there are the cases, which don't make national news but which echo loudly among people who "get it"—probably about once a month, somewhere in America—the father of an autistic child kills the child and himself, to end the despair.

Yet, despite all of this, there is some genuinely good news. The unanimous passage, at the end of last year, of the Combating Autism Act, by both Houses of Congress can be a historic turning point. The act contains, for the first time, specific authorizations of appropriations to combat a single disease—including biomedical research, public awareness and the consolidation and coordination of federal efforts to ensure the early diagnosis of kids with autism (so they can get, when it matters most, the interventions which can give them the best possible quality of life).

Now the burden falls on you, on this subcommittee, to turn Congress' promise on autism into reality.

I know how many important matters come before you. I also know none is more important that this. And in no other case, do you have the opportunity and responsibility to fulfill the commitment made in a historic piece of legislation.

I know you will do the right thing.

Thank you.

AUTISM AND THE ENVIRONMENT

Senator HARKIN. Mr. Whitford, thank you very much. You give a very powerful statement.

I thank you all very much, for taking the time to be here—as I said earlier—but also for your day in and day out efforts, on behalf of our families and our kids with autism.

I'll begin this round of questions now, and then yield to my friend from Illinois.

I want to start with our first panel, Dr. Insel, and I don't know if you're aware of this magazine article, the Discover magazine article that came out—maybe you are, maybe not—but I wrote down what you said in your testimony, you said that we must focus on this as a brain disorder. At least that's what I wrote down. I hope I can challenge you on that, and see what your response is.

This Discover magazine article had a map of Texas, and the top map was the autism rates per 10,000 from 1990 to 1993, up on top, you can't see it, but the bottom two are what's important. It was the autism rates per 10,000 of the last few years of the last decade, and then it had the pounds of environmental toxic release. When you overlay one over the other, it is frighteningly the same.

So, is there something in the environment? Why should we just focus on it as a brain disorder, but maybe it's, maybe there's something environmental out there, that we also ought to focus on, which is one question, and it leads to the second part of it—how much of the money, of the $108 million that you invest in autism research, is on environmental aspects, looking at some of the environmental aspects of this?

Dr. INSEL. These are important questions, Senator Harkin, and the way that we think of this is that there is an environmental component, but it interacts with some genetic component. The reason we believe in the genetic piece of this, which is driving the brain pathology, is that there is such a high concordance in identical twins, it's difficult to explain that based on just an environmental factor, because in non-identical twins, the rate goes way, way down.

Senator HARKIN. Fraternal twins.

Dr. INSEL. Right. So, there's some effect—it's not 100 percent concordance, so there's something beyond genetics—so we're talking about both environment and the genes.

What are we doing about the environment? As you know, the 2007 budget that was approved by this committee involved an appropriation for the Gene Environment Initiative, GEI, that was a particular request from, in this case, the Secretary—not simply through NIH, but it was part of the Secretary's budget. This, you know, our Secretary Levitt came from EPA, and he came to Health and Human Services with a tremendous interest in environmental issues.

What he was recommending here was that we bring the very best genetics and the very best abilities on the environmental side together in this new initiative, and the $40 million will be spent each year for 4 years. The first grants in that arena are just being funded in the next few months——

Senator HARKIN. Did you say $40 million?

Dr. INSEL. Per year, for the next 4 years.

Senator HARKIN. On the environmental aspects?

Dr. INSEL. Not specifically for autism, but generally, if we're looking at gene-environment interactions—part of what's hung us up here——

Senator HARKIN. Through your Institute?

Dr. INSEL. This is the National Human Genome Research Institute doing the genetics part, and the National Institute of Environmental Health Sciences, which is developing the technology.

We have great precision on genetic sequencing, not such good precision on environmental exposure. So part of this will be to develop the tools, so that we'll have sensors, and other ways of looking at environmental exposures, often well after the fact.

Senator HARKIN. I still need to know, and if you don't have it right now, if you'd provide it for the record, about how much of that $108 million goes in for environmental.

Dr. INSEL. We can provide that for the record.

[The information follows:]

ENVIRONMENTAL ROLE OF AUTISM RESEARCH

Of the $108 million invested in autism research in fiscal year 2006, $14 million was invested in environmental aspects of autism research by the following Institutes and Centers: NINDS, NICHD, NIEHS, NIMH, NCRR, and OD.

Senator HARKIN. Second, if we were to provide the increase that the groups have asked for, how would that money, that extra money be utilized in the next fiscal year? I'd like to have some handle on that.

Dr. Gerberding, I was shocked when my daughter and her husband showed me the schedule of vaccinations for my first grandchild in the first 2 years of his life. I was shocked. Evidently this is what is required; and they have good pediatricians, they go to great doctors out on the west coast, but I guess I just never realized that. I think, when my kids were born we had a couple, maybe three shots, but we didn't have this long list. I think 12 or 15, is that correct?

Mr. WRIGHT. Thirty-one.

Senator HARKIN. Thirty-one, thank you, Bob. Thirty-one.

Mr. WRIGHT. Zero to 18 months.

Senator HARKIN. Please, go ahead, what did you say?

Mr. WRIGHT. Between zero and 18 months, there are 31, including influenza.

Senator HARKIN. Okay. That's the list I looked up. They were upset, they were asking me, I said, "Well, I'm not a doctor, how do I know?" So, they wanted me to ask you.

I mean, I'm serious, they wanted me to ask. They're really concerned about this. About all of those vaccinations in the early ages. When you have a small child that's not an adult, I would be concerned if I had that many shots in 18 months. There has been, and there have been some, at least, allegations, some thought that perhaps, many of these, at least with the use of thimerosal, which was a mercury additive for preservatives, might have had some influence in that, although thimerosal has now been taken out.

Mr. WRIGHT. Not entirely.

Senator HARKIN. Except in the influenza, the influenza shot still has thimerosal, am I right?

Mr. WRIGHT. That's right.

Senator HARKIN. I think that's right.

Could you address yourself to that? Just the number of vaccinations, the fact that we still put thimerosal in the influenza shot, but it's been taken out of the measles, mumps and rubella, I understand.

Dr. GERBERDING. It's important, first of all, to recognize how many children are alive today because of those shots, and how little vaccine-preventable disease we see in this country as a consequence of the enormously successful immunization program.

Keep in mind that an immunization is really just a way to expose a child to a specific protein or antigen that causes it to develop an immune response, and that happens to children all of the time, naturally. They're exposed in their food, they're exposed to things they come in contact with their friends and with day care, so while they may receive intentional exposures to protect their health, they're naturally doing the same thing to themselves, just as part of being a child, and being exposed to the environment.

The concern about the safety of vaccine is something that we take very seriously at CDC, and we recognize that we're having our own challenges in keeping up monitoring the safety of vaccines when so many more are out there, and we haven't been able to scale our safety efforts the way we would like to.

But, we do know—and I think the scientists at the Institute of Medicine have provided great leadership in this, is that when all of the information that is available has been looked at by external scientists, not only has the Institute of Medicine said that vaccines are not associated with autism, but they have said that there is not an association, that there is no evidence for an association.

What we say to that is, that's good, and that's what we expected to see, but we have still a lot of work ahead of us to identify what are the safety aspects of vaccines, in general, but also what are the causes of autism? We need to continue the studies that we have in progress, including the study underway to look at the potential association of environmental toxins and autism, and the SEED study that's going on, and not be dogmatic.

I was really struck by Mr. Wright's statement about the similarity between autism and AIDS, because I lived through the very first phases of AIDS, and if you go back to 1981, the situation we were in with that urgent reality for many, many people in our country, is we had no idea what caused it, there was no cure, the people who were affected were driving the agenda because it was so powerfully affecting their lives and their health status, and the people that they loved and cared about. Government was slow to get on board, Government was slow to scale and provide the kind of scientific leadership, the door was open for junk science, and for all kinds of theories to come and go, and ultimately, it was the Congress of the United States that stepped in and provided the leadership and the investment to get that whole picture turned around.

Domestically, back in the eighties, and more recently, internationally with the PEPFAR fund. We don't want to go through that cycle again, and I think we really recognize that this is an urgent threat. While we're sitting here today in these 2 hours, at least six children will be diagnosed with autism in our country,

25,000 children this year. We really do need to regard this as an urgent threat. So, I just wanted to put that perspective in the context of your question.

AUTISM IN OTHER COUNTRIES

Senator HARKIN. Well, Dr. Gerberding, obviously, CDC during your epidemiological studies also, I'm wondering, are they also looking at some of these environmental factors?

Second, has CDC looked at autism rates in other countries? Has any research been done to see if countries in Europe and Asia have different autism prevalence rates? If so, can this tell us about possible environmental factors that can, or may contribute to autism?

Dr. GERBERDING. The SEED study that I mentioned that's going on in six sites initiated this summer is designed to look for a variety of potential associations and causes of autism, including exposure to mercury in the environment, in Rhogam, which is sometimes used to treat mothers with Rh factor incompatibilities, and a variety of other sources. So, it's looking at genes, it's looking at environment, it's looking at the social-behavioral context of the family.

Also looking at occupational exposures in parents that could potentially create a hazard of exposure in the home for children. So, a comprehensive look, as a first study.

You might know about the NIH study that will be starting in Europe in the cohort of Norwegian children—children in The Netherlands, excuse me——

Dr. INSEL. It's Norway.

Dr. GERBERDING. Norway—to follow a cohort of children longitudinally to look for prospective evidence of causality, and then there are studies, for example, in the United Kingdom. that have been tracking children over time, and looking at changes in rates.

Finally, a very important study that we don't have data from, going on in Italy, where just by coincidence, some children were enrolled in a study of a whooping cough vaccine, some of the vaccine was made with thimerosal as a preservative, and some of it was made without thimerosal as a preservative, so the study was designed to compare the efficacy of the two vaccines, we will indirectly be able to determine whether there's any difference in autism among the children who did or did not receive the vaccine that contained the preservative.

So, we have more information coming, but I think we're beginning to work in the international context of a community of investigators all looking for the same kinds of information. This is a global health issue, not just an American health issue.

Senator HARKIN. Well that's, that is comforting to know, that you—CDC is looking at other countries, you are coordinating with other countries to find out about the prevalence rates, and you're also looking at the Norway study, I know.

Are you also coordinating with Dr. Insel, and his Institute on this?

Dr. GERBERDING. The Norwegian study is an NIH study.

Dr. INSEL. But this is an area where there's a lot of coordination between all of these Federal agencies, we're actually organized around this. This is, very much, an integrated effort.

The Norwegian study, if I can just take a moment, because I think it's going to help us over the next couple of years. It makes no presumption about the cause, it says, "We don't know enough, to even have a hypothesis," but it takes 100,000 children, following them, their moms, from the second trimester to birth cohort, waits 5 years to see, 400 or so children with autism, and then it goes back, because samples are collected all the way from the very first prenatal visit. So, we have biological samples, we have a tremendous amount of clinical information. It goes back to ask, what is it, then, that might have been an exposure for the children who ultimately had autism, versus those who didn't?

Senator HARKIN. I'm going to yield to my colleague for some questions now, I have a couple more for Dr. Gerberding and Dr. Insel.

But really, in my next round of questions, I want to focus on you, Dr. Favell, and I want to talk about this intervention program which holds so much promise, and again, involve you and Ms. Colston in that, and also Mr. Wright, in terms of your experiences with your grandson, with Dov, and see how we start getting to families early on, and providing that kind of help and support, if we don't really have an infrastructure for it, and we don't—what's the most cost-effective way of doing it? I am intrigued by this idea of a tele-health distance-type thing where you could support someone in a family 24 hours a day, so I want to focus on that in my next round.

But, with that I would yield to my colleague from Illinois, Senator Durbin.

ALLOCATION FOR AUTISM

Senator DURBIN. Thank you, Mr. Chairman, and thank you to all of the witnesses. This is the first hearing I've attended on this issue. It isn't for lack of interest. There are many things pulling at us, in the position I have in the Senate, and the work that we have to do in so many other places, but I wanted to make a point of being here today. Not because we have any situation in my immediate family, that relates to autism spectrum disorder, but because of the number of friends that have been touched by this, and what appears to be the alarming increase in the diagnosis of autism across America.

My wife and I, fortunately, raised three children, and have a grandchild without a problem in that regard, but we frequently speak of this, the incidence of this, and why it appears to grow as it has, I know there's a serious question as to whether this is an indication of incidents or just identification now, better identification, but I think that begs the question. I think, the fact is, this is a significant challenge.

I thank all of you for testifying, Dr. Gerberding, again we really appreciate your public service, Dr. Insel, I'll have a question for you in a moment, thank you for what you do at NIH, and for all of you on the panel, starting with Ms. Colston and Dr. Favell.

Mr. Wright, you raised a question which comes to the office of a Congressman and Senator more frequently than you can imagine. People visit us from my State of Illinois or other places, and say to you, "Senator, can you possibly explain why they're spending "x"

amount of dollars at the NIH on this issue?" There are people who represent children with juvenile diabetes, there are people with parents who have Alzheimer's, there are victims of Parkinson's—you name it. They all come with the same basic question—how can they possibly rationalize this amount of money for this issue of such gravity, why isn't more money being spent when it comes to research—and you raised that question. You compare the amount of money being spent on autism to other significant diseases and disorders, and I'd like to ask Dr. Insel the question.

Because, as I see the numbers here, in the past 10 years there's been a dramatic increase at NIH in terms of research funding for autism spectrum disorders. In 1998, in the range of $27 million, by the year 2008, about $108 million, and I'd like to ask you, if you could, give me some indication of whether or not this amount is adequate to the task. Do you believe that you are able to fund the promising research proposals that come before NIH in the field of autism with this amount of money, $108 million each year?

Dr. INSEL. Overall, what we call our success rate, that is the possibility that anyone in any area will get funded when they come to NIH is roughly 20 percent. There's a 1 in 5 chance that you're going to get funded.

Senator HARKIN. That's a peer-reviewed.

Dr. INSEL. Peer-reviewed grant, that's right. But, virtually all of our, other than contracts, virtually everything that we fund is through peer review. That's a system that provides the quality control that we need.

Is autism—how does that stack up against other areas? Well, obviously, we're doing better there, because it's growing faster. Overall, the budget's grown, a little more than double since 1997, this area has grown almost by five-fold, but remember, we were starting at a very, very low baseline. So, we still have a ways to go in this area.

I'm not proud to tell you that I can give you the full sum of our knowledge in less than 4 minutes, when we talk about autism. This is an area where we have many more questions than answers. We have a long way to go to fill in those answers. The good news is we have some of the tools now, that were not available 5 years ago. So, we should be able to make progress faster, going forward, than we have in this past period.

Senator DURBIN. So, does your response suggest that 4 out of 5 of these peer-reviewed clinical trials that you think are worthy of investment each year, have to be denied?

Dr. INSEL. Well, this isn't to say that all of the other four would be worthy of investment. We would like to be able to fund, always, more than we can do, that's the reality, it's the same reality we all experience with our pocketbooks, we can't go as far as we'd like.

However, in the area of autism, we've made that a priority, and we've tried to reach as far as we can.

The problem isn't only that we may not have enough funding to do everything we'd like to do, but here also, we haven't until recently, had the capacity, we haven't had the population of outstanding scientists out there really pushing this agenda. That's taken time to build. I think it's there now, and I think part of it has been through the help that we've gotten from this sub-

committee, that's really helped us to grow overall, and it's also helped us to stay focused on areas of public health need, but there has to be the people out there asking the right questions for us to spend the money on.

Senator DURBIN. In order for those people to commit their lives and careers to that research, they have to feel that funding for research is somewhat reliable, and predictable in the years to come, is that not true?

Dr. INSEL. That is absolutely the case, and that is, of course, right now a particularly sensitive question. Because there are many people who are asking whether they can have a career in science, because they find that funding at this 20 percent success rate is a high-risk game.

Senator DURBIN. I think we made some dramatic progress, and I want to thank my colleague from Iowa and Senator Specter from Pennsylvania for all their leadership in that regard, but I'm afraid that we have reached a part where we're flat-lining stagnant here, in terms of the growth in medical research at NIH, and I hope we can change that. We are spending a lot of money in other places in the world, but I think most families would agree that this is a high priority for us to spend.

Mr. Whitford, you talk about, and I thank you, and Mr. Wright for being here, in your public capacities to engage in this issue—but you talk about the frustration of your friends, that you know, who find it difficult to qualify for help in Government programs without making some radical personal decisions about their finances and their marital status and things of that nature.

I think that is the part that Ms. Colston was raising earlier, too, is how do we sustain the families that are doing their level best to help their child, suffering from autism? I really believe that that is something that we overlook. Research is the first place to turn, but beyond that, it's support for these families with children in this circumstance.

One of the things that I've thought about is to view the role of caregivers in America as a special group that receive special consideration. Whether we're talking about daycare centers or personal attendants for the disabled, there is at least one State that gives all caregivers automatic health insurance, provided by the State. It's the State of Rhode Island, provides Medicaid for caregivers. It strikes me that in many instances, families with children with autism would be able better to afford the services of caregivers if they could offer health insurance as part of the bargain, and we can help them do that.

So, I'm hoping we can find some innovative ways to expand the spectrum of services for children who are going to need much more, but I thank you for raising that.

Mr. WHITFORD. I don't think it's possible to overstate the impact that I—actually my, I, subsequent to my involvement with CAN, my godson was diagnosed, and it was a different situation, they live in a one-bedroom apartment, they do not have the funds that they need, and it is absolutely devastating to a family, it is—depending on where you are in the spectrum, you know, these kids, it's 24 hours. There is a tremendous amount of anxiety wondering, where on the spectrum the kid will end up. There is, it's an abso-

lutely full-time job, the career goes out the window, the marriage goes out the window, and you're juggling therapies in a desperate race to see if your kid can live an independent life. So, it sounds like a great idea.

Senator DURBIN. I hope we can interest some people in it.

Ms. Colston, I'll ask you the last question I have, and turn it back to the chairman on this, but your son, Camden is in public schools now?

Mrs. COLSTON. He is, he's in Montgomery County, Maryland.

Senator DURBIN. How is that working out?

Mrs. COLSTON. It's great. I live—I'm lucky, again, I live in Montgomery County, Maryland which is the top 10 counties in the Nation in the way they handle disabilities, and the IDEA Act. It's great—he gets picked up at my door on the school bus, he goes to school, he gets 10 hours a week of intensive therapy, he is mainstreamed, or included if you will—not mainstreamed, he's included with his typical peers for a third of the day, and in a contained classroom for two-thirds of the day. I've seen just remarkable improvement in his socialization and cognition. So, I'm very grateful for that.

Senator DURBIN. Very fortunate to be in Montgomery County, Maryland.

Mrs. COLSTON. That's right, I'd say to people, "I love D.C., I'd love to move there, but I can't."

Senator DURBIN. That just tells the story.

Mrs. COLSTON. Yeah, right.

PREPARED STATEMENT

Senator DURBIN. A few miles away from you live——

Mrs. COLSTON. I can't move there.

Senator DURBIN [continuing]. The schools cannot provide the basic care that these children need. I think, I want to salute again my chairman, it sounds like I'm doing my best to get on his good side, but he had been a national leader on IDEA from the start——

Mrs. COLSTON. He has been, thank you.

Senator DURBIN. We're lucky to have him.

Thanks, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF SENATOR RICHARD J. DURBIN

As a United States Senator, I hear from thousands of people in my State of Illinois. But no stories are as powerful as those of a parent who is worried about their child. Whether the worry is because of the fear of having to pay for their child's upcoming educational debt, the angst of having their child abroad in a war that seems to have no end, or the uneasiness of having a child with autism and not knowing what the future holds for him or her.

As we have heard today, autism is a severe neurological disorder that affects language, cognition, emotional development, and the ability to relate and interact with others. Current estimates suggest that over 1 million Americans suffer from some form of autism, including more than 24,000 children in my State of Illinois. For unknown reasons, the number of children diagnosed with autism has skyrocketed in recent years, from one in 10,000 children born 10 years ago to approximately 1 in 150 children born today—making autism the fastest-growing developmental disability in our Nation.

Last year, I heard from a woman named Ellen whose story represents so well the similar sense of constant worry that I hear from so many others. Ellen wrote to let me know that her son's autism was a constant source of worry for her. She is a

mother that loves her son. At the same time, she worries that her son's siblings carry a genetic tendency and that their own hopes for marriage and children are tainted with concerns about how these genetic tendencies will manifest themselves in the lives of their own children. She worries that her other son one day will have to bear the strain of raising a child who is affected by autism. Ellen writes, "As much as we love our son, we would give anything to have him be 'typical'. He will always require supervision and assistance. He is the great passion of my life and also a very great burden."

My State of Illinois has seen a dramatic increase in the number of autism cases in the past 10 years. The number of children in Illinois receiving special education with autism as a primary diagnosis has grown from 1,960 to 9,455—more than a 450 percent increase. As more and more families become aware of the disorder and the impact on their lives, it is imperative that we all—federal, state, and local levels—make the most of our ability to promote research, advocacy, and policy for autism-related disorders.

The State of Illinois is very involved. Our communities are strongly committed. In 2003, the Illinois General Assembly passed a law to develop an innovative model of service delivery called the Autism Program to help these children and their families. Through a partnership with the CDC, this program offers evidence-based diagnoses, treatments, trainings, resources and referrals. Last year, the program provided more than 4,700 clinical contacts and trained more than 9,400 parents and providers. This year, there is hope to expand the initiative.

Late last year, the President signed into law the Combating Autism Act. The new law says we have authority to provide dramatic increases in federal funding for autism, specifically for medical research, screening tools, therapy interventions and education about the disorder. But the new law says something else, too.

Coupled with State based efforts like those in Illinois, the new law reflects the dawning awareness in Congress and throughout this country that far too many people are affected by autism spectrum disorder. It is my hope that this new law proves to be a significant step toward a better understanding of how to prevent autism, of effective treatments for people living with autism, and maybe even, one day, a cure.

The efforts conducted at the State and now at the Federal level will bring much needed action to address the growing prevalence of this disorder. More importantly, however, these efforts can bring hope to the thousands of families impacted by autism. We may have a long way to go but I look forward to today's discussion and learning what the CDC is doing and will do to help these families and keep such hope alive.

Senator HARKIN. Thank you very much, Senator Durbin. Thanks for your strong support.

Senator HARKIN. As I said, I wanted to get back to questions, I wanted to talk about interventions now, and how we handle, how to handle those now.

Now, Ms. Colston, tell me again, how old was Camden when he was first diagnosed?

Mrs. COLSTON. He was 2½ when he was diagnosed with autism.

Senator HARKIN. Two and a half, and you said that he'd made progress through intensive therapy, Individualized Education Plans, a sizable team of dedicated professionals. I mean, did that start right at 2½ when he was diagnosed?

Mrs. COLSTON. My experience was slightly different, as I mentioned. In addition to having autism, he's got medical ailments that he was born with, so when he was born, he was small for his age, he had horrible acid reflux—you've read the Discover article, so you're going to see a lot of parallels there.

Senator HARKIN. You read this too, then?

Mrs. COLSTON. In full disclosure, I not only read it, but I helped place it with Dr. Herbert, so——

Senator HARKIN. Bob Wright says he individually kept the magazine afloat for a month by buying up all the magazines.

Mrs. COLSTON. Thank you so much, Bob Wright.

Senator HARKIN. Sending them out.

Mr. WRIGHT. Largest single purchaser.

Mrs. COLSTON. It's a great thing. So, he was undiagnosed, but we had horrible acid reflux, we were hospitalized, we had these allergies, and they thought he had something called Noonan Syndrome, the diagnosis changed—all that being said, in the NICU these problems presented, and so therefore, the Georgetown University Hospital made me sign up for Early Intervention. I didn't even know what it was. So he, because he had low muscle tone and these other medical problems, at 6 weeks of age, the team came to my house. I know for a fact that he is where he is because they came to my house, and gave only 4 hours of therapy, but that, I mean, with them, he turned his neck, he sat up, he—they were the ones that actually—the therapists there are amazing, because they encouraged me to really look at the autism before the doctor saw it.

Senator HARKIN. Yeah, I guess what I'm wondering, and I—as I said I had dinner Sunday night, no secret, I had dinner with the former Lieutenant Governor of the State of Iowa, Sally Peterson, who's been very much involved in this issue. Their son, Ron is now, I think 20, 21, doing very well.

Mrs. COLSTON. Oh, good.

Senator HARKIN. But, again, they had early intervention, they could afford it, they had all of the accoutrements, everything that they needed. They asked the question—what happens to families that don't have the monetary resources that we do? How did you happen to—I don't mean to pry, but how is this—this costs money——

Mrs. COLSTON. Oh, oh yeah. I mean, my out-of-pocket annually—and I have good insurance, keep in mind.

Senator HARKIN. Yes.

Mrs. COLSTON. Is between $9,000 and $15,000 a year. That's not easy. At Autism Society of America, we have a 1–800–3AUTISM number, and it's a great resource, but we learned so much from that. Because the calls we get are about desperation financially.

Senator HARKIN. Sure.

Mrs. COLSTON. People—so, I'm lucky to be able to swing that, in good years and bad, but these people mortgage their homes—especially when their children become adults—that's where the rubber hits the road, financially.

Senator HARKIN. Now, this is where I'm going to focus on Dr. Favell. I am so intrigued by what you're doing. As many families tell me, or people I've talked to with autistic children, you know, when they go to the doctor's office, or when they see a behaviorist or a psychologist, maybe the child is not exhibiting anything at that time.

Dr. FAVELL. Right.

Senator HARKIN. When they need help is at home when things, go all to heck, all right? There's no one there. That's why I'm intrigued by what you're doing.

How, tell me, enlighten me a little bit more about how, how many families could a trained psychologist, behaviorist, someone who is trained and knows how to deal with children with autism, how many could they handle on some kind of a system like this?

I mean, on a 24-hour a day basis, I'm trying to figure, could one handle three families? Or two, or five? I just don't know.

Dr. FAVELL. Mr. Chairman, it's an excellent question, and the answer is just evolving, but for example, we did as part of our work with the Celeste Foundation, one demonstration that calculated that, if a professional, like a behavior specialist, was to provide in-home services, they might be able to visit two families a day, given travel distances, given missed appointments, given inclement weather, all of the vagaries of the logistics of supplying services, perhaps they could see two to three families a day. Of course, again, in more rural areas, that number decreases.

On the other hand, if you have a behavior specialist, or a behavior analyst, who is working with this interactive video kind of capacity, you could see potentially 20 families a day. Now, this kind of remote, this tele-health, does not replace face-to-face intervention and support, but it can augment it, and expand, exponentially, the number of families that can be touched a day.

Senator HARKIN. As I understand it, in the beginning you do have face-to-face involvement with the families, is that correct?

Dr. FAVELL. Yes, in the model that we tested in our demonstration project, they spent—the families such as Josh Cobbs' family—spend a week on-site, developing priorities and learning basic strategies of intervention and teaching. Then they went home with their interactive video system, and then that began the process of the interactive consultation, support and training.

It started with about 10 to 14 hours a week of interactive video support—it's a couple of hours a day. We think, actually, and the families tell us, it might be able to be somewhat less, it all is individualized, depending on the needs of the child. Then, it was after three weeks reduced to about 5 to 7 hours a week, and then 3 to 6 hours a week.

Senator HARKIN. I see.

Dr. FAVELL. So, there's yet to be worked out the formula for exactly the parameters for what is needed, and it will always be individualized, just as the IEP and the IHP requires, but the intuitive reasoning behind having one professional who now is able to touch lives through this remote medium is quite clear.

Senator HARKIN. What more do we need to do to test this out?

Dr. FAVELL. Well, I think we need to bring it, as we say, to scale. We need to test fully the economics of it, we need to test it across broader bands, including some other disabilities, and may I say, also, this kind of innovation should not be restricted to children alone. We can't forget the many, many thousands of people who are adolescents and adults who are adolescents and adults who are also living with autism. So, we have further to test there. But, I think probably the single most important element in bringing this to scale, as I say, is to develop the policies behind reimbursement strategies. If I, as a psychologist and a behavior analyst, can be reimbursed for providing services face-to-face in a home, than I should presumably, also be allowed to be reimbursed for providing comparable services, now, over remote interactive video. Yet, easily half of the States do not allow for that kind of reimbursement through Medicaid.

So, and then those States that do allow it, there's wide discrepancy in what they reimburse. Yes, sir.

Senator HARKIN. Let me ask you, Mrs. Colston. If you had had something like this available to you, would that have helped you?

Mrs. COLSTON. Yes, it would have helped me a lot. Not only because, most parents of children with autism work full time, and are probably hourly wage workers, and so getting off to run home for the times you can do an early intervention is tough.

But also, because then the therapist could see, as Dr. Favell says, the bad time of night.

Senator HARKIN. Yes.

Mrs. COLSTON. Where, when the behaviors of autism, it just gets harder to be a kid with autism.

Senator HARKIN. I'm, I have a note here, I'm holding in my hand that says Josh Cobbs is here, the father of Noah Cobbs who is in that news clip, is that right?

Mr. COBBS. Yeah.

Senator HARKIN. Oh, well Josh, welcome to the committee, I should have pulled up a chair for you and asked you a question. Yeah, come up here, come up here, sit down.

I didn't even know you were here. Now, the recorder is going to want to know your name.

STATEMENT OF JOSH COBBS

Mr. COBBS. It's Josh, last name is Cobbs, C-O-B-B-S. I am not prepared, but I'll do my best.

Senator HARKIN. I wasn't prepared to have you here, either.

But, I just want to know—now. We saw that little clip, obviously, you know, TV wants to get in the gane, with all due respect to Mr. Wright, television tries to get it in a very short clip, tell me what this has meant for you and your wife and your son, on this, again, the availability of it, that you can do this during the day, right? On weekends, too, I don't know, can you, weekends?

Mr. COBBS. Sure, we actually had services, initially, 7 days a week, two calls, one in the morning, one in the evening, and we structured them around when we were struggling, such as sitting at the dinner table, or breakfast table, which was very helpful.

The doctors got to see Noah in his true element, so he wasn't acting up because there was a worker in the class, or in his, in our home, and he wasn't putting on, on-stage, if you will, so he was in his natural surroundings, which was very helpful for us, because that's where the behavior was happening. So, that was very important.

One thing I'd like to clarify, it's not just important for our immediate family, but also our, his grandparents, and aunts and uncles who are affected by autism as well, they were able to come in and help and once Tina and I were trained adequately through the Celeste Foundation and our immediate family, we then had the tools to go out and help others, so——

Senator HARKIN. Now, I'm told, I'll just throw this question out. I'm told that many times, what might be the normal reaction of a parent to a behavioral problem of a child, that if that child is autistic, it may in fact, exacerbate the problem, and make it worse, and so you have to have other approaches.

Mr. COBBS. Absolutely.

Senator HARKIN. I'm not a behavioral scientist, or anything like that, I've just been told that. So the answer is yes.

Mrs. COLSTON. We like to say that children with autism don't have osmosis, as many of us do. So, a lot of speech therapies and other therapies are talk, and so when you talk at a child, or even soothe them with your voice, you're changing the environment, and that may make them, there's a term called sensory violation—it may sort of freak them out a little bit.

For example, I was trying to comfort Camden, and I would stroke him—well that, that just makes him feel completely out of his element. So, there are things that a mother does naturally, that sometimes we have to alter, because children with autism like deep pressure, and that grounds them. Or vestibular inputs.

Senator HARKIN. So, something like a tele-health thing could be instructive in that, where you could actually talk to someone and say, don't do this, or do this?

Mrs. COLSTON. Right.

Mr. COBBS. Absolutely.

Senator HARKIN. Has that happened to you?

Mr. COBBS. Excuse me, absolutely. I do want to point out, the actual day that the TV station was there was Noah's worst day. Everything that could wrong, went wrong. He went outside, he was crying, he was kicking, it was—I was thinking to myself, "We are failing right now, as parents," with TV reporters there, and a few other people, and through the project from Celeste, they actually, right there, coached us through the moment, and it, it took about 40 minutes, to get Noah reeled back in, to get him back into the house, and to get him calmed down, but, wow, what a great feeling. That was a true test for us, is we can make that happen with the right help and coaching.

Senator HARKIN. Bob Wright, your grandson, how old is he now?

Mr. WRIGHT. He'll be 6 in August.

Senator HARKIN. Six. He was diagnosed early on?

Mr. WRIGHT. He was diagnosed at 2 years and 3 months.

Senator HARKIN. Now, his parents think about what we were just talking about, this is a new thing, here, about having that kind of tele-health, where someone could come into your home, so to speak, at any time of the day or night, would that have been of help to them?

Mr. WRIGHT. It's hard to say, I can't imagine it wouldn't have been helpful. My grandson has auto-immune problems, and he had gastro-intestinal issues which were not diagnosed at the time. So, they weren't diagnosed until 2 years later, almost 2 years. Which meant that he was suffering during that period of time, and we—nobody understood why. So, it was a very difficult situation with him. I think you made the comment, you're—in some respects a parent is better off, in some respects, if the autistic child has treatable, or at least has traditional medical problems. Because then you get access to doctors and hospitals and insurance. At least for some of it.

If you have no medical problems whatsoever, you don't get access to hospitals, doctors or insurance, really.

Senator HARKIN. Yes.

Mr. WRIGHT. So, if you, if you're awfully serious, on the other hand, and it's not diagnosed, you really are in a pickle. That's what my daughter found.

However, having said all of that, the kind of—anything that would allow a third party to be of help at the time, at the worst time of the day is going to be of benefit to an autistic family. There's no question about it—whether it's on the phone or whether it's in person, or—that is so important. Because the mothers just—I mean, you know, I worry as much about my daughter as I worry about my grandson. I worry about my daughter being on the edge all of the time.

Senator HARKIN. Yes.

Mr. WRIGHT. Because he has these serious problems, and he can't just—he can go from looking and acting very normal to get 104 degree temperature in like, it seems like, 3 hours later. You have to rush him right to the hospital. Of course, they look at him like, you know, "How could this happen?" They don't have a clue what he's, what's happening.

Turns out he has severe colitis, bordering on Crohn's disease, that's an adult, that's an adult condition, not a children's condition. You also find, though, in the case of a lot of these children, when they have medical problems, the medical protocols don't exist for children for some of these conditions. The medical protocols generally require the cooperation of the patient for diagnosis of certain kinds of things, like gastro. Where you can't talk to a child who can't talk. A child who won't express and react to—you point to your stomach, you don't point to his, he looks at you like, you know, you're from another land. So you, they don't, they can't be diagnosed in many cases, either, which makes it extraordinarily frustrating.

So, I would say that—I wrote down the Celeste Foundation, I thought that was an excellent concept, I'm not aware of it, and I think anything—I think one of the issues is how do organizations like that get funding? Do they, they have a foundation that gets them started, how do they get enough funding, so that they can begin to develop data, you know, that won't be sharply criticized by the first skeptical person that comes along.

Senator HARKIN. Yes.

Mr. WRIGHT. So that it can get, you know, it can get enough attention, it is very difficult to get insurance, it's very difficult to get State or Federal funds to support this, because the burden, the burden of proof is so substantial. So, that's a real challenge—how do you take this experiment and build it up and, you know, at some point, you run out of money to do that, and I think that's part of what Autism Speaks—we're trying to figure out how we can help groups like that when they get to a point, to get to the next stage.

Senator HARKIN. Because that's again, what I'm looking at, you said it was costing you $9,000 to $15,000 year, out of pocket.

Mrs. COLSTON. Yes, that's above and beyond—I mean, Camden's non-verbal, so of course, I've had 6.5 years of speech therapy—and it's always declined. So, that adds up, and medical issues and that. So, that's above and beyond co-pays.

Senator HARKIN. So, we do know. I'm going to make a statement, I don't know if it's scientifically sound or not, but everyone I've ever

talked to says that it is factual that, the earlier you get to a kid with autism, and you provide interventions and analysis, intervention, support, training, the proper kind of activities—that it can lead, later on, to them being more self-sufficient, more independent.

My friend Sally Peterson, and Jim Autry whose son Ron is now 21, lives by himself, has a job, takes the bus back and forth to work. They say, if it hadn't been for those early interventions it never would have happened. Because they know other people that didn't have that. Their kids, after 4 or 5 or 6, they just level out, and that's the end of it.

Mr. WRIGHT. Mr. Chairman, my grandson's costs are well over $100,000 a year, out of pocket.

Senator HARKIN. Wow.

Mr. WRIGHT. Now, I can afford to help on that.

Senator HARKIN. Yes.

Mr. WRIGHT. But how many people could do that? That's why we're here.

Senator HARKIN. Well, this is what I'm trying to see, I'm trying to think of two things, here. How do we do more and better research, and I've got a couple of more questions I've got to ask you, too, and I know Dr. Gerberding has to leave. But then, how do we also do the most cost-effective, best methodologies to get the families that have kids now, so that we have that early intervention? I'm thinking that so many people out there can't get it, they may be isolated, they don't have the financial resources that some of us do, and if they don't have an attendant illness, they may not have anything.

So, if we can use something like a tele-health, a thing like that, where one trained person can interact with a number of families, and where families can get help when things go all to heck in the family, it seems to me that that just begs, begs for more expansion, to see how it would work, and to see if we can adapt this, adopt it, adapt it, adapt it to the, to a larger segment of our population. It seems to cry out for that kind of support.

Mrs. COLSTON. It seems to me, as a parent, that there's a natural fit. If you could take this technology, or your funding, and put it towards early intervention, which I think is IDEA Part C?

Senator HARKIN. Yes.

Mrs. COLSTON. You know, there are so many great models in place in this country, that are cost-effective, and that's one of them. And I wonder if you could marry those two through Part C, and see how it worked, or pilot it. Because I know that the early intervention therapists who helped me, they had a tremendously huge caseload. I think they got caught up in overall education funding as well.

Senator HARKIN. Yes.

Mrs. COLSTON. So.

TREATMENT RESEARCH

Senator HARKIN. I wanted to ask you a question, and I'm glad my panels are still here for Dr. Gerberding, Dr. Insel. In this party, in Discover magazine, there's some interesting, interesting language about different approaches to treating kids, people with au-

tism. There's some indication that using chelation therapy, chelation therapy, which I'm not all that familiar with, I just kind of halfway know what it is, after reading this, I looked it up some more, but that it quotes at least one or two families in here whose, I think they had more than one child that was autistic that went through this, and they just, improved immensely. I'm wondering, have you looked at that? Is there something there?

This, the doctor they quote in this is a Dr. Asco, she's a microbiologist, she has a Doctorate in Microbiology and other things. Now, I'm intrigued by this. Is this part of looking at, you know, of treating people with autism?

Dr. INSEL. One of the ways that, at NIH, we've tried to increase our effort in this whole area is to develop an intramural program, the first such program for focusing on autism. It started about a year ago, there are five protocols that have been rolled out there, and this is to have a kind of rapid response team that can pick up an idea and run with it quickly, where we don't have to go through a very long process of peer-review.

They have, as one of their protocols, they do have a chelation protocol, that was approved by our Science Committee in September. It's actually been held by the Institutional Review Board, whose members have some additional questions, they're going to address it again on May 1. So there have been no subjects actually entered into the protocol. But the hope is that will be approved and we can use this intramural program as the first place to do a controlled trial, a real, randomized controlled trial to find out whether there's, a, value in this approach, and b, what the risk is.

Senator HARKIN. Is NCCAM involved in that?

Dr. INSEL. I'm sorry.

Senator HARKIN. NCCAM?

Dr. INSEL. NCCAM is not involved. This is one that NIMH is taking the lead on.

Senator HARKIN. But, you say on May first, you're going to——

Dr. INSEL. May first the IRB, the Institutional Review Board, will be reviewing this particular protocol, and we are hopeful that once it's approved, we can begin to run with it. But I must say, they have has some considerable reservations, the Review Board itself, about the safety of chelation, they've brought in some outside experts who have made them even more concerned about the potential risks involved, based on some very recent animal research.

Senator HARKIN. Dana Halburtson, from Iowa, told me that chelation therapy made a big difference with her 8-year old daughter, Robin. So, again, this is something I don't understand completely, but if things are happening out there, that people are having success with, I would think that NIH would want to look at it.

Dr. INSEL. That's exactly why we have this intramural group put together for just that purpose, and it's not only on this, but on a number of other ideas that have come up, we're trying to move quickly to be able to test them out, but we want to bring the best science to those questions, and we want to make sure that we're doing it in a way that's safe as well as informative.

Senator HARKIN. I know, Dr. Gerberding, you have to go, and I'm respectful of your time, but again, I just, I want to be reassured that you're coordinating with NIH in your, in your epidemiological

studies, that you are coordinating with them, and that you're looking at, in your studies, the different aspects of these vaccinations that we talked about, I mean, look—I agree that, you know, the vaccinations obviously have saved a lot of lives. But, one has to begin to wonder, are there some other side effects that are happening out there that we don't know about? Maybe they need to be modified, or something, I don't know.

But, I'm just, I want to be reassured that CDC is coordinating with NIH, in looking at the possible causes, and maybe environmental factors that might, that might spur on the genetic predisposition to have autism.

Dr. GERBERDING. First of all, we are collaborating across the Department, in particular with NIH in two lanes that are relevant to your question. The first has to do with the autism agenda, and we have the inter-agency approach to doing that.

Separate from that, we have collaborative work going on, on vaccine safety, that includes NIH, CDC, FDA and the National Vaccine Program Office, and those are two separate but related issues, and we are fully engaged. I love to spend NIH's money. So, I have a very strong incentive to collaborate with NIH on the development and research agendas and so forth. I'm concerned, Senator, because I've been long aware of the worries about the safety of vaccine with respect to autism, but we really need to get past that, and I think one of the downsides of focusing on that association is that it's closed us off to really looking, broader, at some of the more biologically tenable hypotheses.

So, I want to reassure your daughter that she's doing the right thing for your grandchildren, but we also know that no vaccine is ever going to be 100 percent safe, and we have a responsibility to investigate safety, not just from this lane, but from the whole spectrum.

Senator HARKIN. I don't want to continue on this, we can discuss this at further hearings that we'll have, Dr. Gerberding. My point is not that these vaccines aren't safe. That's not my point. My point is, that you add them all up, and do we really know that 31 of those, given in the first 18 months—within that short span of time—each one of them may be individually fine, but do we know what the outcomes, what the impact is, say, on someone who may be genetically predisposed, to have autism. Then you hit them with 31 of these vaccines, all combated in a short period of time. What may be—how could that, perhaps, trigger that genetic predisposition? I don't know that you can answer that question.

Dr. GERBERDING. Well, I can tell you that it's not related to thimerosal. Because the childhood vaccines that your child, your children are getting do not contain thimerosal as a preservative, so——

Senator HARKIN. Except that one.

Dr. GERBERDING. If they, some of the flu shot vaccines still contain thimerosal, they're trying to take it out, but it hasn't happened——

Senator HARKIN. Yes.

Dr. GERBERDING [continuing]. Across the board, yet.

Senator HARKIN. Yes.

Dr. GERBERDING. But, it's a very small amount of thimerosal, and you know, we've been talking about, is the prevalence of au-

tism increasing in our country? It's continuing to either stay the same, or increase, even though we have removed the thimerosal as a preservative of vaccine for several years now, so——

Senator HARKIN. But I'm not talking about thimerosal. I'm just talking about the combined effects of all those vaccines on a small body that may be genetically predisposed anyway? That's what I'm talking about. I'm not talking about thimerosal.

Dr. GERBERDING. It's one of the hypotheses that, I think, needs to be evaluated in the studies that are going on. I don't think it's the most likely hypothesis, but it certainly should be included in the risk profile.

Dr. INSEL. I think the message that we'd like to convey is it's too early to reach premature closure on any of this—we simply don't know—I think all of us agree that there must be something beyond the genetics.

Senator HARKIN. There's got to be, because, Dr. Insel—and that's why I asked the question at the beginning—do we know what's happening in other countries? Now, there are other countries that have a pretty decent standard of living in which they do not give all of these vaccinations in the first year or two of life. Do we know what the incidents of autism is in those societies?

Dr. INSEL. We have good prevalence estimates for most of Western Europe and for Japan. So, we have some comparisons, and in fact, the United Kingdom is a good example where, in this case, the thimerosal came out in the early nineties——

Senator HARKIN. I'm not talking about, I'm just talking about all of those vaccines——

Dr. INSEL [continuing]. But in terms of the early child, and vaccines——

Senator HARKIN. Does every child in Great Britain get 31 vaccinations before they're 18 months?

Dr. INSEL. Julie would have a better idea of that.

Dr. GERBERDING. No, and their rate of prevalence of autism, if anything, is higher than it is here.

Senator HARKIN. Well, then I'd, that's what we'd like to look at. Other countries, too, to see what's happening. Now, that would be an interesting epidemiological study. To compare what we're doing here to other countries, and to see if there's any correlation. Now, you say they have a higher incidence in Great Britain than we have here.

Dr. GERBERDING. When we talk about the incidence or prevalence of autism, there's been an issue that hasn't come up in this hearing, and I just want to lay a marker down, so we can talk about it. In order to know how many children have this disease, we have to have access to their health records, as well as their education records. As you know, we are stymied in getting that information. So, in order to compare across countries, we have to be able to get similar information from all of the other countries that are in play here, and that's really touch—that's a tough challenge to make those direct comparisons.

Senator HARKIN. You had, earlier, a memorandum of understanding with the Department of Education.

Dr. GERBERDING. That's right.

Senator HARKIN. I understand that they stopped that because of privacy concerns.

Dr. GERBERDING. Well, smart people have looked at the law, the Family Education Responsibility Privacy Act, and the Department of Education attorneys have interpreted that law, to say that our means of having access to children's educational records is inconsistent with FERPA, that act.

We think, our responsibility is toward the HIPPA Act, the Privacy Act, and under the Privacy Act, public health utilization of data is allowed, so there's a stalemate here, and the Department of Health and the Department of Education are trying to work this out, but right now, it's really jeopardizing our ability to understand the true prevalence of autism in our children, and that's a big concern to me.

Mr. WRIGHT. We've looked at this at Autism Speaks, this is a very serious issue, because it, obviously so much work has been done at Government expense at CDC to put in the system of developing the data that the CDC is publishing, and this whole system relies upon getting information from school records. If you lose that, the system—which has taken several years to build—will collapse, and it would be a lost, you know, tons of—years will be lost.

My personal conclusion is, that having looked at this, hard, that it probably is going to take, it is going to take some congressional action to clarify this. Because it, after all, it is going to end up being the reading of legislation and when you have disagreements, you're going to have different kinds of positions, and at some point or other, I think, that's going to require a congressional, a few lines, in a few bills, to say that this is the interpretation we intended. Because this all comes from congressional legislation over prior years. It probably is absolutely necessary.

Senator HARKIN. Well, I would welcome any suggestions you have that your, or your organization has on legislative changes, legislation that we need to do to change the language so that we can get that kind of information from the Department of Education.

Mr. WRIGHT. We would be happy to help you in any way we can.

Senator HARKIN. I would apreciate that—that could be very, very helpful. Or you, or anybody else. I don't know if I could call on Federal Government people to do that, or not, I don't know if I can ask you to do that.

Well, listen, this has been a very helpful hearing. Again, I feel good that through NIH that we're doing more research.

Now, we have ramped it up, but I do want to say this. I hear every time, I hear people tell me, "Well, you know, the percentage increase has been so great here or there." I always remind people that from zero to one is infinite increase.

Now, I've got to know where you start before you tell me what the percentage increase is. I want to look at the total dollars, and what is needed and what can be used. That's why I ask, Dr. Insel, if we had this increase, could it be used, what it would be used for, and whether or not.

Now, I do believe that your answer to the questions of Senator Durbin, I think informs me that, yes, if only 20 percent of the peer-reviewed are being funded, well, that indicates that, obviously, there are more out there that can be funded, that are peer-re-

viewed, obviously. So, that we can provide that kind of, if we provide that funding for you.

But, I also thank the other panelists for being here. I, we've just got to do something about getting to these kids earlier. Darn it, we just always patch and fix and then later on it costs us a thousand times more. If we can get these kids earlier with the kinds of interventions that we know works. I mean, we've seen what's happened with families that had the wherewithal to do that and we've seen what's happened to their kids and how much better they perform. So, what's most cost effective? How do we reach out?

I am anxious to see how the Celeste Foundation will expand this and we'd like to be helpful in any way we can. But, I just, my senses tell me that this could really be very helpful to a lot of families around the country who are somewhat isolated. I'm thinking of rural areas, obviously in small towns and communities where they just don't have the ability to get that kind of intervention.

So, I'm hopeful that we can take a further look at that. I would, I would invite any from you, Dr. Favell, any suggestions that you have for how we might expand the scope of this. You suggested that in your testimony in response to a question.

Mr. Whitford, I just want to say that, that you mentioned something about celebrity status. I wrote it down here, about celebrity. You know, people pay attention to people like you and, you know, if you're one of those celebrities that are dancing with the stars, or running off to the Riviera and all that, well, people read this, they pay attention. But, if you're a celebrity and you're using your status, and the fact that you reach a lot of people and you're using that to focus people's attention on good things that they can do to help our society, to help people live better, to help us do our job here—I think that's commendable. I just want to commend you for that, for doing that, and being out in front on this issue. It helps a great deal that you would use your status to do that and I appreciate it very much.

Do we have anything else that any of you want to say for the record or, anything before I call this to a close, at all?

Dr. Insel?

Dr. INSEL. I think all of us would like to thank you for your interest in this problem. This is the first such hearing we've had on this topic and for everyone here at the panel, even for somebody who's not at the panel, but right behind us. This is a mission, and we really appreciate your interest and your willingness to support it.

Senator HARKIN. Well, I appreciate all of you, and the organizations that you started or that you've been involved in. Dr. Gerberding, I thank you for your great leadership and Dr. Insel.

Mr. Whitford, no Ms. Favell.

Dr. FAVELL. Yes.

Senator HARKIN. Dr. Favell, and all of you.

So, this, I think, this is the first hearing of this nature, but there will be more. I'm hoping that our budget, again to echo what Senator Specter said at the very beginning, I just hope that within our budget confines that we can move ahead more aggressively on this whole area of autism than we ever have before. It, it almost is like that AIDS epidemic. We've just got to get to it.

Mr. WRIGHT. Mr. Chairman, this reminds me, almost a little bit, of the early 1980s. There were two things going on. It was the AIDS issue was going on and, if you also remember at that point in time, there was this enormous outcry for cancer treatment, effective cancer treatments. People were running off to South America and Mexico and France. It was not like one or two people. It was, that they were just going down there for treatments, they were all considered to be too risky——

Senator HARKIN. Yes.

Mr. WRIGHT [continuing]. For the United States. That brought on a tremendous surge in, in cancer study. Some of it had to do with AIDS, some of it didn't. You had, Herceptin came out of all of that and you had the AIDS vaccine and the AIDS treatment. You know, it took a period of time, but it was an enormous upswing.

I get, I have a sense that this is the same, we're in the same timeframe here with the same kinds of issues.

You know, even though Dr. Insel is, I understand exactly the concerns of safety, but there are thousands of children that are undergoing that Kelation, one or more of those Kelation processes today. The parents are all told, they all know there are risks involved. They're saying, "Look at the risks I have at home. I have to make a judgment. Look at the state of my child. If this has a possibility of making him better, much better, I'm going to have to take the chance. Because I just don't, I don't believe I can't."

So, there is, there is a, it isn't going to Mexico for cancer treatment, but it is going, this Kelation activity, you know, rightly or wrongly, is a little bit like that migration that took place, you know, years and years ago.

ADDITIONAL STATEMENTS FOR THE RECORD

Senator HARKIN. Well, I hope and trust that we'll be looking at that and that NIH will be examining that. I hope this May 1 IRB will come through and it will be moving ahead on that, in that area of research.

[The statements follow:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for scheduling this hearing to discuss autism and the spectrum of disorders related to autism. Since the month of April has been designated by the Senate as "National Autism Awareness Month," it is fitting that we have a discussion on this important issue during this time. We welcome Dr. Gerberding and Dr. Insel as members of the panel today. As leaders of Federal agencies tasked with autism surveillance, research, and treatment, your insight into current programs and your vision of future efforts to combat this disorder is important. We appreciate other distinguished panel members joining us today to provide their unique perspectives of the impact of autism disorders. We look forward to your comments and your direction on how this committee can be helpful in addressing your concerns as we move through the appropriations process.

Autism Spectrum Disorders are developmental disorders which affect a child's social interaction, behavior, and basic ability to communicate with others. The prevalence of autism-related disorders continues to increase, with recent Centers for Disease Control and Prevention reports estimating that 1 in 150 children in our country is affected, referring to this increase as a national public health crisis. Despite the increased attention to autism in recent years, the cause remains unknown and a cure is not available.

Congress has been responsive to this heightened public awareness and focus on autism from the medical community. The Combating Autism Act of 2006, which I cosponsored in the last Congress, was signed into law in December. This comprehen-

sive legislation authorizes approximately $800 million over the next 5 years for research, early detection and intervention of autism. For the upcoming fiscal year, the President's budget contains no new funding for the Combating Autism Act and recommends level funding, approximately $115 million, for existing autism programs at the CDC and the NIH. Autism advocates have requested an increase in this funding to $168 million to expand autism efforts.

I look forward to your comments on the status of the current programs and on how an increase in autism funding would be used.

PREPARED STATEMENT OF ALLISON CHAPMAN

To Whom It May Concern: I am a parent of a child who regressed into Autism after his vaccinations. I have several areas I would like addressed at these hearings and I hope that an A–CHAMP representative will be there to represent my son and the hundreds of thousands of others with the same story. The following are a list of my questions,

—Will there be money for double blind studies using the DAN! (defeat autism now) protocal?

—Is there an understanding that Autism is a Whole Body Illness which can be treated?

—Will there be a vaccinated vs. non-vaccinated study?

—Will there be monies for studies on the dangers and implications of thimerosal (49.6 percent ethyl mercury) like the Burbaker study?

—Will there be an extension to these genetic studies to find out if it is Mercury (a known mutagen) that is causing deletions and mutations in the DNA?

—WILL THERE BE BIOLOGICAL TESTS TO FIND OUT WHAT'S GOING ON IN THESE KIDS BODIES THAT MIGHT BE CAUSING THE BRAIN DIFFERENCES?

—Will there be monies to teach Drs and pediatricians that Autism can have many medical issues that need treatment and to refer them to professionals who understand this like DAN!s, Toxicologists, GIs, etc.

—Will you separate vaccine safety into a separate, independent organization other than the CDC which is the org that mandates them (A tremendous conflict of interest)?

I my mind there are 4 areas of Autism that need attention. Diagnosis, Educational intervention, whole body medical treatments that are already helping these children and research broken into BOTH environmental and genetic pieces. I've seen much in the areas of diagnosis, education, and genetics but by concentrating on those only leaves the biggest areas untouched. This is about the children and making them better or else the windfall of financial assistance it will take to support these kids who don't get treatment for the rest of their life, will most likely bankrupt this country. Thank you so much for your time. I truly do look forward to what happens in this Senate hearing, I am hoping you side with the children no matter what.

PREPARED STATEMENT OF ANNA W. WOLK

I am the very proud mother of a young man diagnosed with PDD/NOS-high functioning Autism at the age of 3. Adam is now 14—nearly 15—and as puberty has set in, so have many new behaviors. He has become frustrated with an inability to express his anxiety over the many changes occurring within his body, and as a result has become aggressive with us, his parents. What has become increasingly clear to me as we travel our journey that is autism is three things:

(1) We all (as parents of any child) have the same destination in mind—we are simply traveling different routes to get there,

(2) There are many books and tons of advice for the parents and families of newly diagnosed children, but nothing of substance for those of us who have made it to the teen years,

(3) The State of Illinois is not servicing our children as well as the rest of the Nation. Why is it that, when my son turns 20 years 364 days old, he is cut loose from the system. Is it the State of Illinois' opinion that, on my son's 21st birthday he is magically cured? If only it were true!

It is a disgrace that we are ranked 48th out of the 50 States in services for our Special Needs children and their families—and we must include the families, as Autism affects the entire family unit.

Luckily, my husband and I have not become one of the many couple who have divorced due to the pressures of raising a child with autism, but I can tell you the

toll—both emotional as well as financial—is a huge burden. And the effect on the siblings is enormous as well, as they don't get ot have a normal childhood either. Simple things like birthday parties, sleep overs or even extra-curricular sports require enormous analyzing before undertaking them. Many times, the siblings just have to forego many of the usual rites of childhood because of their siblings needs.

When it is time to plan for the disabled child's future, there is no central "clearinghouse" of information regarding residential settings, day programs, vocational training, etc. It's purely luck of the draw and word of mouth. Many times, it comes down to who you know.

Well, I don't know anyone. I don't have any idea where to begin this new phase of my son's life, and there' s no direction from the school system. I feel lost to my son, and I feel lost as to how to help him.

ANYTHING you can do to help centralize information for parent's and families would be an enormous help.

Current statistics reveal that 1 in every 150 children is diagnosed with Autism—one of them is my son.

Help create a miracle—support Autism Research and Awareness.

Thank you for your time.

PREPARED STATEMENT OF THE NATIONAL AUTISM ASSOCIATION

On behalf of the Board of Directors and membership of the National Autism Association and SafeMinds, we thank Senator Harkin and all the committee members for holding these hearings to ensure funding the Combating Autism Act. Once fully funded, this landmark legislation will help answer questions of vital concern to the autism community: what causes this disorder, now at epidemic levels, affecting 1 in 150 children, and how can it be most effectively treated and prevented.

Several dozen recently published peer-reviewed scientific papers point to environmental triggers, including vaccines and their components, as a cause of autism. Most recently, a study by the Autism Genome Consortium Project of 1,500 families with multiple affected children failed to identify an autism gene and failed to replicate most highly touted finding from recent genome scans. The negative AGPC findings provide strong evidence that heritability claims are exaggerated, if not false. Provided with massive resource support and under the most favorable study conditions, the AGPC found no evidence of heritability. These powerful findings suggest that the search for the actual cause of autism must focus on the environment to which the mother, fetus, and infant are exposed.

In the report language accompanying the CAA, Congressman Joe Barton stated, ". . . the legislation rightfully calls for renewed efforts to study all possible causes of autism—including vaccines and other environmental causes." Representative Barton also said, ". . . these provisions will insure continuation and intensification of crucial research at NIEHS so that it is able to conduct all necessary research to determine the environmental factors in autism."

Senator Chris Dodd stated in the Senate colloquy, "In our search for the cause of this growing developmental disability, we should close no doors on promising avenues of research. Through the Combating Autism Act, all biomedical research opportunities on ASD can be pursued, and they include environmental research examining potential links between vaccines, vaccine components and ASD."

With acknowledgement from our Federal Government that environmental factors such as mercury from vaccines may play a role in the development of autism, and a clear directive that this will be investigated by the National Institutes of Environmental Health Sciences (NIEHS), the National Institute of Mental Health, and other Institutes, we must now ensure that this area receives the necessary funding to establish a solid program of goal-driven research.

Rather than merely counting the children diagnosed with autism, we now have government confirmation that autism is a national health emergency that must be addressed with all deliberate speed. The government can move quickly and decisively when it wants to. Recent examples include the coordinated responses to E. Coli outbreaks in spinach, SARS, and threats from bird flu and mad cow.

Autistic children deserve and must have this same level of commitment and response. Imagine how quickly the government, indeed every institution of society, would react if 1 in 150 children were suddenly kidnapped. This is the stark reality faced every day by families with autistic children. Autism imposes massive costs to families and society, totaling $3.2 million in lifetime care per individual, according to a recent study from Harvard University.

Epidemiology studies performed by the CDC must now test a clear environmental hypothesis rather than simply count affected children. Also, since it is scientifically

impossible to have a genetic epidemic, the funds spent on finding an "autism gene" should more appropriately be devoted to finding the environmental triggers. NIEHS must play a leading role as such research is within its area of specialization, while NIMH and other Institutes are best equipped to fund research within their areas of expertise.

Placing the major focus of government research on the environmental factors triggering autism and on biomedical treatments reaffirms the National Autism Association's long-standing position that there is hope for all families affected by autism. An environmentally triggered disorder is both treatable and preventable; therefore, there is hope—hope both for families that already suffer with autism and hope that this disorder can quickly be relegated from an epidemic to the annals of history.

To that end, we urge this committee to fully appropriate the Combating Autism Act. In the area of environmental research including vaccines and their components, we ask the committee to include a line item amount of $45 million over 5 years, as was authorized in the Senate-passed version of the bill. These funds should be specifically designated to the NIEHS so that this under-funded area of research can finally receive the attention it deserves. Hundreds of thousands of children suffering with autism spectrum disorders, that we now know is caused by one or more environmental factors, are depending on the wisdom of this committee to fully fund this critical research directive.

PREPARED STATEMENT OF ROBERT J. KRAKOW, ESQ. PRESIDENT, A–CHAMP

My name is Robert J. Krakow. Thank you for this opportunity to submit written testimony regarding the epidemic of autism and neurodevelopmental disorders that exists among our children. The autism epidemic is the most urgent public health issue facing our Nation.

This testimony is submitted on behalf of A–CHAMP, a political action organization that is comprised of thousands of parents nationwide. We have supporters in every state and District Leaders in more than 200 Congressional Districts. Most of our members have evidence showing that their children, labeled with autism, are vaccine injured, heavy metal toxic, with proof that their children are mercury-toxic. Notwithstanding this focus we advocate for all children with autism, irrespective of the possible causes of their disorders. We are a 100 percent volunteer organization that is organized on a grassroots and "netroots" basis. We are all parents or grandparents trying to improve the welfare of our children.

We appreciate the opportunity to submit written testimony and to have an A–CHAMP representative make a statement in person before the committee. As you know, we learned of this hearing only two business days prior to the hearing. We have had many members of A–CHAMP contacting their Senators and the committee to impress upon you our right and desire as stakeholders on this issue to voice our concerns about the autism epidemic and about our children. As a preliminary matter we wish to express our concern that only one organization appears to have participated in the planning of this hearing and to have been invited to testify before the committee, other than representatives of the Centers for Disease Control and the National Institute of Mental Health. We do recognize that once you heard our concerns about this hearing the subcommittee was responsive to our concerns and offered the opportunity to submit our concerns in writing.

It was A–CHAMP that alerted the larger autism community about this hearing and urged other organizations that are concerned with autism to attend, participate and submit testimony. This reflects a core principle of A–CHAMP that our government must recognize that there are many stakeholders that have claim to a voice on the issues affecting children with autism and that, notwithstanding the claims of one organization, it is not the case that a particular organization speaks for all of us. I think you have learned from our telephone calls and other communications over the last several days that no one but A–CHAMP speaks for us or our children.

I also wish to emphasize that our organization represents many constituents of the honorable members of this subcommittee. I have conferred with residents of Iowa, the home of this committee's Honorable Chairman, Tom Harkin, and they have authorized me specifically to state that this submitted statement reflects their views and concerns. These individuals include among others Dana Halvorson, Lin Wessels, John Olsen, Ruby Olsen, Meg Oberreuter, Barb Romkema and many others. Similarly, in Pennslyvania, home of the ranking minority member of this committee, Senator Arlen Specter, Holly Bortfeld, and Colleen Strom, among many others have authorized us specifically to represent their views to the committee. This is but a tiny portion of the parents we represent in every State of the Union.

The issue of which persons or what organization is the authentic voice of our children is one that is not easily answered, despite the claims that you may hear. We appreciate the responsiveness of this committee to our concerns in this regard.

I am the father of a 7 year-old boy named Alexander who became sick in 2001 at the age of 2 years old, after receiving flu shots that were recommended by the Centers for Disease Control. An immunologist and pediatrician first diagnosed him with heavy metal toxicity, immune dysfunction, colitis, hypotonia, endocrine dysfunction, multiple additional autoimmune symptoms and a list of other physiological disorders too long to state here. My wife and I were told to immediately see a neurologist. We later brought our son to a world-renowned neurologist who observed a child who was very ill, in great pain but who had nothing to offer but the label of autism.

My son is unable to speak but is an extremely intelligent and loving child who is very related to his parents and sister. My daughter is 13 years old and is in Middle School and loves her brother dearly.

I am an attorney. I spent the first decade of my career as a prosecutor in Manhattan serving for 5 years as a Bureau Chief with the Office of the Special Narcotics Prosecutor for the City of New York. I have been engaged in the private practice of law for 18 years.

I became involved in working for individuals with developmental disabilities before my son became ill. I have served as chairman of the board of Lifespire, Inc. for 5 years. As you will read in separately submitted testimony, Lifespire is a large 55 year-old not-for profit with 1,500 employees that serves 6,000 developmentally disabled persons every day—in group homes, day centers, supported work, medical clinics, after-school programs, transition counseling and many other areas. Lifespire, formerly Association for Children with Retarded Development ("ACRMD") has always served individuals with autism. In the last 5 years we have devoted a great deal of time and resources to developing programs for children and adults with autism. Lifespire was founded by parents and its Board consists today primarily of parents or relatives of individuals with developmental disabilities. We are a homegrown, local, community-based organization, even if we have grown large over the years. The reason we grown large is because we and others have advocated long and hard over the past half-century to improve services for the developmentally disabled. In our State of New York the response has been good in some areas. In other parts of the nation the response has been uneven. Lifespire's concern is not research or etiology. Our concern is client-centered individually tailored community-based services and supports.

Now we need to confront a new emerging challenge—a very real increase in the numbers of individuals, mostly children aged 4–17 who are diagnosed with autism.

At Lifespire we knew very well in 2002 that there was an unacceptably high number of cases of autism among children, that rates of autism were 1 in 150 or higher and that there existed then, in 2002, a looming crisis for our State. We also knew that the prevalence of autism was something new, because for 50 years we were in the business of serving individuals with disabilities. While autism was always present in some of the population who we serve, it was not nearly as prevalent among our adult population as what we were observing among children.

In 2002 we knew that we needed to act immediately to address the crisis in services that would result as the leading edge of children with autism—the cohort of increased prevalence born around the year 1990—moved forward in age. Sadly, little has been done in the last 5 years by government to address these concerns.

Lifespire provides services and does it well for a long time. The tradition of Lifespire was born in a crucible of parent activism that became necessary because the schools and government were not responding the needs of families. 50 years ago parents joined together to provide for their children, by pressuring government to do what was necessary. 30 years ago ACRMD /Lifespire parents blew whistles outside legislators' windows to call attention to problems with our care for those who area least able to care for and speak for themselves—then they were whistleblowing about infamous Willowbrook and the institutional abuse of disabled children.

As I stated, Lifespire's CEO will be submitting testimony separately.

Sadly, today, things are better but children and adults with developmental disabilities still suffer abuse and often do not get the care that they need.

It is evident from the overwhelming response to this hearing today that parents are once again active. Two years ago, along with some dedicated parents we founded a national political advocacy group called A–CHAMP, and I am honored to serve as its President. We have 10,000 supporters and we are growing. Our volunteer parent-advocates throughout the country have already persuaded legislators in many States to enact provisions to make vaccines safer, thus protecting children, and to make insurance coverage fairer for individuals with autism.

I have a message for you as legislators. Parents are mobilized. We do not need nor do we use professional lobbyists. We find our children's interests are best served by direct parent-citizen communication with legislators. We find that professional lobbyists who may be employed by some large organizations do not necessarily understand what our children need. Parents understand what our children need and we are sufficiently sophisticated, motivated and organized to make sure that our children's voices are heard loud and clear, so that our children's needs may be heard, even though many cannot speak.

We urge you to get it right on this—get it right on the autism issue. The parents know what's right and they will be heard.

I call for what we describe as "A Culture of Advocacy for a Lifetime of Care." Around the State and the country parents are learning to advocate for their children. This echoes the story of Lifespire. My uncle and cofounder of Lifespire was a postal worker who, 60 years ago, had a child with special needs. He was also a labor organizer. In those days there was nothing for children like my cousin, Eugene. He and a few other parents created an organization and changed the laws of New York State by direct parent advocacy, not through professional lobbying. His campaign was called "A Children's Mandate." My uncle is gone now for some 10 years but his son has a home and an extended family to watch over him at Lifespire—for LIFE. My uncle gave him the greatest legacy—a lifetime of care by people who care. His mandate for his son and many other children was realized.

Nothing will stop the advocacy of a parent who fights for his or her child. At A–CHAMP we have worked hard to empower parents around the country by instilling them with the will and desire to advocate for their children so that they will be taken care of with love and generosity. When a parent fights for his own child he or she fights for every child.

I say to you as legislators that this is the problem confronting you—how to use limited resources to create a lifetime of care for our children. Parents expect a lot from our government—you—and our children deserve it. These hundreds of thousands of children will be the responsibility of our government. We need to come to grips with the problem and we need to do that NOW.

We are years too late and we are playing catch-up—we are playing with the lives of children.

I would like to address a few specific areas that are of great concern to me and many parents that address the subject of today's hearing.

COMMUNITY CONTROL OF SERVICES AND RESOURCES

We have developed detailed information on the daunting costs of caring for an individual with autism through his or her lifetime. We know that for a an autistic adult the cost of care from age 23 through 66 will be approximately $17 million for an individual who is severely disabled and at least $10 million for an individual who is less severely disabled. These numbers are based on actual experience and are explained in testimony given by Mark Van Voorst, CEO of Lifespire at a March 8, 2007 hearing conducted by the New York legislature. I have attached a copy of Mr. Van Voorst's testimony. Given the Centers for Disease Control's recent estimate that there are exist 560,000 children under age 21 with autism, and probably many more given the reports of 1 in 94 children in New Jersey having some form of autistic spectrum disorder the costs of caring for our children will be staggering. We know from hard and concrete experience that the costs will be in the trillions.

We are already many years late in addressing the demands that this crisis will make on our resources. We will need innovative ideas in housing, in creating bridges to our communities for our developmentally disabled adults, and in providing therapeutic and loving environments for our children. Most importantly, we must create an environment in which parents will feel confident that as they grow old their children will be provided and cared for—"A culture of advocacy for a lifetime of care."

What does this mean? It means that when we develop a "coordinated response" to addressing the autism epidemic we must understand that we are dealing with individuals and not numbers. This means that we must direct our resources to solutions that are community-based. We see in legislation pending before this committee and laws already enacted that one approach to the autism epidemic is to create large centralized institutions that will address needs on a mass scale. While a massive response to the autism epidemic is required that response must not be overly centralized and it cannot favor one or a few gatekeeper organizations that aim to control the autism industry. We must invest in local and regional institutions so that we may build a community of care. We must involve parents in homegrown organizations because only then will our precious children receive the care and con-

cern that they deserve. I fear that the solutions to services and support issues that have been promoted before Congress, including the Combating Autism Act, do not reflect these values. I have observed that moneyed power organizations driven by a corporate model have gained access to Congress by professional lobbyists and have begun to dominate the public forum on autism. For the sake of our children this trend must stop.

I have spoken with many parents around the county, including those in Iowa and Pennsylvania, among many others. They have told me that what works for their children are integrated community-based programs that address their needs and provide supports where they live. This builds community and provides service. They require a combination of behavioral approaches applied locally in community centers or at home by qualified therapists, in combination with approaches that address the fundamental physiological disorders that have cause our children to become ill. I will address the issue of using effective non-pharmaceutical biomedical interventions for our children later in this statement, but the important point here is to provide services and supports through community-based parent-driven regional and local organizations. Our experience is that these organizations are usually most effective if they are structured on a not-for-profit rather than a for-profit basis. Profit making ventures certainly may have a role in providing services but they should not be the gatekeepers or primary caregivers of our children.

I would like to address another point that has arisen in the context of this hearing. One witness invited to this hearing will address a strict behavioral approach to therapy for children with autism that focuses on delivery of service by interactive video—a method dubbed "telehealth" that involves, in part, installing a video camera in one's home and engaging in therapeutic sessions by video. It appears that the Department of Education and the NIMH have devoted substantial funds to research in this area. I have studied this area over the last few days and consulted with many parents about it. The universal response to this approach to service delivery is surprise and rejection. Children with autism are often characterized by their inability to develop proper socialization. They cannot speak—they need social reinforcement. It is incongruous to think that therapists in remote locations who essentially "phone it in" can address these problems and others.

We urge you to invest in our communities and not some technological fix that can lay claim to addressing children with needs when in reality it presents a method of providing services on the cheap. While I welcome learning more about telehealth I have serious concerns about this approach toward providing therapy for our dear children.

RESEARCH

Autism is not genetic. A recent genetic research study that cost more than $10 million found almost no clear indication of a genetic association with autism. At most, the researchers found genes that might create susceptibility to environmental toxins, but their great breakthrough was finding a gene association in 1 out of 1,168 families. The researchers will dispute what I have said here, but quietly other researchers will tell you I am correct. There is no "autism gene." We can produce well-respected researchers to support our position.

Epidemics cannot be genetic because gene mutations occur very slowly. The unavoidable evidence points to an environmental factor or trigger that has caused the upsurge in the numbers of cases of autism. Yet, little government or private research money is devoted to the study of environmental factors.

For reasons that are not valid, research in autism has been disproportionately devoted to genetic research. Notwithstanding the bias by private organizations and government to fund genetic research a great deal of peer-reviewed replicated research has shown that autism is a physiological disorder. The emerging research research strongly implicates environmental toxins and toxins from vaccines, including mercury, in creating impairment leading to physiological disease.

We must have honest research that inquires into every area of autism etiology regardless of who may find the results of such research inconvenient.

Parents supporting A–CHAMP almost universally believe that vaccines have injured their children, either alone or in combination with other external toxins to which their children have been exposed. We have also found that treatment focused on addressing these problems have worked to improve the health of many children and even recovered some children fully from autism. Our children's physiological disorders are not comorbid or unrelated to their autism. Their physiological disorders collectively are what autism is—and result in the observable behavioral symptoms that we define as autism. We need research into these treatments—re-

search that has shamefully been ignored or set aside because it is too controversial. Backing off from controversy will not help our children.

Some valiant practitioners from the Autism Research Institute, DAN!, Thoughtful House in Texas and others have developed effective treatments and undertaken vital research that is directly helping our children today. Why is this research ignored or actively suppressed by our government agencies? How can "evidence-based" treatments such as these be validated if there exists no funding for the supporting research? The answer, of course, is that it cannot be validated. A highly manipulated scenario has developed that has resulted in a self-fulfilling prophecy: condemn treatments as "anecdotal" and not sufficiently evidence-based while simultaneously blocking funds necessary for research that will validate the same treatments. We regard this process as a cruel and unacceptable joke that has deprived our children of the chance for recovery. The scenario is not acceptable and our parents will work tirelessly to change it.

Recently, we were pleased to learn that the NIMH had initiated a chelation study. Without going into detail we were concerned about the study protocol used for this study because we knew that the protocol did not reflect the methods many of us have used successfully in chelating our children, safely and effectively. We have also heard rumors that this study has been suspended. We urge the committee to investigate why research like the chelation study is not proceeding and further, make sure that practitioners who have used chelation successfully are consulted in constructing meaningful research protocols.

There are some questions raised by some about whether there is a true increase in the incidence of autism among our children. We have observed some so-called experts in the field revise past estimates of prevalence of 1 in 2,000 children affected in the 1980's as being incorrect because current research shows a rate of 1 in 150 or higher. We hear claims that current methods result in better counting and that autism at current rates have always been with us but that individuals with autism were "hiding in plain sight." We reject such claims as the product of an agenda promoted by those who need to deny the existence of an epidemic to protect the vaccine program or avoid potential liability for vaccine related injuries.

So that we may know with certainty how many children and adults are affected we need epidemiological studies conducted by independent researchers outside the CDC or the government. We also need a study comparing individuals who are vaccinated versus those who are unvaccinated to determine which group has more disease. Legislation calling for such as study was introduced last session and will be introduced again. We support it.

Finally, the CDC has placed barriers to access to by independent researchers to the Vaccine Safety Datalink ("VSD"). This database can help answer questions about the cause or causes of the autism epidemic. The Institute of Medicine has severely criticized the CDC's handling of the VSD. A panel of public and private experts has found that productive research can be conducted using the VSD to answer the question of whether vaccines or their components cause autism, a question not yet fully answered using the VSD. Yet to shield the VSD from outside researchers the CDC has paid a private company millions of dollars to house the data—data developed by the investment of millions of dollars of taxpayer funds. We respectfully request the Senate to conduct an investigation of this issue.

An addendum is attached to this statement that contains a non-exhaustive list of areas of research that we believe have been ignored and require attention.

TREATMENT

There is great controversy over treatment for autism, as discussed earlier in a different context. While Applied Behavioral Analysis ("ABA") has helped some children it is not the panacea that some originally thought it would be. Yet, at every turn the only treatment option offered by medical professionals and schools is ABA. The use in legislation of the words "evidence-based" to validate treatments will surely result in the only approved treatment covered by insurance to be ABA.

I can tell you that my son has made tremendous progress not because of some strict regimen of ABA—the technique has been used to some extent with him—but through the use of various non-pharmaceutical biomedical interventions. My son's so-called "tantrums" were the result of one thing: severe gastrointestinal inflammation. He was in pain.

Once this was treated my son was able to become the happy—very related to his family—child he was meant to be. It is a myth that children with autism are all in their own world and cannot relate to others. It is also a myth that little can be done to improve their condition and welfare. Much can be done; we have done it. I know other parents are submitting to the subcommittee information about bio-

medical intervention that can effectively treat autism—a physiological, neurobiological disorder. I have met many children who have completely recovered by children through non-pharmaceutical biomedical intervention. Yet, few research dollars are devoted to this area. Those who criticize biomedical interventions in autism decry the lack of "peer-reviewed" research supporting "evidence-based" research. This criticism is a self-fulfilling prophecy made by those who block the very research that could support diets such as the specific carbohydrate diet, supplements such as methyl B12, hyperbaric oxygen therapy, safe methods of chelation therapy and many more.

At the same time pharmaceutical treatments such as Prozac, Ritalin, Concerta, Adderall, Zyprexa, Seroquel, Geodon and others are used even though they are untested and unapproved for children, and have serious side effects. While Risperdal has been approved for treatment of irritability in autism it gained approval only through the expenditure of large sums of research dollars, and it is most definitely not a treatment for autism. It too has serious side effects that its manufacturer failed to disclose until the manufacturers were pressured to do so.

While there may be place for pharmaceuticals in some cases focus on these non-treatments have sucked the life out of any effort to produce research that will satisfy those who seek peer-reviewed research. Notwithstanding this, the research has been produced, often privately. More needs to be done.

INTERAGENCY AUTISM COORDINATING COMMITTEE ("IACC")

The Combating Autism Act did expand the Interagency Autism Coordinating Committee. But the IACC was not given sufficient authority to conduct oversight over the NIH research agenda. In addition, for too long the community participants in the IACC have been limited to the same individuals from the same organizations. The IACC has been ineffective. The key to making government responsive to the autism crisis is to listen to the parents. They know what their children need. Give parents a central role in fashioning government's response to the autism crisis. Broaden the participation in the IACC to voices outside the ones that bureaucrats may find safe. The IACC and other government/private committees should not be window-dressing that allows government to make empty claims that the community participated in their decision-making on policy. Community and stakeholder participation must be genuine so that members of our community can say that their voices are being heard. Many in our community believe that they are excluded from the process and that the IACC and other committees are not functioning, as they should in a democratic society.

Returning to the theme that introduced by testimony I want to emphasize that our government must give all parents, not just those from one or two self-selected groups, a central role in solving the autism epidemic. If government fails in this area the consequence will be a public health, political and social problem even greater than the one we face today. A–CHAMP's slogan is "We Are Everywhere, and We're Not Going Away." We are watching our government's response to the autism epidemic with great attention because our responsibility to our children's welfare and future mandates such scrutiny.

Parents are mobilized, engaged, empowered. We are sophisticated and smart. We are also beleaguered and our resources are strained to the breaking point. We urgently need help now for our kids. We are ready for government to become our partners in addressing the autism crisis—but that means true partners in our communities, not public-private partnerships with special interest group organizations.

On behalf of all the supporters of A–CHAMP I thank you for convening this hearing today to listen to our concerns. We appreciate the opportunity to be heard. Given that this testimony was prepared on extremely short notice I will be happy to answer any questions from the Committee to clarify or amplify the points I have made in this statement.

ADDENDUM

SUGGESTIONS FOR SOME AREAS OF RESEARCH ON AUTISM

With respect to research we recommend the inclusion of the following areas into a research agenda on autism and environmental factors:

—Research related to treatment of autism as a "treatable" or "reversible" condition. Specifically, the focus must be placed on autism as a chronic impairment, resulting from oxidative stress. For example, there exists evidence showing that autism is characterized by the presence of "sick" neurons rather than "dead" ones or even impaired development processes (e.g., GABAergic neuron migration). This type of research highlights the inherent reversibility of the disorder

and must be pursued with urgency in order to develop and validate treatment of the disorder.

—Research on large cohorts of children to determine their status based on testing for urinary porphyrins, urinary toxic metals, urinary amino acids, organic acid tests, immune panels, cytokine testing, chemokine testing, etc.

—Research of the use in treatment of autism of anti-inflammatory medications such as Actos, Celebrex or Singulaire in quelling inflammation in the gut and brain and in reducing levels or pro-inflammatory cytokines and chemokines;

—Genetic research should be focused on single nucleotide polymorphisms and their relationship to metabolic and other mechanisms that create vulnerability to environmental toxins (including vaccines) rather than the latest genetic research focusing on genetic anomalies or CNV's that have not been tied to a biological mechanism affecting more than a tiny number of children;

—Research evaluating the mitochondrial status of children diagnosed with autism. Mitochondrial impairment plays such a strong role in MS;

—Full investigation of the role of heavy metals, including mercury, aluminum, lead and arsenic, from any source, in any form (including thimerosal), specifically including vaccine exposures in the etiology of autism;

—Complete access to the Vaccine Safety Datalink data by independent researchers outside the government;

—A recognition in developing a research agenda that vaccine sourced exposures may be a contributing factor in many cases of autism alone or in conjunction with other environmental exposures;

—Funding of research of the biological mechanisms that may contribute to autism;

—Full investigation of the role of viruses, bacteria and other infectious agents independently or in conjunction with other environmental exposures in the etiology of autism;

—Research of environmental factors, including the MMR vaccine, as they relate to gastrointestinal symptoms and histopathological findings" and treatment of these underlying bowel problems;

—Investigation of the effect of various metals, viruses, toxins with each other and other environmental agents—also known as synergistic toxicity—in the etiology of autism;

—Research of the role urinary porphyrin profile analysis can play in measuring heavy metal toxicity;

—Research of the role of mercury and other toxicants in ambient air pollution, including toxicants emitted from coal burning power plants, in the etiology of autism;

—A thorough analysis of the role of thimerosal, heavy metals, and other toxins play as mutagens and how this mutagenicity may play a role in autism;

—The role of the hypothalamus-pituitary-adrenal axis in the etiology and trealuient of autism.

PREPARED STATEMENT OF MARK VAN VOORST, CEO/PRESIDENT OF LIFESPIRE

Good morning/good afternoon. My name is Mark van Voorst. I am not a physician, scientist, geneticist, statistician, nor even a practicing clinician so my comments will not address the issue of the rise in the numbers of individuals diagnosed with autism, nor will I attempt to offer any insights regarding the cause of this phenomenon.

However, for the past 29 years I have worked as an administrator in organizations that provide an array of services to individuals diagnosed with Mental Retardation or other forms of Developmental Disability. I am presently the CEO of a large not-for-profit organization in New York City which provides services to roughly 5,000 individuals per day and my comments are intended to enlighten the Committees on the enormous challenges that every New York State voluntary agency will face in the coming years as we struggle to ensure that all children and adults who are diagnosed with an Autism Spectrum Disorder receive the supports and services they will need.

In February 2007, the Center for Disease Control and Prevention released a new finding that concluded that the rate of autism in the United States is now 1 per 150 births. The National Census for 2004 shows that there were 4,115,590 births in 2004. Using CDCs figures, this means that of all of the children born in 2004, roughly 27,437 will be diagnosed with some level of autism. Current national estimates suggest that there are already between 560,000 and 800,000 individuals who are diagnosed with some level of autism.

In 2003 the New York State Office of Mental Retardation and Developmental Disabilities estimated that there were 52,991 individuals with autism.

In 2004 the National Census figures for New York indicated that there were 250,894 births. Using the newly released CDC figures, this means that roughly 1,673 of all new births in 2004 will at some point be diagnosed with autism. Current literature suggests that roughly 50 percent (45 percent—60 percent) of these 1,673 individuals will also be diagnosed with an IQ of 70 or less, which means that in addition to being autistic, they will carry a diagnosis of Mental Retardation. It is safe to say that of the 1,673 children born in 2004 who will be diagnosed with autism, approximately 837 will require some level of support and assistance throughout their entire lives.

As I am not an educator, I do not know the cost of providing supports and services to these individuals from birth to 21. However, I can give you some idea of what it will cost to provide support and services to these individuals once they become adults. The figures I am presenting are based on real, current annual costs for providing day and residential services at Lifespire Inc.

Individual with a high level of need

Day Services—$44,174
Residential Services—$154,764
Combined Annual Costs—$198,983

Individual with a lower level of need

Day Services—$26,686
Residential Services—$109,489
Combined Annual Costs—$136,175

If we now project these figures over the lifetime of an individual who needs ongoing supports and services (between the ages of 23 and 66 = 43 years) and build in an annual increase of costs of 3 percent the total costs rise dramatically.

Individual with a high level of need between 23–66

Day Services—$3,933,615
Residential Services-$13,790,753
Cost over 43 Years—$17,724,368

Individual with a lower level of need between 23–66

Day Services—$2,376,328
Residential Services—$9,756,402
Cost over 43 Years—$12,132,730

Looking only at the 837 children born in 2004 who may well need lifelong supports and services, it will cost between $10,155,095,010 (low side) and $14,835,296,016 (high side) to provide services once they leave the school system.

In 2003 the Office of Mental Retardation and Developmental Disabilities estimates that there are 52,911 individuals with autism currently in New York. Until we have an actual breakdown of the ages of these individuals we have no way of knowing how many are currently being served and how many are about to enter the adult service world. However, I think it is fair to say that the need for increased funding will be staggering.

CRISIS NUMBER TWO: WHO WILL PROVIDE THE SUPPORTS AND SERVICES?

In January 2006 the U.S. Department of Health and Human Services released a report entitled "The Supply of Direct Support Professionals" (DSP). HSS estimated that, in 2003, approximately 874,000 individuals worked full time providing care for roughly 4.3 million Americans of all ages. Most importantly the report noted "DSPs are essential to the quality of life, health and safety of more than one million Americans who are in need of long term services and supports".

By 2020 the demand for DSPs will grow to 1.2 million. This represents an increase of 37 percent. However, during this same time period the available pool of labor will increase by only 7 percent.

HHS also estimates that on a national level there is a 10–11 percent vacancy rate in all Direct Support Professional positions. The situation is so severe that many existing service providers are refusing to expand services to meet the growing demand because they cannot recruit and retain the work force necessary to do so. Additionally, the turnover rate of DSPs is estimated to be 50 percent nationally.

While perhaps not as severe as the "national problem", Lifespire Inc. is experiencing both crises identified in the 2006 HHS report. At any given time we have between 80–100 positions that are not filled and our turnover rate for those individuals providing direct support to our consumers in 2006 was 39 percent. While I have

not seen any figures for all of New York State, I suspect that my experience at Lifespire is shared by most, if not all not-for-profit organizations in the State.

The legislature and OMRDD have done a wonderful job providing resources that enable organizations like Lifespire to serve New Yorkers with developmental disabilities. Unfortunately, the funds allocated by the legislature are still not enough to allow us to attract and retain a skilled work force. Unless we are in a position to both attract new staff while at the same time are given the dollars to retain our existing staff, the wave of individuals diagnosed with autism which will begin to spill over into the supports and services within the "adult world" will simply overwhelm the provider system and will have disastrous consequences for an entire generation of children and their families.

During one of his campaign speeches, Governor Spitzer stated that it was important that we "take care of those who cannot take care of themselves", and that "everyone who has special needs will get the care they need for as long as they need it".

Mr. Chairman, I believe that we have a moral obligation to ensure that all New Yorkers who have been or will be diagnosed with autism have access to a service system that is both sufficient in size and sufficiently well trained to provide the services and supports that they will need. While I certainly hope that there is funding for ongoing research to determine a cause for autism, I also implore the Committees to take this message back to the full Senate and Assembly so that increased dollars flow to the voluntary provider community or to parents so that they can directly purchase the services they feel their children need. If we do not do something soon the provider community will simply not be equipped to deal with the numbers of individuals diagnosed with autism who will need adult services.

ADDITIONAL COMMITTEE QUESTIONS

SENATOR HARKIN. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITED BY SENATOR DANIEL K. INOUYE

AUTISM SPECTRUM DISORDER

Question. I would like to thank the Centers for Disease Control and Prevention (CDC) for their attention to accurate reporting of autism spectrum disorders by each State. The startling rise in the prevalence of autism spectrum disorders presents many challenges to society. The uniqueness of Hawaii raises even further challenges when one considers the remoteness and relative lack of resources available to support individuals affected by autism spectrum disorders. How can the Centers for Disease Control and Prevention (CDC) work with States such as Hawaii with rural areas and other unique needs to contribute to a better understanding of autism spectrum disorders?

Answer. Early identification and intervention hold the most promise for children and families affected by autism spectrum disorders (ASD) and other developmental disabilities. CDC is working with partners on a campaign reaching parents, health professionals, and childcare providers with information on developmental milestones and the early signs of autism. The campaign—*Learn the Signs. Act Early.*—is helping to change perceptions about the importance of identifying developmental concerns early.

Recent ASD surveillance data show concerns had been raised for more than half of the children with autism or related disorders prior to their third birthday, yet children were not diagnosed until well into their fourth or fifth years. Encouraging early intervention will help children reach their full potential during the critical window of early development.

Since the launch of the campaign in October 2004, information about Learn the Signs. Act Early. has been made available to more than 11 million health care professionals, parents, partners, campaign champions, and child care providers. CDC and its partners have distributed more than 83,000 resource kits targeting the three major audiences.

CDC continues to work with campaign partners on new ways to reach parents, child care professionals, and health care providers with the most up to date information about developmental disabilities—including ASD. Also, CDC has been working

with partners to reach underserved populations—including minorities and both urban and rural/remote populations. For example, campaign staff recently worked with the Autism Society of America (ASA) on a project to increase dissemination of campaign materials in underserved communities (including rural populations) through ASA chapters throughout the country.

The campaign is also in the process of piloting multi-disciplinary teams of medical professionals, educators, policymakers, and parents to develop action plans to address obstacles in early identification and intervention at the State and local level. If this model proves to be successful, it could be replicated in additional States.

COMBATING AUTISM ACT

Question. A recent study by the Centers for Disease Control and Prevention (CDC) found that autism spectrum disorders now affect 1 in 150 children in the United States, up more than tenfold from a decade ago. The Congress responded to this growing public health crisis when it passed the Combating Autism Act, which authorized more than $900 million over 5 years for the Department of Health and Human Services' autism activities. How does the NIH and the National Institute of Mental Health intend to implement the Combating Autism Act's recommendations with the budget recommendations that have been sent to us?

Answer. The NIH has made considerable progress in implementing provisions of the Combating Autism Act (CAA) of 2006 (Public Law 109–416). A noteworthy accomplishment was the creation of the Autism Centers of Excellence (ACE) program, which received $25.5 million in fiscal year 2007. The ACE program represents a consolidation of two existing programs, the Studies to Advance Autism Research and Treatment (STAART) and the Collaborative Programs of Excellence in Autism (CPEA), to maximize coordination and cohesion of NIH-sponsored ASD research efforts. The ACE program encompasses research centers and networks focusing on a broad range of autism-related research, including topics such as neuroimaging, biomarkers and susceptibility genes, pharmacotherapy, early intervention, and personal and environmental risk and protective factors.

INTERAGENCY AUTISM COORDINATING COMMITTEE

Question. How does the National Institute of Mental Health intend to implement the recommendations of the Combating Autism Act with respect to the Interagency Autism Coordinating Committee (IACC) strategic plan?

Answer. The Combating Autism Act (CAA) of 2006 (Public Law 109–416) requires the Secretary of the Department of Health and Human Services (HHS) to establish a new Interagency Autism Coordinating Committee (IACC) with the following responsibilities regarding autism spectrum disorders (ASD):

—Develop and annually update a summary of advances in ASD research
—Monitor Federal activities with respect to ASD
—Make recommendations to the Secretary regarding any appropriate changes to Federal activities and public participation in decisions relating to ASD
—Develop, annually update, and submit to Congress a strategic plan for the conduct of, and support for, ASD research, including proposed budgetary requirements

The IACC was chartered under the Federal Advisory Committee Act (FACA) with the National Institute of Mental Health designated as the lead for this activity. With a sense of urgency and a spirit of collaboration, the IACC is developing a strategic plan for ASD research that focuses on the unique needs of individuals with ASD and their families. The plan will encourage public and private partners to work together to rapidly advance our scientific understanding of ASD, improve health and well-being across the lifespan, and help individuals with an ASD lead fulfilling lives. In developing the strategic plan, the IACC assembled expert workgroups to tackle challenging tasks, identified recent investments and accomplishments in ASD research, gathered ideas for research priorities from many stakeholders, and convened four scientific workshops with broad stakeholder participation. Furthermore, the IACC has decided to amplify its efforts and accelerate progress by meeting four times a year (a minimum of two meetings per year are required by the CAA).

The IACC strategic planning workgroup will consider the research initiatives proposed by the scientific workshops. The IACC strategic planning workgroup will review public comment and current ASD research funding to offer recommendations for structuring the strategic plan and estimating budgetary requirements for components of the plan. The IACC will consider the recommendations of the strategic planning workgroup and define the next steps in the strategic planning process, which may include additional opportunities for stakeholder input through Web-based town hall meetings or other innovative approaches for outreach. Once ap-

proved by the IACC, a draft strategic plan will be posted on the IACC website for public comment. Upon completion, the IACC will submit the strategic plan to the Secretary of HHS.

CARE OF INDIVIDUALS WITH ASD LIVING IN HAWAII

Question. Realizing that the care of individuals with autism spectrum disorders requires an interagency approach, what suggestions do you have for those living in Hawaii faced with the unique challenges of remoteness caring for individuals with autism spectrum disorders?

Answer. NIH does not provide direct patient services, but several agencies that belong to the IACC address issues concerning care for individuals with ASD in remote or rural locations, and these agencies have provided information to NIH on their efforts. For example, according to the Centers for Medicare & Medicaid Services (CMS), adults with ASD enrolled in Medicaid receive many home and community-based services through Hawaii's section 1915(c) waiver for children and adults with developmental disabilities and/or mental retardation. The CMS renewed the waiver in June 2006 for 5 years. The waiver provides numerous services to about 3,000 people throughout the islands, including people with ASD, who choose to live in community, rather than institutional, settings. The operating agency for this waiver is the State's Department of Health, supervised by its Department of Human Services, the State Medicaid Agency. These two entities are charged with working together to assure that eligible individuals are aware of and can access waiver services.

The CMS also indicates that the State of Hawaii has included a "self-directed" option in the waiver that permits individuals to hire, fire, supervise, and train direct support workers. This option greatly expands the universe of potential providers, particularly in rural areas, and may include family members and spouses as providers. In February 2008, CMS approved an extension of the State's section 1115 demonstration, which will provide mandatory managed health care starting in November 2008 to aged, blind, and disabled beneficiaries in Hawaii. The expansion of the demonstration to include this group, which likely also includes individuals with ASD, will permit the State to streamline and better coordinate care and expand provider networks in remote areas.

In addition to these efforts from CMS, successful models for providing interagency services within remote and rural settings may be found among the Systems of Care Sites (including programs in Idaho, Wyoming, Alaska, Hawaii, Montana, and other States) funded by Substance Abuse and Mental Health Services Administration (SAMHSA), another member of the IACC. These programs emphasize the core principles and practices of the Systems of Care, focusing on designing services that are child-centered, family-driven, community-based, and culturally competent. Some interagency groups have used technology to employ tele-health, tele-psychiatry, clinical supervision, case consultations, and interactive videoconferencing. Training of local leaders is another important element. Some programs employ culturally-specific approaches developed with community elders that respect native traditions—e.g., oral traditions and storytelling, a holistic "heart centered" approach or understanding that the family is the central unit, rather than the individual. Cross-agency training has been used in several locations. Hawaii is conducting innovative work linking communities of practice at the local and State levels.

Furthermore, SAMHSA's Children's Mental Health Program has a grant in the Kalihi-Palama area in Oahu (urban area) that is focusing on transition-age youth with emotional or behavioral challenges. This cross-agency approach uses combined funding to surround the individual with formal and informal services and supports. The approach is appropriate in rural areas where there are often shortages of trained professional providers.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

AUTISM DEVELOPMENTAL DISABILITIES PROGRAM

Question. The CDC supports autism surveillance through a collaborative program, the Autism Developmental Disabilities Program (ADDP). It is my understanding that the program now has monitoring sites in 17 States. Could you comment on the CDC's plan for expanding this program and project a timeline when all States will benefit from the data collected through this program?

Answer. The dramatic increase in the number of children diagnosed and receiving services for autism spectrum disorders (ASD) suggests that the disorder is more common than was once believed. Understanding the prevalence of a disorder like

autism depends on collecting and analyzing data from multiple sources. In addition, it is important to use this method of data collection in multiple locations across the nation at different points in time. Doing so gives us the best understanding of ASD rates and trend in different communities in the United States

In order to do this, CDC currently supports the Autism and Developmental Disabilities Monitoring (ADDM) Network at 11 sites (including CDC). Together with the ADDM partners, CDC provides critical data needed to answer questions about how common ASD are, whether we are identifying more children with ASD over time, and whether ASD affect certain groups more than others (i.e. boys are affected more often than girls). Also, it provides clues into potential causes that can be investigated further through research.

The goal of the ADDM Network is to provide comparable, population-based estimates of the prevalence rates of autism and related disorders in different sites over time. The program has made significant strides in attaining this goal. During the first phase of the project, as many as 16 sites (including CDC) have participated in the ADDM Network to determine the prevalence and characteristics of children with ASDs in their study areas.

In 2006, CDC awarded funds to 10 ADDM Network sites to allow the network to develop ASD prevalence estimates for 2006 and 2008. The sites are currently working on a report from 2004 and another report to look at changes in ASD prevalence across 3 time periods in 4 sites.

Establishing a national surveillance system for ASD is complex. CDC will continue to support in-depth, ongoing prevalence tracking in the current ADDM sites. Opportunities to enhance autism surveillance efforts in the United States include:

1. Developing and implementing projects that continue to link prevalence studies with screening and early identification efforts,
2. Supplementing national surveys, and
3. Conducting investigations of ASD occurrence in adults. Doing so will enhance our understanding of the population characteristics of ASDs and how they have changed over time.

CENTERS FOR AUTISM AND DEVELOPMENTAL DISABILITIES RESEARCH AND EPIDEMIOLOGY

Question. The Children's Health Act of 2000 directed the CDC to create regional centers of excellence to study autism spectrum disorders and other developmental disabilities. The Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) Network was created in response to this direction. Can you comment on the most recent research developments resulting from implementation of this network?

Answer. The search for the causes of autism spectrum disorders (ASD) is a top priority at CDC. CDC has engaged with partners in the Centers for Autism and Developmental Disabilities and Research Epidemiology (CADDRE) network to develop and implement public health research tools to identify potential causes.

Last year, CDC and CADDRE partners launched the Study to Explore Early Development (SEED). Through this effort, study partners expect to collect information on 2,700 children with ASD and their parents that will help answer questions about the characteristics of affected individuals as well as potential ASD causes. Researchers will explore a number of priority hypotheses such as the role of infections, genetic, reproductive and hormonal factors as well as select exposures.

As the largest epidemiologic study of its kind, SEED holds the potential to be an important complement to the array of other work occurring at the National Institutes of Health and in academia. CDC brings a unique public health perspective of studying health issues in large populations—not just among individuals or families who self-refer for intervention or study.

LEADING RESEARCH HYPOTHESES ON THE CAUSE OF AUTISM

Question. In recent years, certain vaccines have been suggested as being linked to autism. Scientific evidence and the most recent Institute of Medicine report do not support this theory. What are the other leading hypotheses among the research community of the cause of autism? How much of current autism funding is being focused on research to determine the cause of autism-related disorders?

Answer. Most scientists believe that there are multiple causes of autism spectrum disorders (ASD), resulting in various manifestations of the core symptoms. Twin studies provide strong evidence that ASD is highly heritable, but that the disorder involves the interaction of many genes. NIH-funded research has begun to reveal clues about how genetic variations affect the risk of developing ASDs. Although some studies have shown that mutations in individual genes are linked to only a

small percentage of autism cases, new reports suggest that part of the explanation for ASDs may be due to deletions and duplications of genetic material. Many of these are spontaneous de novo mutations not present in the parents. The study indicates that different cases of autism could be traceable to any of 100 or more genes, alone or in combination.

Environmental modifiers may also interact with genes to cause ASD or modify its expression, although such environmental mechanisms have not yet been identified. The delicate interplay between genetic susceptibility and immunological and environmental triggers may lead to differences in the healthy development of brain circuits and brain function. NIH is committed to meeting this complex challenge, determining the potential causes of ASDs.

In fiscal year 2007, the NIH spending for autism-related research totaled approximately $127 million. About 22 percent of the funding supports grants addressing specific risk factors, including genetics, environmental mechanisms, and gene-by-environment interactions. An additional 29 percent supports grants aimed at better understanding the underlying neurobiology of the disorder, which is critical knowledge in order to identify hypotheses about additional risk factors for investigation. Several large initiatives to uncover the underlying causes of ASD involve joint initiatives and activities sponsored by the NIH Autism Coordinating Committee (NIH/ACC). The NIH/ACC functions to synchronize autism research activities funded and conducted by the various NIH Institutes (NIMH, NICHD, NINDS, NIDCD, and NIEHS).

SUBCOMMITEE RECESS

Senator HARKIN. Well, thank you all again very much. It's been a very informative and constructive hearing.

The committee will stand in recess to reconvene at 9:30 a.m., Friday, April 20, in room SD–116. At that time we will hear testimony from the Honorable Richard J. Hodes, M.D., Director, National Institute on Aging.

[Whereupon, at 4:16 p.m., Tuesday, April 17, the subcommittee was recessed, to reconvene at 9:30 a.m., Friday, April 20.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

FRIDAY, APRIL 20, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Specter, Cochran, and Craig.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. RICHARD J. HODES, DIRECTOR, NATIONAL INSTITUTE ON AGING

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Good morning. The Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies will come to order. This is the subcommittee's third hearing on the National Institutes of Health this year.

On March 19 we heard from NIH Director Elias Zerhouni and several topics from real scientists and the following week we heard from Directors of four Institutes that oversee brain and behavior research.

Today we turn our attention to four more Institutes: The National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Heart, Lung and Blood Institute, and the National Institute of Diabetes, Digestive and Kidney Diseases.

As I explained at the last hearing, the subcommittee intends to meet with the Director of every Institute in the Center at NIH this spring. Senator Specter and I have already pledged to reject the President's proposed cuts to NIH for fiscal year 2008 and hearings like this will help us make our case.

It is important that we understand how NIH is spending its money and how additional funding will be used and again we're going to continue to do this sort of in blocks of two, or three or four. Try to get them organized in a certain fashion.

We asked this particular group of four Directors to appear together because they all deal in one way or another with chronic

diseases but again I don't want you to feel constrained that that's all you have to talk about. Anything that goes on in your Institute is pretty fair game. What we want to know is what you want to say and what you want to get across to us.

I'll ask each Director to speak for 5 to 7 minutes, summarize what you have overseen over the past year or so, give us a look ahead at the initiatives that are planned for fiscal year 2008 and beyond. We'll go through the witnesses and then we'll open it up for just general discussion and questions so there will be interplay among all of us here.

At the onset I want to thank each of the Directors for what you are doing to improve people's health. Yours is a noble profession. We're grateful for your dedication and your skill and I would ask if Senator Specter had an opening statement.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman for convening this important hearing and thank you, Dr. Hodes, Dr. Katz, Dr. Nabel, and Dr. Rodgers for joining us this morning to explore the needs of your various Institutes and the impact of the budget cuts proposed by the administration.

As I think it is fairly well known, Senator Harkin and I, over the course of the past two decades, have taken the lead on increasing funding for the National Institutes of Health so that we have taken it from about $12 billion to about $29 billion. At some point we were able by rearrangement of priorities within our subcommittee to add as much as $3, $3.5 billion a year for a number of years in a row. This puts enormous impetus behind medical research. Our joint view which we have persuaded much of the Congress to believe is that this is the secret to finding the cures to the maladies which affect this country and the world.

The administration has come forward with a cut this year, again. The proposal is to cut NIH by $327 million.

The budget resolution does contain an increase this year of $1.3 billion and Senator Harkin and I added an amendment to increase the budget resolution for $2.2 billion more. We have to be candid about it. The budget resolution is confederate money. Until it gets into an appropriation it doesn't count.

I'm looking forward to the day when either Senator Harkin or I will be chairman of appropriations. I have a preference.

But there really ought to be a greater allocation here beyond any question and I never miss an opportunity to emphasize the importance of some political muscle which needs to come from the experts which you four are and others, and those in the research field, and those who come to this town, to pressure the Congress, breast cancer and prostate cancer and juvenile diabetes and Alzheimer's and Parkinson's, they fill our largest hearing rooms, but somehow the political pressure stops there.

Senator Harkin and I have talked about a million person march on the Mall when we finish the stem cell bill which we'll pass again and where there is a veto threat but if the 110 million Americans who suffer personally from these ailments or their families directly would put political pressure on, there's nothing we couldn't do. We

could make it all happen. There's enough political pressure to do that.

So that is my message, Mr. Chairman. I'm not going to be able to stay too late today because I have commitments in Philadelphia. We have a lot of State responsibilities which you all know and Friday's the day when we have to tend to some of that, but I will stay as long as I can and of course, I will follow the hearings.

Senator HARKIN. I appreciate that very much, Senator Specter.

We'll just go down the line and we'll start first with Dr. Hodes. Dr. Hodes has served as Director of the National Institute on Aging since 1993. A graduate of Yale University received his M.D. from Harvard Medical School. A leading immunologist, Dr. Hodes has appeared before the subcommittee several times and we welcome him back and again if you would just take five, seven minutes or whatever to just sort of summarize your testimony. By the way all, for the record, all of your statements will be made a part of the record in their entirety.

So, Dr. Hodes, welcome, and please proceed.

SUMMARY STATEMENT OF DR. RICHARD J. HODES

Dr. HODES. Thank you, Mr. Chairman and Senator Specter, for the opportunity to participate in this hearing on the burden of chronic disease. In past years, advances made through hygiene, public health, and as a result of biomedical research have addressed many of the causes of acute illness so that progressively chronic disease has become a prominent cause of disease, disability, and morbidity. Consequently NIH, particularly the four Institutes who are here, have directed increasing attention to chronic diseases.

DISABILITY AND OLD AGE

As you know, the National Institute on Aging has as its mission to understand the aging process and those disorders that are age related. Chronic diseases are in fact a prominent cause of disability of old age and the constant loss of independence, quality of life and productivity.

The studies of trends in disability with old age are both promising and equally a cause of concern and I would point to the first graph as a handout which illustrates three studies (National Health Interview Survey, National Long-Term Care Survey, and the Medicare Current Beneficiary Survey) over the past 20 years studying individuals aged 65 and older to determine the trends and disability rates over this period.

So from 1982 to the present these studies are rather unanimous, indicating the very encouraging trend towards a decrease in disability equivalent to approximately a 20 percent decrease in disability for older men and women aged 65 and older over this period, evidence that disability is not an inevitable consequence of aging.

Studies carried out concurrently over a spectrum of ages, however, have shown that individuals in their 30s, 40s and 50s, younger adults, over the same period of time have actually seen an increase in disability, pointing out the urgency of our addressing the causes of chronic disease disability.

Senator HARKIN. What do those different letters mean?

Dr. HODES. I apologize. These are the abbreviations which are in the footnotes that illustrate each of the individual studies, which converge, as you can see. Each of these lines is downward trending, showing that in each of the studies there is agreement that the levels of disability in the populations studies are decreasing over time.

Senator HARKIN. What kind of disabilities are you talking about, physical, mental, the whole thing?

Dr. HODES. Yes, the disability definitions have largely to do with the ability to carry out the activities of daily life to function independently.

The major causes of disability are illustrated in the second handout. These are the leading five, and I point out that arthritis, heart disease, and diabetes are topics that are going to be addressed in more detail by my colleagues this morning.

I should add these are grounds for intensive collaboration between the Aging Institute and among all the Institutes at NIH over these common interests.

RESEARCH ADVANCES

The National Institute on Aging supports research to understand the basic mechanisms of aging and of aging-related disorders and to translate them into clinical interventions. The findings of genes and intervention such as caloric restriction which affect life span and longevity in model organisms are now being studied for their translatability to humans.

In the case of specific diseases there are some important advances that have already been made. For example, clinical trials have been successful in decreasing rates of falls and consequent fractures; we pursue this area of research in common with NIAMS.

Studies have shown that treating the most common cause of the most common category of hypertension in older Americans can result in dramatic decreases in stroke and congestive heart failure; we are pursuing this research in collaboration with NHLBI.

Studies show the possibility of using drug as well as behavioral interventions to decrease the incidence of diabetes; we pursue these studies in collaboration with NIDDK.

The studies that I'd like to emphasize in my remaining comments deal with yet a fourth major cause of disability, dementia. In older men and women the most common cause of dementia is Alzheimer's disease.

ALZHEIMER'S DISEASE

We've learned a great deal in past years about three genes which are responsible for causing early onset familial Alzheimer's disease as well as identifying genetic risk factors for more common old age variants, including the demonstration just this past year of a new gene, SORL1, which is associated with higher risk of Alzheimer's disease.

We've also succeeded in translating the leads which come from this understanding of underlying biology and epidemiology into clinical studies, and we have some 25 different prevention and treatment trials ongoing.

Among them, I point to one recently reported which is really the first success in prevention of Alzheimer's disease in a population of high risk. As is shown on this figure which illustrates the effect of the drug donepezil, patients receiving that drug who developed Alzheimer's disease at a slower rate at a lower frequency than those in the other control groups. Of interest, this effect was made demonstrable by targeting individuals with the APO E4 gene, a risk factor for Alzheimer's disease, which underscores the importance of using genetic and other risk factors to identify targets and to monitor success of interventions.

This is a very modest beginning but it is an encouraging illustration of the ability to intervene and in fact to prevent this devastating disease.

Progress has also been substantial in the area of neuro-imaging, important in both early diagnosis and as a means for monitoring more efficiently the success of interventions to treat or prevent disease; it is potentially more efficient, for example, than monitoring the clinical symptoms alone.

The understanding of the lesions that cause Alzheimer's disease, the plaques and tangles which are characteristic of the brain in Alzheimer's, have led to the development of compounds which bind specifically to these plaques and tangles and the use of these compounds to image in patients and study subjects the deposits of Alzheimer's lesions in the brain. This is illustrated quite dramatically in this slide, which shows the result of a compound called Pittsburgh Compound B that binds specifically to amyloid. You can see the contrast in the AD, which is the Alzheimer's disease patient.

The reds and yellows show a high intensity of amyloid plaques in those individuals in comparison to the control, the individual at similar age but without those lesions.

This study is now a part of a larger Alzheimer's disease neuroimaging initiative with the remarkable partnership of Institutes at NIH, the FDA, the foundations as well as pharmaceutical and biotech industry aimed at identifying markers, including new imaging markers which will again serve as vehicles for early diagnosis and to allow better and more efficient monitoring of interventions for their effectiveness.

PREPARED STATEMENT

The challenge posed by chronic illness is indeed a daunting one but one which the Institutes at NIH are addressing with full vigor and with all resources. I again appreciate the opportunity to be here before you and look forward to discussions with you.

[The statement follows:]

PREPARED STATEMENT OF DR. RICHARD J. HODES

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute on Aging (NIA). The fiscal year 2008 request provides $1,047,148,000 for the NIA.

Thank you for this opportunity to provide testimony for today's hearing. I am Dr. Richard Hodes, Director of the National Institute on Aging (NIA). The NIA leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life. I appreciate the opportunity to discuss the burden of chronic disease, a critical issue for our older citizens.

The face of aging in the United States is changing dramatically—and rapidly, according to a recent U.S. Census Bureau report commissioned by the NIA. Today,

older Americans are very different from their predecessors, living longer, having lower rates of disability, achieving higher levels of education, and less often living in poverty. The baby boomers, the first of whom celebrated their 60th birthdays in 2006, promise to further redefine what it means to grow older in America.

While many of our seniors are enjoying their later years in good health, a number of chronic conditions remain common among older Americans. For example, more than half of all Americans over age 65 show evidence of osteoarthritis in at least one joint.[1] Over half of Americans older than 50 have osteoporosis or low bone mass,[2] and cardiovascular disease, cancer, and diabetes remain common among older Americans. Through research, we are discovering new and better ways to diagnose, treat, and even prevent these and other diseases and conditions.

The NIA provides leadership in aging research, training, health information dissemination, and other programs relevant to aging and older people. The Institute's robust research portfolio covers all aspects of aging, from the basic cellular and molecular changes that occur as we age, to the prevention and treatment of common age-related conditions, to the behavioral and social aspects of growing older, including the demographic and economic implications of an aging society. In addition, the NIA is the lead Federal agency for research related to the critically important effort to prevent and treat Alzheimer's disease. Finally, our education and outreach programs provide vital information to older people across the Nation on a wide variety of topics, including living with chronic conditions, maintaining optimal health, and caregiving.

ALZHEIMER'S DISEASE AND THE NEUROSCIENCE OF AGING

While it is true that our senior and elderly citizens are aging far better today than in previous decades, the specter of Alzheimer's disease (AD), one of the most devastating neurodegenerative diseases, is a source of enormous concern as we and our loved ones age because of its enormous impact on individuals, families, the health care system, and society as a whole. Approximately 4.5 million Americans are currently battling AD, with annual costs for the disease estimated to exceed $100 billion.[3] Moreover, the rapid aging of the American population threatens to increase this burden significantly in the coming decades. By 2050, the number of Americans with AD could rise to some 13.2 million, an almost three-fold increase.[4]

AD is a chronic condition that advances gradually but inexorably, from early, mild forgetfulness to a severe loss of mental function called dementia. Eventually, people with AD become dependent on others for every aspect of their care taking a tremendous toll on family members and other caregivers, often for several years. The NIA supports an extensive research program with the goal of facilitating early diagnosis of AD and developing more effective preventive strategies and therapeutic interventions. Moving forward in each of these areas requires the translation of findings from the laboratory through preclinical testing and into full-scale clinical trials. Recent advances have been made on several fronts.

Neuroimaging.—The discovery of compounds such as Pittsburgh Compound B and, more recently, FDDNP that enable the visualization of AD's characteristic amyloid plaques and neurofibrillary tangles in the living brain—an impossibility until several years ago—will not only enable scientists to diagnose AD earlier, but may also help researchers and clinicians develop new treatments and monitor their effectiveness, as well as reduce the time and cost of clinical trials. Research in this area has been intense and productive, with the Alzheimer's Disease Neuroimaging Initiative (ADNI) continuing to be a major venue for facilitating neuroimaging research relevant to AD.

Genetics.—Discovery of risk factor genes will help illuminate the underlying disease processes of AD, open up novel areas of research, and identify new targets for drug therapy. Researchers recently determined that variations in a gene known as SORL1 may be a risk factor for the development of late onset AD. This discovery provides a new genetic clue about the late onset forms of AD. Further research is needed to determine the role of SORL1 in AD pathogenesis.

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[1] See "Handout on Health: Osteoarthritis," National Institute of Arthritis and Musculoskeletal and Skin Diseases, July 2002.

[2] See America's Bone Health: The State of Osteoporosis and Low Bone Mass in Our Nation. National Osteoporosis Foundation, February 2002.

[3] Data from the Alzheimer's Association. See also Ernst, RL; Hay, JW. "The U.S. Economic and Social Costs of Alzheimer's Disease Revisited." American Journal of Public Health 1994; 84(8): 1261–1264. This study cites figures based on 1991 data, which were updated in the journal's press release to 1994 figures.

[4] Hebert, LE et al. "Alzheimer Disease in the U.S. Population: Prevalence Estimates Using the 2000 Census." Archives of Neurology August 2003; 60 (8): 1119–1122.

Research is continuing in this important area through the AD Genetics Initiative, which to date has recruited nearly 1,000 families to establish a data base for studies of familial inheritance of AD. In addition, the NIA has established a national genetics data repository to facilitate access by qualified investigators to genotypic data for the study of the genetics of late-onset AD. Investigators have already begun submitting data to this repository and requesting additional data for genetic studies.

Pre-Clinical and Translational Research.—NIA plans to speed drug discovery and movement of promising new treatments and prevention strategies into clinical trials. The launch of a major new translational research effort to expand the range of novel compounds to be tested for their effect in preventing or slowing progression of cognitive decline, mild cognitive impairment, and AD, and to more quickly move research from the laboratory to clinical trials in humans, will further support our efforts in this regard.

Clinical Research.—The NIA is currently supporting approximately 25 AD-related clinical trials. NIA plans to use the knowledge gained through basic and mechanistic studies to select the most promising imaging and biological markers, as well as improved clinical and neuropsychological evaluation methods, to design and perform less expensive, shorter, and more efficient drug trials. Recent progress in understanding the basic genetic and molecular processes of AD has provided new mechanism-based approaches to designing interventions. NIA-supported researchers are also studying simple lifestyle changes that may confer protective benefits on cognition. For example, in one recent study, increased vegetable consumption was found to be associated with reduced risk of cognitive decline in women. In another, certain mental exercises were found to help older individuals maintain their cognitive abilities; the benefits may last as long as 5 years.

HEALTHY AGING

Preservation of cognition in specific domains can be of particular importance to the safety and independence of aging adults. For example, NIA-supported researchers have provided the underlying research for and developed the Useful Field of View (UFOV) test to help predict the degree to which a person may safely perform activities such as driving. The measure is now a major component of assessments tested and about to be adopted by three State Departments of Motor Vehicles for use in screening older drivers. NIA-supported research will also provide the foundation for development of training to help older adults improve their visual attention and speed of processing based on UFOV testing, and for the translation of this training as part of driving safety programs for older adults.

In addition to testing ways to maintain cognitive function, NIA-supported investigators are actively seeking ways to maintain physical function into older age. For example, several studies suggest that physical exercise may prevent physical disability, including impaired mobility, in healthy and frail older adults. To develop definitive evidence regarding the effectiveness of such interventions, NIA and grantee researchers have designed the LIFE (Lifestyle Interventions and Independence in Elders) study, a clinical trial testing the effects of a physical activity program vs. a health education program among older Americans in preventing major disability. A successful pilot study (LIFE–P) completed in 2005 showed both feasibility and positive preliminary data, permitting design and consideration of this large-scale clinical trial.

A large body of research in animal models indicates that substantially reducing caloric intake while maintaining optimal nutrition results in significant increase in life span. The NIA-supported Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy (CALERIE) will help to determine if these beneficial effects extend to humans. Results from pilot studies demonstrated that overweight people who cut their calories by 25 percent for 6 months have reduced fasting insulin levels and core body temperature, two markers that have been associated with increased longevity in animal models, and that may be similarly associated with human longevity. A two-year study will begin in early January 2007 to determine whether healthy non-obese men and women ages 25–45 who reduce their caloric intake by 25 percent maintain these metabolic changes, and will measure other long-term effects of sustaining lowered caloric intake on factors related to aging changes and risks for age-related diseases.

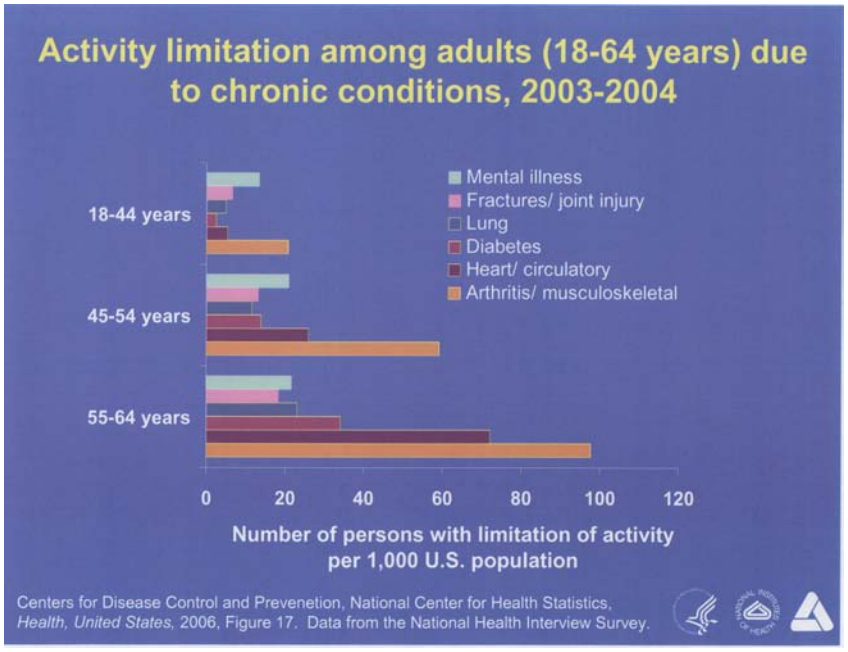
Because an intensive regimen of restricted food intake may prove difficult for many people to follow over the long term, and may in fact have adverse consequences in some circumstances, investigators are also searching for compounds that mimic the effects of caloric restriction on the body. One compound currently under study is resveratrol, an activator of a family of enzymes called sirtuins, whose cell-protective activities are themselves the subject of intensive scientific inquiry. In

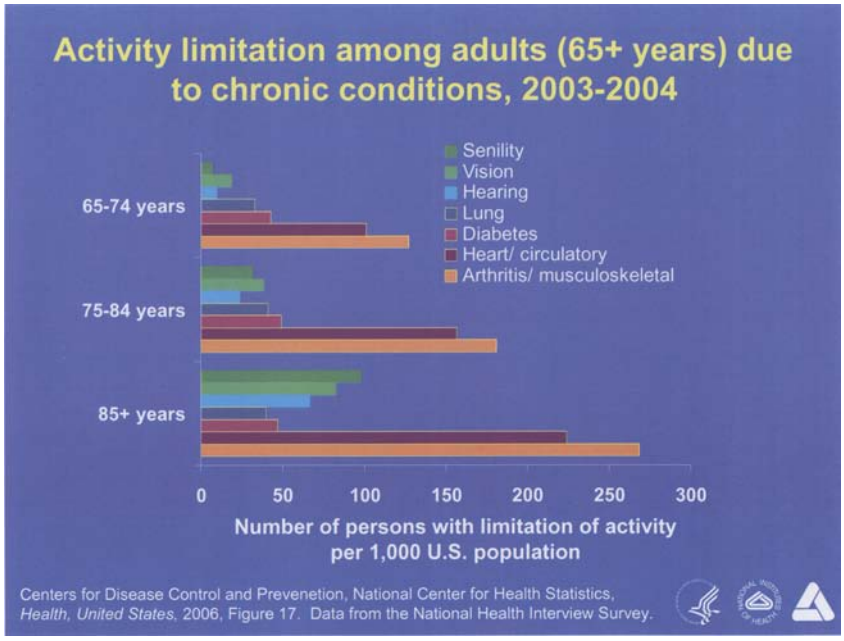
a recent study, overweight, aged male mice given a high-fat diet supplemented with resveratrol had better health and survival than aged overweight mice who did not receive the compound. Resveratrol's safety and effectiveness to address aging and age- or obesity-related conditions in humans have not been demonstrated, and further research is needed on the short- and long-term effects of resveratrol in animals and humans.

The NIA Intervention Testing Program supports the testing of compounds with the potential to extend the lifespan and delay disease and dysfunction in a mouse model. Plans are to renew this promising initiative in fiscal year 2007 for funding in fiscal year 2008. In addition, NIA is continuing to search for genes and biological pathways that influence longevity and aging through the Longevity Associated Gene initiative, which to date has identified over 100 new longevity-associated genes, along with many conserved biological processes and pathways that regulate longevity in a host of divergent species, including humans.

New research findings may one day translate into better ways to support the aging immune system. A new initiative on "Membrane Associated Signaling Defects in Immune Cells with Aging" seeks to shed light on the cellular processes that may lead to impaired immune function in older people. This research may ultimately lead to the development of interventions to bolster the immune system and reduce vulnerability to disease and disability in older people.

Thank you for the opportunity to provide my testimony to this Subcommittee and to describe these examples of research targeted at improving the health and quality of life of aging and older adults. I would be happy to answer any questions you may have.





Senator HARKIN. Well thank you very much, Dr. Hodes for a very succinct and straightforward presentation. We appreciate it very much.

Now we turn to Dr. Steven Katz, who has served as the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases since 1995. Dr. Katz received his B.A. from the University of Maryland, his M.D. from Tulane University School of Medicine and his Ph.D. from the University of London. His own particular research, I am told, focuses on skin diseases and immunology. Dr. Katz, welcome to the committee, please proceed.

STATEMENT OF DR. STEPHEN I. KATZ, DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Dr. KATZ. Thank you very much, Mr. Chairman, Senator Specter, subcommittee members. It's indeed a privilege to be here this morning to present priorities and programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases that I will abbreviate by calling it NIAMS.

Our support is of a broad range of research, training and health information activities related to diseases of the joints, bones, muscles and skin. Many of the conditions that we study are common, chronic and costly both in economic and societal terms. Collectively they have a major impact on quality of life and disability for affected patients and families.

The slides that I've provided, these two blue slides really reinforce the point that Dr. Hodes made, that is, that not only is there significant disabilities measured by activity limitation in older individuals, but also younger individuals also suffer from a wide range of chronic conditions.

This disability is related to diseases and injuries of the bones and joints which the NIAMS covers as well as other chronic conditions that are represented by my colleagues on this panel.

I'd like to paint a picture of recent progresses at the Institute as well as areas of future progress by highlighting three specific conditions: osteoporosis, low back pain and osteoarthritis.

I'll begin with osteoporosis. A thinning of the bones often associated with aging, it puts people at risk for fractures and related complications. That's the real problem, the fractures. Osteoporosis is a major chronic public health issue. Ten million Americans have osteoporosis. Thirty-four million other Americans are at risk for osteoporosis, almost 70 percent of those affected are women.

More than 1.5 million fractures occur as a consequence of osteoporosis, including 300,000 hip fractures and 750,000 vertebral fractures. We've gained many insights from our investments in osteoporosis research, many in collaboration with the Aging Institute. These investments have aided in the development of effective interventions, both in the treatment as well as the prevention of the disease.

In a long-term study co-funded by the Aging Institute, scientists have found that increased age and low body weight are two of the most important risk factors, and that sedating drugs and failing visual acuity contribute to osteoporatic fractures by increasing falls. A family history of fracture also contributes to an individual's risk.

More recently we've turned our attention to osteoporosis in men. Osteoporosis usually occurs a decade or decade and a half later in men than in women, and these new studies in the next years will tell us about factors that increase the risk in men for fracture occurrence.

Many questions remain including how best to measure bone strength in a reliable way. How can we better predict who is susceptible to a fracture?

Current methods that are used include DXA which is good, but not great in terms of predicting fracture. To fill this gap the NIAMS is putting together a collaborative initiative on bone strength. The public/private partnership will help us identify better markers of bone strength that can better predict fracture risk and can be used in clinical trials to assess new therapies.

LOW BACK PAIN

Now I want to turn to low back pain. How common is low back pain? Approximately half of adults have low back pain in any given year. An estimated 32 million Americans have frequent low back pain. For the past several years, NIAMS has invested in a large multi-center clinical study comparing surgical versus non-surgical intervention for three different types of back pain.

The one I'll talk about today is the first of these studies that has come out, on herniated discs, and this study is called the SPORT study. Scientists have worked on this effort for the past seven years and have recently reported results with important clinical implications.

They found that patients with low back pain from herniated discs improve over time even without surgery. This new information,

that non-operative therapies may offer similar benefits to those who forgo surgery, will guide future treatment decisions by patients and physicians. In other words, the rush to surgery is not so great because some of these people will actually get better without the surgery.

Over the next few years we anticipate additional findings from this study, which is addressing other forms of low back pain; for example spinal stenosis where the bones in the vertebra become less patent and also a form of arthritis in the back that causes low back pain.

OSTEOARTHRITIS

Now I'd like to turn to osteoarthritis or OA, a condition like osteoporosis that presents a growing public health problem as our population ages. A few quick statistics, an estimated 12 percent of the U.S. population aged 25 and older have osteoarthritis, nearly 21 million Americans. A recent analysis shows that 5.3 percent of all U.S. adults ages 18 to 64 reported work limitations due to arthritis in 2002, including absenteeism. This relates to the point in your discussion with Dr. Hodes about absenteeism, reduced productivity, work loss and lower income.

Osteoarthritis is the most common form of arthritis as people age and is often called the wear and tear disease. It can also develop following injury to the joints. Now in going back to my elementary school experiences, I thought that a show and tell might be interesting because we hear a lot about osteoarthritis, the most common form of arthritis.

This is a knee, this is a knee cap, and let's unfold the knee cap and just look at the knee. This is the part of the bone that is covered by the cartilage and it's the cartilage that's here in the knee. It's here and here and this cartilage on each side of the bone opposes each other. This really takes the wear and tear of walking, of injury, of running. If this little, thin layer is damaged in some way, then you get bone on bone. Bone on bone doesn't even sound good, does it?

Basically that's what causes the disability and the limitation of motion, and that's really what we're trying to address.

One of the areas that holds tremendous promise for people affected by osteoarthritis is regenerative medicine, and this emerging field includes tissue engineering and efforts that cut across the life, physical and engineering sciences.

Recently scientists supported by the NIAMS developed an innovative three-dimensional fabric to aid in joint cartilage repair. In other words, the end of the line is a new joint, but what we're trying to do is prevent that. We're trying to identify risk factors, prevent those risk factors, but also develop methods that are not as invasive as putting in a new joint.

So using a unique weaving machine, one tries to build a matrix on which cells will grow, and if you get cells to grow on that matrix, it will form this cushion. That's part of the goal before the endpoint of total knee or total hip replacement. These are very good forms of surgery, but still we'd like to avoid that for as long as we possibly can.

PREPARED STATEMENT

So, as I hope I've illustrated this morning, the NIAMS has made significant strides in our efforts to improve the outlook of patients affected by a number of common chronic conditions, and we are poised to make further progress in the near future as well as in the long future and I'm delighted to be here and look forward to answering any questions that you may have.

[The statement follows:]

PREPARED STATEMENT OF DR. STEPHEN I. KATZ

Mr. Chairman and members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The fiscal year 2008 budget includes $508,082,000.

INTRODUCTION

The NIAMS supports a broad range of research, training, and health information activities related to arthritis, musculoskeletal, and skin diseases. These disorders are among the most common, chronic, and costly conditions affecting the U.S. population, and have a major impact on quality of life and disability for patients and families. In many ways, the mission of the Institute is defined by its diversity—the disorders that are studied afflict adults and children, and affect individuals and families of all races, ethnicities, and economic strata. While it is critical to support investigations across the research spectrum—from basic, to translational, to clinical studies—the NIAMS places a strong emphasis on work that has the potential to benefit patients directly.

Recent results from two clinical studies supported by the Institute underscore this commitment: in the first, researchers showed that, while surgery may be an effective route to relief from low back pain for patients with herniated (slipped) discs, over the longer term, non-operative therapies may offer similar benefits for those who cannot or elect not to have surgery. In the second, scientists in the NIAMS intramural research program discovered that the Food and Drug Administration (FDA)-approved arthritis medication anakinra brings marked improvement both in symptoms and the inflammation underlying a rare, debilitating, and often fatal disorder in children and young adults called neonatal-onset multisystem inflammatory disease (NOMID).

Looking ahead, NIAMS is also investing in emerging areas of science, such as tissue engineering and regenerative medicine, which hold the promise of substantially reducing the disability and health care costs associated with many common conditions. For example, insights gained from examining the development of connective tissues in the laboratory could be translated into approaches for the repair and regeneration of tissues in clinical settings. Over time, patients affected by disabling disorders such as osteoarthritis could benefit from this multidisciplinary work.

PREVENTIVE MEDICINE

The NIAMS continues to place a high-priority on studies to identify risk factors and biomarkers of disease, in an effort to facilitate the early identification of signs and symptoms, and to develop interventions that are more effective. To this end, scientists funded by the Institute are improving the understanding of the factors that affect bone mass in older men—to complement the considerable work that has been done in women—so that clinicians can better identify individuals potentially at high risk for fractures associated with osteoporosis, and help determine appropriate treatment and prevention approaches. To date, investigators have identified lifestyle, medical, and demographic traits that are associated with low bone mass and potential fracture risk. In other work, researchers have identified biomarkers for lupus-related kidney disease. These biomarkers can be used to indicate the type and severity of renal disease, as well as the extent of kidney damage. Ultimately, this discovery could form the basis for a test that would save patients with lupus the expense, discomfort, and potential complications of repeated kidney biopsies.

In the coming year, NIAMS will continue its commitment to two novel public-private partnerships that are designed to improve prevention of osteoarthritis and osteoporosis—conditions that already affect millions of Americans, with many more at risk as the population ages. The first, the Osteoarthritis Initiative (OAI), is a long-term effort, developed with support from numerous NIH components, private

sector sponsors, and with the participation of the FDA, to create a publicly-available research resource to identify and evaluate biomarkers of OA for use in clinical research. The study has 4,800 participants who are at high risk for knee OA and, as of early fiscal year 2007, clinical data from approximately 2,000 of them were available for research projects. The second, the Collaborative Initiative on Bone Strength (CIBS), will enable researchers to identify markers of bone strength to be used as surrogate endpoints for fractures in clinical trials, and to find measurements that are more accurate than bone density to predict risk of fracture. Information collected through this partnership—which also involves several NIH components, the FDA, academic centers, and industry—will facilitate the development of new treatments to prevent fractures because it enables the design of clinical trials that are smaller, shorter, and less expensive than current studies.

COMPLEX GENETIC DISEASES

The NIAMS is harnessing the explosion of information related to genomics and proteomics to better understand the causes of complex genetic diseases, and how best to treat and prevent them. This year, scientists supported by the Institute identified a gene that causes susceptibility to psoriasis, an autoimmune disease characterized by patches of thick, inflamed skin which are often itchy and sore. With this information, it may be possible to target the product of this particular gene in developing new treatments—rather than using current therapies which suppress the entire immune system, leaving patients vulnerable to infections. Progress has also been made in understanding the genetic underpinnings of rheumatoid arthritis (RA), due in part to a twin study which revealed three genes involved in the disease. Using a sophisticated technique called microarray analysis, the scientists discovered three genes that were consistently overexpressed in the RA-affected twins—pointing to new potential mechanisms of disease that can guide future research activities.

In fiscal year 2008, the NIAMS will enhance its efforts in this area, in part by pursuing genome-wide association studies for diseases of interest to the Institute. Such work—which will likely focus on analyses of phenotypes for autoimmune diseases and musculoskeletal disorders which collectively affect millions of Americans—would build on investments being made at the NIH level through the Genetic Association Information Network (GAIN). Over time, identification of the genetic bases of these conditions could lead to new predictive, preventive, diagnostic, and therapeutic approaches.

TRANSLATIONAL AND CLINICAL RESEARCH

A hallmark of research success is translation: work to bring insights from the laboratory bench to the patient bedside, and back again, with the ultimate goal of improving patient care and public health. To this end, the NIAMS recently launched the new Centers of Research Translation (CORT) program, to bring together basic and clinical researchers in a way that helps translate fundamental discoveries into new diagnostics and treatments. This year, the Institute funded four new centers focused on the following areas: the biological basis of fracture healing and the efficacy of a potential new treatment for healing of fragility fractures in the elderly; the role of different cell types in lupus pathogenesis, the development of markers of disease activity and severity, and the identification of new targets for therapies; the molecular contributors to a genetic form of rickets, and the development of new treatments; and the molecular basis of scleroderma, by using functional genomics and gene networks to understand the underlying causes of the disease.

In the coming year, the NIAMS will fund a second set of CORTs, in addition to supporting translational and clinical studies in a number of other promising areas. For example, together with the National Institute of Neurological Disorders and Stroke and the National Institute of Child Health and Human Development, the NIAMS is placing a high-priority on translational research for therapeutics development for the muscular dystrophies (MDs). Additional research in the MDs will be supported through the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers, which promote side-by-side basic, translational, and clinical research. Further, within the Institute's intramural research program, work is being done to facilitate patient-oriented studies with a particular emphasis on the genetic, inflammatory, and immune-mediated mechanisms of arthritis, musculoskeletal, and skin diseases.

CONCLUSION

Since the Institute's inception 20 years ago, significant progress has been made to better understand the causes of many disorders of the bones, muscles, joints, and skin, as well as to develop treatment and prevention approaches for these diseases.

In the coming year, NIAMS will place a particular emphasis on leveraging resources with public and private sector partners to support key initiatives. In this vein, the Institute plans to fund training fellowships in partnership with scientific organizations to support orthopaedic surgeons and dermatologists to pursue epidemiology, clinical trials, and health outcomes research across our mission areas. Within the intramural research program, a clinical scholars training program will be pursued to foster interactions among existing trainees with common scientific interests. As well, as part of efforts to enhance the research pipeline, the Institute will fund promising new investigators through the NIH Pathway to Independence program.

In addition, the NIAMS will continue to be an active partner with other Institutes and Centers in implementing the NIH Roadmap for Medical Research. In particular, the Institute is helping to lead one of the Roadmap initiatives designed to reengineer the clinical research enterprise. The Patient Reported Outcomes Measurement Information System, or PROMIS, network is developing new ways to measure patient-reported symptoms such as pain, fatigue, physical functioning, and emotional distress that have a major impact on quality of life across a wide variety of chronic diseases. Investigators funded through this initiative are creating a computerized adaptive test that, once validated, will be publicly available for use by the clinical research community. Over time, this tool will benefit patients who suffer from chronic conditions, as well as their health care providers.

Finally, as part of other efforts to serve patients, providers, and the American public, the NIAMS remains committed to a robust program to disseminate research results and science-based health information. In the coming year, the Institute will place an increased emphasis on underserved populations. Work in this area will include expanding the development and distribution of patient publications in Spanish and selected Asian languages, as well as low-literacy materials. Outreach activities with a variety of minority communities will also be enhanced, to increase awareness about NIAMS clinical research studies and health information resources.

Senator HARKIN. Thank you again, Dr. Katz for again for a very straightforward presentation. I appreciate it and we'll get into a discussion on many of these things.

Now we turn to Dr. Elizabeth Nabel, who has served as Director of the National Heart, Lung and Blood Institute since 2005, received her M.D. from Cornell University Medical College. A cardiologist, Dr. Nabel focuses her current research on the genetics of blood vessel diseases. Dr. Nabel, welcome again to the committee.

STATEMENT OF DR. ELIZABETH G. NABEL, DIRECTOR, NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Dr. NABEL. Thank you, Senator Harkin.

Senator Harkin and members, it is my pleasure to come before you this morning to talk about the exciting research program that's part of the National Heart, Lung and Blood Institute, or NHLBI.

As you know we have responsibility for heart, lung and blood research in this country and our responsibilities include three of four leading causes of death in this country: heart disease, chronic obstructive pulmonary disease or COPD, and stroke in collaboration with the Neurological Institute.

I'd like to highlight briefly advances in each of the areas in heart, lung and blood and then I look forward to expanding on those conversations later this morning.

HEART DISEASE ADVANCES

In the area of heart disease, we're learning more about the consequences of childhood obesity and its effect on heart disease. As you know, we do have an obesity epidemic in this country, but what's alarming is that many of our children are becoming overweight or obese at very early ages and as Dr. Rodgers will elaborate, many of those children are developing diabetes, type 2 diabe-

tes, earlier and we're beginning to see risk factors for heart disease in our children, much earlier than we ever saw in our generation.

This is obviously alarming to many of us but in the past year we've completed studies that show that girls who are overweight at age 9, are 10 times more likely than normal weight girls to have an elevated blood pressure and they're much more likely to develop risk factors for heart disease that can appear even as early as age 18.

Senator HARKIN. This is at age 10?

Dr. NABEL. This is at age 10. You can begin to predict those individuals who are going to be at risk for heart disease and diabetes as early as elementary school and that quite honestly is frightening.

We have other studies from our population cohorts that suggest that as young adults enter their 20s, the presence of risk factors for heart disease will predict those individuals who will develop heart disease by middle age. Individuals who enter middle age or who reach age 50 with reduced or no risk factors for heart disease have longer life span and improved quality of life and indeed individuals who enter older age, being overweight or obese, consume a large proportion of our Medicare dollars, no real surprise.

So the picture that I'm trying to paint is really a continuum that begins very early in life and builds over the years. If one is in poor health early in life, overweight, developing risk factors, the more likely you are for developing heart disease and its complications later in life and consuming more health care dollars.

Now that's the fairly sobering news. The good news is that we are learning that interventions early in life do make a difference. In other words, if we can focus and help our young children learn to make good, healthy lifestyle decisions early in life, we can begin to see reductions in blood pressure, begin to see weight loss and improve risk factors for heart disease.

So what are those interventions? The introduction of physical activity, P.E. back into the schools, something simple that we grew up doing thinking not much about it, but as you know, P.E. is lost among many of the public schools now in this country.

It's helping children to make healthy food choices. Helping children to understand that drinking the quantities of soda and eating the bags of chips is not healthy; they have to reach for an apple or a piece of fruit or vegetables as well.

Encouraging kids to remain physically active rather than coming home from school and sitting in front of the video game or the TV. Get out there and ride your bike, do sports, et cetera.

They sound very simple but studies do show that these types of interventions clearly make a difference.

The other piece I'll share with you is through our Framingham Heart Study, for many years we understood that high blood pressure was the leading risk factor for heart disease in this country. That's improving with our treatments for hypertension, but the sobering news is that diabetes is now carrying a greater and greater weight in terms of risk factors for heart disease and we think that in the future diabetes will be the dominant risk factor for heart disease in this country. So clearly, obesity, diabetes, heart disease are all very tightly linked.

GENETIC SUSCEPTIBILITY TO HEART DISEASE

Some of the very exciting research that we're doing in the NHLBI is really surrounding trying to understand the genetic susceptibility to heart disease. As you know for many years we have sponsored wonderful population studies, the Framingham Heart Study, the Jackson Heart Study and others.

We now are beginning to do what is known as genotyping, which is an analysis of a predisposition to various diseases and understanding the genetics of susceptibility of heart disease in these populations so we can then bring together the genetic understanding together with clinical characteristics that we have been determining, say in the Framingham since 1948 and really understand which families and which individuals may be at risk.

When an individual or family understands the risk, they then can be encouraged and empowered to take action to reduce that risk, and that might be through life-style interventions or it might be through medication or other approaches. So we believe that we will be able to understand risk for some of the chronic diseases at a much earlier age.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Let me move on quickly to the lung. Chronic obstructive pulmonary disease, it's a mouthful, but it's the fourth leading cause of death, COPD. It's on the rise. We don't understand it, but it's disconcerting to us.

The face of COPD is changing. We used to think of COPD predominately in men, but more and more, older women are developing COPD, women who smoke, women who don't smoke.

There are many more non-smokers who are developing COPD which suggest to us that's there's something in the environment or something genetic that we don't quite understand yet.

We, this past year, in partnership with many of the respiratory associations across the United States developed a new public awareness campaign called, Learn More, Breathe Better, and it's really to help create a brand out of COPD, simply to raise awareness that if you're having symptoms of COPD, see your doctor, get a simple breathing test. There are direct things that you can do.

We are very proud of a trial that we're funding in collaborating with CMS to look at the benefit of long-term oxygen treatment to improve morbidity mortality and the quality of life in COPD and that study is going very well.

SICKLE CELL DISEASE

Finally in the area of blood, as always we are very, very committed to the area of sickle cell disease. We are continuing a very promising study looking at the potential benefit of a drug called hydroxyurea in treating sickle cell infants before nine months of age and we're hopeful that early treatment will prevent some of the devastating organ damage that these young children develop from sickle cell disease.

We are very excited about the future as you can imagine. We have a tremendous number of wonderful research projects that we

can fund going from basic science to clinical trials to population studies and particularly public awareness.

PREPARED STATEMENT

In our Institute we're very proud of our public awareness programs: women and child heart disease, childhood obesity, asthma and now COPD and we believe very strongly that we have a responsibility to take our research advances and translate them into language and programs in an understanding that the public and the individual can incorporate to improve their own health. So Senator, thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. ELIZABETH G. NABEL

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's Budget request for the National Heart, Lung, and Blood Institute (NHLBI). The fiscal year 2008 budget includes $2,925,413,000. The NHLBI provides leadership for an outstanding, visionary, and highly productive research program in heart, lung, and blood diseases. I will briefly describe the Institute's strategic planning process, and then highlight advances in three important research areas.

NHLBI STRATEGIC PLAN

With the extensive involvement of the scientific, professional, and patient-advocacy communities, the NHLBI has just completed development of a comprehensive Strategic Plan to guide its efforts in the near future. The Plan identifies a number of basic research areas of focus with the intent of delineating normal and pathological biological mechanisms and exploiting the emerging understanding of these mechanisms to identify biomarkers of disease. Such biomarkers—broadly defined as measurable indicators of genotype, biological or pathological processes, or responses to therapeutic intervention—will facilitate identification of disease subtypes and point the way toward new molecular targets for prevention, diagnosis, and treatment.

The Plan's clinical and translational research goals emphasize transmission of knowledge between basic and clinical research so that findings in one arena rapidly inform and stimulate research in the other. More precise methods of risk-stratification and diagnosis are expected to arise from application of new approaches (e.g., noninvasive imaging, biomarkers) from basic science laboratories. A critical challenge will be to develop personalized preventive and therapeutic regimens based on one's genetic makeup in combination with developmental and environmental exposures. Insights are already emerging, but robust and efficient means of validating both individualized and population-based treatments will be needed to establish an evidence base to guide medical practice.

The Institute is cognizant of the need to improve understanding of the processes involved in translating research into practice and to use that understanding to enable improvements in public health and stimulate further scientific discovery. Particular emphasis will be placed on conducting research in primary prevention and identifying interventions that work in the practice communities that will ultimately constitute the targets for translation and education. As well, the NHLBI will continue to investigate and evaluate new approaches to communicate research advances to the public, and will stress the importance of public involvement in the research process. These are ambitious tasks, but we are eager to take them on and optimistic about their ultimate success.

Over the past year, the NHLBI has made significant progress on a number of research fronts, but we highlight major advances in three areas.

MARFAN SYNDROME

Marfan syndrome is a genetic disorder of connective tissue—the framework that binds and supports the body. Although the syndrome has many manifestations, the most serious is a weakening (aneurysm) of the aorta that sets the stage for life-threatening ruptures. New research offers hope that losartan, a drug commonly prescribed to treat hypertension, might be effective in preventing this frequent and devastating complication.

After the discovery that Marfan syndrome is associated with a mutation in the gene encoding a protein called fibrillin-1, researchers tried for many years, without success, to develop treatment strategies that involved repair or replacement of fibrillin-1. Recently, a major breakthrough occurred with the discovery that one of the functions of fibrillin-1 is to bind to another protein, TGF-beta, and regulate its effects. After careful analyses revealed aberrant TGF-beta activity in patients with Marfan syndrome, researchers began to concentrate on treating Marfan syndrome by normalizing the activity of TGF-beta. Losartan, which is known to affect TGF-beta activity, was tested in a mouse model of Marfan syndrome. The results, published only last April, showed that the drug was remarkably effective in blocking the development of aortic aneurysms, as well as lung defects associated with the syndrome.

Based on this promising finding, the NHLBI Pediatric Heart Network is now undertaking a clinical trial of losartan in patients with Marfan syndrome. About 600 patients aged 6 months to 25 years will be enrolled and followed for 3 years. This development illustrates the outstanding value of basic science discoveries in identifying new directions for clinical applications. Moreover, the ability to organize and initiate a clinical trial within months of such a discovery is testimony to the effectiveness of the NHLBI Network in providing the infrastructure and expertise to capitalize on new findings as they emerge.

SICKLE CELL DISEASE

Excellent progress is being made against sickle cell disease, another genetic disorder that affects about 70,000 persons within the United States, mostly of African ancestry. The underlying defect, which deforms red blood cells, wreaks havoc on nearly every organ in the body. Fortunately, NHLBI research has yielded vastly improved treatment for this disease and an increase in life expectancy from the mid-teens to about 50 years of age.

Hydroxyurea, the first specific therapy, was shown in clinical trials to be safe and effective for adult patients and, subsequently, for children between the ages of 5 and 15 years. The treatment reduced anemia, the frequency of painful episodes, and the prevalence of acute chest syndrome—the main hallmarks of the disease—and also reduced mortality. Moreover, hydroxyurea did not adversely affect either normal growth or pubertal development in the children who received it. Two ongoing trials are now exploring other beneficial effects of hydroxyurea. Baby HUG is determining whether administering the drug to infants can prevent early damage to their spleens and kidneys. A second trial, SWITCH, is studying the possibility that children who have suffered a stroke and are now on chronic transfusion and iron chelation therapy can be switched to hydroxurea treatment to prevent another stroke. It would be of great benefit to these patients to have a treatment that could be taken orally without the side effect of iron overload.

The NHLBI also has an active program exploring cord blood/bone marrow transplantation for sickle cell disease. Heretofore, transplant procedures have been curative but limited to the few patients who have a compatible donor. However, recent cord blood transplant research is showing that success can be achieved with a less-than-perfect tissue match and, consequently, many more patients may be eligible to receive this treatment and avoid the disease's grim consequences.

Overall, it is expected that hydroxyurea therapy, future transplant protocols, and other therapeutic approaches will dramatically improve the lives of many patients with sickle cell disease and reduce the costs of recurrent hospitalizations and long-term care of complications. The NHLBI now has in place a pipeline for drug therapy, a drug screening program, and platforms for clinical trials for this orphan disease that will require multiple therapies for its many sequelae.

COPD

At long last, COPD is moving from obscurity to prominence. Now the 4th most common cause of death in the United States, COPD claims more than 120,000 lives annually—5.1 percent of the death toll. Moreover, for every person who will die of COPD this year, an estimated 200 others will suffer from impaired airway function, more than half of whom are undiagnosed. Once primarily an affliction of cigarette-smoking men, COPD now affects American women nearly equally and occurs surprisingly often among lifelong nonsmokers.

Progress against COPD has been slow and difficult, in part because the illness is complex and often perceived as being self-inflicted. Unlike diseases defined by a particular molecular defect or infectious agent, COPD has no single risk factor, no diagnostic blood test, and no definitive treatment. However, we are now entering a period of rapid discovery and translation into clinically effective interventions for

patients. Investigators are exploring mechanisms of injury and repair to the lungs, pathways involved in the regulation of airway mucous secretion, and genetic and environmental determinants of COPD. Applied studies are developing new methods of lung imaging and testing their ability to provide a better characterization of changes that occur in disease. The NHLBI-supported Lung Tissue Research Consortium is collecting lung tissues for preparation and distribution to researchers for innovative studies. Just this year, we embarked upon the Long-Term Oxygen Treatment Trial to test the efficacy of supplemental oxygen therapy in COPD patients with less-than-severe hypoxemia, and the COPD Clinical Research Network has been in place since 2003 to provide an infrastructure for rapid evaluation of emerging disease-management approaches.

An important and immediate challenge is to narrow the gap between what is commonly being done for COPD patients today and what can, in fact, be done. Many approaches—including drugs, pulmonary rehabilitation, smoking cessation, oxygen therapy, and surgery—are available to improve longevity and quality of life for people with COPD, but they are by no means universally applied. To address this shortfall, the NHLBI has launched a new educational campaign, Learn More, Breathe Better. The campaign encourages men and women over age 45 with respiratory symptoms, especially current or former smokers and people who have risks associated with genetics or environmental exposures, to seek spirometric testing and discuss treatment options with their doctors. Physicians are urged to be alert for indicators of COPD among their patients, to offer appropriate diagnostic testing, and to update their strategies for managing the disease. Our hope is that this educational campaign will yield an immediate public health benefit and also set the stage for translation and implementation of new discoveries that are on the horizon.

Thank you for the opportunity to present this snapshot of NHLBI activities. I would be pleased to respond to any questions by committee members.

Senator HARKIN. Well, again, Dr. Nabel, thank you very much, again, for a great statement.

Now we turn to our last witness. Dr. Griffin Rodgers has served as the Director of NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases for about 3 weeks.

Although I would hasten to add that he's been either the Deputy Director or the Acting Director since 2001. Dr. Rodgers received his undergraduate, graduate and medical degrees from Brown University. Dr. Rodgers, welcome and please proceed.

STATEMENT OF DR. GRIFFIN P. RODGERS, DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Dr. RODGERS. Thank you, Mr. Chairman and members of the committee. I'm really pleased to be here as the newly appointed NIDDK Director and to thank you for your continuing support of NIDDK funded research to combat an array of chronic health problems.

For millions of Americans, these diseases are common, costly and consequential. Our research mission is quite broad. It includes diabetes and other endocrine and metabolic diseases, digestive problems including liver and bowel diseases, kidney diseases including polycystic kidney disease, urologic conditions such as interstitial cystitis and prostate disorders, blood and nutritional disorders, and obesity.

Today I will provide research highlights on just a few of these areas. As noted by Dr. Nabel, obesity is a major risk factor for other diseases, including heart disease and type 2 diabetes. We are testing promising approaches to combat obesity and break these links.

Of grave concern, as Dr. Nabel pointed out, is the increasing rate of overweight and type 2 diabetes in children, particularly in certain racial, ethnic, minority groups.

One in 14 American children between the ages of 12 and 19 has pre-diabetes. Many of them also have risk factors for cardiovascular disease. Therefore our HEALTHY study is testing whether interventions in a group of middle school kids, sixth graders through eighth graders, predominately minority students, can successfully reduce overweight and other diabetes risk factors.

Another important effort is an evaluation of gastrointestinal surgery to promote weight loss, the so called Longitudinal Assessment of Bariatric Surgery; the acronym is LABS. This study doesn't provide for the surgery, but rather, collects and analyzes data in order to assess the safety and efficacy of these procedures for different groups of people with extreme obesity. We have also recently begun a parallel effort to examine the effects these procedures may have on severely overweight adolescents during development.

For people who already have type 2 diabetes, NIDDK has contributed to recent developments and approval of powerful new medical treatments. These include the drugs exenatide and gliptin. The drugs work to improve the body's own capacity to produce insulin. At the same time new avenues of intervention are likely to emerge from our advanced understanding of basic biology of appetite control and energy balance. For example, NIDDK researchers have recently demonstrated the key role of a protein called mTOR in influencing eating behavior.

We are also making strides in type 1 diabetes research. Type 1 diabetes in contrast to type 2 is not associated with being overweight or obese. It is an autoimmune destruction of the insulin producing cells of the pancreas. For example, NIDDK supported basic research contributed to the development and recent approval of continuous glucose monitors. These devices can make it much easier for patients to manage their blood sugar effectively, a vital means of preventing kidney, eye, nerve and heart damage, characteristic complications of both type 1 diabetes as well as type 2 diabetes.

These new monitors are really a critical step towards the development of an artificial pancreas and such a device would both recognize and respond to the body's need for insulin as quickly as possible and thus greatly improve diabetes management.

Just as obesity is a leading cause of type 2 diabetes, diabetes in turn is a leading cause of chronic kidney disease and irreversible kidney failure in the United States. When the kidneys fail, patients are dependent on costly kidney transplantation or dialysis for survival. New data has suggested that there is finally some cause for optimism now that the incidence of kidney failure has stabilized after a two decade increase of 5 to 10 percent annually.

Very recently there seems to have been a plateau in this change. This may be partly attributable to better preventive care that implements findings from a number of NIH studies.

These trials established the importance of proper glucose control, for example, in cases of diabetes, better blood pressure control and the use of medications that block the angiotensin II system to help prevent progression of kidney disease. Unfortunately, however, troubling racial disparities in kidney health persist. This is why our National Kidney Disease Education Program has developed materials specifically designed to "get the word out" about the im-

portance of kidney health in African Americans, Latinos, and American Indian communities, and the health care workers who provide services to them.

I'd also like to talk about some exciting work in the fight against chronic digestive diseases. One example of this is the recent discovery of a second major susceptibility gene for Crohn's disease, a form of inflammatory bowel disease. From such research springs hope of improved diagnosis and treatment.

In hepatitis C research, scientists have now identified a gene that helps determine how patients respond to therapy with the anti-viral agent, interferon. This finding may enable a more personalized and effective medical approach for a subset of patients. I think a few weeks ago you heard, Dr. Zerhouni testify to you about his vision of more "personalized medicine." This is just one example.

The handouts that I have brought for you are two that simply illustrate the risk factors and complications of diabetes: retinopathy, neuropathy, nephropathy, and cardiovascular disease. Diabetes is the leading cause of non-traumatic amputations in this country. The second slide just illustrates the stages of the natural history of type 2 diabetes. There are roughly 54 million Americans in this country with pre-diabetes and roughly 21 million with type 2 diabetes and I could discuss this later if you like.

We've posted copies of these handouts on our website for the public to view as well.

PREPARED STATEMENT

Thank you for the opportunity to present a few examples of chronic disease research that are within the mission of NIDDK. Again, thank you for inviting me and I would certainly be pleased to respond to any questions that the committee might have.

[The statement follows:]

PREPARED STATEMENT DR. GRIFFIN P. RODGERS

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) a sum of $1,858,045,000, which includes $150,000,000 for the Special Appropriation for Research on Type 1 Diabetes through sec. 330B of the Public Health Service Act. The NIDDK transfers some of these funds to other Institutes of the NIH and to the Centers for Disease Control and Prevention (CDC).

Our Institute supports research to combat a wide range of chronic health problems that affect many millions of Americans, and which can be debilitating, deadly, and expensive to treat. These include diabetes and other endocrine and metabolic diseases; digestive and liver diseases; kidney and urologic diseases; blood diseases; and obesity.

LEVERAGING PRIOR INVESTMENTS

Through continued investment in research, NIDDK-funded scientists have valuable assets at their disposal as they strive to mitigate or prevent chronic disease. These assets include both accumulated knowledge of life processes and the highly valuable data and cohorts of patients assembled through long-term investment in clinical research. For example, the landmark Diabetes Control and Complications Trial proved that tight control of blood glucose greatly diminished risk of eye, kidney, and nerve complications of type 1 diabetes. Patients who volunteered for this effort are providing scientists an invaluable opportunity to study long-term benefits of such care by participating in the follow-up study, Epidemiology of Diabetes Interventions and Complications. This study has now demonstrated that intensive blood

glucose control also greatly diminishes risk of heart attack and stroke, with remarkably long-lasting benefits. Important knowledge is also being gained through the long-term follow-up of participants in the Diabetes Prevention Program (DPP), which established that regular physical activity and modest weight loss can prevent or delay type 2 diabetes in those at risk. In a recent advance, NIDDK-supported researchers capitalized on DPP data to study the effect of a gene in an Icelandic population identified by industry, confirming that variants in the gene predispose people in a diverse U.S. population to type 2 diabetes. Importantly, this study showed that the intensive DPP lifestyle and metformin interventions successfully delayed or prevented type 2 diabetes in people with the genetic risk factor. Thus, building on prior investments in clinical trials is yielding profound new insights into diabetes treatment and prevention.

Similarly, consortia for studying inflammatory bowel disease (IBD) and type 1 diabetes are leveraging years of careful, classical genetic analyses with findings of the Human Genome Project and HapMap to elucidate the complex genetic foundations of these diseases. Already, the IBD Genetics Consortium has identified a major genetic risk factor for the disease. The Beta Cell Biology Consortium is capitalizing on genomics with the PancChip, a tool that permits the study of genes in the pancreas. The NIDDK has created central repositories for saving and distributing data and biologic samples, and established its research consortia to synergize progress via these repositories, and trans-disciplinary cooperation.

More important than leveraging the opportunities for researchers are the direct benefits to patients that flow from these efforts. The Institute is committed to helping patients and health-care providers adopt research-driven innovations in disease treatment and management to improve lives. Crucial to NIDDK's approach are its education campaigns, including culturally-sensitive materials for disproportionately affected minority populations. These include the National Kidney Disease Education Program and the National Diabetes Education Program, which launched a new campaign to prevent diabetes in women who had gestational diabetes, and their offspring. The Interstitial Cystitis Awareness and Celiac Disease Awareness campaigns spotlight these often undiagnosed chronic illnesses. A key NIDDK goal is to derive the maximum benefit from prior investments, even as we continue to build for the future.

DEVELOPING PARTNERSHIPS

The NIDDK has strong, productive relationships with other NIH Institutes and Centers due to the intersection of our Institute's research responsibilities with those of other NIH components. For example, diabetes can lead to heart disease, blindness, and nerve disease, so we frequently collaborate with the NHLBI, NEI, and NINDS. The NIDDK also recognizes the vital importance of collaborating with other Federal and State agencies and non-profit groups, as well as with external experts from the scientific, health care, and patient advocacy communities. For example, the Institute led the development, with broad stakeholder input, of strategic plans for type 1 diabetes research and for pediatric urology. The Institute is currently providing leadership to the development of a long-range research plan by the National Commission on Digestive Diseases. By engaging in highly collaborative strategic planning, the Institute endeavors to maximize use of its resources to best support future research advances.

In addition, the Institute is positioned to capitalize on opportunities for public-private partnerships. The Foundation for the NIH recently announced the formation of a Biomarkers Consortium, which combines resources and expertise of the NIH, the Food and Drug Administration, and the Pharmaceutical Research and Manufacturers of America. Biomarkers are measurable molecular, biological, or physical characteristics that indicate a specific underlying physiologic state and can facilitate accurate diagnosis, assessment of risk for or severity of a disease, and/or gauging response to therapy. The Consortium is seeking to accelerate the development of these biomarkers to a degree beyond the capacity of an individual partner. The NIDDK proposed and the Consortium accepted the "Diabetes and Pre-Diabetes Biomarkers Project." Building on an existing NIDDK study, the Project may make it possible to achieve significant health care savings and advantages by enabling more rapid and accurate detection of diabetes.

The NIDDK also values its important partnerships with the research community and with the patients who participate in clinical trials. Critical to the continued development of this human-capital resource is our commitment to new investigators, through priority funding, small grant and career awards, and mentoring workshops.

GENES AND THE ENVIRONMENT

New genomics technologies enable us to address scientific questions of enormous complexity and importance. For example, the Institute is very interested in the effect of genetics on liver health and response to therapeutics. NIDDK intramural scientists recently identified a gene that helps determine how people with hepatitis C respond to interferon therapy. Also, NIDDK's Drug Induced Liver Injury Network plans to look for genes that have an impact on whether various drugs cause liver damage.

Genetic data is key to deciphering the equation of health. The other key term in that equation is the way the environment influences health. "The Environmental Determinants of Diabetes in the Young" study is designed to solve this equation for type 1 diabetes, in which a one or more as-yet unidentified environmental triggers spark autoimmune destruction of the body's insulin-producing cells. The hope is that a vaccine or change of diet, for example, could one day prevent the disease in those at risk. The project may also provide key insights on environmental causes of celiac disease, which has overlapping genetic susceptibility with type 1 diabetes. In celiac disease, gluten—a major protein in wheat, rye, and barley—triggers an immune response that damages the small intestine and interferes with the absorption of nutrients. Microbes that live in the human gut represent a key part of our environment. Recent NIDDK-supported research has established that there is bidirectional induction of genes between the host and intestinal bacteria, influenced by other environmental factors, such as nutrients. Future NIDDK efforts seek to expand understanding of the genomes of the gut bacteria (the microbiome) and detail the microbes' impact on human health.

The NIDDK Metabolic Clinical Research Unit established at the NIH Clinical Research Center will permit intramural and extramural scientists an unprecedented opportunity to take environmental, dietary, and metabolic snapshots of normal, overweight, or obese patients. The facility will be an excellent resource for understanding the gene-environment interaction as it affects metabolic health, as well as for answering other research questions pertinent to obesity and overweight. Another effort to tie environmental variables to metabolic health outcomes is an initiative on the obese and diabetic intrauterine environment, which seeks to shed light on long-term consequences for offspring that can arise during this developmental period.

FORGING NEW PATHWAYS TO CARE

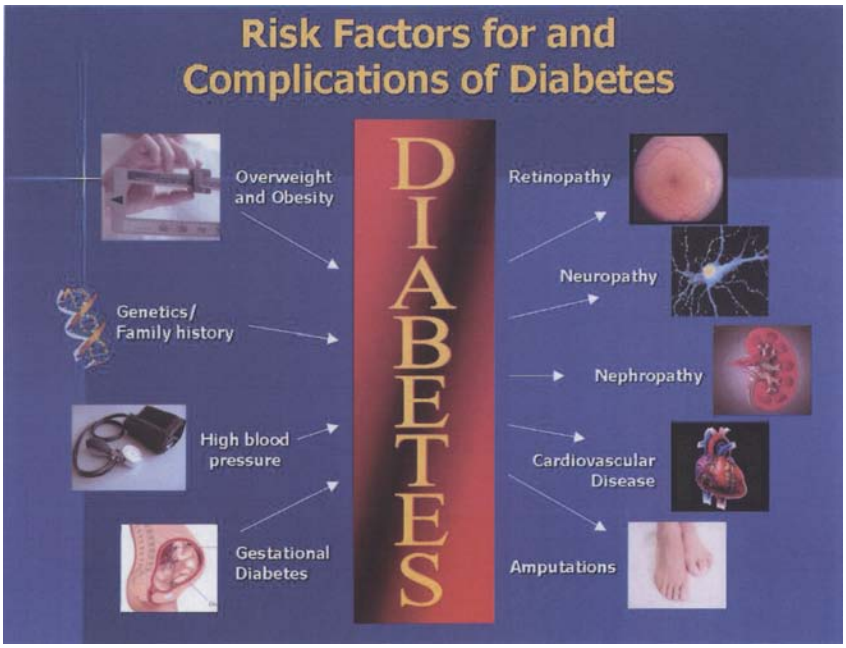
NIDDK-supported researchers continue to make dramatic strides in improving the health and well-being of people with chronic diseases. Institute and industry support combined to enable the development of continuous glucose monitors which can, in the short and medium term, reduce the number of painful, daily finger sticks for people with type 1 diabetes. Through better blood glucose control, the monitors may reduce their chances of serious complications in the long term. The NIDDK is also forging a new path to prevention through approaches such as the HEALTHY trial. This study is testing a school-based intervention to reduce students' type 2 diabetes risk factors in middle schools with predominantly minority populations. More than half of the children in these schools are overweight, and 15 percent have two additional disease risk factors. The NIDDK is also seeking to enhance evidence-based medicine through studies such as the "Randomized Intervention for Children with Vesicoureteral Reflux," a disease of the bladder. The trial is testing whether long-term use of antibiotics could prevent urinary tract infections in affected children, as well as scarring of the kidneys. For people with end-stage renal disease, NIDDK is conducting a trial to determine if more frequent dialysis improves quality of life and reduces cardiovascular risk.

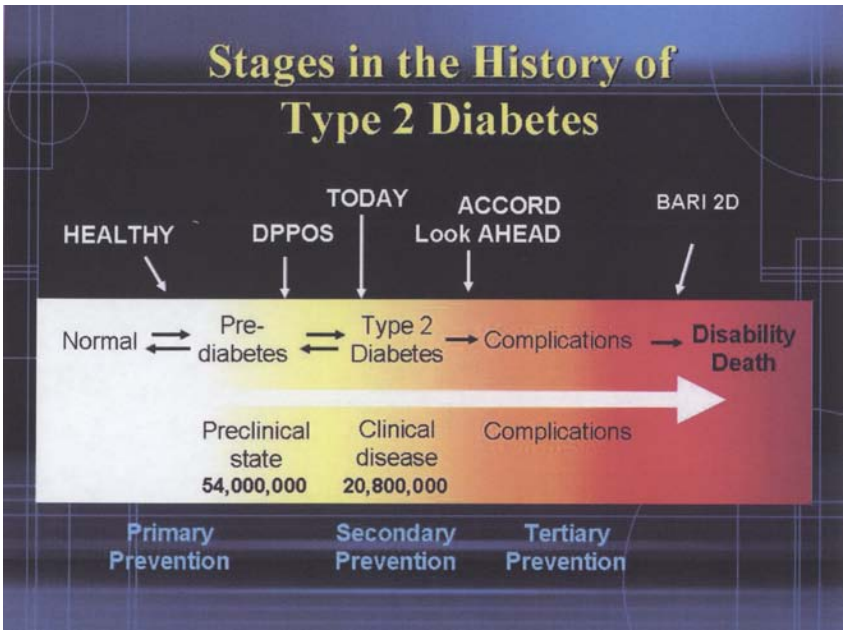
Other new pathways to patient care may emerge from the "Biliary Atresia Clinical Research Consortium." This network is shedding light on this rare, poorly understood, but extremely serious disease by conducting basic studies to identify its causes and by testing the ability of a drug regimen to improve outcomes following surgery to improve bile drainage. Improvements in patient care may also come from the NIDDK's Molecular Therapy Centers, which are working to realize the potential of gene therapy care for patients with cystic fibrosis and other devastating genetic disorders.

The studies, trials, and initiatives I have highlighted represent just a few of the important elements in NIDDK's research agenda, made possible through a robust core of investigator-initiated studies, representing the solid foundation of NIDDK's research portfolio. Recent findings from this core research include: the discovery that the amount of a protein in blood correlates with insulin resistance in people at risk of type 2 diabetes; new technologies for imaging insulin-producing cells in

the pancreas; and the identification of genes and proteins that regulate the absorption and utilization of iron and have key effects on development of red blood cells—discoveries that may have great importance in the treatment of common forms of anemia.

Thank you, Mr. Chairman, and members of the Committee, for this opportunity to share with you just a few highlights of NIDDK's vigorous research program. I would be pleased to answer any questions you may have.





STAGES IN THE HISTORY OF TYPE 2 DIABETES—LEGEND

The NIDDK and other ICs support a range of clinical studies related to diabetes, with interventions at different stages of the disease.

Primary Prevention—Preventing disease onset

—HEALTHY—A school-based trial to prevent middle school children from developing risk factors for type 2 diabetes by exercising and improving their diets.

—DPPOS—A follow-up study to test the long-term impact of interventions used in the extremely successful Diabetes Prevention Program (DPP). The initial, three-year DPP trial showed that people at risk of developing type 2 diabetes could markedly reduce their likelihood of developing the disease through an intensive diet and exercise program or with the generic drug metformin. http://www.bsc.gwu.edu/dpp/index.htmlvdoc

Secondary Prevention—Preventing those with a disease from developing complications

—TODAY—Treatment Options for type 2 Diabetes in Adolescents and Youth is designed to compare three treatment strategies for type 2 diabetes in the growing number of adolescents diagnosed with the disease. (http://www.todaystudy.org/index.cgi)

—ACCORD—Action to Control Cardiovascular Risk in Diabetes is a trial initiated by the NHLBI in collaboration with the NIDDK that focuses on preventing heart attack, stroke and other cardiovascular problems in people with type 2 diabetes. (www.accordtrial.org/public/index.cfm)

—Look AHEAD—Action for Health in Diabetes is a trial initiated by the NIDDK in collaboration with the NHLBI to examine a lifestyle intervention designed to achieve and maintain weight loss in people with type 2 diabetes over the long term through decreased caloric intake and exercise, in order to prevent cardiovascular disease. (http://www.lookaheadtrial.org)

Tertiary Prevention—Preventing disease complications from worsening or causing death

—Ban 2D—Bypass Angioplasty Revascularization Investigation 2 Diabetes is an NHLBI study, with additional support from NIDDK, to compare surgical or angioplasty to medical treatments for type 2 diabetes patients who have cardiovascular disease and also to compare two strategies to control blood sugar in these patients (http://www.bari2d.org/)

Senator HARKIN. Dr. Rodgers, thank you very much. Thank you all. I don't seem to have a clock here so I'll have to look at the one up there. I'll just take maybe 7 minutes and just go down the line here.

Boy, I have a lot of questions from your testimony to look at here. Well, I'll start with Dr. Rodgers.

Tell me about GERD. That falls within your jurisdiction and eating disorders and I was told a couple of years ago that the leading cause of young women dropping out of college was eating disorders, the largest single cause of women dropping out of college or interrupting their school was eating disorders and then a lot of this has to do with GERD. What does this stand for?

Dr. RODGERS. Esophageal reflux disease.

Senator HARKIN. So, can you address yourself to that? What kind of research is being done into eating disorders that seem to be so prevalent in our country?

Dr. RODGERS. Thank you, Senator. The NIDDK is involved in a number of studies related to GERD and other so called functional bowel diseases. These diseases range from GERD, or gastroesophageal reflux disease, gastroparesis, in which the stomach is unable to empty its contents, and then a number of motility disorders, particularly functional bowel disease or irritable bowel syndrome.

The research at the NIDDK and other Institutes at NIH involves better understanding the brain, gut coordination of the function and motility of the gastrointestinal tract and the critical role that a number of neurotransmitters such as serotonin play in emptying the contents of the gastrointestinal tract.

Very recently we have developed a National Commission on Digestive Diseases, Functional Bowel Disorders, which include GERD and IBS, or irritable bowel syndrome, are critical areas that have been identified by this group of outside experts who are currently developing a research plan, to guide efforts over the next 5 to 10 years.

We've also been working on gastroparesis—the inability of the stomach to empty. A major risk factor for gastroparesis turns out to be diabetes and this is a very disabling problem for a number of Americans. A gastroparesis consortium of leading experts and centers throughout the country is really studying these patients very carefully to understand their natural history and develop a better treatment method for these patients.

Senator HARKIN. Let me see if I wrote this down right. One in four Americans aged 12 to 19 has a condition of pre-diabetes.

Dr. RODGERS. That was 1 in 14, Senator.

Senator HARKIN. That's still pretty high, not quite as bad as 1 in 4. Then you mentioned something about surgery for adolescents. What is this all about, surgery?

Dr. RODGERS. They are bariatric surgical procedures.

Senator HARKIN. We usually think about that for people like my age who are obese and have a hard time getting rid of it but we don't think about in terms of teenagers.

Dr. RODGERS. For a number of Americans who are morbidly obese, particularly adults, the surgery offers a great deal of prom-

ise. However, what has not been done is to carefully determine who are the optimal patients for this form of surgery.

Surgery can be very corrective in many cases. Patients with prediabetes or even frank diabetes who undergo this surgery actually lose a substantial amount of weight and have a correction of their diabetes and other risk factors for cardiovascular disease. However, the surgery does have its complications and what we're trying to determine is for which individuals this is an optimal form of treatment.

Now the Agency for Healthcare Research and Quality reported in January this year there were roughly 121,000 bariatric surgeries done in 2004. They also estimate that among kids between the ages of 12 to 17 there were roughly 350 or 400 of these surgeries that year.

Senator HARKIN. Well, I guess my mind rebels of something like that. Just thinking about the fact that is really sort of a catastrophic type of intervention and that there are other things that could be done. I'll have to think about that a little bit more. That kind of shocked my conscience when you talked about that.

I wanted to know, getting back to my first question on eating disorders. So is your Institute working with NIMH for example, are you correlating and doing some combinations of studies of the neurotransmitters that maybe affect that? How the mind interacts with the eating disorders?

Dr. RODGERS. Our Institute principally focuses upon the molecular basis of what controls hunger and satiety and eating.

Senator HARKIN. I'm sure you are. The answer is you are working with NIMH.

Dr. RODGERS. Partially, but by and large the National Institute of Mental Health is really the lead Institute on eating disorders per se, not in terms of the understanding of the molecular biology of eating.

Dr. Volkow, the NIDA Director I think testified.

Senator HARKIN. Yes, we did.

Dr. RODGERS. Is really one of the leading experts in this area and has published a number of studies using imaging techniques of the brain to characterize patients with various eating problems.

Senator HARKIN. Well, I followed this very closely. It just seems you've got a couple of things. You've got what the mind is doing but you also have people that have what's called irritable bowel syndrome where they have something going on in their gut that tends to feed on that and tends to make it worse so one kind of feeds on the other and I've wondered for some time whether or not we're focusing too much on the brain and not enough on physical things that are going on.

Dr. RODGERS. Absolutely, those are areas we are clearly beginning to address, particularly with this national commission.

Senator HARKIN. I've used up my time. I would yield to Senator Cochran. Thank you.

Senator COCHRAN. Thank you very much, Mr. Chairman. It is a pleasure to join you for this important hearing this morning.

I would ask each of you who chair or are representing the Institutes this morning to comment about the adequacy of the funding

levels and what could be done if we were able to increase those above the President's level.

I don't know if we would be able to but it would be good to know what the money would go for, how it would be used. Would there be other beneficial uses of additional funding if we were able to increase these appropriations levels. I guess Dr. Hodes; we should start with you and then have each Institute Director comment on the research in their areas of interest.

Dr. HODES. Well, it is an important question. Thank you for raising it. Let me try to respond at two levels. The first having to do with the limitations which current funding might place on research initiatives. What clearly each of us does with a level of budget we have is to make judgments that maximize the use of the funds and that generally means an appropriate balance between the basic research which a promise for the future and the translation of what we know in the more immediate outcomes.

The ability now to fund research across this whole spectrum is certainly limited. It's reflected in numbers, such as success rates, the proportion of applications, outstanding applications that we are able to actually fund, but those numbers really have meaning in terms of the studies that cannot be done because we cannot fund them.

In the case of the Aging Institute, I think representative of others this means, I think some of the studies understand basic underlying biology it also means the number of clinical trials, be it Alzheimer's disease, or to prevent frailty, to prevent diabetes, to prevent other age related outcomes are being limited. That is there are proposals by scientists which are judged by their peers to be highly meritorious but which cannot be funded, if they fall outside of our pay line.

There's some particular areas of vulnerability that I think have been stressed by Dr. Zerhouni and across all of NIH in addition to these concerns about what's happening in immediate areas of research.

We're very concerned about particular vulnerabilities having to do with the workforce, young investigators, vulnerable populations that concern that even if we were able to carry it through with some bridging funds in small amounts for a year or two that the duration period we have been going through is such that we have very real concerns that individuals are going to be discouraged from entering the workforce and this would truly be a long lasting adverse consequence.

As a result with funds that we have and continue the high priority if we had additional funds we would attempt to make special efforts to provide incentives to continue entry of new investigators in the workforce and carry them through the vulnerable periods so this generation will be the one that can generate discoveries 10, 20, and 30 years from now.

Senator COCHRAN. Dr. Katz.

Dr. KATZ. Well, I would reiterate Dr. Hodes' point with regard to the success rate. The success rate is the number of applications that are actually funded over the number that are applied for and in fact there are many outstanding applications that we just don't fund now so we would increase the success rate.

We also have even in constrained times made a special effort for new investigators to keep them in the pipeline because even before they get to that new investigator stage, there's a tremendous investment before they get there. There's a tremendous investment in their training, not only their clinical training, in many cases, but also in their post clinical training to learn how to do science because you have a long lag period before when you actually apply for your grant so we're trying to address that this year. I think we need to address that in a bolder, more robust way in the future. Specifically in our Institute we have initiatives that I talked about in regenerative medicine. Will we continue those initiatives, yes. Will they be at a slower pace, yes.

We have also clinical studies that we will continue to do. The doubling really enabled us to do many clinical studies, some of which I mentioned during my opening statement with regard to surgery verses non-surgery for low back pain, but they will be slowed down.

Finally, we have a major initiative we embarked upon with the Aging Institute and other Institutes as well as private industry, the pharmaceutical companies, called the osteoarthritis initiative. The goal is to be able to identify biomarkers and predictors for progression of disease—to know who is at risk, number one and number two, to do clinical studies that don't take 10 years to get an answer. If you've got a biomarker, you can do it in a much shorter amount of time.

Well this research resource, in which we have invested collectively about $60–$65 million over the last 7 years, is now coming to fruition. The data are coming out. It is publicly available. The data on 2,000 individuals who are being followed are coming out. We want to take advantage of that and stimulate the communities to be able to utilize this resource. We will do it, but we will do it at a slower pace.

Senator COCHRAN. Dr. Nabel.

YOUNGER GENERATION

Dr. NABEL. Thank you, Senator Cochran. I'm quite concerned about the effects of our current budget status on the young people in this country.

I just got back from San Francisco where I had a chance to visit with medical students, residents and fellows at the University of California at San Francisco, many of whom are desperate to go into medicine. Their passion is to make discoveries and help their fellow humankind, but they're discouraged, they're fearful about job security. Will I be able to get a NIH grant, will I be able to support my family, and will I be able to find a job at the end of my training?

This is a concern that we're hearing not just from one university in the country, but we're hearing from universities across this country and it really is something that we take quite seriously because we know the future of medicine, science and health care in this country relies in our younger generation.

We have many, many bright people going into medicine now and we want to do everything we can to support their career development so training is a major issue that we're very concerned about.

Like my colleagues, we have many grants that come from investigators at universities that are very, very worthy of funding that we're not funding right now.

CLINICAL TRIALS

In addition we have clinical trials that we would love to go forward with. Two of them are programs to reduce heart risk in young adults by preventing weight gain. I told you about some of our studies previously in children. We now want to look at this in young adults.

We have a new blood pressure intervention trial that we're eager to get going on. Looking into what level should we treat a lower blood pressure to reduce heart risk, but those studies are delayed as well.

We have just begun a very large study of heart disease in four Hispanic communities in this country, but we had to cut back on that study and cut back on the number of indicators of disease that we could measure because we simply did not have enough money to fully fund it.

Those are just some examples.

Senator COCHRAN. Dr. Rodgers.

Dr. RODGERS. Thank you, Senator Cochran. I really echo the sentiments expressed by my colleagues here at the table. If I would sort of put my finger on it, I think training is critically important. To get an investigator in biomedical research through college, through graduate or professional school, and through medical school or dental school represents a tremendous investment, and also for them to do the post-doctoral training necessary to secure a career.

If we allow them to have some additional funding but then the next time around they lose that funding, it's quite likely we could lose a generation of investigators.

In addition to what's already been said, some of the things that we have not been able to do is for example to fund small innovative grants of new ideas at a low level. Many of these ideas end up accelerating into a larger grant. Support for these small innovative types of awards is one concern.

Another issue is that we offer supplements to people to bring in new talent, such as physicists and people involved in nanomedicine, to supplement existing grants. We've had to scale back on that. It is important to bring in new ideas to the pipeline. Also, supplements can replenish equipment to keep the research ongoing. That has been an area that we have had to cut back on.

Like my colleagues I have a number of very basic investigations and clinical studies that we really would like to fund. One example is to determine whether if you intervene early, right at the time the diagnosis for diabetes is made, you can forestall, prevent, delay, or reverse some of the morbidity and mortality associated with the disease. It seems intuitively obvious but until we actually do a study to examine this, we just won't know. This is something we would love to study.

Senator COCHRAN. Thank you very much. Dr. Nabel, as you pointed out in Jackson, Mississippi is the Jackson Heart study and it's directed to give us answers to questions about why there's such

a disproportionate high rate of death and disease from cardiovascular diseases in my State than in any other State. The age adjusted rate is highest. Is there money in the budget to continue this program and could you tell us what we need to do in terms of funding for your Institute or some way to be sure that study is continued at an aggressive level?

Dr. NABEL. Thank you, Senator Cochran. As you know we're all extraordinarily proud of the Jackson Heart study. It's the largest longitudinal study of heart disease of African Americans in this country. We've had the pleasure of visiting Jackson and visiting the site of the study in the Cochran Medical Mall and it is an enormous, enormous contribution.

This has been a wonderful collaboration between the Heart, Lung and Blood Institute and the National Center for Minority Health Disparities, which Dr. John Ruffin leads and so we partnered together and we co-fund the study. Dr. Ruffin and I are very committed to the continuation of the Jackson Heart study. We have ensured that we have budgeted monies in the out years for the study, but of course, we are always limited in what we can do.

With the last contract period we had to scale back some of the analysis that we had intended to do because we just didn't have sufficient monies in the budget.

Senator COCHRAN. Thank you very much for that report and the good work the National Institute is contributing to that effort.

PREPARED STATEMENT

Mr. Chairman, I would like to have my full statement printed in the record at the beginning of the hearing if that is ok and I will be glad to yield whatever time I have left. I've probably gone way beyond what we agreed today, but thank you for your generosity.

Senator HARKIN. Without objection your statement will be made a part of the record and we kind of engage a little bit more in depth to look at all the different Institutes so I appreciate your being here if you can stay.

Senator COCHRAN. I'll stay for a little while. Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for giving us this opportunity to review the proposed budget for the National Institutes of Health for fiscal year 2008. I am pleased the Committee has four NIH Institute Directors with us today to discuss the budget and to provide their important perspectives on research priorities. We appreciate the participation of this distinguished panel and their sharing with us their vision for the future of their respective Institutes.

Many people in our country suffer from a disease that decreases their quality of living or ends life prematurely. Whether it is a disease that occurs as part of the aging process, such as age-related dementia, or one affecting a child in the early stage of life, such as Type 1 diabetes. Many Americans are searching for improved therapies and cures for these debilitating diseases.

The NIH is leading the research effort to identify these new and improved treatments. Dr. Zerhouni testified before this Committee in March about many of the medical advances that have resulted from NIH-supported research. Each Institute has a special and significant role in helping improve the chance for a healthy life for all Americans.

Cardiovascular disease affects nearly 80 million people in our country and continues to be the leading cause of death from disease. In 2007, the cost associated with heart disease is estimated to be over $430 billion. This is of special interest

to my constituents because Mississippi has more cardiovascular disease than any other State. We also have the highest death rate from heart disease, particularly among our African American population. The Jackson Heart Study, the first large-scale epidemiologic cardiovascular disease evaluation in African Americans, is currently underway at the University of Mississippi Medical Center to examine factors leading to heart disease in this population.

This is only one example of the important work sponsored by the National Heart, Lung and Blood Institute. Dr. Nabel, I look forward to your comments on NHLBI's broader plan to reduce cardiovascular disease through NIH research efforts.

Diabetes is another example of a chronic disease that continues to increase in prevalence throughout our Nation. What was once thought to be "adult" diabetes is occurring more often in children as we see the numbers of overweight and obese young people increase. Progress in this area is also very important in my state because we have higher occurrences of diabetes than any other State, especially the Mississippi Delta region. Diabetes leads to such problems as blindness, nerve damage, kidney failure, and heart disease. Scientific advances in this area would help a significant number of people who suffer from these painful outcomes.

The contributions of each Institute at NIH are important to accomplishing our national goal. Translating basic science knowledge into improved and life-saving therapies for individuals is challenging, but it is the key to improving disease outcomes. I appreciate your hard work and your dedication to helping the NIH be successful in these most important efforts.

Senator HARKIN. If you have more questions or any follow ups, I'd be glad to turn to you at any time.

Dr. Nabel, first of all let's go back to what you were saying about healthy lifestyles the Institute has been good at. I like to see NIH applying research and doing outreach to improve people's health.

I remember the first person that chaired this committee that I'm now privileged to chair, when I first came here, was Lowell Weicker, Senator Weicker, and at hearings he always said, you know NIH does not stand for the National Institute of basic research. It's called the National Institute of Health for a reason, to try to make people healthy and to get outreach out. Now obviously one of the biggest factors in that is for NIH to fund basic research, but not to just end there, it's to take the findings and move it out and so I compliment you on that and other Institutes for doing that. Institutes should do more of that kind of work, of getting information out.

Just the things you said, interventions early in life, reducing incidents of heart disease, physical activity in school, healthy food choices, we need to hear from you and from the science community more on this. We know that we're building elementary schools in America today without a playground.

I had a frightening quote from a principal at an elementary school, I won't say where, but it was, he was quite profound. Someone said why are you building these schools without playgrounds? He said we're in the business of education, not building monkey bars. What a narrow view on education. When we were younger, I'll bet we were always kicked outside for recess.

We had to go out and do things and run around and get physical activity and no longer is that happening. So again, we need your strong voice out there again promoting this and healthy food choices in schools.

For some reason we allowed schools to put in more vending machines and soda pop and junk food and all that kind of stuff and kids eating that and not only getting obese but also leading to heart disease. So we need, again, to have more input from your In-

stitute to do the studies that are necessary and also to just inform us what we need to do on these healthy food choices.

There is one area I want to cover with you and that has to do with blood pressure. Now you made the point that blood pressure, high blood pressure is a dominant factor leading to heart disease. Is that a correct statement?

Dr. NABEL. Yes.

Senator HARKIN. Well, now, is it also not true that high intakes of sodium will elevate your blood pressure? Am I being scientifically correct here?

Dr. NABEL. Yes.

Senator HARKIN. Well I've always had good blood pressure until recently, a year or so ago, all of a sudden my blood pressure started going up, not dangerously high so I decided what I was going to do, I was going on a low sodium diet. Have you ever tried to go on a low sodium diet?

Dr. NABEL. It is tough, isn't it?

Senator HARKIN. It is tough and how about all these kids out there? I mean, try to buy a prepared meal that is not just loaded with sodium. Try to buy a can of soup. We have a chef over in the cafeteria in this building, in the basement of this building and I like to have soup for lunch, so one day I sat at my desk and had soup brought up to me by staff. Staff got me some soup so I could eat and do some work. Suddenly it occurred to me that I was eating salt and so I got a hold of the Senate chef and I said this is loaded. How much sodium is in this?

Well, it was just loaded with salt and so I said why can't you just get soup with low sodium. Well they do now. They have it on the menu. You get low sodium soup, very low, hardly any sodium at all. It tastes just great, but that's what you have to go through to get it done.

Try to buy a frozen dinner, a frozen dinner, Healthy Choice, Healthy Choice it says. What's some of the other ones, I forget. So you go through and start looking at the Healthy Choice, yes it's low in fat, no trans fats and then you see the sodium, just packed with sodium. How can that be a healthy choice?

Dr. NABEL. It is not, it's not.

Senator HARKIN. What are you doing about it?

Dr. NABEL. I wish I had a magic wand.

Senator HARKIN. Seriously, are you working with, we've got to get the FDA to start looking at this too. We need your scientific background to buttress things.

Dr. NABEL. Absolutely, we see our role as providing the scientific evidence that then helps make these directives and we're working very, very closely with the Food and Drug Administration and CMS and other Federal agencies, CDC on these areas.

I do want to credit many of the professional groups, organizations in this country, for example, the American Heart Association has fantastic public awareness programs in public health, obesity, heart risk factor reduction and they have in particular developed a number of alliances with members of the food industry to begin to look at the quality of foods that are prepared, particularly those given to our young people.

Senator HARKIN. Do we need any more research into the effects of sodium or do we know all of that?

Dr. NABEL. We know a fair amount. We know blood pressure is controlled by the kidneys which regulates water and sodium intake. It's controlled by the brain by a series of hormones, but blood vessels themselves also control blood pressure and the reality is we all get older, our blood vessels stiffen a little bit and that's probably a good reason why our blood pressure tends to get a little bit higher as we get older.

In fact we've had conversations recently with Dr. Hodes and his superb scientists about potential ways to address this issue in individuals, but getting back to your earlier point, I think you're absolutely right, we have shifted in this society toward a dependency on prepared foods and that is really, I think that the shift that has occurred post World War II.

We don't rely on using fresh ingredients to make home prepared meals like we did when many of us were growing up and I think we are seeing the untoward consequences. So much of what we tried to help young families with, is just learning how to eat fresh fruits, fresh vegetables, fresh food products and learning how to prepare very simple meals that are healthy and less dependent on prepared foods.

We have got a long way to go, but there is a lot of energy and a lot of momentum that is building through a number of organizations around the country.

SCHOOL NUTRITION PROGRAMS

Senator HARKIN. Well, Senator Cochran and I are trying to do our part in the school nutrition programs in fruits and vegetables. We've worked together on that and tried to get more fruits and vegetables into the schools, that type of thing, but it's good to have the National Institutes of Health out there again promoting this, again the outreach, the information, the translation of your research into better public knowledge and awareness.

The statements by the Director of the National Heart, Lung and Blood Institute carry a lot of weight, it has a big impact and so we encourage you to continue on this.

Dr. NABEL. Thank you. We realize that and we know that we have a major role to play in helping to promote health, prevent untoward consequences.

COPD CAUSES

Senator HARKIN. I just have two other things I want to cover with you, Dr. Nabel.

Chronic obstructive pulmonary disease, the fourth leading cause of death. Tell me again, in layman's terms, what is that?

Dr. NABEL. So COPD is what we used to call emphysema. So it's shortness of breath. They can't breathe and you probably remember the picture of the individual and historically it's been caused by smoking and what the smoking does is it literally destroys the lung tissue. So you lose the air sacs.

Senator HARKIN. Is the biggest factor for COPD, smoking?

Dr. NABEL. It continues to be smoking and what we're particularly concerned about is while there are fewer smokers in the older

generation, there are more and more smokers in the younger generation, particularly young women and again, it's getting the message out that what may appear to be a simple act early in life leads to real problems.

Senator HARKIN. What does you research show other causes? You mentioned other factors that may be involved.

Dr. NABEL. There are other causes. There are some environmental factors, pollutants, toxins that can lead to lung scarring. We know that there are certain infections that go on for a long period of time, if not adequately treated can produce this. We also have the sense that there may be some genetic susceptibility that we don't quite understand.

I had a visit the other day from a woman from Honolulu, Hawaii, 45 years old. She came to my office and said, you know at 45, I've got COPD. I've never smoked. I don't understand this. It is those types of individuals that we really need to reach out and try to understand.

So we have made a major investment in trying to understand the factors that contribute to COPD and it's going to take a major investment, a few years of study, but we will be looking at genetic causes, environmental causes, biochemical causes, et cetera.

LAM LONGITUDINAL STUDY

Senator HARKIN. One last thing and here I'm going to try to pronounce the word, Lymphangioleiomyomatosis.

Dr. NABEL. Lymphangioleiomyomatosis.

Senator HARKIN. LAM, ok. A constituent of mine suffers from LAM. I understand there's been a lot of distress among LAM patients across the country about your decision, your Institute's decision to close the intramural program on this disease and end a longitudinal study that has collected LAM tissue samples for many years. These patients are concerned that one, the data collected through the longitudinal study will be wasted and two, they will no longer have access to dedicated care providers at NIH. Could you address those concerns?

Dr. NABEL. Sure, if I could, Senator, I would like to correct some of that information.

Senator HARKIN. Absolutely.

Dr. NABEL. We are very committed to LAM. This is really a very, very tragic lung disease that occurs predominately in young women. It probably has a very strong genetic etiology.

Senator HARKIN. How does it manifest itself?

Dr. NABEL. Shortness of breath, all lung diseases manifest in shortness of breath, fatigue, inabilities to do activities that one once could and there are certain types of cells. We think that they might be like smooth muscle cells that grow within the lung tissue and slowly destroy the lung tissue.

Now we're very proud of the fact that, for probably the past 5 to 10 years, our Institute constituted the first natural history study of LAM, through our intramural program and many, many young women with LAM throughout the country came and participated in that study.

LAM TREATMENT TRIAL

That study is near completion and the next phase then will be a treatment trial. One always likes to go from understanding the disorder to a treatment trial so we have a very active treatment trial ongoing in the intramural program, so that is what I wanted to correct.

Senator HARKIN. So the longitudinal study is coming to an end, but the data collection will be used?

Dr. NABEL. Absolutely and in addition, the data collection, we're embellishing and building upon that and now making that tissue available through a repository to many extramural investigators so our extramural program will be involved in the data collection in addition to the intramural program.

Senator HARKIN. Can you assure me the LAM research will not suffer as a result of this decision to end the longitudinal study and that every effort is made to place the patients with new, highly qualified care providers?

Dr. NABEL. Absolutely and in fact, the ending of the longitudinal study was really a decision made by the investigators themselves, not by the Institute. They said look, we have collected all the data we need. We now need to begin the treatment trial and so we are clearly inviting the same group of women who participated in that natural history study to come now and join us in the treatment trial.

As part of their coming to visit at the clinical center, we do visit with them about their care that they're receiving in other areas and as we have in the past, we are strongly committed to continuing that and helping them to receive the best care that they can, whether we can provide it at the NIH or we can refer them to physicians around the country.

Our commitment to this program is extraordinarily strong.

Senator HARKIN. I thank you for that reassurance. I'm sure my constituent will be reassured also. Senator Cochran.

Senator COCHRAN. Mr. Chairman, I want to thank you for the hearing. I think the witnesses have done an excellent job of putting information before us that we can use to have a better bill of appropriating money for these important activities.

Our goal, of course, is to have a healthier America and make sure that the therapies and cures that are being discovered as a result of this research are translated into patient care and improving the health of individuals in our country. That is why we put some more emphasis in last years budget on cures and therapies and some of us are pushing that, Senator Harkin and I, and others to improve the way we get the information to physicians and other health care providers so that we make sure we are getting the best possible remedies out there available to the people who are sick and want to stay healthy.

So, thank you all for the role that you play. It's enormously important and we appreciate what you do.

OSTEOPOROSIS

Senator HARKIN. Thank you, Senator Cochran. Dr. Katz, let's turn to you now.

Osteoporosis, so all the research has been done on this. What's the best preventative measure that people can take now to prevent osteoporosis?

Dr. KATZ. Well, to start with they can pick their parents because there is a genetic factor. Obviously that's outlandish, but what they can do goes back to some of the points that you made with Dr. Nabel. Diet is important, and adequate dosages of vitamin D and calcium, as well as exercise, are particularly important. Going back to another point that you made earlier, exercise in young people becomes really important in building a bone bank, for both men and women, because the better your bone mass is early on, the more you can actually lose and get away with it.

What we don't know is, we have a pretty good index of bone density using these DXA machines, but we don't really know much about the architecture of the bone in terms of what predisposes to fracture. So what we're trying to do is learn more about that, but in terms of addressing osteoporosis, exercise and certain medications can help. Also one must avoid certain medications that are being found to decrease your bone density.

Senator HARKIN. Such as?

Dr. KATZ. Such as certain types of sedatives. For example there's a drug, rosiglitazone, that is actually used for diabetes that we've had discussion with Dr. Rodgers about that suggest that, in addition to doing well with diabetes, it decreases bone mineral density. We're under discussion now about actually studying why that happens, not only for the patient and the physician, but to better understand what the balance is between taking such a drug for diabetes, while on the other hand decreasing bone mineral density.

Senator HARKIN. If you have one of these tests, these bone density tests they take and your caregiver, or doctor, or whoever does that says, yeah, it's not that good. We recommend you take some calcium and magnesium. Is that valid?

Dr. KATZ. Calcium clearly. Magnesium is thought by some to play an important role, but certainly you need vitamin D as well to help absorb the calcium, and so there has to be adequate intake of both as a start.

Senator HARKIN. Because this is, well, I can tell you, I don't know what the incidence of osteoporosis is, but I am hearing more and more and more people who have osteoporosis and I'm not certain what's causing it, whether it's just genetic, all genetic. People are just living longer, not having the proper diet or all of the above, I suppose.

Dr. KATZ. Lack of exercise.

Senator HARKIN. Lack of exercise, yes.

Dr. KATZ. Also for a long time people were using estrogens, for example, to build bone strength, particularly women at the time of menopause. But the long-term study the NIH supported over a 10-year period, the Women's Health Initiative, has shown that there are adverse effects of estrogens on the one hand, and number two, we now have alternatives to estrogens in terms of preserving bone strength.

OSTEOARTHRITIS

Senator HARKIN. Let's turn to the other osteo, osteoarthritis. You said 12 percent of the population?

Dr. KATZ. 12 percent of the population over the age of 25. That becomes really a tremendously large number when you figure that in the year 2030 we will have 70 million people who will be at risk for osteoarthritis.

REGENERATIVE MEDICINE

Senator HARKIN. Then you mentioned regenerative medicine. Could you explain that a little bit further?

Dr. KATZ. So, regenerative medicine is something that we're all concerned about in terms of support. It really means to try to re-grow certain tissues, and in our case, the major emphasis is on the re-growth of cartilage.

Regenerative medicine is also being used to re-grow certain cells in the pancreas, which the Diabetes Institute is particularly interested in, but this isn't such an easy thing.

First of all one needs either one's own stem cells that will replenish the tissue, or one needs other stem cells that will replenish the tissue. Regenerative medicine involves building some sort of matrix or material upon which cells will grow into the type of tissue that you want them to grow into, and stem cells have the ability to grow into cartilage cells, fat cells, muscle cells, etc, depending on what their environment is, so basically regenerative medicine in terms of cartilage repair requires a matrix on which cartilage cells will grow.

Then when you put the matrix back into an individual the matrix dissolves. It's sort of like resorbable sutures. If you have sutures, the body absorbs them and you are left with the actual tissue so that is what regenerative medicine is about.

Many, many organ systems are being looked at in terms of the potential for regenerative medicine.

It's a form of tissue engineering. It's bringing biologists together with engineers to try to build a new organ system.

Senator HARKIN. What you're giving out in terms of research projects, how much of this is in the area of regenerative medicine? I mean, looking at stem cells for example, is this a big area of study that you're promoting perhaps, or looking for proposals for research grants?

Dr. KATZ. So we work with other Institutes on this. Our investment in regenerative medicine is about $42 million.

Senator HARKIN. What's your budget?

Dr. KATZ. It's about $507 million.

Senator HARKIN. $507 million, and about $42 million.

Dr. KATZ. Basically most of that is from an engineering standpoint—building the materials upon which cells can grow—but you can't do one without the other, so you have to invest in the cells that will replenish tissue.

With cartilage we think this is really important because it will delay the need for total knee or total hip replacement.

Senator HARKIN. Well, that is one of the big problems of stem cell research. Whether it's adult stem cells or it's embryonic stem

cells or placental stem cells or amniotic stem cells and that is to do just this.

Dr. KATZ. Right.

Senator HARKIN. Are you getting research requests in those areas?

Dr. KATZ. Yes, actually we're probably not able to support all of the outstanding applications that we get, but fortunately there are other Institutes. The National Institute of Biomedical Imaging and Bioengineering, with which we work very closely in this area, has a major investment in trying to understand some of the really fundamental areas, much more proximal to the tissue part of the investment.

In other words, our focus is on the translational part of tissue engineering and our major focus is not only in cartilage, but also in skin because as you know, wound healing, burns, are a very, very big problem. There have been products on the market with regard to regenerative skin products, but not in the area of cartilage and people are actually trying to regenerate bone as well and other tissues as well.

OSTEOARTHRITIS

Senator HARKIN. Just a couple of other items here, on osteoarthritis. I see glucosamine and chondroitin and SAM-E out there touted for relieving the effects or curing, at least mitigating the effects of osteoarthritis. What can you tell me about those?

Dr. KATZ. With the tremendous support that we've had, about 8 years ago we embarked on a study with the National Center for Complementary and Alternative Medicine and they actually took the lead after they were established, but we work closely with them.

The study was a four-arm clinical trial to address the question of whether glucosamine and chondroitin sulfate, which are used very widely for osteoarthritis, were actually beneficial.

The results of that study came out early last year and showed that glucosamine and chondroitin sulfate in mild osteoarthritis, do not help much. In moderate to severe osteoarthritis, they are thought to be beneficial. Those studies need to be validated, certainly.

Our particular interest in that trial continues, because we also supported an ancillary study to look for structural changes. In other words, we didn't want to lose the opportunity of just seeing whether these compounds were beneficial in terms of symptoms, so we invested in x-ray studies and MRI studies to see whether there was actually improvement in the widening of the joint space, and the results of those studies are soon to come out.

We don't know the results. It's a blinded study, but I assure you, it will come out very soon and I will send you those results. I understand the investigators are going to try to have the results by the time of the American College of Rheumatology meetings in October, but I can't tell you for sure. I did check on it actually yesterday with Dr. Clegg, who runs that study from Utah.

AUTOIMMUNE DISEASES

Senator HARKIN. I would like to know about that. There's just one other, or two other areas I want to cover with you. Autoimmune diseases, your Institute handles autoimmune diseases, lupus, and scleroderma. Again, it's hard in many of these to get a proper diagnosis. Sometimes it takes a long time, years, before the patient finds out what they have. When they have the doctor says, there's not much we can do.

Again, are these conditions on the rise? It seems to me just to the untrained eye, seems to me that these are on the rise or I'm getting more information about it. What progress are we making in understanding and treating these autoimmune diseases?

Dr. KATZ. So, I don't know if it's on the rise. I can tell you when I was a medical student going on the wards in 1965, the patient with lupus, who had central nervous system involvement, was basically considered dead, no treatment, no hope for a patient like that. I think nowadays we're diagnosing patients much earlier.

We have much better diagnostic tools in all of these areas whether its scleroderma, whether it's lupus, whether it's rheumatoid arthritis. The diagnosis is made earlier, number one and number two, getting to the treatment side of it, in the last years, there's been much more learned in terms of approaches to the treatment.

So at the NIH Clinical Center there was a tremendous investment in the use of an immunosuppressive agent, which was a cancer chemotherapeutic agent, cyclophosphamide. For many years, as a consequence of long-term investment in the intramural program on the Bethesda campus, treatment with cyclophosphamide was thought to be the best way to prevent renal disease.

Nowadays, there are new approaches. Last year there was a study using a drug that's called CellCept with probably fewer side effects than long-term use with cyclophosphamide has. Most recently we've been investing in studies in lupus and dermatomyositis, another autoimmune disease, using a drug called, rituximab.

Now, what is rituximab? Rituximab is an antibody that actually kills off cells that produce autoantibodies. So it kills the cells that produce the autoantibodies in lupus and presumably in dermatomyositis and in other of these autoimmune diseases. So basically, there are new drugs that are being used to try to intervene in the earliest stage.

We're trying to identify those patients who are most susceptible to more severe disease, and this has been the approach to new therapy. So I think there's much greater hope. Lupus and other of these diseases have been chronic diseases. For some of these diseases, rheumatoid arthritis, for example, there are now studies being done for early intervention to actually stop the progression and even potentially cure the disease, if there's very early intervention.

It goes back to what Dr. Rodgers was saying about diabetes. What do we know about early intervention? In order to do early intervention, one needs to have a good diagnostic test to know that that person is going to progress in terms of, particularly, rheumatoid arthritis and I assume the same in diabetes.

Senator HARKIN. Do you know of any research being done to look at any connection between autoimmune diseases and vaccines? Now here's why I ask that question and I brought it up the other day at a hearing on autism. By the time a baby is now 1 and a half or 2 years old, 31 vaccines. Of course, when I was young we didn't have any of that stuff, now 31. Individually, they're fine. The real question that I have and others have is, put together in that short space of time, in a small person, that there's some thought that this may lead to the prevalence of autoimmune diseases and I don't know what research is being done on that. Do you know?

Dr. KATZ. I don't.

Senator HARKIN. Could you find out for me?

Dr. KATZ. I certainly can. I'll send you a note for the record. Actually, I think Dr. Fauci, who's the Director at the NIAID, can answer that question directly when he testifies before this subcommittee.

FIBROMYALGIA

Senator HARKIN. Tell him to be prepared for that one.

I just want to know what research is being done in that area.

Now, fibromyalgia. I have two former staff persons of mine with fibromyalgia and my niece now and I watch what's happened to them. This is really debilitating. They can't work. They're in pain all the time, tired, depression. They say there is no cure. They just feel like they are going to spend the rest of their lives with it so that kind of feeds on depression.

Again, tell me about research in the area of fibromyalgia. Any hope for any of these patients?

Dr. KATZ. There is hope. Actually we're just finishing up a clinical trial on gabapentin which is being used in some patients. I will send you the results of those studies. They should be out very, very shortly. This is a double-blind study led by an investigator in Cincinnati, Dr. Arnold I believe.

Senator HARKIN. What is the name of that?

Dr. KATZ. Gabapentin. G, A, B, A, P, E, N, T, I, N. It's a pain relieving medication, but there are other approaches that we've taken all along the way in fibromyalgia. It's a multi-system disease, as you know and can affect different organ systems in different people, affects women primarily but it also can affect men—it certainly can affect men.

The approaches have been from the standpoint of self efficacy and have been used with patients who have rheumatic diseases and this is that the patients themselves can do something about it. They can energize their physicians to treat whatever their symptoms are because we don't know the underlying cause of it. It is not a muscle disease. For a while it was thought to be. Some people called it fibromyositis, but it's not a muscle disease at all.

It's a multi-system disease. You described it perfectly. It affects various organs, and it does produce depression as many of these chronic diseases with unrelenting pain produce depression. So, there's a lot of research going on there.

How does exercise fit into it? Those are the types of studies that we're doing. We're happy to provide you with more information on that.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
NATIONAL INSTITUTES OF HEALTH,
Bethesda, Maryland, May 7, 2007.

Hon. TOM HARKIN,
U.S. Senate, Washington, DC 20510.

DEAR SENATOR HARKIN: I am writing to follow-up on the issues that you raised at the April 20, 2007, hearing on the Burden of Chronic Diseases with respect to selected activities of the National Institute of Arthritis and Museuloskeletal and Skin Diseases (NIAMS), a component of the National Institutes of Health (NIH).

First, I would like to provide you with a brief update on recent progress that we have made in understanding and treating fibromyalgia syndrome. For your reference, I have enclosed two articles from the scientific journal *Arthritis and Rheumatism* that I think will be of interest. The first reports on the results of a randomized, double-blind, placebo-controlled trial supported by the NIAMS to assess the efficacy and safety of gabapentin in patients with fibromyalgia. Overall, the researchers found that this drug, an anti-convulsant approved by the Food and Drug Administration, is safe and efficacious for the treatment of pain and other symptoms, such as sleep disturbance, associated with this condition. Further, the scientists reported that, although patients taking gabapentin in this study experienced more dizziness, sedation, lightheadedness, and weight gain than those taking placebo, in general the medication was well-tolerated.

In the second enclosed article, researchers funded by the Institute describe their assessment of social functioning and peer relationships in adolescents with juvenile primary fibromyalgia syndrome (JPFS). Their findings, based on data collected from the patients themselves, as well as from their teachers and peers, suggest that adolescents with JPFS experience more difficulties with peer relationships compared with matched adolescents without a chronic illness, placing the JPFS patients at risk for social isolation from their peers and psychosocial adjustment problems. Additional studies are needed to determine the specific links between JPFS and social challenges in adolescents, as well as to identify the most effective interventions to facilitate psychosocial adjustment and improve the overall sense of well-being for this population.

Second, as I noted at the hearing, we are awaiting results from the ancillary study of the NIH's Glucosamine/chondroitin Arthritis Intervention Trial (GAIT), which is looking at whether glucosamine and chondroitin sulfate can alter the progression of osteoarthritis (OA), such as delaying the narrowing of the affected joint spaces. As soon as those results are published, we will send you and your staff a copy of the article, along with a brief overview of its conclusions.

Finally, you asked me about the findings of Dr. John Sarno, who looked at the relationship between back pain and stress management. I am now reading some of Dr. Sarno's work, and I will write to you under separate cover about how his research helps inform our knowledge base.

We very much appreciate your active interest and support of the work of the NIAMS and the NIH. Please do not hesitate to contact me directly at (301) 496–4353 if I may provide you with any additional information.

Sincerely yours,

STEPHEN I. KATZ, M.D., PH.D., *Director,*
National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Senator HARKIN. There doesn't seem to be any precursors at all. It just seems to be very random. I don't know if any genetic studies have been done.

Dr. KATZ. Genetic studies have been done; unfortunately the person who led those studies died, but those studies are actually going on. Unfortunately, it also occurs in children, not only in adults. In children it can manifest various symptoms of fibromyalgia.

Senator HARKIN. Children? I had not heard of that.

Dr. KATZ. It does occur in children.

Senator HARKIN. Well, I've seen it in late teens, early twenties, but.

Dr. KATZ. Children in the first decade, age eight to age ten, have symptoms of fibromyalgia.

Senator HARKIN. Is it really an autoimmune disease?

Dr. KATZ. There is no evidence that it is an autoimmune disease. Lots of people have looked, but there is no evidence that's it's an autoimmune disease.

Senator HARKIN. So we really don't have it classified yet?

Dr. KATZ. We have it classified as a pain syndrome. It's a multisystem pain syndrome, with the manifestations of the loss of cognition, for example, and loss of sleep. I'm sure these people whom you know share some of these symptoms—pain, really, all over their body and depression. Those are four of the most common of these symptoms of fibromyalgia, but we are supporting studies in these areas and hopefully they will yield useful information.

ALZHEIMER'S DISEASE TREATMENTS

Senator HARKIN. Dr. Hodes, Alzheimer's. You covered that quite a bit in your testimony. I had one question about a chart here, this one right here. You mentioned this drug, denepozil. Now I'm looking at this chart and don't understand it very well, but it almost seems like the other two have almost as much affect as denepozil.

Dr. HODES. I apologize for the complexity of what is a standard way of presenting the results of the clinical studies. What this shows is the time scale of the trial, which is about 3 years. What you see at the top at zero means that no one has Alzheimer's disease to begin with and then over time, as that curve goes down, this is indicative of more and more people developing the disease.

The placebo group represents the number of people developing Alzheimer's in the absence of intervention.

Vitamin E is overlapping with that curve. Vitamin E had no effect whatsoever on disease progression, and donepezil, the yellow line above, shows a slower decrease that is a slower development of people with Alzheimer's disease over time.

Senator HARKIN. In the end it looks like it's even worse.

Dr. HODES. What's deceptive is that line, where it drops off at the end, really is the end of the study, and there are too few people to analyze. I think a more meaningful graph would not have shown that apparent drop. You can ignore that. It is at the end of the study, so few people reach that time point. The lines that go through the point before that drop that are really significant.

Senator HARKIN. Again, I don't know why they did vitamin E, but I keep hearing that ginkgobiloba is being prescribed more and more. How come that wasn't done, I wonder, in that?

Dr. HODES. So, there is a study of ginkgobiloba that is currently in progress being carried out again by the National Center for Alternative Medicine in collaboration with the NIA. It is expected that within a year or so, that study will reach completion and we will have the result.

As you're leading to, there are a number of studies and anecdotal observations suggesting ginkgo might play a role, but no promising lead is being left unturned. We have pursued that. I would hope to have an answer shortly.

Senator HARKIN. There's another, I think over the counter thing, called huperzine. Is that right?

Dr. HODES. Yes.

Senator HARKIN. Three years ago, NIH launched the first study of huperzine A as a treatment for mild to moderate Alzheimer's because evidence from small studies suggest it may be effective as some of the drugs being used by Alzheimer's patients. What's the status of that trial?

Dr. HODES. It's also in progress. We don't have people who have used it long enough to have an answer, but it will be forthcoming.

Senator HARKIN. Well, it's been 3 years. How long is this trial going to be?

Dr. HODES. Typically, what occurs when a study begins is the starting point is when subjects begin to enter and of course, they all don't enter at once. So, again, it may take 1 to 2 years for all of the patients to enter into the study and then, in the case of Alzheimer's disease, when we study the onset by clinical symptoms, generally it's necessary to follow up people for 2, 3, 4, or even 5 years.

ALZHEIMER'S DISEASE AND NEUROIMAGING

This is one of the reasons I was emphasizing the potential importance of surrogate markers, such as neuroimaging, where we're hopeful that when we can image objectively the lesions of Alzheimer's in the living person and track this over time, we have more rapid, more objective signs of whether an intervention is effective or not, and we won't have to follow so many people for so long before we have the outcome of each of these trials.

Senator HARKIN. That's good. Four months ago researchers supported by your Institute reported finding a new imaging molecule that could lead to an earlier diagnosis of Alzheimer's disease. Can you tell me a little bit more about that?

Dr. HODES. So there have been two molecules described and studied that function in neuroimaging. One, illustrated in the slide that I showed you, was this, which is called Pittsburgh compound B. We described this one to you a couple of years ago. This bonds with apparent specificity the amyloid protein that is in the plaques, one of the lesions of Alzheimer's disease.

The newer, more newly described compound developed by a group at UCLA has a similar effect but appears to be capable of detecting both the amyloid plaques and the other lesion of Alzheimer's disease, the so-called neurofibrillary tangles.

So studies are currently ongoing to determine the relative merits of each of these in tracking the disease to see first, the degree to which they correlate with disease progression and the diagnosis.

If they pass this first hurdle—that is, they appear to be good correlates of clinical disease—then the next step is to then see how effective they'll be in monitoring the success of interventions to treat or to prevent disease, because some of these lesions can be seen in these individuals before there are any symptoms.

Of course, the great hope is that the disease can be detected before damage has caused symptoms to individuals and that that is the point at which intervention will prevent damage. In all likelihood the task of reversing damage, once it involves death of the brain cells is going to be far more difficult than prevention, a theme which you've heard across a number of disorders and diseases.

Senator HARKIN. Well, but again, you raise another question. If you've got early diagnosis, that's fine. What do you do about it? What hope do you hold out there for people that they can actually slow it down or stop it?

Dr. HODES. That's a very important point. At this point in time for Alzheimer's disease, one very important and real advantage of early diagnosis is that it allows people to enter studies of interventions to see what will work at an early point unless or until the time when we have effective interventions. You're quite right.

One can ask this question—what is the usefulness for early diagnosis? In fact real bioethical issues exist about whether individuals should seek early diagnosis or early information about genetic risks until the time when there is something to be done about it. It's very much an individual choice but where I think it is far more clear cut is in the area of research to try to develop interventions and prevention there. We want to test those interventions on individuals who have early pre-clinical signs of disease.

Senator HARKIN. Ok, I want to sort of join up you and Dr. Nabel here.

We talked about early childhood physical activity and diets. Now, let's shift to the elderly in our society. Anecdotally, I suppose, what I've observed and others, is that a lot of times elderly people who are on a lot of drugs and taking a lot of drugs and interventions that if given a better diet and exercise and social interaction, they can actually get off a lot of those drugs and live healthier so you did this.

PHYSICAL ACTIVITY IN PREVENTING DISABILITY IN THE ELDERLY

You have a life clinical trial which was testing the effects of a physical activity program versus a health education program in preventing major disability among the elderly, so you've been doing some of that. Tell us about it.

Dr. HODES. I'd be happy to comment on a number of trials in this area. LIFE is a study that was carried out in pilot form. It's still in pilot form. It's a very substantial study to look at individuals who are known to be at high risk for developing disability. The end point of this study is loss of the ability to walk at least a quarter mile, which turns out to be a very good predictor of quality of life and independence.

Individuals known by their characteristics to be at high risk for falling into this category were initiated into this study and were treated with a very responsible program: either conventional information (you should exercise, you should go on this diet) or a much more explicit and rigorous controlled, clinical intervention.

As a pilot, the initial study was largely to determine whether this was a practical trial, whether people would comply, and whether it was safe. By all those accounts the answers were very positive.

But even more so, despite the fact that it was not initially predicted to have sufficient power to see an effect, it did detect an effect, even in the pilot version. The intervention was capable of preventing people from becoming disabled, from losing the ability to walk—to remain mobile. This is an example of a study now that's going to be carried to a more extensive level to produce really sig-

nificant outcomes. It will be a very expensive and extensive study. This study relates to some of the things my colleagues have said, too, that although in some ways it is self-evident, exercise must be good.

This is actually already, to our knowledge, the largest randomized trial to look at the effect of exercise on outcomes such as this (e.g., the prevention of disability and the preservation of mobility and independence.) So things that may seem intuitive need to be addressed scientifically.

If we can prove that an intervention such as this is important, then we would hope that these interventions can translate much more to the public.

EXERCISE AND DIABETES

On the general theme that older people can profit very much from behavioral interventions such as exercise and diet: I alluded to, very briefly, a study carried out in connection with NIDDK that looked at individuals who are at high risk to develop diabetes over the next year or two. Study participants were young adults when they entered, middle aged, or individuals 60 and over.

The study, again, compared a placebo group, which was responsibly educated but received no specific treatment, with metformin, an oral drug that is used to treat diabetes. The third arm was a behavioral intervention, which was a moderate diet and exercise intervention. It was interesting not only that the study was carried out prospectively, but that it was terminated prematurely.

Now we fear often premature termination because of side effects. This study was terminated because the treatment was proving to be so effective that it was deemed irresponsible to continue and not to inform subjects of the results.

The results were further interesting in terms of the effective age for each intervention. Both the drug and the behavioral interventions worked at the youngest age group, approximately and substantially able to reduce the incidence of diabetes by some 50 percent or so.

In the older age group, and this was not predicted, the drug did not work. However, and this was also not predicted, the exercise and diet intervention was more effective than it was in any other age group, producing a 71 percent decrease in diabetes.

So this said a number of things. It said older individuals are quite capable of modifying their behavior. Furthermore, when they do modify their behavior, it's possible for this to make a difference.

Again, together with NIDDK, this study is continuing. Further questions we are exploring include whether these interventions will, in subsequent years, as we follow these individuals, translate into a reduction of cardiovascular events, of eye changes, of all of the kidney changes, of all of the very important sequelae of diabetes. The potential significance of this study—I don't think it can be overemphasized.

If these behavioral interventions are in fact capable of producing a 71 percent decrease in diabetes in this older age group, where the risk is the highest, the consequences for quality of life or our healthcare system may be enormous and could translate, as has

also been a theme here, into the next challenge: To educate the health providers and the public and to achieve compliance.

Senator HARKIN. But therein lies, of course, this is not your area, but for us, as policymakers lies a problem. That is Medicare doesn't reimburse for anything like that. Medicare reimburses for surgery or whatever later on, but not for the kind of interventions you're talking about.

Dr. HODES. Well, again, as I expressed, we at NIH feel our role is to develop the evidence base that will then inform policy makers.

Senator HARKIN. Well, we should be informed on that and quite frankly, I need to get what you just told me, Dr. Hodes, I need to get in a nice short form and with some of the data that you have, this could be very helpful. If it is that startling, 71 percent, then it seems to me that, just really informs us as to what we ought to be doing to change how we use Medicare for reimbursements.

That is pretty startling; I've never heard this before.

Dr. RODGERS. We'd be happy to provide you with that.

Senator HARKIN. Can you help us with this too?

Dr. RODGERS. Absolutely. One interesting aspect about this, as Dr. Hodes recognized and commented upon, is that after the study is over, we have a follow on study to actually see whether, in fact, this intervention will have persistent, sustained beneficial effects. From a cost effective analysis, the original cost of the study has already been paid as these people continue to show positive benefits.

This spreads the cost over a number of years in terms of cost effectiveness. So as we envision the follow on to these studies, we're really doing the economic analysis to provide you and your committee members with additional cost effectiveness and outcome data.

Senator HARKIN. Well I really want to get my hands on this. I want to get it better in my own head as to what this study, how you did it, what the results were, what some of the data show. So if you could provide that, I would sure appreciate it.

Dr. HODES. Dr. Rodgers and I will certainly work on that.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES,
Bethesda, Maryland, May 17, 2007.

Hon. TOM HARKIN,
U.S. Senate, Committee on Appropriations, Labor, HHS, Education Subcommittee, Washington, DC.

DEAR MR. FATEMI: Enclosed please find information about the *Diabetes Prevention Program* (DPP) clinical trial, in follow-up to my discussion with Senator Harkin and National Institute of Aging Director, Dr. Richard Hodes, at the Senate Appropriations Committee Theme Hearing on the Burden of Chronic Disease, April 20, 2007.

The enclosures include a three page synopsis which focuses on the aspects of the research that were discussed at the hearing, and also provides some updates on related, more recent work, and on our efforts to translate these important results. Also included are the *New England Journal of Medicine* article that first reported the central DPP findings, NIDDK press releases issued regarding that result and subsequent developments, information on the *Small Steps, Big Rewards* program of our National Diabetes Education Program, and an NIA-prepared summary of some non-DPP studies that also show the value of diet and exercise interventions in elderly populations.

Please let me know if you would like additional information.

Sincerely yours,

GRIFFIN RODGERS, *MD., M.A.C.P.*

Enclosures

THE DIABETES PREVENTION PROGRAM (DPP)

The Diabetes Prevention Program was the first major, randomized, multi-site clinical trial to demonstrate that type 2 diabetes could be prevented or delayed in individuals at high risk for developing the disease. Led by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with support from the National Institute on Aging (NIA) to allow inclusion of a significant number of participants over age 60, it was conducted in 3,234 people with impaired glucose tolerance (IGT)—now commonly known as pre-diabetes. This three-year trial compared three preventive approaches: standard medical advice about diet and exercise, intensive lifestyles modification aimed at losing 5 percent to 7 percent of body weight through diet and a moderate, consistent increase in physical activity (e.g., walking 5 days a week for 30 minutes a day), and treatment with metformin, an oral drug commonly used to treat individuals who already have type 2 diabetes. The goal of the study was to determine if it is possible to stave off progression to type 2 diabetes in the estimated 54 million American adults who do not yet have the full-blown disease, but whose risk factors put them on the path to developing it.

Major Findings.—As reported in the February 7, 2002, issue of the *New England Journal of Medicine*, the DPP demonstrated that the lifestyle intervention reduced risk for type 2 diabetes by a dramatic 58 percent. The metformin intervention reduced risk by 31 percent. These interventions worked in all ethnic and racial minorities studied and in both men and women. Participants over 60 years of age responded particularly well to the lifestyle intervention, showing a 71 percent risk reduction, whereas both metformin and the lifestyle intervention were similarly effective for the younger participants (ages 25 to 44) and for participants who were very obese.

Public Health Campaigns Launched Based on DPP Findings.—Based on the DPP findings, in 2002 the National Diabetes Education Program (NDEP)—which is sponsored by the NIH and the CDC with over 200 private partners—launched a new campaign called "Small Steps. Big Rewards. Prevent Type 2 Diabetes." This educational campaign emphasizes the effectiveness of a healthier lifestyle in preventing the disease. The campaign includes: lifestyle change tools for the public similar to those used in the DPP; a health care provider's tool kit; participation of businesses and consumer-based programs as partners in diabetes prevention; and messages and materials for a national public awareness campaign including TV, radio, and print public service announcements. Subsequently, tailored campaigns were developed with materials directed toward the African American, Hispanic/Latino American, American Indian and Alaska Native, and Asian American and Pacific Islander populations.

In 2005, the NDEP reached out to older adults at risk for type 2 diabetes with the campaign, "It's Not Too Late To Prevent Diabetes. Take Your First Step Today," and developed tailored materials for seniors to motivate them to make modest lifestyle changes to prevent the disease. The most recent undertaking of the NDEP is a new educational campaign on gestational diabetes mellitus (GDM), which also builds upon the prevention message of the DPP. GDM is a form of the disease that occurs during pregnancy endangering both the mother and the offspring and placing them at risk of developing type 2 diabetes at a later point in life.

Translational Research Efforts.—An NIDDK initiative focused on "Translational Research for the Prevention and Control of Diabetes and Obesity" supports studies to translate recent advances in the prevention and treatment of diabetes and obesity into clinical practice for individuals and communities at risk. Several studies supported under this initiative involve communities with large minority populations disproportionately burdened by type 2 diabetes and obesity, and focus on translating and tailoring the positive prevention message of the DPP for "real-world" settings. Examples of studies in the area of diabetes prevention are developing interventions to promote physical activity; testing integrated primary care and web-based intervention on preventing diabetes in adolescents at high-risk for developing type 2 diabetes, testing the effectiveness of a healthful lifestyle intervention designed to reduce behavioral and clinical risk factors for type 2 diabetes in pregnant and postpartum African American and Latino women; and a family-based intervention, for families with at least one member who has type 2 diabetes, to help the whole family learn how they can adopt healthy lifestyles that are known to reduce risk for diabetes or its complications and better utilize existing community resources. In particular, two NIDDK translational research grants are currently supporting a pilot project in which YMCA staff deliver the DPP lifestyle intervention at YMCA Centers. If the program proves to be effective, the YMCA organization will explore

ways to expand the program to its 2,617 centers nationwide. Preliminary data from this project are extremely promising.

Other Important DPP Results.—Since the 2002 publication of the landmark DPP findings, important new results have continued to flow from analyses of the original DPP data and samples and from a follow-up study of participants in the DPP, the DPP Outcomes Study (DPPOS). These include:

Genetic Variant Linked to Type 2 Diabetes.—A genetic analysis of DPP participants who did and did not go on to develop type 2 diabetes has confirmed that a version of the gene *TCF7L2* is the most important genetic risk factor for the disease. Importantly, researchers showed that even this serious genetic risk does not make type 2 diabetes inevitable: the lifestyle intervention was protective, whether or not participants had this genetic risk factor.

DPP Lifestyle Intervention Reduced Incontinence.—In addition to delaying or preventing diabetes, losing a modest amount of weight through dietary changes and increased physical activity reduced the occurrence of urinary incontinence in women with pre-diabetes. In the National Health and Nutrition Examination Survey 2001–2002 sample, one out of three women with diabetes or prediabetes levels reported weekly or more frequent episodes of urinary incontinence. As reported in the February 2006 issue of *Diabetes Care*, the DPP lifestyle intervention was particularly effective in reducing episodes of stress incontinence—leakage of small amounts of urine during physical movement, such as coughing, sneezing, and exercising.

Diabetes Eye Changes Occur Earlier Than Previously Recognized.—Previous studies have not accurately defined when type 2 diabetes begins, so it was not known if diabetic eye damage begins during pre-diabetes, when blood glucose levels are higher than normal but not yet in the diabetes range. DPP investigators found diabetic retinopathy in nearly 8 percent of pre-diabetic participants. These findings suggest that retinopathy—which often leads to blindness—is starting earlier and at lower glucose levels than previously thought. They also reinforce the benefits that could be gained if patients with newly diagnosed type 2 diabetes were screened for retinopathy so that vision-preserving therapies might be applied in a timely manner.

Future Directions.—The Diabetes Prevention Program Outcomes Study (DPPOS) is investigating the durability of the effects of the DPP interventions in preventing or delaying type 2 diabetes, and how the intervention impacts the development of cardiovascular disease and other complications of diabetes. Cardiovascular disease accounts for two thirds of diabetes deaths. While rates of cardiovascular disease are increased two- to four-fold in diabetes, they are also increased by about 50 percent in pre-diabetes. Rates of heart attack, stroke, cardiovascular death and other diabetes complications will be ascertained through this follow-up study to determine the value of the DPP interventions in preserving health and limiting morbidity in people with pre-diabetes. In addition, translational research efforts have been initiated to develop more cost-effective methods of achieving the lifestyle change that delayed or prevented diabetes, and better methods to identify those with prediabetes.

Diabetes Costs and DPP Cost-Effectiveness.—According to the American Diabetes Association, the per capita annual cost of health care for people with diabetes was $13,243 in 2002, while health care costs for people without diabetes amounted to $2,560 that year (Diab Care 26:917–932, 2003). An estimated 54 million Americans are at risk for type 2 diabetes. Nearly 21 million Americans already have diabetes, of which 90 to 95 percent is type 2 diabetes. The overall cost of diabetes—direct medical plus indirect economic cost—in the United States was estimated at $132 billion in 2002.

A cost-effectiveness model estimates that the DPP lifestyle intervention would cost society about $8,800 and metformin would cost about $29,900 per quality-adjusted life-year saved over the lifetime of a patient—costs that are within the range that are typically acceptable for health care interventions (Ann Intern Med 142: 323–332, 2005). The cost-effectiveness data will be reanalyzed in 2008 based on data from the DPPOS, which will follow participants' weight and diabetes onset for 5 additional years. If the intervention proves to be durable in its effect, it will greatly increase the estimated cost-effectiveness. Preliminary DPPOS weight data are particularly promising in the older subgroup of participants.

According to 2005 estimates, more than 6 million of those who have diabetes are undiagnosed—many of them elderly. Much larger numbers of those with pre-diabetes are also undiagnosed. A new Medicare benefit beginning in 2005 paid for diabetes testing, which may help identify a larger pool of people who can benefit from the DPP intervention.

OTHER BENEFITS OF LIFESTYLE INTERVENTIONS IN OLDER ADULTS

The National Institute on Aging has several studies which suggest that physical exercise may prevent physical disability, including impaired mobility, in both healthy and frail older adults. To develop definitive evidence, NIA and grantee researchers have developed the Lifestyle Interventions and Independence in Elders (LIFE) study, a clinical trial testing the effects of a physical activity program versus a health education program among older Americans. A successful pilot study (LIFE–P) completed in 2005, demonstrated that a structured physical activity improved 400-meter walking ability and speed in participants (ages 70–89 years) who were at an identified risk for mobility disability.

Other studies have examined the protective benefits of diet and exercise on cognition. For example, in one recent study, increased vegetable consumption was found to reduce risk of cognitive decline in women. In another, certain mental exercises were found to help older individuals maintain their cognitive abilities for up to 5 years. These kinds of interventions hold promise to help preempt disease and disability and help personalize health care.

—Physical activity or exercise as a possible lifestyle factor involved in maintaining cognition and preventing cognitive decline has been identified from epidemiological studies of humans in groups or in large populations. Recent examples include:

—Higher levels of long-term physical activity in older women were strongly associated with better cognitive performance and less cognitive decline [Weuve et al., 2004].

—Older women with higher levels of baseline physical activity were less likely to develop cognitive decline [Yaffe et al., 2001].

Encouraging results from several NIA-funded clinical studies show that aerobic exercise has a short term positive effect on some areas of cognition.

—A meta-analysis of exercise interventions indicated robust but selective effects of physical activity on cognitive function in older adults, with the largest fitness-induced benefits occurring for executive control processes [Colcombe & Kramer, 2003].

—Research comparing older adults with high levels of aerobic fitness to older adults with low levels of aerobic fitness revealed declines in size of several brain cortical regions with age but that the losses were substantially reduced as a function of cardiovascular fitness [Colcombe et al., 2003].

—A small randomized trial of 6 months duration demonstrated that older adults who received aerobic training (walking) showed substantial improvements in performance on tasks requiring executive control compared with anaerobically trained (stretching & toning exercises) adults [Kramer et al., 1999].

Senator HARKIN. Well it would be very helpful. I'm running out of time, but Dr. Rodgers, there's one other, a couple of other things I wanted to ask you.

We talked about adult diabetes, how about juvenile diabetes, type 1. I understand you and Dr. Fauci's Institute are working together on ways to prevent juvenile diabetes, any progress?

Dr. RODGERS. That is right. We have a number of studies conducted in collaboration with the National Institute of Allergy and Infectious Diseases. There are large consortia. The Allergy and Infectious Disease Institute has what's called the Immune Tolerance Network with the goal of preempting autoimmune diseases early on with a variety of drugs similar to the type that Dr. Katz mentioned to you. We want to see if, at the very first step of the autoimmune disease, one could use these antibodies or other forms of therapy to interrupt the autoimmune response in type 1 diabetes and thereby preserve the beta cell function.

One of the benefits that really derive from genetic studies is that we know which patients are at risk of developing diabetes. We can account for about 50 percent of that genetic risk currently. We're looking for the other genetic associations, but it is this Immune Tolerance Network, in a number of Institutions here in the United

States and also in Canada, that is really looking very carefully at ways of interrupting this immune response very early to preserve beta cell function and thereby diminish or prevent these complications.

Our Institute is involved in a number of trials as well. I mentioned continuous glucose monitors. Through our clinical trials network called TrialNet, we're also looking at a number of interventions early on.

One other approach to try to determine the early aspects of the disease actually relates to a question you asked Dr. Katz a moment ago, about studies that, for example, might look for triggers of autoimmune diseases. I think you raised that question.

We have a study that is ongoing, called the TEDDY study, T, E, D, D, Y. This is a study that looks at the environmental triggers of diabetes of youth by following kids who are at high risk for developing type 1 diabetes. The plans now are to follow them from birth through 15 years of age.

The idea is that we will have them come in periodically to obtain urine, blood, stool samples, to take very careful looks at their dietary history, vaccine history, so that we can determine the trigger that sets the immune system against their pancreas and actually leads to autoimmune type 1 diabetes.

This is a fairly long study; 15 years we have to follow them. We estimate the study won't be completed until the year 2021. It is very important if it turns out that it is a virus; for example, some people speculate that it could be a rotavirus, or intestinal virus. Then, a vaccine in susceptible individuals may be highly effective.

We're also, at the same time, looking at the other genetic determinants, susceptibility genes, because as I indicated, we know about 50 percent of the responsible factors but we want to look for the others.

Senator HARKIN. I understand, very good. Well, this has been a very, very informative meeting and I appreciate it very much.

LOW BACK PAIN

Oh, there's just one last thing I have to ask you, Dr. Katz. Low back pain, how could I have forgotten to ask you about low back pain. Talk about epidemics. I want to ask you this, have you ever heard of, or come across, approaches, studies, done by Dr. John Sarno in New York City? Does that name ring a bell at all with you?

Dr. KATZ. It does not.

Senator HARKIN. Well, I was recently at the hospital for special surgery up in New York and I'm not going to go into my own history of that, but having had some problems with low back pain in the past. Again, a friend of mine in the medical field said that I should see this Dr. Sarno, who has written a couple of books. He's a medical doctor.

I forget where he went to school, Harvard, Yale, one of those fancy schools and he had been in Kenya for some years and he was interested in why certain people had back pain and certain people didn't and he came to the conclusion in one of his books that of disc problems, collapsed discs.

If that was really the problem, if that was really the cause of back pain then 9 out of every 10 adults would have back pain because all of our discs, as we age, degenerate, but he started finding people with horribly degenerated discs who had no back pain whatsoever.

There are others who had herniated discs and had back pain. So he didn't think that was much of a correlation. So he began to look at other things.

Well, to make a long story, short, when I was at the hospital for special surgery, I'd mentioned this and they've all heard of this guy. They knew who he was, but his approach was that most, with the exception of, what do you call it when your thing narrows up?

Dr. KATZ. Spinal stenosis.

Senator HARKIN. Spinal stenosis, yes. With the exception of that or cancer of the spine or other things that would, MRIs, for example. With that exception he felt that most low back pain was caused by stress through his studies.

I really want you to look at this because his theory—and now I'm going beyond my knowledge base here—was that stress leads to lack of oxygen in muscles and when the muscles have a lack of oxygen, that affects your nerves and that once you start to have back pain due to stress, then that leads you to have more stress. This hit home with me because once you start having lower back pain, you start saying I can't do this. I can't move that way. I've got to be careful and then that gets you more stressed out. It seems to feed on itself.

So his theory was that the first avenue of approach in dealing with back pain, with the exception of really physical, structural problems that you have, is to examine the stress level of people and to try to get them off of the stress, that type of thing. Either through drugs or whatever, just whatever other interventions might be applicable there so it wasn't surgery, or steroid injections, that type of thing. So I just bring that up, if anyone in your Institute could take a look at that.

Dr. KATZ. We will.

Senator HARKIN. I would appreciate that. I'm very intrigued by it and he seems to be a very knowledgeable doctor and has done some interesting research.

Dr. KATZ. I think his points about pain are very generalizable, as we talked about with fibromyalgia. Chronic pain syndromes cause depression and it feeds on itself.

ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. Sure it does, exactly. Well, I just wanted to bring that up. I made a note on that one to ask you about that one before you left.

Dr. KATZ. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

SODIUM

Question. Dr. Nabel, salt is widely recognized as a significant cause of high blood pressure, which, in turn, is a significant cause of heart attacks and strokes. Please provide the Subcommittee with detailed information on what the NHLBI is doing to achieve its goal of reducing the general public's consumption of sodium, including any efforts to find acceptable salt substitutes.

Answer. The NHLBI supports an extensive portfolio of research projects on the causes of cardiovascular disease and on strategies to prevent and manage it. This includes research on salt and its role in development of high blood pressure. Recent studies continue to support the recommendations of the U.S. Dietary Guidelines regarding consumption of salt and sodium. Of particular relevance are NHLBI-funded clinical trials which found that blood pressure can be lowered by following a particular eating plan—called the Dietary Approaches to Stop Hypertension (DASH)—that emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products with a reduced content of saturated fat, trans fat, and cholesterol. The DASH eating plan is lower in sodium than the typical American diet, and research has shown that stricter limitations in sodium intake produce even greater blood pressure lowering.

The NHLBI focuses national attention on high blood pressure and reduction of salt and sodium intake through its "Preventing and Controlling High Blood Pressure: Mission Possible" effort. Recently the Institute, in collaboration with the Centers for Disease Control and Prevention, the American Heart Association, and the Cardiovascular Health Council, assembled and made available a variety of tools based on the Mission Possible materials for use by State health departments in their public education programs. One key component of the Mission Possible program is the DASH eating plan, and the DASH fact sheet was the mostly frequently used document by the States in their outreach activities. The NHLBI Mission Possible Web site features a variety of educational resources for use in program planning and implementation.

The NHLBI has an extensive outreach and education program that uses lay health workers to engage communities in the prevention of heart disease and the promotion of healthy lifestyle behaviors. As respected members of their communities and effective educators, lay health workers serve as extenders of care between health care settings and patients/families, especially within underserved and low-resource communities. A heart health curriculum for training lay health workers has been developed for use particularly in high-risk population subgroups such as African Americans, Latinos, and American Indian/Alaska Natives and Filipinos. It is designed to build community capacity to engage in heart disease prevention and health promotion activities. Sessions of the curriculum address the major sources of dietary sodium (e.g., processed food, "fast" food, restaurant food) and provide instruction on how to read nutrition facts labels to compare the amounts of sodium in foods. Rather than promote use of "salt substitutes," the sessions focus on ways that individuals can develop their own alternatives to salt based on cultural taste preferences.

LAM

Question. Dr. Nabel, I appreciate your assurances at the hearing that LAM remains a high priority for NIH despite the decision to end the LAM longitudinal study. Many LAM patients who have enrolled in NIH clinical studies remain confused about whether they will continue to be treated at the NIH clinical center. The website http://patientrecruitment.nhlbi.nih.gov/LAM.aspx suggests that eligible patients will receive an evaluation at the center. Please clarify whether that is still the case.

Answer. New subjects are being enrolled into the longitudinal study at the Clinical Center to screen for inclusion in the MILES study and for inclusion in translational research studies. Subjects are not being enrolled for longitudinal follow-up. This is a transitional situation to ensure access of LAM patients to studies while the LAM Foundation, in collaboration with NHLBI, updates its data base of physicians across North America with the interest and expertise required to provide optimal care for LAM patients. We are now updating the website to indicate that new participants are not being enrolled in a longitudinal study.

BLOOD CELL FORMATION

Question. Dr. Rodgers, NIDDK supports research into basic mechanisms of blood cell formation and function, as they are intimately linked to determining the health

risks of different diseases and in developing novel therapies for treatment. An example of this is the study of anemias of inflammation and chronic disease, which would greatly improve our understanding of chronic infection and immune activation, severe trauma, heart disease, arthritis, and diabetes. NIDDK held a workshop on this topic in 2006; what is NIDDK currently doing on this topic?

Answer. The anemia of inflammation and chronic disease is very common and is a major cause of reduced red blood cell mass that often accompanies aging. It is characterized by a decreased availability of iron for support of red blood cell production, caused largely by acquired abnormalities in both iron absorption and release of iron from tissue stores.

As you mention, the NIDDK convened a two-day workshop in May 2006 that focused on this common form of anemia. The workshop featured current insights into the clinical presentation and underlying causes of this anemia. It also highlighted unanswered questions and promising new opportunities for basic and translational research. Based on scientific recommendations from this workshop, the NIDDK, in collaboration with other Institutes, plans to issue a Program Announcement in 2007 to encourage and promote research that will lead to advances in the detection, prevention, and treatment of the anemia of inflammation and chronic disease. The Institute is also preparing a Congressional Appropriations Committee Report on hematology research at NIDDK that will include this area of research.

PKD

Question. Dr. Zerhouni, it has come to my attention that, over recent years, certain "coding errors" have occurred regarding NIDDK's public disclosure of the amount of dollars allocated to specific research areas. My understanding is that these errors may have led the NIDDK to significantly inflate the actual amount of Federal funding that was allocated to polycystic kidney disease (PKD) research. For instance, the NIH has publicly reported that overall Federal PKD funding for fiscal year 2003 was $37.3 million. However, because of the presence of certain errors in the method of reporting, the actual fiscal year 2003 funding level may have been much lower. If upon further review the actual funding for fiscal year 2003 and other years is found to be substantially understated, this would present a very troubling development for the 600,000 Americans with PKD and the PKD research community in that they rely heavily on this funding for clinical trials that could lead to a treatment for PKD. My question is: What caused these "reporting errors" to take place, and what is being done to correct the situation? Would you please provide the Subcommittee with accurate funding levels for PKD research from fiscal year 2000 through fiscal year 2006, broken down by individual Institute and Center, specifically for NIDDK, NHGRI and NCRR?

Answer. The NIDDK considers advancing PKD research a very high priority, and has built a strong portfolio of investigator-initiated research grants, research centers, and pivotal clinical studies. Driven by major advances in the field, NIH funding for PKD research has increased substantially over the past ten years. Your understanding that funding for certain years may have been lower than was reported is based largely on changes in reporting methodology instituted after fiscal year 2003 that changed how project dollars are attributed to the research related to PKD. Importantly, the changes do not imply a diminished commitment by the NIH to PKD research. The official NIH report for PKD research funding for fiscal years 2000 through 2006, by Institute and center, is:

[In thousands of dollars]

I/C	Fiscal year						
	2000 actual	2001 actual	2002 actual	2003 actual	2004 actual	2005 actual	2006 actual
NIDDK	$15,166	$18,085	$24,586	$31,365	$32,579	$24,076	$30,202
NHGRI	.....	.....	.....	4,988	281	339	336
NCRR	.....	659	814	924	956	977	1,281
Total	15,166	18,744	25,400	37,277	33,816	25,392	31,819

With respect to the above data, the NHGRI beginning in fiscal year 2004 changed its methodology used to calculate funding amounts on projects relevant to PKD. The change that NHGRI made for reporting PKD research impacted only one large project. Previously, 100 percent of its funding had been reported as PKD research. As a result of the methodology change in fiscal year 2004, only five percent of the project is now reported as PKD research. This change reduced the total NIH funding figure from fiscal year 2003 to fiscal year 2004 by more than $4 million.

In fiscal year 2005, the NIDDK changed its methodology and began to report funding for only the directly-relevant portion of large research projects, such as clinical trials and research centers, instead of reporting 100 percent of the project amounts. For example, for large kidney disease clinical trials, the NIDDK reported only the proportion of funds that were related to the number of PKD patients who participated in such trials. This change in methodology resulted in additional downward adjustments of funding figures.

In an effort to be completely transparent regarding the methodological change that occurred, the NIH has presented this information, along with detailed grant listings, to the Polycystic Kidney Disease Foundation.

It is important to re-emphasize that these changes do not imply a diminished commitment to PKD research; rather, they reflect a change in the methodology used to determine the reported funding.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

DIABETES AND NATIVE HAWAIIANS

Question. Dr. Rodgers, the prevalence of diabetes is much higher among Native Hawaiians compared to other members of society. Native Hawaiians and other Pacific Islanders aged 20 years or older are more than two times as likely to have diagnosed diabetes as whites after adjusting for population age differences. In 2004, Native Hawaiians had the highest mortality rate as a result of diabetes mellitus in the State. What efforts has your NIDDK taken to understand diabetes in Native Hawaiians?

Answer. The NIDDK is continuing its support of diabetes research and education efforts for Native Hawaiians and other Pacific Islanders disproportionately burdened by type 2 diabetes. The NIDDK is supporting the Diabetes Prevention Program (DPP) Outcomes Study, which is following the Native Hawaiian and other participants in the original DPP clinical trial to assess the long-term effects of the interventions. The DPPOS has a site in Hawaii. The landmark DPP multicenter clinical trial demonstrated that people at increased risk for type 2 diabetes can prevent or delay disease onset through relatively modest changes in diet and moderate physical activity.

The NIDDK is also supporting a study that is expected to provide a better understanding of dietary and behavioral factors related to excess body weight and diabetes in Native Hawaiians. This information can help to identify preventive strategies to modify lifestyle factors. The National Center on Minority Health and Health Disparities supports a Hawaii EXPORT Center, which aims to reduce or eliminate diabetes related health disparities in Native Hawaiians and other Pacific Islanders through grass roots partnerships to foster research, research capacity building, and community outreach. The National Heart, Lung, and Blood Institute supports a study examining heart disease in Native Hawaiians; diabetes is a major contributor to heart disease.

We are also intensifying research on type 2 diabetes in children, which is an emerging public health issue that predominantly affects minorities. To determine the prevalence and incidence of both type 1 and type 2 diabetes in children, the NIDDK is supporting the CDC-led SEARCH for Diabetes in Youth epidemiological study. One of the six nationwide SEARCH centers is in Hawaii. SEARCH is providing important information on how to characterize childhood diabetes.

To disseminate the positive results of the DPP, the NIDDK and CDC co-sponsored National Diabetes Education Program developed the "Small Steps. Big Rewards. Prevent Type 2 Diabetes" educational campaign, which includes materials tailored for Pacific Islanders. The NIDDK also supports research efforts to translate advances in the prevention and treatment of diabetes and obesity into clinical practice for individuals and communities at risk.

HEPATITIS B

Question. Dr. Rodgers, 1 out of 10 Asian Americans are affected with hepatitis B, which, along with hepatitis C, is associated with an increased incidence of liver cancer. In fact, liver cancer is the only cancer experiencing continuing increases in mortality. It is my understanding that the best treatment protocols for hepatitis B and C are really effective only in approximately half of the cases. In your testimony, you discuss the use of biomarkers, which may allow for early screening and diagnosis of the disease. Dr. Rodgers, how can biomarker technology be used to diagnose and treat those patients who will respond to the treatments and thus spare the expense, not to mention the harsh side effects, of treating patients who will not respond?

Answer. Though new treatments are now available for chronic hepatitis B that are effective in the majority of patients, the only effective therapy for chronic hepatitis C remains a standard combination of antiviral drugs (peginterferon alfa and ribavirin). Unfortunately, only about half of patients with chronic hepatitis C respond to this antiviral therapy.

To understand and improve upon this response rate, the NIDDK is engaging in several ongoing studies focused on such issues as identifying biomarkers to assess response to antiviral therapy for hepatitis C in different study populations. These investigations include the Study of Viral Resistance to Antiviral Therapy of Chronic Hepatitis C (Virahep-C) in African American and Caucasian American adults; the trial on Peginterferon and Ribavirin for Pediatric Patients with Chronic Hepatitis C (Peds-C); and the trial on Hepatitis C Antiviral Long-term Treatment against Cirrhosis (HALT–C). Through these NIDDK-supported efforts, researchers are identifying potential biomarkers to predict hepatitis C treatment response, such as gene products induced by interferon, which modulates the body's immune defense system.

In addition to these ongoing NIDDK-supported efforts, other promising potential venues for research to develop biomarkers for various diseases include biomarker initiatives sponsored by the NIH and a new Biomarkers Consortium administered by the Foundation for the NIH.

ASTHMA AMONG HAWAIIANS

Question. Dr. Nabel, about 4.3 percent of Hawaiians have asthma. Native Hawaiian adults had a much higher prevalence of asthma compared to other adults in Hawaii—71 percent higher than the total State prevalence. In Hawaii, children have the highest rates of asthma. Recently, the CDC funded the Hawaii Department of Health (HDOH) to establish a lung function monitoring program and asthma intervention for children from eight schools in Hilo, Hawaii, near the Kilauea Volcano. Currently, HDOH is finishing an assessment of the health effects that may be associated with potentially toxic volcanic emissions from the Kilauea Volcano. How can the NIH contribute to a greater understanding of asthma among Hawaiians?

Answer. The NHLBI supports a research project titled "Does Shared Decision-Making Improve Adherence in Asthma?" for which one of the study sites is in Hawaii. Results from this study can be expected to contribute importantly to our understanding of effective ways to improve asthma control and reduce asthma burden among Hawaiians. The project will evaluate two different educational interventions for clinicians to use with their asthma patients and it will compare results among three different study centers—Hawaii; Oakland, California; and Portland, Oregon. Thus, data from the study will provide critical insights into ethnic and cultural differences in asthma management. The NHLBI will work with the investigators to disseminate the findings, giving guidance to clinicians and patients alike about new ways to reduce the burden of asthma.

NHLBI-supported research on the origins of asthma includes projects that explore the interactions between genetics, exposures to environmental factors such as allergens and respiratory tract infections, and the development of the immune system. Several epidemiologic studies are investigating the impact of exposures to air pollutants on the development of asthma and the progression of asthma severity in children. All of these studies include children of diverse ethnicity from throughout the United States. Data from these studies will be available to the research community to examine and compare asthma development in children from Hawaii.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

ALZHEIMER'S DISEASE

Question. Dr. Hodes, several years ago, a vaccine for Alzheimer's disease was touted as a potential cure for the disease. What progress has been made toward creating a vaccine for Alzheimer's disease? Does a vaccine remain a likely treatment for Alzheimer's Disease? What other progress has been made to address this devastating disease?

Answer. The vaccine approach that was used in a clinical trial for treatment of Alzheimer's disease had previously been shown to successfully reduce deposits of beta-amyloid (the major component of the plaques that develop in the brains of people with AD) in mice, and to improve performance on memory tests in these animals. Unfortunately, preliminary clinical trials in humans had to be stopped because of potentially life-threatening brain inflammation that occurred in some participants. The pharmaceutical industry and NIA-supported investigators are continuing to refine this strategy in animal models of AD, and hope to find ways to

maintain the therapeutic effects of the vaccine while reducing unwanted side effects. For example, NIA investigators are studying several novel immunogens that show promise for future AD vaccines that can reduce brain beta-amyloid load without the adverse inflammatory side effects of the original vaccine. In addition, several pharmaceutical companies have recently obtained permission from the FDA to test several of these new strategies for safety in early stage clinical trials.

Another promising approach is passive immunization, in which antibodies that can bind directly to beta-amyloid are injected into a patient's body. Several studies over the past few years have indicated that passively administered anti-beta-amyloid antibodies can effectively remove beta-amyloid peptides from the brain. One passive immunization approach utilizes Intravenous Immunoglobulin or IVIg. IVIg contains naturally-occurring antibodies against beta-amyloid, and preliminary studies in humans have shown that IVIg may improve cognition. In addition, research has demonstrated that IVIg increased levels of anti-beta-amyloid antibodies in plasma and promoted clearance of beta-amyloid from cerebrospinal fluid. The NIA is funding a Phase III clinical trial of IVIg through the Alzheimer's Disease Cooperative Study (ADCS), a large consortium of clinical research sites throughout the country, to test whether IVIg is useful clinically for treating AD.

NIA investigators continue to study other promising approaches to delaying or preventing the onset of AD. Such approaches focus on a number of health, lifestyle, and environmental factors that could make a difference in preventing or delaying the onset of AD. For example, NIA investigators are studying whether lowering cholesterol and high blood pressure may decrease a person's risk for AD. Too much insulin in the blood (which happens as a result of insulin resistance) may encourage inflammation and oxidative stress, which are thought to contribute to the damage seen in AD. Another promising area of research focuses on highly active molecules called free radicals. Some population and animal studies suggest that antioxidants from dietary supplements or food may provide some protection against this damage (called oxidative damage), but other studies show no effect.

NIA investigators are also studying the impact of regular social engagement and intellectual stimulation as strategies to prevent or delay the onset of AD.

NIA continues to conduct and support a broad portfolio of research to develop new therapeutic approaches and prevention strategies for AD.

HEALTHY AGING

Question. Dr. Hodes, in your written testimony you note that certain simple lifestyle changes may induce beneficial effects on cognition and overall health as we age. Could you please expand on your statement by giving some specific examples of these simple lifestyle changes?

Answer. Knowing how the brain ages provides important information on which to base strategies for maintaining and enhancing cognition through biological and behavioral interventions. For example, it was recently shown that some new neurons form in adulthood in certain regions of the human brain, contrary to prevailing beliefs. This advance presents the possibility that methods could be found to compensate for neuron loss and cognitive decline resulting from disease or traumatic injury. Behavioral strategies also are being developed to maintain cognitive function. For example, several NIA studies suggest that physical exercise may prevent physical disability, including impaired mobility, and perhaps cognitive decline, in healthy and frail older adults. To develop definitive evidence, NIA and grantee researchers developed the LIFE (Lifestyle Interventions and Independence in Elders) study, a clinical trial testing the effects of a physical activity program vs. a health education program among older Americans. A successful pilot study (LIFE–P) completed in 2005 showed both feasibility and positive preliminary data, permitting design and consideration of a large-scale clinical trial.

Other research indicates that higher levels of long-term physical activity in older women were strongly associated with better cognitive performance and less cognitive decline. Older women with higher levels of baseline physical activity were less likely to develop cognitive decline. Encouraging results from several NIA-funded clinical studies show that aerobic exercise has a short term positive effect on some areas of cognition. For example, a meta-analysis of exercise interventions indicated robust but selective effects of physical activity on cognitive function in older adults, with the largest fitness-induced benefits occurring for executive control processes. Research comparing older adults with high levels of aerobic fitness to older adults with low levels of aerobic fitness revealed declines in size of several brain cortical regions with age but that the degeneration was substantially reduced as a function of cardiovascular fitness. A small randomized trial of 6 months duration demonstrated that older adults who received aerobic training (walking) showed substan-

tial improvements in performance on tasks requiring executive control compared with an aerobically trained (stretching & toning exercises) adults.

NIA co-sponsored the Diabetes Prevention Program (DPP), which was led by the National Institute of Diabetes and Digestive and Kidney Diseases. The DPP was the first major, randomized, multi-site clinical trial to demonstrate that type 2 diabetes could be prevented or delayed in individuals at high risk for developing the disease. This three-year trial compared three preventive approaches: standard medical advice about diet and exercise; lifestyles modification aimed at losing 5 percent to 7 percent of body weight through diet and a moderate, consistent increase in physical activity (e.g., walking 5 days a week for 30 minutes a day); and treatment with metformin, an oral drug commonly used to treat individuals who already have type 2 diabetes. Participants over 60 years of age responded particularly well to the lifestyle intervention, showing a 71 percent risk reduction in the incidence of diabetes, as compared to groups treated with metformin or standard medical advice. Another observation of these data is that the lifestyle intervention had increasingly greater impact with increasing age (from age 25 to over 60) while the metformin treatment had progressively less impact with increasing age.

NEUROIMAGING

Question. In 2004, you launched a neuro-imaging program to develop techniques that will help researchers identify Alzheimer's much earlier, and also assist in developing new treatments. What's been accomplished and when do you expect to complete this project?

Answer. The Alzheimer's Disease Neuroimaging Initiative (ADNI) is a 5-year public-private partnership with the Foundation for NIH and industry that will determine the ability to detect brain and biological changes before memory decline and other symptoms appear, allowing the effectiveness of drugs to be evaluated at the earliest possible time. The study is planned to continue through 2009. ADNI recently completed recruitment of 800 older adults for the study. Approximately 200 cognitively normal older people will be followed for 3 years, 400 people with mild cognitive impairment will be followed for 3 years, and 200 people with early AD will be followed for 2 years. Researchers will compare neuroimaging, biological (analyzed from samples of blood and cerebrospinal fluid), and clinical information from the participants, looking for correlations among the data to develop standards for tracking the progression of memory decline.

Knowledge gained from these scans and other tests may lessen the time and cost of testing drugs and to bring treatments to patients much sooner.

Among ADNI's early achievements is the creation of a publicly accessible database available to qualified researchers worldwide. To date, over 200 scientists have requested access to the database, which is available through the ADNI Web site, http://www.loni.ucla.edu/ADNI. It contains thousands of magnetic resonance imaging (MRI) and positron emission tomography (PET) scan brain images.

The project's principal investigator, Dr. Michael Weiner at the University of California, San Francisco, will present a progress report on ADNI in June 2007 in Washington, D.C., during the Alzheimer's Association International Conference on the Prevention of Dementia. Other findings will be presented by a dozen other ADNI scientists. Among their findings:

—A University of California, San Diego, study found that semi-automated analyses of MRI and PET images could detect early changes in the thickness of the cerebral cortex that could add to other information on brain anatomy to predict a person's conversion from mild cognitive impairment to Alzheimer's.

—A study at Banner Alzheimer's Institute, Phoenix, compared changes over six months between PET scan images from healthy older adults, people with mild cognitive impairment and people with Alzheimer's. The study found that brain images could be correlated with patients' symptoms and that comparisons of images made at different clinical sites were valid, which is necessary to document before using PET scans in future clinical trials.

—A Mayo Clinic, Rochester, Minn., study found that use of an anatomical model of a brain (or phantom) can be used to monitor performance of MRI scanners, making sure they remain accurate over time. ADNI will produce MRI images on 800 volunteers using 80 MRI scanners over five years. Use of the phantom could improve reliability of ADNI results and of those subsequent clinical trials.

—A University of Pennsylvania, Philadelphia, study compared analyses of samples of cerebrospinal fluid collected from study participants and analyzed at seven laboratories. The study evaluated differences within and between the labs' performance. This validation study will help ensure that ADNI methods for measuring biomarkers are accurate and comparable across laboratories.

DRUGS FOR CHILDREN

Question. Dr. Katz, on April 11, 2007, I met with Mrs. Lori Todaro and a group of mothers from PA. Mrs. Todaro's son, Anthony, has been participating in an NIH protocol since 2003 and his been receiving his medication through that protocol. I understand that patients like Mrs. Todaro's son, once they are no longer participating in the NIH protocols, will need to find other ways to obtain and pay for these drugs. In many instances, the drugs are not covered by the insurance companies because they are approved for specific illnesses, but not approved for use for other disorders (in this case periodic fever syndrome). What can NIH do to ensure that these children continue to receive drugs for the treatment of their disease after the protocols have ended?

Answer. All patients who are treated at the NIH are part of a clinical protocol—whether it is an observational (natural history) study, or a trial to test an experimental therapy. Patients who meet the criteria for our clinical studies—whether they are children or adults—are given the appropriate medications for the duration of their participation. Once a study has ended, however, the NIH is not able to continue to provide medications since this is beyond the agency's authority. Nonetheless, we fully understand the challenges that patients and their families face when needed medications are no longer available through a clinical study. In light of this, we encourage patients and their physicians to work with insurance companies to arrange appropriate coverage.

OSTEOARTHRITIS INITIATIVE

Question. Dr. Katz, in your written testimony you note the implementation of an osteoarthritis initiative. I understand that this initiative is a public-private partnership between the NIH and private industry that seeks to improve diagnosis and monitoring of osteoarthritis. Please give us some specifics on the initiative and update us on the progress being made.

Answer. The NIAMS places a high-priority on studies to identify risk factors and biomarkers of disease, in an effort to facilitate the early identification of signs and symptoms, and to develop interventions that are more effective. To this end, the Institute will continue its commitment to a novel public-private partnership to improve prevention of osteoarthritis (OA), or degenerative joint disease. The Osteoarthritis Initiative (OAI) is a long-term effort, developed with support from numerous NIH components, private sector sponsors, and with the participation of the Food and Drug Administration, to create a publicly-available research resource to identify and evaluate biomarkers of OA for use in clinical research. The study has close to 4,800 participants who are at high risk for knee OA, or with relatively early disease. At present, clinical data from approximately half of the OAI participants are available for use in research projects, as are images (both x-ray and magnetic resonance) from more than 350 study subjects.

Over the next 5 years, the OAI will provide an unparalleled, state-of-the-art longitudinal database of images and clinical outcome information, as well as biological specimens such as blood and urine samples, available to researchers worldwide to facilitate the discovery of biomarkers for development and progression of OA. To date, there are over 500 registered users of the OAI clinical dataset, and over 30 users of the related images. In this effort, a biomarker would be a physical sign or biological substance that indicates changes in bone or cartilage. Today, 35 million people—13 percent of the U.S. population—are 65 and older, and more than half of them have radiological evidence of OA in at least one joint. By 2030, an estimated 20 percent of Americans—about 70 million people—will have passed their 65th birthday and will be at increased risk for OA. Thus, the OAI provides a critical research resource to the scientific community at a time when greater numbers of Americans are affected by OA.

MUSCLE DEGENERATION

Question. Dr. Katz, I understand that your Institute, together with the Neurology Institute, funded research showing that a common blood pressure drug reduces muscle degeneration in mouse models of Duchenne muscular dystrophy. Could you please describe that research and any implications that it may have on human treatments for Duchenne muscular dystrophy?

Answer. NIH-supported researchers at Johns Hopkins University recently demonstrated that the weakness and muscle wasting that occur in a mouse model of Duchenne muscular dystrophy could be delayed by six to nine months of treatment with losartan, a drug approved by the Food and Drug Administration for the treatment of high blood pressure. In addition to its known mechanism of action, the re-

searchers demonstrated that another action of losartan is to block the effects of transforming growth factor beta (TGF-?), a protein present in the diseased muscle that limits regeneration and promotes the replacement of muscle with fibrous scar-like tissue (fibrosis). The dystrophic mice treated with losartan exhibited increased muscle mass and strength and decreased fibrosis in comparison to untreated dystrophic mice. Additional clinical research is needed in order to further examine the use of losartan as a potential treatment for individuals with Duchenne muscular dystrophy. However, this discovery is an excellent example of how a drug already approved for one disease may have a potential therapeutic application for another disease.

HEART DISEASE IN CHILDREN

Question. Dr. Nabel, it is my understanding that heart defects are the most common type of birth defect. What efforts are being made by your Institute to address heart disease in children and in infants?

Answer. The NHLBI has a long history of supporting research in congenital heart disease, which dates back to 1949 when the first grant was awarded to explore surgical treatments for "blue babies." Today the Institute continues to recognize the public health importance of congenital heart disease, and is addressing the problem through an extensive portfolio of basic, translational, and clinical research, as well as efforts to educate the public about the importance of pediatric research.

To encourage translational research, the NHLBI established the Specialized Centers of Research in Pediatric Cardiovascular Disease in 1994 with the purpose of encouraging a clinical focus to bench research. In 2003, the NHLBI revamped the program to encourage more clinical research and renamed it the Specialized Centers of Clinically Oriented Research in Pediatric Heart Development and Disease. The NHLBI increased its investment to accommodate the costs of clinical research, and funded 4 centers conducting cutting-edge research on the causes, treatments, and outcomes of congenital cardiac malformations.

In 2001, the NHLBI launched the Pediatric Heart Network (PHN), which heralded a new era in congenital heart disease clinical investigation. With 8 principal sites and several additional auxiliary sites, the PHN has undertaken 7 studies in its first 5 years, a remarkable track record for any clinical network. One of these studies is a comparison of two surgical procedures for newborns who have such severe congenital heart disease that they require lifesaving surgery during the first week of life. This study, which began recruitment in 2005, represents the first time in the history of the specialty that a new surgical procedure has been compared systematically to the standard procedure. The success of the PHN was widely acknowledged when it was chosen in 2006 as a network that exemplified "best practices" through the NIH Roadmap program Inventory and Evaluation of Clinical Research Networks. One of its practices that merits special mention is its function as an active and nurturing training ground for fellows and junior faculty interested in clinical research.

Through the PHN and other activities, NHLBI is also taking the lead in educating patients and families about research on children with congenital heart disease and, more broadly, on pediatric research in general. The PHN's public web site, www.PediatricHeartNetwork.org, provides information to parents (and community physicians) about participating in research as well as about PHN studies, and offers direct access to NHLBI's pediatric cardiologist and pediatric cardiac study coordinator when parents have questions. Also through the PHN, the NHLBI is funding a documentary resource for families and researchers that will guide families, in simple language, through the research process, and tell the stories of a diverse group of parents about their participation in research. Although resources similar to this exist for specific disease conditions, no other resource that applies to pediatric research generally, or that is accessible to families from all walks of life, is currently publicly available.

WOMEN AND HEART DISEASE

Question. Dr. Nabel, I am concerned that while heart disease is the leading cause of death of women in the United States, but many women do not perceive heart disease as a top health risk. I understand that the NIH Heart Truth Campaign is raising women's awareness of heart disease. What results have you seen so far from the Heart Truth Campaign as it celebrates its 5th anniversary?

Answer. The Heart Truth campaign, sponsored by the NHLBI, continues to reach millions of women across the country, raising awareness about heart disease—the #1 killer of women. The Red Dress, introduced by the NHLBI as the national symbol

for women and heart disease awareness, serves as a powerful reminder for women to talk with their doctors about heart disease and to take action to lower their risk.

Considerable progress has been made since the campaign began five years ago. Awareness among women that heart disease is their leading cause of death grew from 34 percent in 2000 to 55 percent in 2005. In 2007, 57 percent of U.S. women recognized the Red Dress as the national symbol for women and heart disease, up from 39 percent in 2006 and 25 percent in 2005.

The Heart Truth campaign partners, including corporations, other government agencies, the U.S. fashion industry, health professionals, nonprofit and women's organizations, and media outlets, have helped to extend the campaign's reach. Over 350 locally sponsored Heart Truth events, many in high-risk areas, have been held since the campaign began. Media outreach and partnership development have resulted in an impressive 1.5 billion media impressions to date, including 486 million from Fashion Week 2007. Since 2003, The Heart Truth and Red Dress symbol have been promoted on 109 million product packages and in newspaper advertising inserts with a combined circulation of 509 million.

The campaign launched "The Heart Truth Champions" program in April 2006, which recruited health advocates and educators in local communities to increase awareness about women and heart disease. To date, the champions have conducted more than 60 community events to raise awareness of women's heart disease and screen for heart disease risk factors. The Heart Truth has also formed partnerships with leading national organizations and media outlets representing women of color, and is engaging in national and local activities, including a faith-based initiative, to reach these women. Moreover, the NHLBI has awarded grants to three national organizations for women of color that have significant membership and outreach potential on the regional and local levels. The grantees will implement a variety of national, regional, and local heart health awareness activities based on The Heart Truth and on two NHLBI-sponsored community-based minority outreach programs—With Every Heartbeat is Life and Su Corazón, Su Vida.

DIABETES

Question. Dr. Rodgers, I understand that several lines of research are showing promise in addressing type 1 and type 2 diabetes. I noted the recent publication of findings suggesting that adult stem cells may be useful in treating new onset diabetes. Could you please describe progress being made in this area and explain why this treatment appears to only be useful in new onset diabetes? What progress has been made in using stem cells to make insulin-producing cells?

Answer. Indeed, there have been encouraging results from studies of several approaches to treating diabetes. One reason why a particular approach might be successful only in new onset type 1 diabetes is that these patients often have some insulin-producing capacity remaining. This is sometimes referred to as the "honeymoon phase" of the disease. In theory, a treatment might prolong this honeymoon phase, reducing or eliminating the need for insulin administration either permanently or temporarily. Some approaches we are investigating, for example, seek to interfere with the autoimmune destruction of the insulin-producing beta cells of the pancreas, which could conceivably allow for their re-growth. Other recent studies include a private company's reported generation of insulin-producing cells from human embryonic stem cells (Stem Cells Express, published on-line May 17, 2007), and a similar, private foundation-supported finding using umbilical cord ("adult") stem cells (Cell Proliferation, 40:367). The Type 1 Diabetes Special Statutory Funding Program supports the NIDDK-administered Beta Cell Biology Consortium (BCBC), which has a goal of facilitating interdisciplinary approaches that will advance understanding of the development and function of beta cells. BCBC investigators are therefore probing the pathway and signals involved in producing beta cells from both adult and embryonic stem cells. It is hoped that new insights about the development and differentiation of stem cells, obtained through BCBC studies, will contribute to research progress in making or regenerating insulin-producing beta cells.

ARTIFICIAL PANCREAS

Question. I understand that some efforts are underway toward the development of an artificial pancreas as a way to help people better manage their diabetes. This device would continuously measure the glucose levels in the body and then dispense doses of insulin based on those measurements. Can you comment on the role the National Institutes of Health has played in the development of this technology and why, from your perspective it might be exciting?

Answer. The NIH is playing an important role in the development of an artificial pancreas, a device that would essentially "close the loop" between the measurement of glucose levels in the body and the therapeutic delivery of insulin. For example, the NIH supported the development of continuous glucose monitors recently approved or under consideration for approval by Food and Drug Administration (FDA). These monitors are an essential first step in making an artificial pancreas. Moreover, an NIH initiative led by the National Institute of Child Health and Human Development (NICHD) is testing glucose monitoring technologies for use in children. We are also working with researchers and industry, as well as sister agencies, to overcome scientific obstacles to achieving the goal of an artificial pancreas. For example, in December 2005, the NIDDK, the Juvenile Diabetes Research Foundation International, and the FDA hosted a key workshop with academic and industry representatives to examine challenges and opportunities for artificial pancreas development. The NIH now participates in a new FDA-led interagency working group to provide scientific information that can assist FDA in its decision-making regarding new artificial pancreas technologies. The new technologies are exciting because they could revolutionize care for people with diabetes. They could enable precise control of blood glucose to help avert complications, and also reduce the likelihood of dangerous episodes of low blood sugar—thereby improving patients' health and well-being.

DIABETIC RETINOPATHY

Question. I understand that diabetic retinopathy is the leading cause of blindness in working age adults. Can you tell the Committee about progress and potential research opportunities to prevent this complication of diabetes?

Answer. We believe that the NIH is making substantial progress toward the prevention and treatment of diabetic retinopathy. A landmark NIDDK-supported clinical trial in people with type 1 diabetes, the Diabetes Control and Complications Trial (DCCT), showed that intensive control of blood sugar levels reduced risk for developing diabetic retinopathy by over 70 percent. It is estimated that patients on intensive therapy who maintain near normal blood sugar for life could gain, on average, an extra eight years of sight. For people who have an advanced stage of diabetic retinopathy, laser surgery and appropriate follow-up care can reduce the risk of blindness by 90 percent. This progress has had significant positive impacts on patients' health and quality of life. The National Diabetes Education Program, co-sponsored by the NIDDK and the Centers for Disease Control and Prevention, is spreading the word about the vital importance of blood glucose control in preventing complications, such as retinopathy in people with diabetes. The National Eye Institute's (NEI) Diabetic Eye Disease Public Education Program, part of the National Eye Health Education Program, seeks to increase awareness among people with diabetes that diabetic retinopathy is treatable, and that when caught in time, it need not lead to blindness.

We are now working to identify additional strategies for prevention or treatment. For example, the NEI leads the Type 1 Diabetes Special Funding Program-supported Diabetic Retinopathy Clinical Research Network. This is a nationwide network of eye doctors and researchers supporting clinical trials and studies of diabetic eye diseases. Examples of potential therapeutic agents currently being tested for diabetic eye disease by this network are drugs that inhibit excessive new blood vessel growth in the eye—a process called angiogenesis. The NIH also supports a pipeline to propel progress in drug development by facilitating research to identify promising therapeutic targets and agents in the laboratory. It also generates animal models that mimic human complications of diabetes. Moreover, the NIH tests promising agents in these animal models, and tests promising therapies in people. Lastly, results from the NIDDK's Diabetes Prevention Program clinical trial suggest that diabetic retinopathy develops even earlier than was previously recognized. Diabetic retinopathy was found in people with pre-diabetes, and researchers are now examining whether the interventions that were successful in delaying progression from pre-diabetes to diabetes will also slow development of retinopathy. Continued research on prevention and early detection of this complication is critically important.

OBESITY

Question. There has been an alarming increase in obesity in this Nation, especially in youth. This Committee has recognized and highlighted this trend with initiatives focusing on wellness, physical activity, and nutrition. In your testimony you mentioned a school based intervention study regarding obesity called the HEALTHY trial. Please expand upon your description of this trial and give us a time line for this important research.

Answer. The HEALTHY trial, which was launched in August 2006, will investigate whether a concerted, integrated program in middle schools will help reduce the prevalence of obesity-related harbingers of type 2 diabetes. The trial enrolled sixth graders and is following them through the end of eighth grade. The majority of children enrolled in the study are from minority groups disproportionately burdened by type 2 diabetes, including Hispanics and African Americans. Half of the 42 enrolled schools are receiving the intervention, which consists of improving cafeteria lunches, vending machine offerings, and physical education, as well as promoting behavioral change. HEALTHY will examine changes in the students' body mass index, as well as changes in their blood glucose and blood insulin levels, to determine if the interventions are effective in reducing these risk factors for type 2 diabetes.

The timeline for this study is: (1) recruitment and baseline data were collected in the first semester of sixth grade (Fall 2006); (2) the intervention will be administered from the second semester of sixth grade (Winter 2007) through the second semester of eighth grade (Spring 2009); and (3) the final data collection will be performed in the second semester of eighth grade (Spring 2009). Data analysis is expected to continue through 2010.

EARLY DETECTION OF LIVER CANCER

Question. Dr. Rodgers, it is my understanding that liver cancer is the only cancer experiencing continuing increases in mortality and treatment options for physicians remain limited. However, with early detection the chances for recovery are much increased. In your written testimony, you noted the Biomarkers Consortium, a public/private partnership to accelerate the development of biomarkers to facilitate accurate and early diagnosis of disease. Would the development of liver cancer biomarkers be within the scope of the Biomarkers Consortium? What other ailments might be targets for biomarker development?

Answer. The NIDDK and other NIH Institutes and Centers, such as the National Cancer Institute (NCI), are keenly interested in efforts to develop biomarkers for early detection of liver cancer, which occurs largely in individuals with chronic liver diseases such as hepatitis B and C. The Foundation for the NIH (FNIH) administers the Biomarkers Consortium. This Consortium—along with other biomarker development initiatives sponsored by the NIH—is a promising potential venue for research to develop and qualify biomarkers for various diseases. Approval of specific projects for the Biomarkers Consortium will be made by members of its Executive Committee, which includes representatives from the FNIH, the NIH, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, pharmaceutical companies and trade groups, and non-profit advocacy groups. This public-private partnership could decide to pursue biomarkers for aspects of liver disease, such as identifying early forms of liver cancer.

NIH research on liver diseases is guided in part by recommendations contained in the Action Plan for Liver Disease Research, which was developed by the NIH in 2004 in response to congressional interest. The Action Plan includes research goals to develop and validate biomarkers for the early detection of hepatocellular carcinoma (HCC), a common form of liver cancer. In a recent review of progress toward achieving the Action Plan's research goals, external experts highlighted advances being made toward developing biomarkers for early detection of HCC in high-risk individuals. These advances are facilitated by programs such as the NIDDK-supported Hepatitis C Antiviral Long-term Treatment Against Cirrhosis (HALT–C) trial and the NCI-sponsored Early Detection Research Network.

The NIDDK is also pursuing biomarker development for other conditions within its mission. For example, one of the first projects being undertaken by the Biomarkers Consortium is focused on discovering new biomarkers of type 2 diabetes and prediabetes, based on an NIDDK pilot study. The Institute also supports efforts to develop biomarkers for diseases of the kidney, genitourinary tract, and digestive, hematologic, endocrine, and metabolic systems, as well as for obesity.

CHRONIC KIDNEY DISEASE

Question. Dr. Rodgers, it has come to my attention that recent studies have shown that cardiovascular disease is the number one cause of death for people with Chronic Kidney Disease (CKD). I understand that the rate of death from cardiovascular disease may be between 10 to 30 times greater in the 20 million Americans currently suffering from some form of CKD than in the general population. What are you, in cooperation with NHLBI, doing to address this growing problem? What else could be done? Is there a coordinating committee?

Answer. The NIDDK and NHLBI recognize the problem of cardiovascular disease (CVD) in people with chronic kidney disease (CKD), and are working together to address it. For example, the NIDDK is supporting a kidney study as part of NHLBI's Genetic Epidemiology Network of Arteriopathy (GENOA) study. The project is assessing the kidney function in a subset of GENOA's patients to learn more about the genetic factors that influence kidney function in people with high blood pressure.

Another example of collaboration between the NIDDK and NHLBI on CVD and CKD is an upcoming meeting entitled "Scientific Forum of Chronic Kidney Disease (CKD): Opportunities from Observational Cohort Studies." This scientific workshop will examine the opportunities to study CVD and CKD that are presented by a number of NHLBI-supported cohort studies. These studies include the Jackson Heart Study, the Coronary Artery Risk Development in Young Adults (CARDIA) Study, and the Cardiovascular Health Study (CHS). The meeting will be held June 4, 2007. A goal of this meeting is to enhance collaboration between investigators to maximize information from cohort studies supported by NHLBI in order to better understand the relationship between CVD and CKD. We are hopeful that this meeting will aid our pursuit of promising future research directions.

It has long been known that high blood pressure, elevated blood fats, high blood sugar, tobacco use, and physical inactivity are all important, traditional risk factors for cardiovascular disease in patients with chronic kidney disease. However, the relative importance of each of these risk factors is not known compared to nontraditional risk factors such as chronic inflammation, infection, oxidative stress, and elevated levels of homocysteine. To address this gap in knowledge, the NIDDK is funding the Chronic Renal Insufficiency Cohort (CRIC) Study. CRIC is a prospective study of over 3,000 people with mild to moderate CKD that is examining nontraditional risk factors for progression of CKD and development of end-stage renal disease. Importantly, it is also examining nontraditional risk factors for CVD and measures of CVD progression in these patients.

The statutory Kidney, Urologic, and Hematologic Diseases Interagency Coordinating Committee, which is Chaired by the Director of NIDDK's Division of Kidney, Urologic, and Hematologic Diseases, encourages cooperation, communication, and collaboration among all Federal agencies involved in kidney disease research. Members share information and advice about ongoing, new, and planned activities and identify potential areas of collaboration. Members include representatives from the CDC, VA, IHS, FDA, and other Federal agencies.

SUBCOMMITTEE RECESS

Senator HARKIN. Well listen, thank you all very much, very informative. I enjoy these sessions. I think they inform us, or me anyway and my staff and those who actually work in this area.

So I thank you all and thank you for being here this morning. Thank you for the work you do. The subcommittee will stand in recess to reconvene at 1:30 p.m., Monday, May 7 in room SD–116.

[Whereupon, at 11:32 p.m., Friday, April 20, the subcommittee was recessed, to reconvene at 1:30 p.m., Monday, May 7.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

MONDAY, MAY 7, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 1:31 p.m., in room SD–116, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senator Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. JEREMY BERG, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Committee will come to order.

This is the subcommittee's fourth hearing on the National Institutes of Health this year. We've heard from nine institutes, today we'll hear from four more: The National Institute of General Medical Sciences, the National Human Genome Research Institute, the National Library of Medicine, and the National Institute of Biomedical Imaging and Bioengineering.

We asked these four Institutes to appear together because they're all involved in expanding the frontiers of science. Unlike many of the institutes at NIH, none of these are charged with attacking a particular disease. Instead, they develop cutting-edge tools and resources that benefit research on all diseases—things like sequencing the human genome, combining huge, easily searchable databases, developing new imaging technology or basic research training.

What I'd like to ask is if each of you could speak for 5 to 7 minutes. Summarize the research that you've overseen over the past year or so, and give us a look ahead at the initiatives that you are planning for fiscal year 2008 and beyond.

Senator Specter cannot be here today, but I will keep the record open for his opening statement, and any questions that he might want to submit.

At the outset, I just want to thank each one of you for the work that you do in the Institutes that you direct, all that you're doing

to improve people's health. We are grateful for your dedication and skill, each and every one of you, for so many years.

I started these forums—these hearings, like this—I don't know if you've talked to any of your fellow Institute Directors, but I feel it's good to be able to get into these in a little bit more depth. Actually, the first person that started these in this room, and having them in this manner was Senator Lowell Weicker, and I was a freshman Senator at the time. I just thought they were great sessions for us to learn more in depth about what the Institutes are doing, and that's why we're doing it in this manner again.

So, I've had, basically, four at a time, like this, and try to group them in some kind of a semblance of rationality of what the Institutes were doing.

So, I'd like to, again, just kind of get into it. I'll have some questions when you finish, but I'd like to just go through, perhaps all the Directors once, I may even ask you a question in between, so we have kind of a free-flow, more than any structured kind of a presentation.

So, I will start first with Dr. Jeremy Berg, Director of the National Institute of General Medical Sciences since 2003. He received his M.S. in Chemistry from Stanford, his Ph.D. in Chemistry from Harvard. His own research focuses on the way that proteins regulate gene activity.

Dr. Berg, welcome and please proceed. By the way, all of your statements will be made a part of the record in their entirety.

SUMMARY STATEMENT OF DR. JEREMY BERG

Dr. BERG. Well, thank you very much, Senator Harkin, both for your leadership and for this opportunity.

NIGMS, the National Institute of General Medical Sciences, is often referred to as the "basic science institute," because we support research on fundamental biological processes. As one measure of how successful this approach has been, NIGMS has supported a total of 62 Nobel Prize winners over the 45-year history of the Institute, including three this past year.

The research that NIGMS has supported has also done things like enabling the Human Genome Project and contributed substantial, to the technology that led to the biotechnology industry, which current estimates indicate has created about 200,000 jobs in the United States and has an annual revenue base in the United States of about $40 billion.

The research that we support really depends on scientists working on the advances that others have made in the past, as all of our research does. One illustration of this, there's a handout which I think you have a copy of——

Senator HARKIN. Or, do I have it?

The "Central Dogma" of Molecular Biology

FIGURE 1

Dr. BERG. Figure 1 reveals the so-called "Central Dogma" of molecular biology. This goes back to the 1960's, and shows the information flow from DNA, where the genetic information is stored, through RNA, and converted into proteins, which are the molecules that do most of the work in the body.

RNA VERSUS DNA

Senator HARKIN. What's the difference between RNA and DNA?

Dr. BERG. Chemically, there's a very minor difference, there's one extra hydroxyl group in RNA. The major difference: is that DNA is very stable, and is present in the cell very robustly. RNA is used much more as a signal or a messenger, so the DNA information is translated to RNA, that's then used, and the RNA is degraded, in general, very rapidly. It is a way of sending a message out, and then the message is destroyed, so the new messages can——

Senator HARKIN. So, RNA exists for short periods of time?

Dr. BERG. Most RNAs exist for just seconds or a few minutes, some much longer than that.

But, as you'll see in one of the examples I've described, RNA is also very actively involved in many processes, some of which we're just beginning to understanding.

Even though this idea has been around for 50 years or so, there are still lots of new discoveries, both bolstering it and adding new loops to this simple information diagram.

The Nobel Prize last year in chemistry went to Roger Kornberg for determining the structure of RNA polymerase. This is something that's been known since the late 1960s, and is exactly how the information in DNA is converted into RNA. It was known that there was this very important and very complicated protein enzyme, RNA polymerase, that converts the information in DNA into RNA. See figure 2.

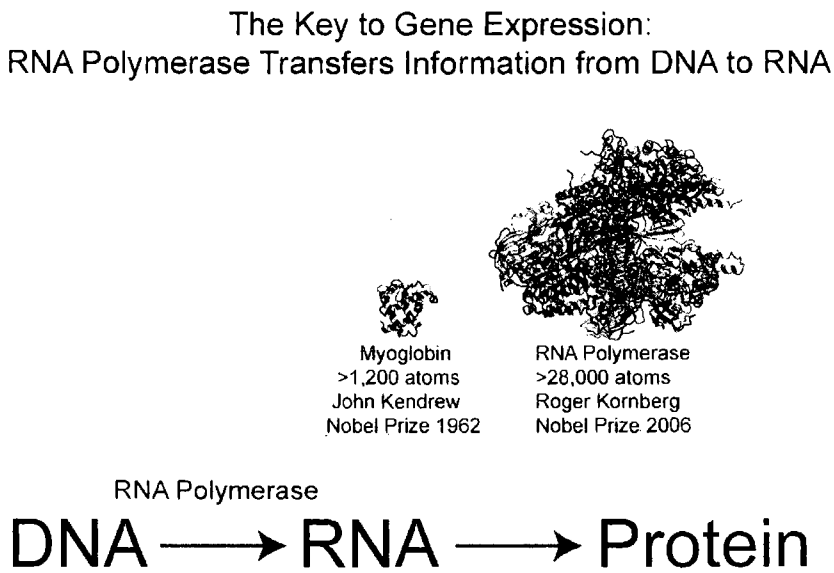


FIGURE 2

It was known to be very complicated, and starting about 20 years ago, Dr. Kornberg made it one of his missions in life to figure out what this enzyme looked like, in order to understand how it works. It is the key protein which collects information and figures out which genes should be turned on and which ones should be turned off.

He was funded for a long period of time when he started on this quest, and I must say, personally, that I think a lot of people regarded it a sort of a Don Quixote-esque quest to go do something very important, but that had a very small chance of ever succeeding.

Starting in 1999, he got the first real glimmers that he was going to succeed. Subsequently, he has been reporting more and more interesting structures, revealing the overall structure, which is incredibly complicated, and how it works—both the chemical mechanism, and now more and more information about how it collects information from the outside, and from the other things within the cell.

This really sets the stage for a much deeper understanding of gene regulation, a process that is fundamental to many aspects of health, and also a mechanism that is regulated in diseases like cancer and many others as well.

The other Nobel Prize that we supported was in physiology and medicine to Andrew Fire and Craig Mello for something that was really much more of a discovery, something that was completely unanticipated, which is that RNA actually regulates itself. The discovery was the result of an experiment that turned out very differently than they thought, and they were clever enough to realize that there was something very interesting going on. It was an experiment that was predicted not to work, that worked. They fol-

lowed that up, and discovered this process which we call RNA interference, or RNAi, which allows small pieces of RNA, that are either present in the cell, or introduced into the cell, to shut down genes in a very specific way. Again, this was something that was completely unanticipated.

One measure of how important it is, is Fire and Mello's discovery was reported in 1998, and they won the Nobel Prize only 8 years later, which is incredibly fast on the Nobel Prize timescale. One, RNAi is a fundamentally important discovery, second, it's a very powerful research tool. See figure 3.

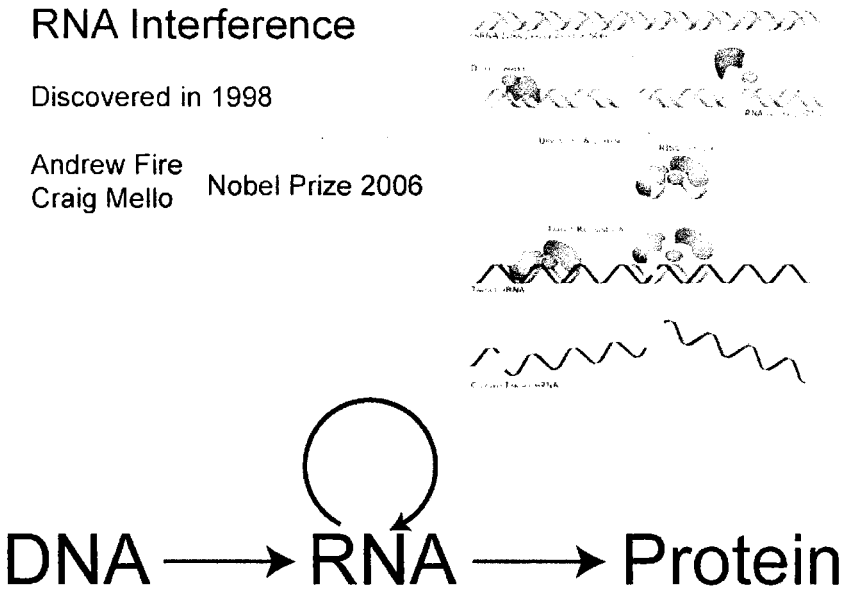


FIGURE 3

As investigators are building on the work from the Human Genome Research Institute, one of the questions they are pursuing is, what does each gene do? RNAi gives a way for scientists to specifically go through and turn off one gene at a time in a given cell type, then see what happens. The tool just didn't exist before, and it has dramatically cut down the cost of doing this type of gene-by-gene analysis.

The second really exciting thing about RNAi, is that it's immediately adaptable to new therapeutics, and there are a large number of different therapeutics being developed using RNAi. The most advanced is a treatment for macular degeneration, which is now in Phase II clinical trials. Basically, there's a specific RNA molecule that can be injected directly into the eye to shut down the expression of a particular protein, which blocks the process that underlies macular degeneration.

There are many other areas that are being advanced with RNAi. One particularly exciting area is pandemic influenza. With RNAi, one of the challenges of planning for pandemic influenza is the virus has not yet—thank goodness—been transferred from birds

into humans to a very large degree. If we have to wait for that to occur to develop medicine, or develop a vaccine, that puts in a lag-time which could be very devastating to the human population. With RNAi, we already know a lot about influenza viruses, and can find things which are common to all of the different influenza viruses, and potentially develop a therapy or a sort of a vaccine-like treatment that will be completely independent of the strain, some sort of a universal flu vaccine.

Again, this is still very much in development, and there are lots of problems to be solved. The RNAi approach opens up a new avenue, which has the potential to save hundreds of thousands of lives, and billions of dollars to the world economy.

In terms of the future, there are two important aspects. First off, although we can't anticipate and predict what new discoveries will be made, we can anticipate that they will occur. If you look at what's happened since the Central Dogma was first coined, on average about, every 5 years there's some new, revolutionary discovery that no one anticipated and that really changes the landscape of biomedical research. We still don't think we know all there is to know by any stretch of the imagination, so there will be new discoveries. I can't tell you what they will be, but I can tell you that they will exist.

To foster those sorts of discoveries, NIGMS has been involved in two new programs: one is the NIH Director's Pioneer Award, which was started a few years ago as part of the NIH Roadmap; and more recently, the NIH Director's New Innovator Award, which was started this year, thanks to the funds that were provided in the joint resolution.

The idea of these awards is really to encourage the scientific community to send forth their most creative ideas, really out of the box sorts of things, and have a home for funding some of those ideas. We want to push the sort of creative things that might be difficult to fund in the relatively conservative environment that we find ourselves in.

The second thing that we're sure we're going to have to deal with is complexity. If you look at the last handout, even though the Central Dogma is relatively simple, it's occurring with, about 20,000 genes. There are many other modifications to the Central Dogma that we know occur, and all of these things take place in concert in each of thousands of different cell types in our body and respond to interactions from other cells and environmental signals. We need to find the sort of conceptual frameworks for dealing with systems that are this complicated. We know what the parts are now, but trying to understand systems or machines, this is complicated, really a daunting challenge.

PREPARED STATEMENT

We have a program, Centers for Systems Biology, which is bringing together biologists, computer scientists, and other people who are accustomed to dealing with this sort of complexity to try to take the first baby steps to address this. Not only do we have to deal with complexity, but also variations from individual to individual, which are key to health and disease. With the information that's coming from NHGRI and other Institutes, we now are start-

ing to know more and more about what sort of variability there is, and we're trying to stay ahead of the curve in developing conceptual frameworks and tools that will help us interpret this information when it becomes available.

So, with that, thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. JEREMY BERG

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute of General Medical Sciences (NIGMS). The fiscal year 2008 budget includes $1,941,462,000.

Throughout its 45-year existence, NIGMS has been a wellspring of discovery. The fundamental knowledge generated by NIGMS research impacts every other NIH component and has broad applications in the pharmaceutical and biotechnology industries. NIGMS contributes to the health of the biomedical research enterprise in other important ways, as well. A prime example is our cutting-edge research training program, which produces a substantial number of well-prepared new scientists. Their ideas and talents contribute to our growing knowledge base, allowing continued progress toward treatments and cures for countless diseases that rob us of friends, family, and years of productive life.

NURTURING INTELLECTUAL CAPITAL

When discussing science and medicine, we often focus on compelling research advances and medical breakthroughs. But behind every "what" is a "who," a creative individual asking and answering a crucial question—the brainpower driving scientific progress. NIGMS is steadfast in its commitment to nurturing and maintaining this intellectual capital through its significant support of investigator-initiated research and research training.

In the context of this opening statement, it has become habit to reference the past year's NIGMS-supported Nobel Prizes. Of course, this is a ritual I am extremely proud to continue by reporting that the 2006 prizes in the two areas most relevant to biomedicine, physiology or medicine and chemistry, went to three NIGMS grantees. But I would like to go further, using the prize-winning research to show you how NIGMS support creates opportunities for major discoveries to happen.

Two geneticists, Andrew Fire and Craig Mello, received the 2006 Nobel Prize in physiology or medicine for their discovery of a gene-controlling mechanism called RNA interference. Their breakthrough came about by surprise, when they had the keen insight to figure out why an experiment failed. Fire and Mello's seminal finding, made relatively recently in 1998, has dramatically transformed biomedical research and has already led to new treatments that are being tested in the clinic for a range of diseases.

The 2006 Nobel Prize in chemistry is a very different story. In this case, the achievement resulted from painstaking persistence on a fundamentally important question. The prize went to a biochemist who refused to give up on a problem that even today would be perceived as ferociously difficult. Combining biochemical research with novel biophysical methods, Roger Kornberg captured a detailed, three-dimensional snapshot of the enzyme that reads our genes. This work has deeply enriched our understanding of one of the most fundamental life processes: how DNA gets copied into RNA. While the mindset, creativity, and acumen were Kornberg's, decades of unwavering NIGMS support enabled him and a talented set of coworkers to pursue this groundbreaking accomplishment, which has had a significant impact on biomedical research.

TOOLS BREED INNOVATION

To capitalize on creative ideas, scientists need tools as well as funding. These tools can take many forms, from new technologies to model organisms. Research with bacteria, yeast, insects, worms, and rodents continues to confirm that the basic operating principles are nearly the same in all living things, and that studies in other organisms yield important knowledge applicable to human health.

Thus, we are no longer surprised to learn that a gene or a process in a mouse, a worm, or a fruit fly is the same, or very similar, as that in a person. Examples of high-impact research done using model organisms abound, including the 2006 Nobel Prize-winning discoveries, which were made in roundworms and yeast. A more recent study in roundworms showed how early cell damage contributes to the development of Huntington's disease. The researchers who did this work discovered

that an error in how proteins fold leads to the massive protein clumping inside cells that typifies Huntington's disease. Because protein clumping is also linked to other neurological conditions such as Alzheimer's and Parkinson's diseases, it is likely that this work will have far-reaching implications.

Along with essential new knowledge about life processes, health, and disease, basic research can yield technologies with direct medical relevance. A case in point is an unexpected discovery by bacteriologist Yves Brun. While studying bacteria to better understand cell division, he found that the organisms produce a remarkable, natural form of "superglue." Additional studies revealed that the bacterial glue is the strongest biological adhesive ever measured, capable of holding nearly 5 tons per square inch. What's more, it doesn't dissolve in water. Brun is now working to learn more about the properties of the natural glue, which could be an ideal candidate for a surgical adhesive.

For a further demonstration of uncharted exploration as a powerful engine of discovery, consider the study of the three-dimensional structures of biological molecules. This research, which relies heavily on tools and expertise from the physical sciences, has been a prime source for the development of life-saving medications like those used to treat AIDS, many types of cancer, asthma, and several other health conditions. NIGMS has provided significant support for structural studies and other research at the interface of the biological and physical sciences. In addition, we continue to communicate and collaborate with Federal agencies focused on the physical sciences to maximize the benefit of our funding activities to the scientific community.

Of course, technology is only useful if it is available and affordable to many bright minds across the country. Every investment NIGMS makes has this end goal in mind, and currently the Institute is supporting several databases, materials repositories, genetic and genomic tools, and other shared resources that provide vital information and equipment to thousands of biomedical researchers. The Institute's team science efforts in such areas as high-throughput protein structure determination (the Protein Structure Initiative), how genes affect individual responses to medicines (the Pharmacogenetics Research Network), and new approaches to significant and complex biomedical problems via collaborations among scientists from diverse fields ("glue grants"), have all matured to a level where the fruits of progress are being shared widely with scientists everywhere.

INVESTING IN THE FUTURE

Perhaps the most important element in determining the future of biomedical research is providing young people with opportunities to develop an understanding of the scientific process and to become fascinated with the challenges and opportunities that scientific careers present. Who will make the discoveries that will drive research in the future? If we went back in time, could we have known that Fire, Mello, Kornberg, and many other unnamed scientists would have gone so far in advancing our understanding of key life processes?

Some individuals can hardly avoid catching the science bug. Roger Kornberg grew up in a household dominated by science: His father, Arthur (also a long-time NIGMS grantee), shared the Nobel Prize in physiology or medicine when Roger was 12 years old. Roger took advantage of the many opportunities available to him and began learning about science at a very early age.

Most people, however, do not grow up in such a rich scientific environment. Take Ryan Harrison, who caught the science bug a few years ago, while attending a Baltimore City public high school that has a large population of underrepresented minority students. Ryan, the son of a teacher and a former corrections officer, met Jeffrey Gray, a biophysicist at Johns Hopkins University, through an outreach program. Ryan spent 2 years working in Gray's laboratory and then came in 5th place in the Intel Science Talent Search, the most prestigious high school science competition in the country. He continues to pursue research as an undergraduate at Johns Hopkins, and we look forward to following his progress and achievements.

In order to address the health needs of our Nation, we must tap the full diversity of the talent pool of our country to attract the best minds into research. NIGMS has been a pioneer in this arena through its programs that provide opportunities for underrepresented minorities to pursue scientific careers. We recognize that underrepresentation is a challenging and complex problem. Single interventions are unlikely to effect lasting, multidimensional changes in diversity. As these programs mature, we are committed to conducting and rigorously evaluating the effectiveness of a broad range of biomedical workforce diversity programs.

Once scientists have embarked on their careers, we must continue to provide opportunities for them to contribute fully to biomedical research. An effort to do just

that is the new NIH Pathway to Independence award, which facilitates the transition of highly promising postdoctoral scientists from mentored to independent research positions. NIGMS was delighted this year to receive, and fund, a healthy number of applications for this unique program. In addition, we continue to give special consideration to regular research grant applications from new investigators as another way to help them get a solid start.

We also realize the need for scientists to be able to test unconventional, potentially paradigm-shifting hypotheses and use novel, innovative approaches to solve difficult technical and conceptual problems that impede scientific progress. Toward this end, we are developing a new grant program based primarily on the innovativeness and potential impact of a scientist's ideas. We will launch the program later this year and anticipate that it will serve as a model for other NIH institutes and centers. The design of this program has benefited from our experience with the NIH Director's Pioneer Award program, an intriguing experiment on how to fund scientific research that is part of the NIH Roadmap for Medical Research.

Through the efforts I have described today, we hope to continue our strong record of identifying and supporting the talented and creative scientists whose work paves the way for future medical advances.

Thank you, Mr. Chairman. I would be pleased to answer any questions that the Committee may have.

Senator HARKIN. Thank you very much, Dr. Berg. I've got some follow on things, but we'll move on through here.

Dr. Francis Collins, has served as Director of the National Human Genome Research Institute since 1993, received his Ph.D. from Yale University, and his M.D. from the University of North Carolina School of Medicine. Dr. Collins has discovered numerous important disease genes, and is well known for his leadership from the beginning to the end of the Human Genome Project.

Again, my thanks for your leadership in that area, but I continue to hear just glowing comments, last week, about your presentation to our group about a week and a half ago. It was just a great presentation.

Welcome, again, Dr. Collins, to the committee, and please proceed.

STATEMENT OF DR. FRANCIS S. COLLINS, DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Dr. COLLINS. Thank you, Senator Harkin, thank you for those kind comments about the event 10 days ago.

I'm very happy to be here with my colleagues, as part of this hearing on Frontiers of Science, and ever since this Congress—led by your vision, Senator Harkin—got the Human Genome Project off the ground, we've had the privilege of working at that frontier. I'm pleased to report, we've made a lot of progress in the 4 years since the Human Genome Project completed all of its goals, in April 2003, famously ahead of schedule, and famously under budget—we've used that foundation to build a real future for personalized medicine.

You're going to hear a lot more about exciting developments in that regard in the coming weeks and months, describing dramatic genetic discoveries for common diseases, with important public health consequences.

Let me tell you about one that's particularly exciting for me. Just last week in Science magazine there were two reports about identifying genetic risks for heart disease, for heart attacks, specifically. These funded—one of them by the Heart, Lung and Blood Institute—are very important, because they scan the entire genome and identified a region that confers a substantial increased risk of heart

attack in an area of the genome we had no idea was involved in this disease before.

But stunningly, just a week before, my team and two other teams, who had been studying Type II Diabetes, the adult-onset form of diabetes, reported also in Science magazine, the identification of a total of 10 genes involved in that important disease, where as previously, only three had been known.

Stunningly, one of the regions of the genome identified in the diabetes study appears to be the same one that is involved in heart attack. Nobody expected this. This is like winning the lottery 2 weeks in a row by picking the same number. It just shouldn't happen. After all, the genome is a big place. But instead, we've zeroed in on this place on chromosome 9, which must be a very important part of the genome in terms of its role in human health, and identified ways in which it can influence risk of diabetes on the one hand, and heart attack on the other. Everybody involved in these studies is scratching their heads, not having expected this outcome, but clearly we're onto something pretty important.

Now this kind of discovery can open new doors to prevention and treatments. Take diabetes, for instances, where we sorely need that. Estimates are we spend $132 billion a year in the treatment of diabetes and its complications, as well as the consequences to the 21 million Americans who have this disease, as far as loss of work, and premature mortality and morbidity. Yet, we don't really understand that disease nearly as well as we need to, in terms of the precise molecular basis of what's going on.

With this outpouring, now, of these 10 new gene variants, I would say, only three of which you might have guessed at, and the others are complete surprises—we can finally shine a light on this mysterious disease in a way that should, both offer us the chance to do better prevention, and we know prevention can work for diabetes. We know that if you identify the people at high risk, and get them into an exercise program, you can reduce their chance of becoming diabetic by as much as 58 percent.

We can also use these new discoveries to pinpoint pathways for which new drug therapies could be designed, instead of continuing the same process we have up until now, based upon what we knew about the disease, now we know so much more.

How did this come about? Well, in the little handout, figure 4 and I hope it's somewhere there in your little pile. Okay, so this is a simple diagram that shows what it is that geneticists are doing now with common diseases, which we couldn't do before.

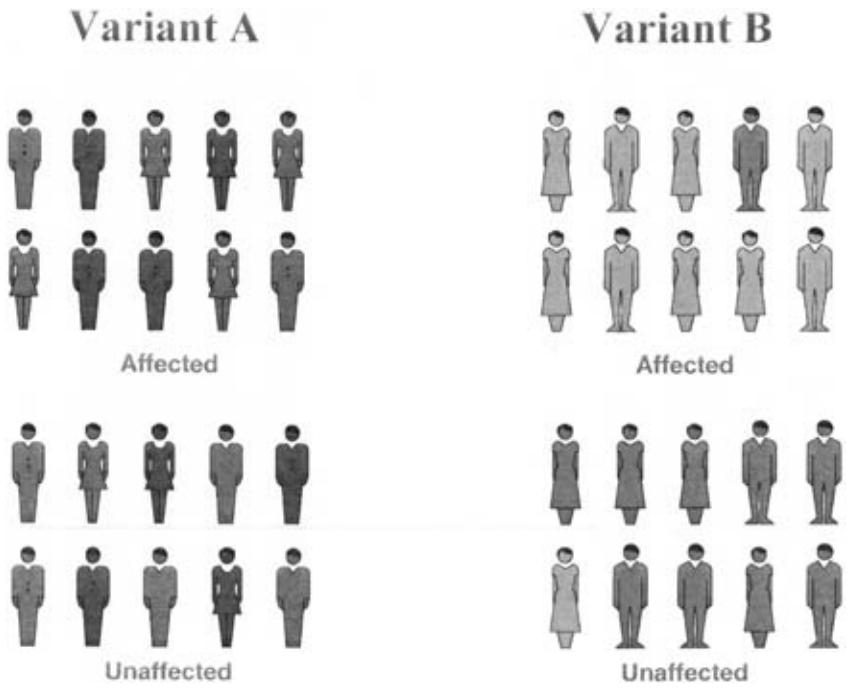


FIGURE 4

It looks very simple in this cartoon—basically, you identify people with the disease, the affecteds, as it were, and you identify controls, that is, people who clearly don't have the disease—and then you want to check, across the entire genome, places where there are difference in the spelling, "variants" as we call them, and see, are there any out there that look like Variant B—where, in my color-coding here, the orange spelling of Variant B is more common in the "affecteds" than the "unaffecteds" and that will tell you that Variant B may be a risk factor for that disease.

Most of the variants in the genome aren't going to look like B, they're going to look like A, where there really isn't any difference, because most variation doesn't affect diabetes.

But, the problem with this strategy was, until very recently, we didn't have the power to do this. Because, while this cartoon looks very simple, to do this right, you need 1,000 or more affected individuals, and 1,000 or more unaffected individuals, and we thought you might have to check as many as 10 million different places in the genome in order not to miss the answer.

Well, the HapMap came along, a project which I had the privilege of leading, as a natural follow-on the Human Genome Project, which basically built a catalogue about all of these variants, and figured out how they traveled in neighborhoods, so that you didn't have to check all 10 million if you chose wisely, you could choose a much smaller set, and they served as proxies for the ones that you didn't actually look at. That made it possible to do something which, 5 years ago, would have cost $10 billion, the study of diabe-

tes that I just mentioned. Now we can do that for less than $1 million. I don't know too many areas of science where costs have come down by that kind of curve, in just 5 years.

If you look at the next image figure 5, the next thing in your little packet, you can see what the consequences of this are starting to be, in terms of this are starting to be, in terms of discovery, so above the line are, in fact, major common diseases for which we have been learning about genetic factors involved, and you can see, as we sort of blow up the scale here, in the last 2.5 years, a lot of findings coming along, prostrate cancer, lupus, macular degeneration, inflammatory bowel diseases, Type 2 Diabetes, psoriasis, heart attack.

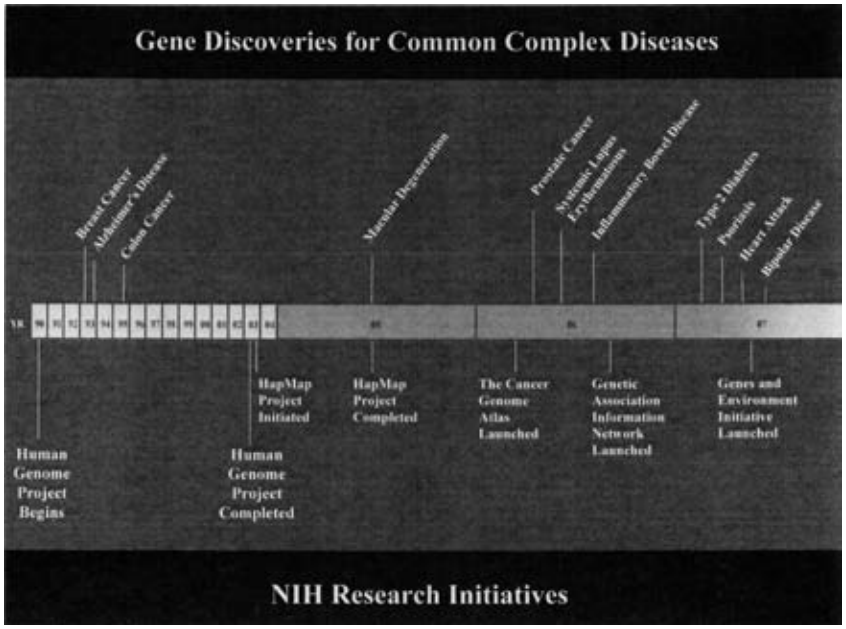


FIGURE 5

I put bipolar disease on here, because in a publication tomorrow in a major journal, there will be a description of what happened to a group at the NIH, led by Dr. McMahon that applied this same strategy to looking at manic-depressive illness, and came up with a very surprising finding of a gene that appears to be involved in that disease, that maybe is even involved in the lithium pathway, which makes a certain amount of sense, but it's not a gene that anybody would have guessed that. I hear through the rumor mill, there are other studies of bipolar disease, also using this same new, very powerful strategy, discovering similar findings.

So, this is really the year, where all of a sudden, we're going to learn a great deal about the genetics of common disease, with many consequences, and if you go to the last picture here, it's an attempt to show how that's going to play out in terms of the practice of medicine.

The top part of the diagram, figure 6, which says, "Accelerated By Human Genome Project," is what's now happening—the ability to identify these genetic risk factors using the tools that have come out of this effort.

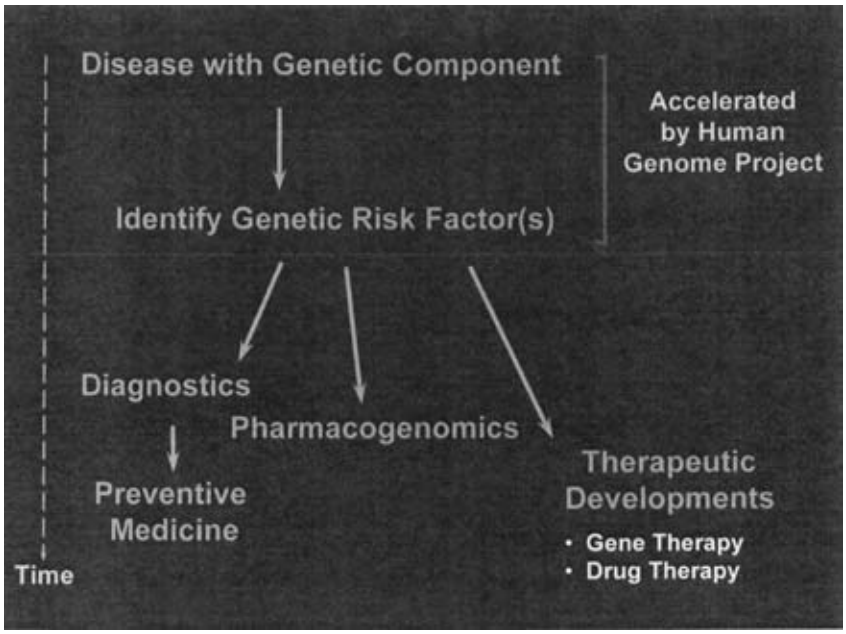


FIGURE 6

What happens next, in the clinic, is going to be the ability, diagnostically, to predict who's at risk, and if you have an intervention that will reduce that risk, people will probably be interested, especially now that we're seeing the Genetic Information Nondiscrimination Act getting close to passage, finally——

Senator HARKIN. Finally.

Dr. COLLINS [continuing]. Which will mean that people won't be afraid to take advantage of that information, as they have been in the past.

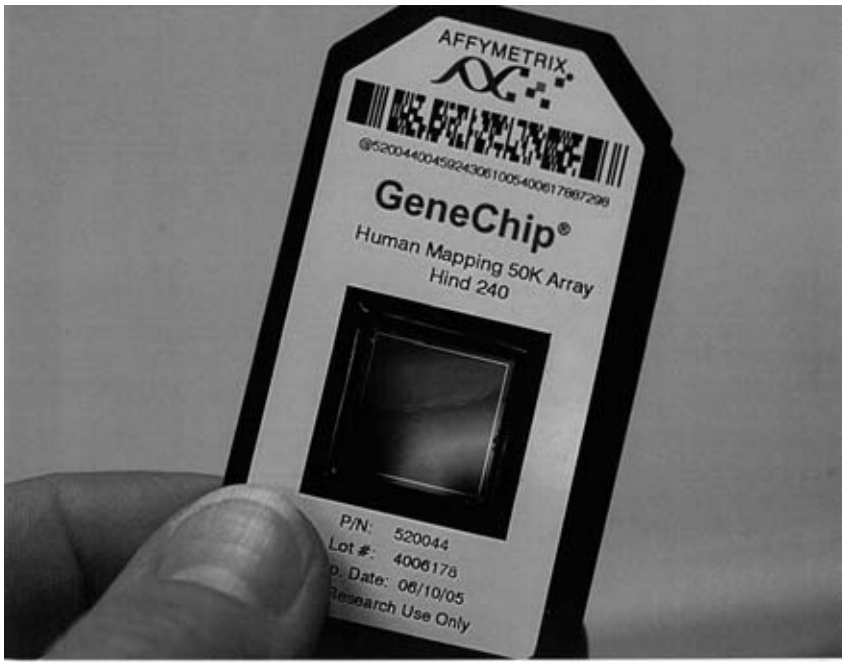
We'll also be able to use these same tools for pharmacogenomics, this effort to identify the right drug at the right dose for the right person, knowing that we're all a little different there, too, the same tools can be used to figure out why that is.

Perhaps most importantly in the long term, these gene discoveries shine a bright light on pathogenesis that gives you the chance to develop treatments that will be more efficacious, because they're really targeted towards the primary problem, and perhaps, if we do this right, also less likely to cause side effects, because you are going right to the primary problem.

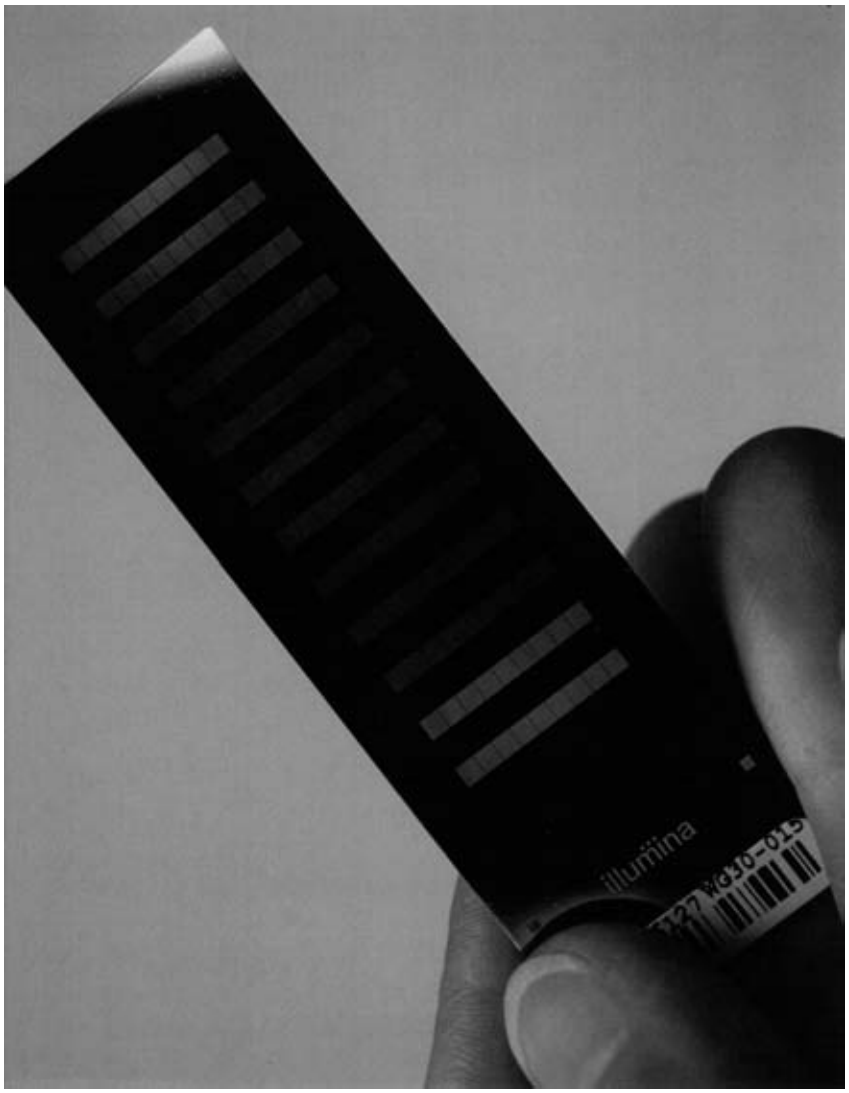
So, it's a very exciting time for this kind of strategy. How are we able to do that? I should bring along my show-and-tell here, I brought you a couple of chips to indicate the kind of technologies that have come out of this sort.

Senator HARKIN. What am I looking at?

Dr. COLLINS. The one in the little plastic case, here, is an Affymetrix Gene Chip, this one chip can be used to detect 50,000 different variable places in the genome in one experiment. This particular company, Affymetrix, was actually founded on an NIH SBIR grant from the Genome Institute, about 14 years ago, and has now become a major contributor to the revolution in genomic medicine that we see.



The other one, called Illumina, is a separate company, what you're looking at there is a microscope slide, and you see stripes on it, each one of those stripes has about 60,000 different DNA spelling detectors, so it is basically a detector, and so with the whole slide, you can then look at a very large number of variations in a single DNA sample, and test those extremely reliably, and for a cost of about an 8th of a penny per particular genotype, per particular DNA spelling. Again, that's come down dramatically in cost, over the last 5 years.



So, these are exciting times, not only are we focused on this approach to look at those variants in the genome, I might mention, we're also pushing hard, Senator, to get to the point of being able to sequence anybody's complete genome, all of the letters of their 3 billion letter code, for $1,000.

Senator HARKIN. I read that in your testimony.

Dr. COLLINS. Yeah, that's ambitious, isn't it?

Senator HARKIN. Yeah.

Dr. COLLINS. A couple of years ago, it would have cost $10 million, we are now probably on the brink of a totally new technology, really turning out to work in high throughput that will bring that cost down to, perhaps, $100,000 for human genome. So that's three

orders of magnitude—I'm sorry, two orders of magnitude in a fairly short period of time.

To get down to $1,000, we've got two more orders of magnitude to go, but that's an explicit goal of our Institute, working with other collaborators, and we are putting a lot of our own technology development money into that. So, imagine what that's like, that you get your entire genome set?

Senator HARKIN. What makes you think you can do that?

Dr. COLLINS. We don't have to——

Senator HARKIN. That's a big order.

Dr. COLLINS. It is. We don't have to violate any laws of physics, though, it is quite possible to do this, so investing in various technologies, and Dr. Pettigrew has some of these same approaches in his portfolio, particularly using nanotechnology, one of the more promising ideas, is you take a nanopore, a tiny little pore in a membrane, and you thread DNA through it in a way that there's a change in the electrical current as each base goes by, whether it's an A, or a C, or a G, or a T, it gives you a slightly different signal. People are seriously looking at that, as a way to read out—very fast—because DNA would just fly through this pore, from a single molecule of DNA—a very large amount of DNA sequence.

Whether that's actually going to work in practice? I guess I'd give it about a 50/50 chance right now, but there are other kinds of technologies right behind it, that are also lining up to do this. I'm counting on the ingenuity of the investigators that have already pushed this envelope so far, that I would think it would be a mistake for anybody to bet against it, and we do expect that the $1,000 genome will be a reality, sometime in the next 10 years.

One of the areas, just to conclude, that we're specifically focused on, in terms of applying all of these technologies, is cancer.

So, working with the Cancer Institute, we have gotten together in a partnership called the Cancer Genome Atlas, where we are applying, not only DNA sequencing technology, but also a host of other ways of looking at what's going on in cancer, in terms of which genes are turned on or turned off, which parts of the genome are duplicated or deleted.

We have a large number of investigators all working together, initially on brain tumors, on ovarian cancer, and on lung cancer. But, if this pilot looks as promising as we expect it to, we hope to expand that to perhaps as many as 50 different cancer types, after the pilot concludes in a period of 3 years. That's a very exciting project, and all of the data is being placed into a database, where any qualified investigator can see it right away, following up again on our premise that data access is really important, for speeding up this kind of research.

PREPARED STATEMENT

So, in this brief time, I'm just scratching the surface of some of the things that are happening now in the field of genomics. Having been at NIH for 14 years, people are occasionally asking me, "Well, aren't you getting tired of it? Isn't it time to move on?" My only answer is, "This is the best part." This is the part that we really worked to get to, where we have the foundation, and now we can apply it in ways that are really going to transform medicine.

Thank you, Senator, I'd be glad to answer your questions.
[The statement follows:]

PREPARED STATEMENT OF DR. FRANCIS S. COLLINS

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Human Genome Research Institute (NHGRI). The fiscal year 2008 budget included $484,436,000.

The theme of this hearing is "The Frontiers of Science." In leading the Human Genome Project, we at NHGRI have had the privilege of working at the frontiers for many years. And the projects I will describe today demonstrate how research at NHGRI is advancing ever more rapidly to catalyze a true revolution in medicine.

In February 2006, the Department of Health and Human Services announced the creation of two related groundbreaking initiatives in which NHGRI is playing a leading role. The Genetic Association Information Network (GAIN) and the Genes, Environment and Health Initiative (GEI) will accelerate research on the causes of common diseases such as asthma, schizophrenia, the common cancers, bipolar disease, diabetes, and Alzheimer's disease and help develop strategies for individualized prevention and treatment, thereby moving towards the possibility of personalized medicine.

GAIN is a public-private partnership among the NIH, the Foundation for the NIH, Pfizer, Affymetrix, Perlegen, the Broad Institute, and Abbott. GEI is a trans-NIH effort combining comprehensive genetic analysis and environmental technology development to understand the causes of common diseases. Both GEI and GAIN are powered by completion of the "HapMap," a detailed map of the 0.1 percent variation in the spelling of our DNA that is responsible for individual predispositions to health and disease. Beginning in fiscal year 2007, GAIN will produce data to narrow the hunt for genes involved in six common diseases and GEI will provide data for approximately another 15 disorders. Additionally, GEI will develop enhanced technologies and tools to measure environmental toxins, dietary intake and physical activity, and an individual's biological response to those influences.

ONGOING NHGRI INITIATIVES

Use of Comparative Genomics to Understand the Human Genome

NHGRI continues to support sequencing of the genomes of non-human species because of what they say about the human genome. The honey bee genome was published in the journal Nature in October. This bee's social behavior makes it an important model for understanding how genes regulate behavior, which may lead to important insights into depression, schizophrenia, or Alzheimer's disease. The genome of the sea urchin was sequenced and analyzed in November, revealing unexpected sophistication among its sensory and immune system genes.

Medical Sequencing

When it becomes affordable to sequence fully any individual's genome, the information obtained will allow estimates of future disease risk and improve the prevention, diagnosis, and treatment of disease. NHGRI is particularly interested in having a sequencing program that both drives technology and produces data useful to biomedical research. To this end, NHGRI has developed a medical sequencing program that utilizes DNA sequencing to: identify the genes responsible for dozens of relatively rare, single-gene diseases; sequence all of the genes on the X chromosome from affected individuals to identify the genes involved in "sex-linked" diseases; and survey the range of variants in genes known to contribute to certain common diseases.

Sequencing technology advances, on the way to the $1,000 genome

DNA sequencing enables a detailed ordering of the chemical building blocks, or bases, in a given stretch of DNA, and is a powerful engine for biomedical research. Though DNA sequencing costs have dropped by three orders of magnitude since the start of the Human Genome Project (HGP), sequencing an individual's complete genome for medical purposes is still prohibitively expensive. However, bold new advances in sequencing technology developed by NHGRI-funded researchers promise to reduce this cost greatly. NHGRI's ultimate vision is to cut the cost of whole-genome sequencing to $1,000 or less. This could potentially enable sequencing of individual genomes as part of routine medical care, providing health care professionals with a more accurate means to predict disease, personalize treatment, and preempt the occurrence of illness.

New findings in genetics of common disease

Technology development and new research approaches enabled by the HGP, the HapMap, and related NIH initiatives have led to important new understanding of the role of genetic factors in a number of common diseases. For instance, the Hap Map made possible research that recently identified two major genes that influence risk for developing adult macular degeneration, a leading cause of vision loss, with those at lowest risk having <1 percent chance of developing the disease, and those at highest risk a 50 percent chance (Klein et al., Science 2005; Yang et al., Science 2006). Other similarly derived recent discoveries include that variations in the genes *TCF7L2* (Helgasson et al., Nature Genetics 2007) and *SLC30A8* (Sladek et al. Nature 2007) elevate risk for developing type 2 diabetes, variations in the genes *IL23R* (Duerr at al., Science 2006) and *ATG16L1* (Hampe et al., Nature Genetics 2007) affect risk for Crohn's disease, a gene on chromosome 8 plays a role in prostate cancer, and the gene *SORL1* (Rogaeva et al., Nature Genetics 2007) plays a role in Alzheimer's disease. Each of these discoveries opens a new door toward prevention and treatment.

Knockout Mouse Project

The technology to "knockout" or inactivate genes in mouse embryonic stem cells has led to many insights into human biology and disease. However, gene knockout cells in mice have been made available to the research community for only about 10 percent of the estimated 20,000 mouse genes. Recognizing the wealth of information that mouse gene knockouts cells provide, NHGRI coordinated an international meeting in 2003 to discuss the feasibility of a comprehensive project. These discussions have now resulted in a trans-NIH, coordinated, 5-year cooperative research plan that will produce gene knockout cells in mice for every mouse gene and make these mice available as a community resource.

Chemical Genomics and the Molecular Libraries Roadmap Initiative

The NHGRI has taken a lead role in developing a trans-NIH chemical genomics. Part of the NIH Roadmap, this project offers public-sector researchers access to high throughput screening of libraries of small organic compounds that can be used as chemical probes to study the functions of genes, cells, and biological pathways. This powerful technology provides novel approaches to explore the functions of major cellular components in health and disease. In its first year, the ten centers in the Molecular Libraries Screening Centers Network entered screening data from 45 assays in the PubChem database at the National Library of Medicine. The team also published a new high-throughput screening approach that is speeding the production of data to be used to probe biological activities and identify leads for drug discovery.

NEW AND EXPANDED INITIATIVES

Population Genomics

To promote application of genomic knowledge to health, NHGRI recently established an Office of Population Genomics. The mission of the office is to stimulate multi-disciplinary epidemiology and genomics research and develop new resources for the study of common disease. It will take on challenges such as developing standards for genetic and phenotypic data and improved analytic strategies for relating them, stimulating novel research approaches, and supporting cross-disciplinary training to prepare researchers for new opportunities to improve health made possible through programs such as GEI and GAIN. This February, NHGRI's Advisory Council approved two new initiatives in this area. One funds development of a "basic tool set" for phenotypic and environmental exposure measurements in large-scale genomic research; the other supports existing biorepositories to conduct genome-scale studies with phenotype and environmental measures in electronic medical records. In the tradition of the HGP, the Office will promote widespread sharing of data, to stimulate the broadest possible application of knowledge and maximize public benefit.

The Cancer Genome Atlas (TCGA)

The Cancer Genome Atlas (TCGA) is a joint NCI–NHGRI effort to accelerate understanding of the molecular basis of cancer through application of genome analysis technologies. Technologies developed by the HGP and recent advances in cancer genetics have made it possible to envision mapping the changes in the human genome associated with all forms of cancer. TCGA began in 2006 with a 3-year, $100 million pilot project to determine the feasibility of a full-scale effort to explore the universe of genomic changes involved in all human cancers. Over the 3 years, NCI and NHGRI each plan to contribute a total of $50 million. The first diseases being explored are glioblastoma multiforme, ovarian cancer, and squamous cell lung cancer.

TCGA will provide (1) new insights into the biological basis of cancer; (2) new ways to predict which cancers will respond to which treatments; (3) new therapies to target cancer at its most vulnerable points; and, (4) new strategies to prevent cancer.

The Human Microbiome

There are more bacteria in the human gut than human cells in the entire human body. Furthermore, gut microbes have a profound effect on many human physiological processes, such as digestion and drug metabolism, and play a vital role in disease susceptibility and even obesity. The human microbiome project represents an exciting new research area for NHGRI, which, except for the bacterium *E. coli*, has focused its large-scale sequencing program on higher organisms rather than bacteria. Sequencing the genomes of 100 microorganisms that represent a significant, but unknown, fraction of all microbes in the human gut should provide a more complete picture of this aspect of human biology than has been available previously.

OTHER AREAS OF INTEREST

The U.S. Surgeon General's Family History Initiative

The family medical history is an effective and inexpensive means to determine more accurately an individual's risk for specific diseases; however, it is underutilized in health care. The U.S. Surgeon General's Family History Initiative was established to focus attention on the importance of family history, and NHGRI has taken a lead role in this initiative. To further the effort in 2006, NHGRI selected the 12,000 employees at Brigham and Women's Hospital for a 1-year demonstration project to educate and engage the health care community about the family history. To spread the importance of family history to the public, the software tool, "My Family Health Portrait," was enhanced for easier use, and resource materials were distributed to chronic disease and genetics experts in the State health departments of every U.S State and territory.

Genetic Discrimination

NHGRI remains concerned about the impact of potential genetic discrimination on research and clinical practice. A wealth of research has demonstrated that many Americans are concerned about the possible misuse of their genetic information by insurers or employers. The Genetic Information Nondiscrimination Act of 2007, S. 358, and its companion House bill, H.R. 493, are presently under consideration by the Congress. In 2005, the administration supported S. 306, the Genetic Nondiscrimination Act of 2005. In January of this year, President Bush visited the NIH and reiterated the administration's desire to see Congress pass a bill to protect Americans from genetic discrimination.

Thank you, Mr. Chairman. I hope I have offered you an informative view of the newest frontiers of science from the front lines of genomic science. I would be pleased to answer any questions that the Committee might have.

Senator HARKIN. Thank you, Dr. Collins. I want to come back to this knock-out project. I don't understand it, but I want to understand it a little bit more, but we'll get to that later.

Dr. Donald Lindberg has served as the Director of the National Library of Medicine since 1984. He has an M.D. from Columbia University. Dr. Lindberg is a noted pathologist and a pioneer in applying computer technology to health care.

Dr. Lindberg, welcome again to the committee. You've been here many, many times over the years. Good to see you again.

STATEMENT OF DR. DONALD A.B. LINDBERG, DIRECTOR, NATIONAL LIBRARY OF MEDICINE

Dr. LINDBERG. Thank you, Senator Harkin.

Senator HARKIN. Please proceed.

Dr. LINDBERG. Since 1836, the National Library of Medicine (NLM) has been extremely fortunate to have received good help and consistent funding from the Congress. Thanks for this, and for today's opportunity to be present, again, before the committee.

What does NLM do? Libraries, we too, are really part of science infrastructure. For much of our history, it was sufficient for NLM

to acquire, organize and disseminate biomedical knowledge from the world for the benefit of the public health. But, biomedical knowledge has radically changed, both in volume and in form, and now, in addition to doctors and scientists, we also serve the public directly.

To do this work, we now spend a lot of time, money, effort and space in creating and maintaining the electronic networks, databases, and information technology standards. These are essential now to support both new discoveries, and the use of these in good patient care. The number of papers we're indexing has gone up roughly 100-fold, database entries 1,000-fold. In addition, we now link genetic data directly online to the formulary and even the three-dimensional structures of the small molecule and protein products, pretty different from the old days.

These, and over 40 highly specialized NCBI databases are important to researchers exploring the questions, how genes work, and how genomic medicine can help us. In some ways, the task of helping patients and families to understand their medical situations, is as difficult—maybe more difficult—as helping the scientists.

Taking both groups together, we responded by computer to a billion online inquiries last year. They tell me that—petabytes and all of that doesn't mean too much to most people—but basically every 3 days, we download an amount of data totally equivalent to the contents of the Library of Congress. So, this information is really used.

NLM is the largest medical library in the world and, by far—more than even an ordinary modern library. Since our beginning, Congress added a number of explicit responsibilities, and I'll mention some. The two large ones, of course, are the Lister Hill Center for communications research, and more recently, NCBI for biotechnology information.

In addition, we have responsibility for collection of information on toxicology, environmental health, healthcare technology, and most recently, for the establishment of a national—speedily becoming international—clinical trials registry.

So, we're infrastructure. As such, we note that scientific infrastructure responsibilities, and hence, expenses, must increase faster than the growth of the experimental science we serve. This is because all of the Institutes share Dr. Collins' infectious belief that molecular biology and whole genome studies are science's best bet. I do, too.

Thus, more experimental data needs to be acquired, organized and made available online to investigators. Successful databases grow in size, and in the number of users, and the costs go up, even with increases in our efficiency.

We are most grateful to the committee for increases in funding, specifically for that which it provided for this purpose this year.

Some might think that infrastructure role a bit dull, but for us, with the current growth of insights and discoveries stemming from use of our information service, it's more like a great roller coaster ride on a sunny day.

ELECTRONIC HEALTH RECORDS

I want to mention very briefly, we have an interest in the full deployment of electronic health records. Across the United States, this is one of our top priorities. It's one of the Department's top priorities. It's important for two major reasons.

First, long experience has shown that quality control warnings, clinical guidelines, best practices are simply so numerous and complex that they are not helpful when left to either doctors or patients alone to remember and use. We need computer-based medical informatics support. NLM does, in fact, support informatics research and training in the universities. We ourselves produce and disseminate information technology standards nationally, and as an official HHS function.

Electronic health records are key for a second important reason, namely to get family and genomic studies into the patient record.

ACCESS TO SCIENTIFIC LITERATURE

Briefly, the future now holds new discoveries that will come from new directions and new measurements, such as the genomic work that Dr. Collins describes. These will be based on ready access to full text sources of scientific literature and scientific databases, but new discoveries will also come from reexamination of some old ideas.

The following shows Barry Marshall and Robin Warren on October 4, 2005, receiving their telephone call from the Nobel Prize Committee in Stockholm; lifting a glass, of course, on the occasion.

[From The New York Times, October 4, 2005]

TWO WIN NOBEL PRIZE FOR DISCOVERING BACTERIUM TIED TO STOMACH AILMENTS

(By Lawrence K. Altman)

Barry Marshall and Robin Warren, celebrating their Nobel Prize

. . . "made an irrefutable case that the bacterium Helicobacter pylori" causes ulcers and other diseases. . . .

. . . A famous experiment Dr. Marshall conducted on himself. . . .

. . . Dr. Marshall said that information he obtained from the National Library of Medicine, a part of the National Institutes of Health in Bethesda, Md., aided his discovery. . . . Dr. Marshall worked in a hospital in Port Hedland, in the Australian outback about 1,000 miles from Perth. . . .

. . . bundles of references . . . "a whole lot of literature showing that many patients with ulcers had gastritis that the ulcer experts in the 1980's had forgotten about."

The prize honored their discovery that—and proof—that peptic ulcer is actually caused by infection by a bacterium, *Helicobacter pylori*—not by neurosis, stress, spicy food or all the other nonsense we used to be taught about.

Now, when he received the call, Marshall immediately said to the press, "Information from the National Library of Medicine aided my discovery." Dr. Marshall himself worked in a hospital in Port Hedland, Australia in the outback, 1,000 miles even from Perth, but he got what he described as "bundles of references" showing that many patients with ulcers had gastritis that the ulcer experts had forgotten about.

So, of course, we're grateful for this discovery, and for the acknowledgement. But frankly it makes one hope that whatever else in medicine is not true will also get re-examined by some doubters with library cards.

NLM FUTURE PRIORITIES

Now, for the next year, just three areas we have great interest in. Dealing with the space problem, which we're seriously at NLM and the committee has helped us with that in the past by providing money for planning. We are also very keen on the outreach to consumers, patients' families and the public, and the NIH MedlinePlus magazine, which again, you helped us with a Capitol Hill launch. That was great.

Senator HARKIN. Yeah, I remember that. Yep, yep.

Dr. LINDBERG. Mary Tyler Moore. Then we think we ought to be doing something more in our Long-range Planning Committee from the Board of Regents thinks that we ought to be doing more to try to be involved in helping the country with disaster—at least health information management. So those are our hopes and desires.

Senator HARKIN. Yeah, it was, a nice event. How often do you come out with that?

Dr. LINDBERG. Quarterly.

Senator HARKIN. Quarterly. Online also?

Dr. LINDBERG. Online also. Anyone can actually request it online and get it free.

Senator HARKIN. Yeah, oh, I understand. Yeah.

PREPARED STATEMENT

Dr. LINDBERG. Lance Armstrong was on the cover of the first edition, as you remember. He was helpful, too.

Senator HARKIN. Oh yeah?

Dr. LINDBERG. Mary Tyler Moore was on the cover of the second edition.

[The statement follows:]

PREPARED STATEMENT OF DR. DONALD A.B. LINDBERG

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Library of Medicine (NLM) for fiscal year 2008, a sum of $312,562,000.

The National Library of Medicine has a remarkable track record of preserving the past while serving the present and preparing for the future. A just completed Long Range Plan done by the Library's Board of Regents lays out in broad terms the challenges the Library will face over the next decade and charts a course for action to successfully meet these challenges.

Prominent among the challenges is the need to create the information resources essential to achieving the goal of "personalized medicine," in which prevention and treatment strategies are tailored to an individual's specific genetic make-up. The first step is to provide huge linked databases and software tools that allow scientists to correlate clinical, genomic, and chemical compound data with published research findings to determine how genetics and a person's environment interact to cause disease and to identify potential new therapies. Such resources, now being developed by NLM, will speed scientific discovery and can ultimately transform medical care by allowing clinicians to customize treatments to a patient's genetic characteristics.

In an era of increasing chronic disease, a related challenge is the need to empower people with the knowledge and motivation to improve their health and play a more active role in their health care. The information that pours out of the Nation's laboratories—and often finds its way into the public media—has the potential of improving the health status of our citizens. The National Library of Medicine has created heavily used Web-based information services aimed at the public. These services transmit the latest useful findings in lay language and provide guidance that can be easily understood by the public. NLM works with libraries and community-based organizations to increase public awareness and use of these valuable resources.

Electronic health records with advanced decision support capabilities will be essential to achieving personalized medicine and will also help people manage their own health. Much of the seminal research work in this arena was supported by the National Library of Medicine or undertaken by people who received NLM-funded informatics education. This work builds on two decades of research and development of the Unified Medical Language System (UMLS) resources which help computer systems behave as if they "understand" the language of biomedicine. The NLM also serves as an HHS coordinating center for standard clinical vocabularies and supports, develops, or licenses for U.S.-wide use key clinical vocabularies.

No information source is useful if it is unavailable. A third major challenge facing the National Library of Medicine is ensuring uninterrupted access to critical information resources in the event of disaster or other emergency, natural or man-made. As recent hard experience demonstrated, this requires careful advanced planning, strong inter-organizational arrangements, and skillful management of information during the emergency, in addition to robust technical backup arrangements for computer and communication systems. NLM's new Long Range Plan specifically recommends that the Library establish a new Disaster Information Management Research Center and ensure effective recognition and use of libraries as a major and largely untapped resource in the Nation's disaster management efforts.

This opening statement is built around these three themes—scientific information resources that can lead to personalized medicine, information services that enable greater personal involvement in health and health care, and marshalling the Library's resources to assist the country's in emergency situations.

SCIENTIFIC INFORMATION RESOURCES—NEAR AND LONG TERM

Fueled in part by funding from the National Institutes of Health, the pace of discovery in today's world of biomedical research is amazing. The NLM is now at the center of much biomedical research—not only receiving, storing, and disseminating published research results, but actually serving as a crossroads for the genomic and other data coming from laboratories around the world. NLM databases and systems are essential tools in all aspects of biomedical research. Users conducted more than 1 billion searches of them in the last year.

The core of the National Library of Medicine is its expanding collection of more than 8 million books, journals, and other materials. The Library subscribes to more than 20,000 periodicals of which some 5,000 are indexed for Medline/PubMed, the immense online database of the journal literature. From the more than 16 million records in Medline/PubMed one may link to a tremendous variety of relevant Web-accessible online resources at NLM and elsewhere. NLM's National Center for Biotechnology Information (NCBI) has already begun building the Medline/PubMed of the future by redesigning its displays and interfaces to make it easy for users to see important links and retrieve information they might not otherwise have noticed.

The NCBI is the source of GenBank, the genetic sequence databank that contains all publicly available DNA sequences. GenBank is produced from thousands of sequence records submitted directly from researchers and institutions prior to publication. NCBI has also created PubChem, a repository for what are called "small molecules" that are crucial in drug development. Small molecules are responsible for the most basic chemical processes that are essential for life and they often play an essential role in disease.

The NCBI's effective performance on these and other trans-NIH priorities has earned NLM a prominent role in the important new Genome-Wide Association Studies (GWAS) project. GWAS is an NIH-wide initiative directed at understanding the genetic factors underlying human disease. It involves linking genotype data with phenotype information in order to identify the genetic factors that influence health, disease, and response to treatment. NCBI is building the databases to incorporate the clinical and genetic data, link them to the NLM's molecular and bibliographic resources and, for the first time, make these data available to the scientific and clinical research community. dbGaP (database of Genotype and Phenotype) debuted in December 2006 to archive and distribute data from Genome-Wide Association Studies.

PubMed Central, a Web-based archive of biomedical journal literature also developed by the NCBI for the NIH, provides free access to the full-text of peer-reviewed articles. PubMed Central is also home to full-text journal articles submitted by scientists with NIH funding under the NIH Public Access policy.

NLM's Lister Hill National Center for Biomedical Communications also produces important tools for biomedical and informatics research, including digital image libraries—sets of image data that can be used in research, clinical care, and training. In one example, NLM is currently collaborating with NIH and other researchers to

develop advanced imaging analysis tools for research in human papillomavirus infection and cervical neoplasia. The tools will allow effective analysis of some 100,000 images of the uterine cervix and they will become the primary resource for professional training and testing in this field. Another set of imaging tools being widely applied in the scientific community, for education and other purposes, is related to the "Visible Humans." These two enormous data files (one male and one female) were created under the guidance of the Lister Hill Center and provide detailed image data sets that serve as a common reference for the study of human anatomy, for testing medical algorithms, and as a model for image libraries that can be accessed through networks.

INFORMATION SERVICES FOR THE PUBLIC

The audiences served by the Library have multiplied in recent years. In addition to providing researchers and health care providers with access to scientific information, the NLM also now has services for the public—from elementary school children to senior citizens. The Library's main portal for consumer health information is MedlinePlus, available in both English and Spanish. Much of this information is based on research done or sponsored by the NIH Institutes. In addition to more than 700 "health topics" (main entries on diseases and disabilities), MedlinePlus has interactive tutorials that are useful for persons with low literacy, medical dictionaries, a medical encyclopedia, directories of hospitals and providers, surgical videos that show actual operations, and links to the scientific literature. Just last September we launched here in the Congress a major initiative to put into doctors' offices and share with the public good health information in the form of a new publication, the NIH MedlinePlus Magazine. We were joined in unveiling the publication by Senator Tom Harkin and Congressman Ralph Regula.

Several databases for consumers are byproducts of research in NLM's Lister Hill Center. One of these is the ClinicalTrials.gov database, which describes clinical research studies funded by NIH and others around the world. The site contains information on more than 37,000 federally and privately supported trials and is searched daily by some 30,000 people. Another Lister Hill Center database is the Genetics Home Reference, a Web site for consumer-friendly information about genetic conditions and the genes or chromosomes related to those conditions.

NLM's toxicology and environmental health program also produces heavily used consumer information resources. The Household Products Database provides easy-to-understand data on the potential health effects of more than 2,000 ingredients contained in more than 6,000 common household products. The colorful Tox Town looks at an ordinary town and points out many harmful substances and environmental hazards that might exist there. ToxMystery, an unusual interactive Web site for children between the ages of 7–10, provides an animated, game-like interface that prompts children to find potential chemical hazards in a home.

Of inestimable help to the NLM in meeting its varied responsibilities—both to the scientific community and to the public at large—are the 5,800 member institutions of the National Network of Libraries of Medicine. The Network comprises eight Regional Medical Libraries, 120 "resource libraries" primarily at schools of the health sciences, and thousands of hospital libraries and community-based organizations. Together they form an efficient way to ensure that the published output of biomedicine is easily accessible by scientists, health professionals, and the public. They cover the critical "last mile" to familiarize researchers, health professionals and the public and to develop sustainable partnerships with community organizations to improve access to health information for underserved populations.

MANAGING VITAL INFORMATION IN TIMES OF DISASTER

A number of NLM's advanced information services and tools are designed for use by emergency responders when disaster strikes. The Library has a history of providing assistance in such cases, for example the gas leak disaster in Bhopal, India, in the eighties, and Hurricane Mitch and the earthquakes in Central America in the nineties. NLM's TOXNET, a cluster of databases covering toxicology, hazardous chemicals, toxic releases, environmental health and related areas, provides a foundation for services to first responders, such as WISER (Wireless Information System for Emergency Responders). Used in Louisiana after Hurricane Katrina, WISER provides information via handheld mobile devices to help identify unknown substances.

Among other such projects, the Library: (1) supported pioneering work on automated biosurveillance, self-healing wireless networks, and smart tags to track patients during emergencies; (2) built the Influenza Virus Resource with the National Institute of Allergy and Infectious Diseases to provide vaccine researchers access to

genomic data of many influenza strains; (3) developed OSIRIS (Open Source Independent Review and Interpretation System), a software package to assist in identifying 9/11 victims' remains via DNA; (4) worked via the National Network of Libraries of Medicine to re-establish and maintain a level of health information services in the Katrina-affected region; and (5) developed the Radiation Event Medical Management (REMM) system, in collaboration with the HHS Office of Public Health Emergency Preparedness, the National Cancer Institute, and the CDC.

In summary, the National Library of Medicine is well positioned to make a maximum contribution to the Nation's health—by making increasing amounts of scientific data available to researchers and health practitioners, by contributing to the national effort to improve the information infrastructure of the health care system, by providing to the public access to authoritative information for use in maintaining their personal health, and by enabling health sciences libraries to make substantial contributions of disaster information management. All of these activities will depend on a strong and diverse workforce for biomedical informatics research, systems development, and innovative service delivery. To that end, the National Library of Medicine will continue its longstanding support for post-graduate education and training of informatics researchers and health sciences librarians and redouble its efforts to improve the diversity of these fields.

Senator HARKIN. Right, right.

Thank you very much, Dr. Lindberg.

Now we turn to Dr. Roderic Pettigrew, first appointed as the first Director of the National Institute of Biomedical Imaging and Bioengineering in 2002. He received his M.S. in Nuclear Medicine and Engineering from Rensselaer Polytechnic Institute and a Ph.D. in Applied Radiation Physics from Massachusetts Institute of Technology and an M.D. from University of Miami School of Medicine. His own research has focused on imaging of the heart using MRI. Interesting.

Welcome, Dr. Pettigrew. Please proceed.

STATEMENT OF DR. RODERIC I. PETTIGREW, DIRECTOR, NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Dr. PETTIGREW. Thank you, Senator Harkin. It is my pleasure to report to this committee, the remarkable advances that have been made in another frontier of science, that of medical technology. This field claims the top ring advance in clinical medicine of the last quarter century, three-dimensional human imaging via magnetic resonance imaging, or MRI, and computed tomography, or CT.

In addition, the U.S. medical technology industry has grown to be a $90 billion enterprise with positive trade surplus, and perhaps more importantly, these technologies have significantly improved the Nation's health care.

My Institute, the National Institute of Biomedical Imaging and Bioengineering is the youngest at the NIH and leads the development of a broad range of emerging biomedical technologies. It was created to focus on the science of technological innovation, create new tools that will improve our understanding of disease, and translate these types of new knowledge into practical solutions.

Our research domain is the interface of the physical and the life sciences, and our vision is one of disease detection on a personalized basis, sufficiently early to pre-empt serious consequences of many illnesses, such as heart disease and cancer.

When therapies are needed, these too, will be personalized, and targeted to the offending biologic process. I offer from our young, but broad, portfolio illustrative examples, and you have a handout.

Senator HARKIN. Got it here.

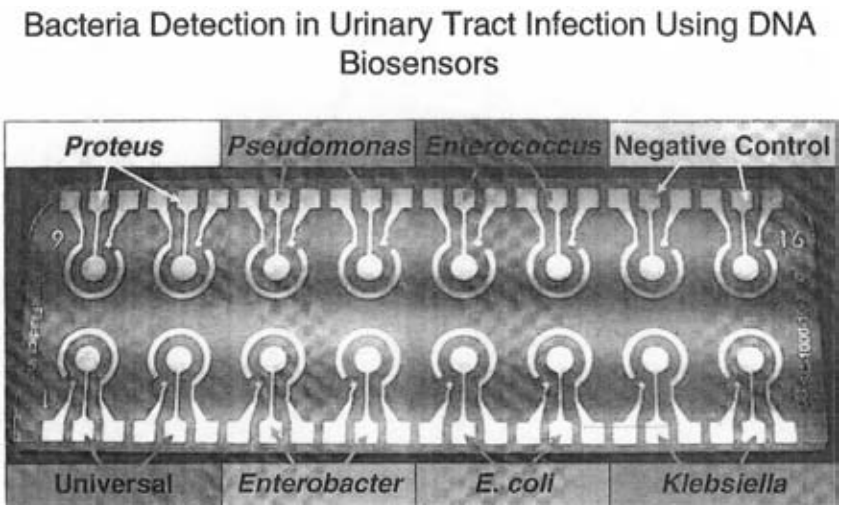


FIGURE 1

Dr. PETTIGREW. See figure 1.

These are three examples, or from three areas that are already transforming modern healthcare. We have just heard about the tremendous advances being made in understanding the genetic basis of disease, such as diabetes and heart disease from Dr. Collins. The use of DNA sequences and genetic variations, as determined in HapMap studies, combined with advanced bioengineering technologies is beginning to be used for routine diagnostics at the first point of physician contact, and this, we term the point of care. A practical example of a very recent development of a DNA-based electrochemical sensor that can quickly identify the specific bacteria responsible for an infection is shown here.

This is actually similar to the type of chip that Dr. Francis Collins gave you. Normally, identifying bacteria responsible for urinary tract infections or infections in general, takes about 2 days. But, with the euro-sensor that you see there, this can be accomplished in about 30 minutes. This——

Senator HARKIN. What you mean, is the specific type of the bacteria can be identified.

Dr. PETTIGREW. Yes.

Senator HARKIN. Within 30 minutes.

Dr. PETTIGREW. That's right.

Senator HARKIN. Okay.

Dr. PETTIGREW. Thank you for clarifying that, the bacteria specifically responsible for the urinary tract infections can be identified in 30 minutes, from the normal panoply of bacteria that are commonly responsible for this type of infection.

This also allows for a more personalized prescription of the most specific and effective antibiotic treatment, and helps reduce the growing problem of antibiotic resistance caused by non-specific use of antibiotics.

Perhaps more importantly, Senator, this type of device as indicated, is indicative of the type of exciting technological innovation

that is leading to tools for personalized diagnostics on a routine basis. These systems, like the one you have on the board there, obviously are portable, they employ nanotechnologies that are ultimately responsible for this type of portability, and as a result of the portability, these can be available in all communities, including the rural and underserved areas.

Another example of an engineered point of care diagnostic device is figure 2, a contact lens that senses the glucose in tear fluid, and shows a level of glucose simply by changing colors.

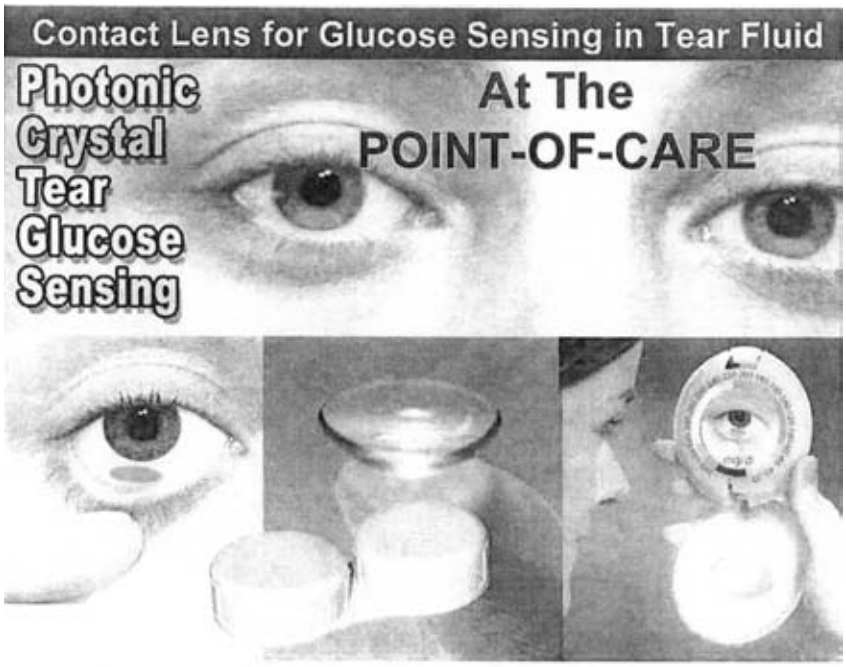


FIGURE 2

A second area of transformative technology supported by my Institute is tissue engineering and regenerative medicine. This, as you heard from the National Institute of Arthritis and Musculoskeletal Disease, in the earlier testimony session, is an emerging technology in which tissues are grown to repair or replace diseased or damaged tissues or organs.

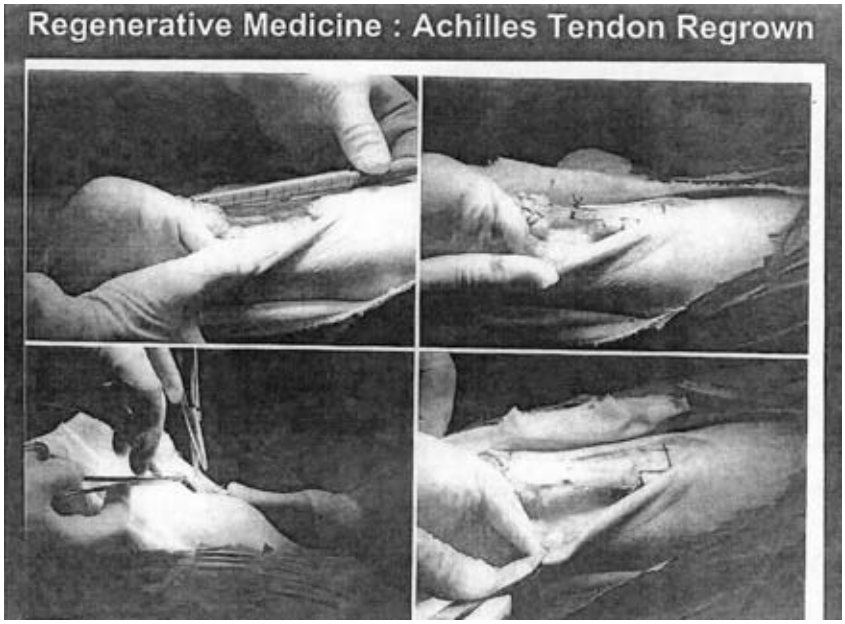


FIGURE 3

Figure 3 shows a subject who has a ruptured Achilles tendon in the upper left quarter panel. You can see the defect which was completely re-grown after placing a matrix material seeded with biologically active molecules. In the bottom right quarter panel, you can see the placement of this matrix material, on which normal Achilles tendon tissue was re-grown. Six months after this particular procedure, this individual patient had a normal tendon repair.

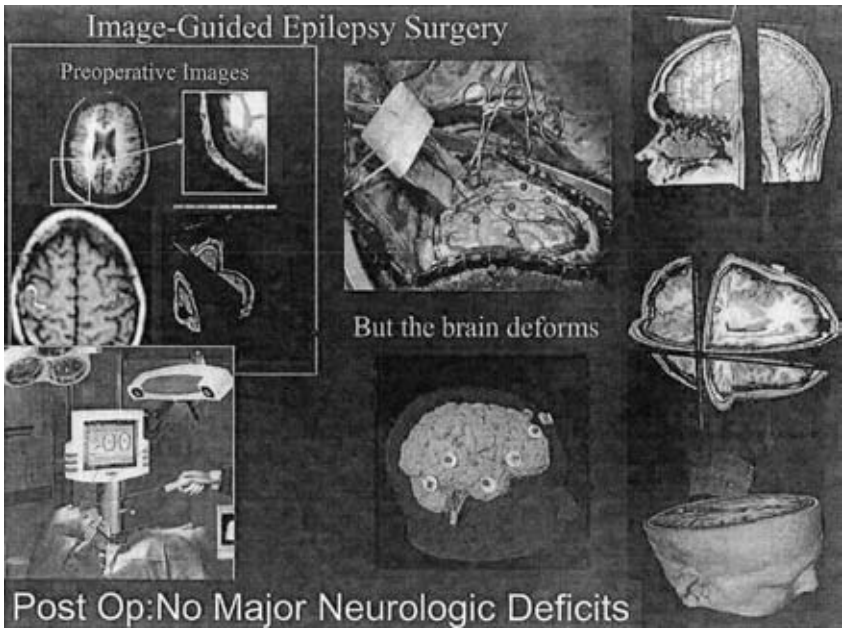


FIGURE 4

Figure 4, the innovation is on a larger anatomic scale. This example illustrates the additional modern advances of image-guided interventions, or also team or inter-disciplinary science, as it has been referred to in the recent past.

These are areas that we also specifically promote at our Institute. The problem being addressed in that particular handout that you have is identifying in the brain the very tiny site responsible for epileptic seizures, while also identifying surrounding normal critical structures. The goal is to show all of this structural, metabolic and electrical information in three dimensions to the surgeon with live updates while he or she is operating, so as to affect a successful removal of the offending tissue with minimal damage to the normal brain tissues.

The team involved in this study is truly inter-disciplinary. It involves a neurosurgeon, mechanical engineer, radiologist, computer scientist, bioengineer and so forth, all who have worked together to dramatically transform the way in which brain surgery will be performed.

Specifically, this team already reports being able to treat up to 60 percent more patients with epilepsy, and in doing so, they've also been able to reduce the operating time by 1.5 hours, and perhaps even as importantly, if not more so, they accomplish this with no neurologic deficits after the operative procedure.

PREPARED STATEMENT

In the future, the vision of an even earlier, preemptive identification of disease will be achieved, as will less invasive approaches to treatment, which will target disease at the cell, and molecular,

level. The NIBIB is working to create more of these types of transforming technologies, that will help realize this vision and improve the Nation's health.

I thank you for this opportunity to present this overview, and also will be delighted to respond to any questions that you might have.

[The statement follows:]

PREPARED STATEMENT OF DR. RODERIC I. PETTIGREW

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The fiscal year 2008 budget included $300,463,000.

BRIDGING THE PHYSICAL AND LIFE SCIENCES

The mission of the NIBIB is to improve human health by extending the frontiers of biomedical science, through the development and application of innovative biomedical technologies. A major focus of NIBIB is bridging the physical and life sciences in order to develop new biomedical technologies and methodologies that have a profound, positive impact on human health. Translating these technological breakthroughs from the bench to bedside is also a very important aspect of the NIBIB mission, and is demonstrated in some of the examples given below.

TRANSLATING EMERGING TECHNOLOGIES INTO PRACTICE

A Quantum Project to Treat Stroke

Ultimately, NIBIB seeks to translate technological advances into solutions that improve human health by reducing disease burden and enhancing quality of life. To accomplish this goal, NIBIB must be well-positioned to utilize ideas and techniques that are at the cutting edge of science. Also, NIBIB must be bold and far-reaching in generating some of its initiatives in order to more rapidly facilitate discoveries and translate them to clinical practice. NIBIB recently launched the Quantum Grants Program, which supports very high impact, high risk, interdisciplinary and transformative research focused on major biomedical problems. The goal of this program is to solve or dramatically improve a major, previously intractable medical problem through the development and application of new and/or emerging technologies. Interdisciplinary teams of scientists will conduct collaborative research resulting in a prototype product, technology or procedure that promises to solve a significant healthcare problem, and that can be translated into clinical practice in an accelerated time frame. The first grant, awarded in September 2006, aims to develop a novel treatment for stroke, based on implantable units that will lead to neurovascular regeneration of cerebral tissue. This is the first application that has as its target, a treatment for stroke that seeks to restore functional tissue.

Seeing and Treating Heart Arrhythmias

Heart arrhythmias are a major health problem. In particular, atrial fibrillation, a disorder found in about 2.2 million Americans, is a significant cause of stroke. This occurs when a blood clot forms in the fibrillating heart chamber and then breaks loose and travels to the brain. Minimally invasive surgery can be used to treat atrial fibrillation. However, the procedure is complicated and lengthy, often lasting many hours. NIBIB investigators are developing new imaging techniques that permit the abnormal electrical activity to be identified and mapped onto a patient-specific image of the heart. This potentially permits the procedure to be done in one hour instead of six. Beyond the time saving, this approach has the potential for lower cost, decreased exposure to x-rays, greater success rates, and fewer complications. The effort involves collaboration between radiologists, computer scientists, bioengineers, and cardiologists.

Addressing heart diseases of a medically underserved population is the central focus of the Jackson Heart Study. The National Heart, Lung and Blood Institute, the National Center for Minority and Health Disparities, and NIBIB co-fund this study to assess risks factors for cardiovascular diseases, including diet, exercise, and co-morbidity factors such as diabetes and obesity.

Help for the Paralyzed

Paralyzed or "locked in" individuals who retain normal cognitive function but are unable to move parts of their bodies to communicate now have a means of using the computer, based on an interface technology developed by NIBIB grantees. Brain

waves, detected by a skullcap with attached electrodes, are decoded and used to communicate with a computer. By simply thinking of the letters, the user can spell words on the computer. No interaction with a keyboard or mouse is required. Over the past year, a team of neuroscientists has worked intensively to move this system from the laboratory to home use. For one NIH-funded neuroscientist with late-stage amyotrophic lateral sclerosis (ALS, or Lou Gehrig's Disease), this device has enabled him to continue his research. "I couldn't work independently without it," he wrote recently for an article posted on the NIBIB web site entitled "Brain-Computer Interfaces Come Home."

NANOTECHNOLOGIES FOR PERSONALIZED AND PREEMPTIVE MEDICINE

Point-of-Care Systems

Empowering clinicians to make decisions at the bedside, or the point-of-care, has the potential to profoundly impact health care delivery and to help address the challenges of health disparities. The success of a potential shift from curative to predictive, personalized, and preemptive medicine will rely in part on the development of portable diagnostic and monitoring devices for near-patient testing. The NIBIB has contributed to advances in this area by funding the development of sensor and platform-based microsystem technologies. These instruments combine multiple analytical functions into self-contained, portable tabletop devices that can be used by non-specialists to rapidly detect and diagnose disease, and can enable the selection of a definitive therapy at the time of the visit to the physician. A prototypic example under development and funded by NIBIB can identify, from a single drop of urine, the DNA of the specific bacteria responsible for a given urinary tract infection. Moreover, this test can be completed in just a few minutes, compared to the 2 days often required by standard culture techniques.

A second example is in the area of improved diabetes control through non-invasive continuous glucose monitoring. Several NIBIB-funded researchers are working to engineer such a device. One has developed a contact lens that changes colors in response to the concentration of glucose in tears. The lens wearer can compare the color of the contact lens to a chart in order to determine his glucose concentration. If indicated, medications to control blood glucose, such as insulin, can then be administered.

NEXT GENERATION MINIMALLY-INVASIVE TECHNOLOGIES

Restoring Touch in Robot-assisted Surgery

Robot-assisted surgery is expanding the applications and reducing the complications of minimally invasive surgery. Nonetheless, this expansion has been inhibited due in part to the lack of a sense of touch. When surgeons operate on their own, their hands provide important tactile feedback. Although all fields of surgery could benefit from tactile feedback, cardiac surgery is among the fields that have the most to gain. Because of the large number of sutures used, the delicate tissues involved, and the need for precise work, tactile feedback is essential in cardiac surgery. An NIBIB-funded research team is working closely with a cardiac surgeon to create a robotic system that delivers required touch sensitivity. Use of this system could result in fewer broken sutures, more consistent application of force to tissues during surgery, and suture knots with superior ability to stay together. This system is now in development, and it could also serve as an important teaching tool for surgical residents. Rather than the current practice of teaching students exclusively on live patients, new surgeons could obtain more extensive practice in the lab before performing live surgery. Using computer algorithms that recognize motion, a trainee's movements can also be compared to an expert's performance and assessed.

NON-SURGICAL BIOPSY THROUGH NEW APPROACHES TO OPTICAL IMAGING

The diagnosis of many conditions such as cancer depends on microscopic evaluation of tissue samples. Typically these samples go through a process of fixation and staining before they are looked at under a microscope in the pathology laboratory. NIBIB researchers have made significant progress in developing techniques to image tissue in place without the need for surgical biopsy, fixing, and staining. This new imaging approach makes use of the different fluorescent characteristics of normal and diseased tissue, and offers the potential for examining the tissue at the point of care, in the operating room or medical office. Many potential human applications exist, including imaging tissues that form as a sheet such as the bladder or bowel lining. Physicists, biophysicists, imagers, engineers, biologists and clinicians are working together to advance this technology.

FEEDING AND SUSTAINING THE SCIENTIFIC TALENT PIPELINE

Interdisciplinary Training Programs

An important goal of the NIBIB is to train a new generation of researchers equipped to meet the modern needs of interdisciplinary and transdisciplinary research. The Institute's proactive approach is to develop creative and flexible opportunities that will fill critical gaps in the career continuum while also enhancing the participation of underrepresented populations. As examples, the NIBIB has a program to co-train basic and clinical investigators, a Residency Supplement Program to provide research experiences to clinical residents and fellows, and postdoctoral support programs for interdisciplinary training to individual postdoctoral fellows.

The NIBIB also supports and participates in a number of programs to address gender and diversity issues in biomedical imaging and bioengineering. The NIBIB partners with the NSF in the University of Maryland, Baltimore County, Meyerhoff Scholarship Program alliance. This has been an exceptionally effective diversity honors program. Eighty-five percent of the 511 students who have graduated since 1993 have earned a science, technology, engineering, or math doctoral degree.

The NIBIB has also partnered with the Howard Hughes Medical Institute to support the HHMI–NIBIB Interfaces Initiative, a program to develop new curricula to train Ph.D.-MD level scientists at the interface of the physical and life sciences and give them the knowledge and skills needed to conduct research. Collectively, these programs will help to train a new generation of researchers equipped to better meet the challenges of the 21st Century.

Once trained, it is critical that we encourage those who aspire to be great scientists to pursue research careers. New investigators are the innovators of the future and their entry into the ranks of independent researchers is essential to the health of the research enterprise. In addition, the recent closure of the Whitaker Foundation—a catalyst in the evolution of bioengineering as a forefront discipline—has left many in the scientific community concerned about new and early career investigators. For these reasons, the NIBIB is specifically targeting new investigators for special funding consideration. This policy has proved to be successful; in fiscal year 2006 nearly one-third of the NIBIB-funded traditional research grant investigators were new NIH investigators. The NIBIB also participates in the trans-NIH "Pathways to Independence" program which will support recently trained scientists conducting independent, innovative research.

Senator HARKIN. Thank you very much, Dr. Pettigrew.

NIH COLLABORATION

You know, it just seems like, every one of you, in your written testimony that I read, and sort of what you were saying here, you're all involved in this sort of personalized medicine. I guess I'm curious about that, and how that is proceeding, and whether or not there's enough correspondence, or I think, overlap—what's the word I'm searching for, when you talk together?

Multiple SPEAKERS. Collaboration.

Senator HARKIN. Collaboration, thank you, that's the word—is there enough collaboration going on among you and other people at NIH on this? Is this a direction that's sort of, something new at NIH that I'm picking up on? Is there enough collaboration? I just throw it out there for anybody.

Dr. LINDBERG. I think it's endorsed by all.

Senator HARKIN. Yeah?

PERSONALIZED MEDICINE

Dr. COLLINS. If you've seen Dr. Zerhouni's presentations—and I know you have because he's been in front of this committee, he has very articulately, I think, put forward this notion of the four P's—of personalized, preemptive, predictive and participatory—as the emblems that need to be applied to medicine of the future, if we're going to move away from treating advanced disease in a direction

that, in fact, prevents that disease in the first place, because clearly we can't sustain the curve we're on right now, as far as healthcare costs.

I think we are all very much attached to that vision as the promise of the future. You know, you wouldn't go to a shoe store and just pick up a pair of shoes without noticing what size it was, and carry it off to the cashier. But, for medicine, we've been doing the one-size-fits-all approach, most of the time, because it was the best we could do, we didn't have enough information about how to personalize the prevention strategy, so everybody kind of got told to do the same thing, and most of the time they ignored us. Or the treatment strategies, because, you know, you had a diagnosis, well, here's what you're supposed to do, but that might not be the right drug for that person.

We now have, I think, a golden opportunity to really change that perspective into one that is much more individualized, recognizing that while we're a lot alike, we're also different in really important ways that affect our chances of getting sick, and our abilities to prevent that. I do think—to answer your question about collaboration, this is one of the major topics the Institute Directors have gotten together on, the road map the common fund, has provided opportunities to bring projects of this sort more to the forefront, even when no single institute could do.

So, certainly for me, after being at NIH for 14 years, I've not seen an atmosphere more in favor of collaboration and sharing of initiatives and willingness to not worry too much about which Institute gets the credit than what I see right now. Of course, in times of budget constraints, it's even more critical to do that, it's critical at any time. But now, with things being so tight, I don't think any of us want to let an opportunity go by that we might be able to get together and do.

That also extends to collaborations outside of NIH. One of our big projects to look at the genetics of common disease is a public/private partnership where a good deal of the costs of the project are being covered by a pharmaceutical company, even though they get no benefit from it, other than the assurance that it's going to get done right, and the data will be accessible to them and everybody else and everybody else at the same time.

NIH COLLABORATIONS

Senator HARKIN. Anybody else on that?

Dr. COLLINS. Just on pharmacogenetics, pharmacogenomics, are the differences in responses to drugs, that's actually a trans-NIH program that's been in place before the Roadmap, the pharmacogenetics research network and then now involves, I think, 10 or 11 different Institutes and Centers, working on different diseases and different drugs, but sharing a common knowledge base, and sharing expertise in how to design trials appropriately, and, I mean, use the available technology. I think it's very much a collaborative effort that's much more than the sum of the parts, because it's been so well coordinated from the get-go.

Senator HARKIN. In the back of my mind in all of this is that the cost of healthcare keeps going up and up and up and up. It seems

like every time we come up with new discoveries, it just costs more money. So, should we quit discovering things?

Dr. LINDBERG. I'd like to comment on the collaboration, because——

Senator HARKIN. Oh, okay. Because I want to follow-up on this idea that I was, just a—but, go ahead, go ahead, on the collaboration, go ahead.

Dr. LINDBERG. Well, often we've been asked, "Do you ever collaborate with anyone?" I always come prepared with, starting to make a list, and it's—it always is a very, very long list for NLM——

Senator HARKIN. Yeah.

Dr. LINDBERG [continuing]. Because it's natural to collaborate.

But, I think in this list that I made for this particular moment, in case you asked, I was surprised to find that we're actually, there's more collaboration within HHS than I've ever seen in 23 years.

For example, we work with FDA now, you know, when you get a medication, there's a little tiny thing in there that tells you all the things that could happen, and if you can, got eyesight good enough——

Senator HARKIN. You need a 50 power magnifying glass, that's for sure.

Dr. LINDBERG. Yeah, I mean, it's a totally ridiculous thing.

But anyway, we have a team that has worked to produce a new thing through a RX Norm that's a new way to identify those drugs, and it was done with VA and with FDA, surprisingly enough, and FDA now sends us, every day, 300 or 400 new sort of packaging of that stuff, so it can go up online, and an ordinary person can read and halfway understand it.

That's—that's sort of amazing. We're working with the Office of the Secretary on a Radiation Event Medical Management little, a chippy, like this one, and—for toxicology with the National Institute of Environmental Health, and also the CDC, so actually, there's more collaboration in the health agencies than I've seen in past years. Of course, lots at NIH, as well.

I think you'd—I think you actually can be sure that that's happening.

Senator HARKIN. That's good, that's reassuring.

Dr. BERG. Senator, can I comment, briefly on your point about costs going up?

HEALTH CARE COSTS

Senator HARKIN. Yes.

Dr. BERG. With improved diagnostics—and actually knowing what disease it is that you're treating, and treating the right people—I think there's a real hope that the costs will go down. One example is breast cancer treatment. One of the first personalized medicine products that's out there is a gene chip that looks at expression patterns and is reasonably good at predicting whether or not someone is likely to benefit from chemotherapy.

Senator HARKIN. Yeah.

Dr. BERG. The potential consequences of this is that you do this test early on and only treat the people who are likely to benefit

from the very expensive treatment. Don't treat in the same way, people who aren't going to benefit from the expensive treatment anyway.

Senator HARKIN. Well, it was said to me once, you know, if you took the money that goes into health care now, how many trillion is it now? Whatever it is. I don't think people would mind so much the expenditure, in terms of percentage GDP if, in fact, that money went for preventative medicine, early detection, so that people didn't have to go through these excruciating illnesses, and have to go through chemos and radiation and all of the other things you go through—we've done pretty well there, in terms of patching and fixing and mending later on, but that costs a lot of money.

In fact, it ought to be shifted, now, to an earlier point in time for identification, risk factors, and then getting people on the right course of action as they go through their life to prevent the onset of illness—I don't think there would be that much consternation on the spending of money. Most of the people just see it as just going for the same old, you know, patch and fix me up once I get in trouble.

So, I'm encouraged that, what you're all talking about here is moving that point of interaction with the patient earlier on some point in time. That's going to cost money. It's going to cost money, but hopefully as we reach—as we develop these new research regimes, and new techniques, new interventions, that some of the other stuff will start coming down. That's our hope, anyway. I hope it's not a false hope.

Dr. COLLINS. No, I think that's a very wise vision, and one that could be achieved, it really does require a change in mindset, and of course, it requires a change in reimbursement also——

Senator HARKIN. That's true.

Dr. COLLINS [continuing]. In terms of how health care is paid for in this country.

Senator HARKIN. That's the ticket.

Dr. COLLINS. Which is a big issue.

Senator HARKIN. Is how we reimburse.

Dr. PETTIGREW. If I could just interject here, and follow-up on an earlier question—what you just described, Senator, is the paradigm that we currently operate under in health care, and that is a curative paradigm.

Senator HARKIN. Sure.

Dr. PETTIGREW. Where the response is after there's a symptom, and an obvious problem. And, what you also described is, where we're headed and going as a preemptive paradigm, in which technologies—like the one we've talked about, that we've all talked about—will be able to provide an indication that there is a developing disease, early enough so that we can intervene at a time where the technologies that we have to prevent serious consequences, are effective.

You notice that all of us sounded the same tone of personalized health care. I think the reason for that, is that the more that we learn about disease, the more we appreciate that a disease that has a given name can be quite different in different people, and typically is quite different in different people. So, Dr. Berg mentioned breast cancer as an example, and we know that there are signifi-

cant differences in the gene expression patterns associated with breast cancer, and consequently, the treatment should be different—it's not a one-size-fits-all-type of paradigm or approach. That is certainly where we're headed.

I think all of the technologies that we certainly support, really are aimed at being able to see things when they are earlier in the disease process, and in addition to that, developing therapies which are very targeted, specifically to the offending biologic process.

NIH GENES, ENVIRONMENT AND HEALTH INITIATIVE

Dr. COLLINS. Senator, can I add one other thing to this discussion, because I think it's a really important one, and that is the importance of paying attention to the environmental contributions, as well as the genetic ones. I think sometimes people get the sense that we're so excited about genetics—and, believe me, some of us are—that we're ignoring the fact that common diseases like heart disease and diabetes and cancer, are some interplay between hereditary predisposition, and some environmental trigger, and we need to understand both.

We particularly need to understand the environment, because that's the part we might be able to change in somebody who's at high risk, in order to reduce that risk.

In that regard, and this also plays into your question about collaboration, there is this initiative called the Genes, Environment, and Health Initiative, which has now participation by virtually all of the NIH Institutes, and for which $40 million a year have been allocated for the current year, and three more years after this, assuming the budget allows for that.

This is explicitly an intent to both identify what hereditary factors are involved in common disease, but also to develop new and more accurate technologies for assessing environmental exposures—in the air, in the water—and also what the effect of those exposures are on the individual. So, you not only want to know what's out there, and you not only want to know what the body burden is, you want to know what the response was, biologically, of that person. Because it might have been that a particular substance was handled just fine by one person, was actually quite dangerous for another.

David Schwartz, the Director of NIEHS, and myself, are co-leading this effort, this Genes, Environment and Health Initiative, and already a large number of scientists have gotten engaged in helping to lead this, and we will fund, in the next few months, a substantial number of new proposals to try to accomplish this hand in hand, not studying genes in isolation, or environment in isolation, but really getting those two fields together, in a cohesive way. And, I think that's a very exciting and timely effort, at the present time, where we could finally really begin to get our minds around what are the causes of these common disorders, and what we could do about it.

KNOCKOUT MOUSE PROJECT

Senator HARKIN. One other thing you mentioned in your written testimony, you didn't mention it here, was this—tell me about this Knockout Mouse Project, I just don't understand it.

Dr. COLLINS. All right, I'm happy to, Senator. That's another example of a wonderful collaborative effort, because this involves 19 Institutes that have gotten together to support this.

So, what's a Knockout Mouse? Probably conjures up images of people in a boxing ring punching a little rodent, that's not quite what we had in mind.

Senator HARKIN. Or just rubberstamping the same mouse or something, I don't know.

Dr. COLLINS. No, the idea here is, the mouse remains our best laboratory research model for trying to understand human disease, and mice have about 20,000 genes, just like humans do. If you can find a human gene and look at it, you can almost certainly find the mouse homologue of that gene, and it will have a similar sequence. Many times, what we've learned about human diseases, in terms of exactly what's wrong when a gene is misspelled, we've learned first by looking at what happens when that gene is misspelled in the mouse, because there we can do breeding, we can do careful examination in ways that we can't with people.

So, about 2000 or so, mouse genes have been systematically knocked out, that is, inactivated, to see what the consequences would be. That has been a major part of NIH-funded research now, for more than 20 years. But, it's been done in an individual laboratory way. Many of the papers in the medical literature describe the consequences of these knockouts, and it's taught us a prodigious amount about biology and disease.

But, we think we've reached a point where this kind of cottage industry knockout is maybe not the way to go forward. We want to see what happens, now, systematically, if you were to knock out, one at a time, all 20,000 genes, and do it in a sort of Genome Project mindset where you would do it with high-efficiency, low-cost, and easy access to the outcome. That's been another problem, some of the mouse knockouts have been made multiple times, because people haven't been willing to share, and we want to make sure that this time these are all made in a way that anybody with a good idea can get access.

So, all of the institutes got together—even in a tough budget time—and agreed to donate parts of the budget here to make this happen, and we also joined up, quite vigorously, with the Europeans, who have a similar interest in this, and the Canadians, who have a similar interest. Just this past March, we had an international meeting in Brussels, where we pulled together an International Knockout Mouse Consortium, with all agreeing to work together to get this done, as quickly as possible, at low cost as possible, with high quality, and to make all of these mice accessible to any investigator who wants it.

So, basically, what we're going to end up doing here, is saving the NIH a ton of money.

Senator HARKIN. Help me understand this, you're going to knock out one gene——

Dr. COLLINS. At a time.

Senator HARKIN [continuing]. At a time.

Dr. COLLINS. Yes. These days that can be done in a sort high through-put way.

Senator HARKIN. So then you've got a mouse with a gene knocked out.

Dr. COLLINS. Yes.

Senator HARKIN. What are going to do with that mouse?

Dr. COLLINS. So, basically, those will be available as frozen embryonic stem cells to anyone who then wants to investigate that one, and see, "Okay, what happens when that gene is knocked out?" We, at the present time, we don't have the funds to take all 20,000 and put them through a very elaborate set of measurements to see, "Well, is there a problem with the nervous system, is there a problem with the blood system, do they have some birth defect of some sort?" We're going to count on the community to, one by one, as they get interested in a particular knockout, to do that, and then put that information in the public domain. But, what we won't expect them to do, is to actually go and do this tricky thing of knocking out that specific gene, which people have been doing, but at a very inefficient sort of basis.

Senator HARKIN. How long will it take you to do this?

Dr. COLLINS. Five years is the estimate, to get all 20,000 of these knocked out and available, I hope we can do it sooner.

Senator HARKIN. They're done in different places around the globe?

Dr. COLLINS. So we at NIH, we're funding two major centers to do this, but in Europe, there's a major center, in Canada, there's a major center. We are all now working together to make it clear that we don't duplicate the effort—each center has their own list of which genes they're responsible for, we watch closely to see what progress is being made, we'll reassign some if people fall behind in one place, and get the centers that are going faster to pick up the slack, just like the Genome Project, it's international, it requires a lot of careful management and tracking, but it's very achievable.

Senator HARKIN. That's interesting. The one thing that comes to mind is that if I'm not mistaken, genes interplay. So, if you knock out one gene, maybe that doesn't do much. But, maybe if you knocked out one 10 notches down, it might have another effect.

Dr. COLLINS. It's a very good point, Senator, and in fact, if you have them all generated as knockouts one at a time, by mouse breeding, you can make any combination you would then, like, to look at the interactions.

Senator HARKIN. Yeah, I guess that——

Dr. COLLINS. That's the beauty of being able to figure out who mates with whom—which you can do in the mouse cages.

Senator HARKIN. I guess that just comes about through various studies and things, and looking at different genes that have an effect on one thing or another, and matching those up. Yeah, I can see how that would work.

Dr. COLLINS. So, take for cancer, for instance, what we're learning about these "tumor suppressor" genes, that is, genes that normally keep cells from growing out of control when they're not supposed to. A lot of what we've learned is to knock those genes out in the mouse, those mice generally do develop a cancer of some sort, you can then understand by breeding in other kinds of mouse genetic changes, is there some way to suppress that cancer, by activating some other part of the pathway—exactly like you say. It's

a very powerful system. You can do some of these things by cells growing in laboratory dishes, but there's no substitute, really, for having an intact animal, where you have complete control over the whole system.

EXPLANATION OF HAPMAP

Senator HARKIN. Explain that HapMap to me again.

Dr. COLLINS. Yeah, what is this thing?

Senator HARKIN. My question is, cost reduction on studies?

Dr. COLLINS. Yes.

Senator HARKIN. Detailed map of the one-tenth percent variation—tell me about that?

Dr. COLLINS. All right, sure, I'm happy to, this is one of my favorite topics, Senators.

So, your DNA and mine are 99.9 percent the same, that would be true if I picked anybody else to compare myself to, we're all that similar. But, that point .1 percent is still a lot of differences, because the genome is such a big place, with 3 billion letters in the genome, .1 percent of that, well, that's still 3 million changes between you and me, and if we looked at the whole room, and asked, "How many places are there in the genome where, as a roomful of people, we have common differences?" I'm not going to talk about the rare ones that you might find only once, but the common ones, because those are the ones that often drive the risk of common diseases—there would be about 10 million of those in the whole genome.

So, in that collection of 10 million variants, there are some we really want to discover, that play a role in diabetes risk, or heart disease or cancer or asthma or schizophrenia. Yet, finding which one is a real needle in a haystack.

What HapMap set out to do, was two things. One was, first of all, to build that catalog of those 10 million variations, because when HapMap started in 2002, we only knew of about 2 million, and we clearly needed a more thorough look.

But, the other thing that HapMap did, which turned out to be an incredibly useful shortcut, was it figured out that these variations in the genome are not traveling independently of each other. They're basically traveling in neighborhoods. So, if there's a neighborhood on a chromosome where you have 30 or 40 SNPs, there's a good chance if you check two or three of those, and see what their variation is—a SNP, by the way, is a Single Nucleotide Polymorphism which is just a fancy word for saying a "difference in DNA spelling." If you check two or three out of those 30 or 40, you can probably predict what the others are going to be without even looking at them, and that's a reflection of the fact that we're a young species, and these segments of the chromosomes, neighborhoods, if you will, have been traveling in unbroken form since our common ancestors.

Well, you see how that's valuable. That means, if you're looking for a variant that plays a role in asthma, for instance, you don't have to check all 10 million. If you check a carefully chosen 300,000, it turns out, is about the number—and I say carefully chosen because you've got to know what the boundaries of these neighborhoods are, some of them are little, some of them are bigger,

what HapMap did was to tell you how those neighborhoods are organized—then for a fraction of the effort, you can actually look at the entire genome, and you won't miss the answer, you'll find the neighborhood where the culprit is hiding. That saves about a factor of 30 or 40 in the amount of work you have to do.

That, plus these technologies, like these chips that I brought to show you—which have greatly cut down the laboratory costs, mean that we got from this $10 billion price tag for doing a diabetes study, to less than 1 million, and that is a profound change in the space of just 5 years.

So, HapMap plus technology forward is a magnitude drop in cost. Phenomenal.

INTRAMURAL PROGRAM

Senator HARKIN. All right, nice explanation.

Dr. Berg, I want to ask you some—I was reading over your testimony, you mentioned Jeffrey Gray and Ryan Harrison, caught the bug, he was in high school, he met a person at Johns Hopkins through an outreach program, he spent 2 years working in his laboratory, came in fifth place in the Intel Science Talent Search, et cetera, et cetera—what outreach program got him interested?

Dr. BERG. There's a program he attends at the Baltimore Polytechnic Institute that has a program of scientists from around the area who can come and just give talks about what careers in science. I think it was when he was in 10th grade he went to one of these, and thought this sounded, he didn't——

Senator HARKIN. It wasn't an outreach program from you?

Dr. BERG. It wasn't supported by NIH, no. Although we do have programs—not at the high school level—but at other levels that try to do the same sort of thing.

Senator HARKIN. I guess that was my question. Is there a specific program for high school kids to intern with scientists in labs that's backed by NIH? Is there such a thing?

Dr. BERG. We have a diversity supplement program for high school kids. If someone has a lab and wants to have a high school kid come in and work in their lab, there's a way of, to get some support through that program for a particular person. But it's an NIH-wide program.

Senator HARKIN. What do you mean, it's NIH-wide, I mean, don't you handle it?

Dr. BERG. Every Institute has their own version of it. For us, it's a supplement to a grant. So if they have a grant from NIGMS, they can apply, but if they have a grant from any other institute, they can apply as well, and that particular grant is supplement.

Dr. COLLINS. The other big program we have is summertime internships in the intramural program at NIH, we have hundreds of high school students who compete avidly for the opportunity to come and spend 10 or 12 weeks in a laboratory. Generally, in my lab, I take one or two each summer. They are full of talent, it's a very competitive program——

Senator HARKIN. High school? High school?

Dr. COLLINS. High school kids. We also take college kids, but the high school program is very hotly sought after.

Senator HARKIN. How about—that would be a limited number, I mean, these come here for your intramural program.

Dr. COLLINS. Right.

Senator HARKIN. But, I mean, this kid was at a lab at Johns Hopkins?

Dr. BERG. Yes, he is now an undergraduate at Johns Hopkins, and working.

Senator HARKIN. How about when he was a high school student, he worked in a lab?

Dr. BERG. Right.

Senator HARKIN [continuing]. At Johns Hopkins?

Dr. BERG. Right.

ADOPT A SCHOOL PROGRAM

Senator HARKIN. How much of this is done around the country? We've got labs all over the country that are funded by NIH. Do we have any program, that you know of, do you know of any program at NIH where high school students, who have exhibited an interest in science, and would like to spend an internship, a summer, testing out whether or not they really want to get into this kind of research, and do that? Is there a——

Dr. LINDBERG. This is a little bit harder to do than it sounds like, but we're trying to get at that.

I should say, first of all, that many of the Institutes at NIH have an Adopt-A-School Program. We, for instance, have adopted, in Series Two inner-city high schools in The District of Columbia and that's pretty successful, so there's a lot of movement back and forth there. But, I mean, high school kids are young, so they can't just drop out and tool around, they might get a summer. But, anyway, we're trying hard to do that, we've had several outreach programs with high school—large numbers of high schools, five or six together, for instance, New York we just did, with NYU being the host.

You can get them for a day, and that's about it. We tried one in Chicago, and they, the schools let us down on the transportation with busses, and we had—so we had those kind of basic problems.

I would say the best program that I know of is in Houston, and it's the, now-called the Michael DeBacky High School for Science, and it's associated with Baylor. It's taken them over 25 years to get the thing really working, it took 20 years before they even called it the Michael DeBacky School, but he and the other Baylor faculty have pitched in, and it is, again, an inner-city school, but it's got something like 98 percent of the kids going into college, and most of those going into science. So, it's a very intense activity, but a very successful one.

We're trying to follow that model, of course.

Dr. BERG. Let me add one other program, so, another way that we try to influence early science education is we have a series of curriculum supplements that are developed that we make available to teachers from around the country, and NIGMS developed one less than 2 years ago on doing science, so it's not on any particular disease, but it's about the scientific process, curiosity, and designing experiments and controlled experiments, intended for 7th and 8th graders, and that is—was developed in partnership with the

NIH Office of Science Education. We went through all 25,000 copies of it in, I think, a little less than a year, I think it's the first—most widely-distributed supplement that they've done. So, this gives tools for the, for teachers to develop strong programs.

Senator HARKIN. How many students come out to NIH every summer for this?

Dr. COLLINS. I don't know the exact numbers, it's in the hundreds.

Senator HARKIN. Oh, yeah?

Dr. COLLINS. Yes, and every university I know——

Senator HARKIN. These are high school kids, they've got a place for them? I'm getting into the weeds now, on this, but I'm really curious as to——

Dr. COLLINS. I can get you those numbers, Senator. I don't actually know how many high school, how many college are there in the summer, but the place is crawling with summer trainees, which makes it a great place to be in the summertime, all kinds of irreverent questions being asked about science.

Every university that I've ever been involved in has a similar program in the summer in their own location to try to bring students in.

One thing we do, on April 25, which is DNA Day every year, because of the publication of Watson and Crick's paper in 1953 on April 25—we send all of our post-docs and graduate students out to high schools, and they spend the day, all over the country, talking about the excitement about the science that's happening as a consequence of our understanding of DNA. That's been, this has been the fifth year we've done that, this year. It is both great for the students, and it also activates the post-docs to take this on as part of their own professional future, that they're going to spend some part of their time reaching out to high schools in their own vicinity, and trying to teach about what they do.

Senator HARKIN. I'm looking for, I just, ideas, ways of which we get high school students interested, provide access to post-docs and people like that who can kind of bring them along a little bit.

Dr. LINDBERG. I can give you another number, because every summer we bring a dozen to 15 students from this inner-city school, and we used to bring six faculty. So that we were, we thought, helping them. I would say that the net results of that is that the students are fantastic, they're really good, and I think they make progress even in the course of one short summer, and the faculty flunk.

We've stopped—we think that's throwing good money after bad, and we stopped supporting it. We still bring the students. But, they have different things to learn, I mean, for instance, the first bunch we brought through, we gave them—like you're giving us—5 minutes to say something about what do they accomplish in the course of the summer, and two actually passed out, I mean, this was a tremendously threatening thing. You know, a board room, and all of these adults, and you know, it was awful. So, we decided that, you know, one of the top things they've got to learn over the course of the summer, is stand up and make a presentation, look in the eye and tell you, and that is top of the list, and they do very, very well.

Now, they're actually doing multi—they're doing Power Point and Keynote and all of these kinds of things.

PUBLIC ACCESS

Senator HARKIN. Yeah, sure.

There's a lot of talk about publication of research articles, and how soon it should be done. We're getting input from private publications and others, I don't know the answer, but I just want to know—if Congress were to require that all NIH-funded research articles be deposited in the PubMed Central Database, which is the public access plan that NIH has proposed—how would that improve scientists' ability to conduct research?

Dr. LINDBERG. Well, I think it probably would improve it quite a bit. I mean, one of our tests, probably, is from PubMed Central right now, and that is the place that these things would go and the proposals that we've described. The number that are coming in voluntarily is way less than 5 percent of the amount that should come in, but lots of other sources are putting in articles, that are free forever, the publishers and so forth—there's a million articles now in that three set, and it's very, very heavily hit, something like 12 million per month get looked at.

If you looked at it another way, like, "Are all of those of any interest?" Well, 75 percent are of interest. This includes many that we're scanning in from, well, the old issues, let us say, when one publisher says, or society, "You may have this thing," then we say, "Okay, if at our expense you would allow us to go and scan in all of these old ones, back to Volume 1, Number 1, you know, which you have copyright to," so they have a right to say yes or no, would you do that, and then we'll do that if it can be made freely available forever.

Well, lots have said yes, and the Wellcome Trust in England has partnered with us on that, I mean, they, it's dollar for dollar, although actually the pound is going up faster than the dollar has, so we've made a little money on the deal, and so that's going forward very, very well, and that's part of this experiment, in which I said, David Lipman is here, he can confirm all of this for me, but he tells me that 75 percent of those articles do get used right away, so they are of real interest. I think it would make a big difference.

MEDLINE PLUS MAGAZINE

Senator HARKIN. Well, I appreciate that for the record. We don't really know exactly what we're going to do yet.

But, I wanted to ask you about MedLine Plus magazine.

Dr. LINDBERG. Great, I love it.

Senator HARKIN. Again, I've felt for a long time that——

Dr. LINDBERG. There's a new one.

Senator HARKIN [continuing]. That NIH—yeah, you just showed it to me.

Dr. LINDBERG. Yeah, okay, good.

Senator HARKIN. I've got it right here, I have it right here. I have felt for a long time that NIH had to be more aggressive in getting their stuff out to the general public, both at basic science base, but also in translation, so people can understand it. That's why I was happy to join you when you started putting this magazine out, be-

cause this is readable. I mean, you know, even I can understand some of this stuff.

So, I think it's a great resource. And, again, I'd like to see copies of this in every doctor's office around the country. People ought to come in, and they ought to have access to it, and online, you say they can get access online now.

Dr. LINDBERG. Yeah, but most people don't yet have computers and access.

Senator HARKIN. I understand that.

Dr. LINDBERG. I'd like to see it, just as you say, sitting in that waiting room, when they're so boring.

Senator HARKIN. Well, how many copies are you putting out?

Dr. LINDBERG. Well, we're putting out around 50,000 right now, between 40,000 to 50,000, and that's being financed partly by the Friends of NLM found the money to do this, some contributions from the NIH Institutes on a passing-the-hat basis. In order to do what you said, we think that we probably could do it by—there are around 500,000 doctor's offices, so if you schedule, say, three per office, that would be 1.5 million each quarter, 6 million per year, would cost around $3.6 million.

Senator HARKIN. $3.6 million per year?

Dr. LINDBERG. Yeah, and we have about $.4 million, so we're lacking $3.2 million. How to get it, obviously would be childishly simple, to get it through advertising, but that would defeat the purpose, we think, of the whole operation, so——

Senator HARKIN. Yeah, true.

Dr. LINDBERG [continuing]. We've just sworn we're not going to do that. So, we've got to get it either by private contributions, or appropriations.

Senator HARKIN. Well, would doctor's offices subscribe to it? I mean just, you know, would they pay for it out of their——

Dr. LINDBERG. I don't know, we could try it. We haven't tried it, I must say. But we could try it.

Senator HARKIN. There's some good stuff in here.

Dr. LINDBERG. Actually, it would be—it is the only case in which NIH is delivering information, publications, directly to patients. I mean, of course, there's lots of information on all of the Institutes' websites, just as ours, but that's a little different, that's not a publication, often it's as much for scientists as for patients, but this is aimed right at, between the eyes of the patient.

I must say, I was interested in the conversations we've just had, because some of the things Dr. Collins spoke about are really, the doctors and the researchers. You're communicating with them magnificently, even if you've got to go to poor old Belgium to do it.

But, a lot of the other things you spoke about first just won't happen, at all, unless the patients understand it, and agree to it. Including this environmental thing. Because, I mean, who knows where the exposure is, the patient is the expert on the exposure. Unless they believe in this, and participate and understand it, you know, maybe through this kind of a magazine, maybe through everyone else's efforts, none of this stuff will happen. First of all, if they don't trust us, I mean, you have now your Federal legislation pending, that would be a big help. But, I think they have to understand, as well.

I mean, if this whole genetic experiment runs up against stem cells, that's, that we don't want to put up with, we don't want to have it stopped, we want it understood and welcomed.

Senator HARKIN. I missed that, if it's up against what?

Dr. LINDBERG. Well, if people were to conclude that the genetics, the experiments you're talking about have any sort of a political or religious bias, or——

Senator HARKIN. Oh.

Dr. LINDBERG [continuing]. Obstacle, that would be very, very bad. It would be incorrect, we don't want that to happen, but it would be an obstacle to getting this work done, this personalized health experiments. So, I think these magazines, this effort is an important one.

Senator HARKIN. Well, I'm just saying——

Dr. LINDBERG. I appreciate your help.

Senator HARKIN [continuing]. Is there, what more can we do? I mean, $3.2 million, that gets it to every doctor's office, now you want to get it also out to community health centers. I suppose maybe your doctor's offices include community health centers——

Dr. LINDBERG. Yeah.

Senator HARKIN [continuing]. Maybe.

Dr. LINDBERG. Well, I think the higher the volume, the less, you know the prices decrease. These things are about a dollar apiece, I think they can get it now for something like 50 cents, that would give us our 6 million, if you get that, maybe we can drive it below that, find some other way to get it done. Because they can download them right now, free, and copy it themselves.

Senator HARKIN. I thought you said I could download this.

Dr. LINDBERG. You can, yes, yeah, sure. But, I don't know how many people would do it, maybe we can more people doing it, maybe that's what the doctors could do, instead of paying a fee.

Senator HARKIN. Yeah, still, people like to pick up stuff, and read it.

Dr. LINDBERG. I agree, I agree, I agree. But, I think the volunteer agencies, for instance, the alliances have been wonderful to work with, you have lots of work with them and——

Senator HARKIN. Which one can I get the money from?

What are your budgets here?

Dr. BERG. Senator, let me give you one other thing we've been doing, in terms of trying to communicate the basic science messages. It's an electronic newsletter called Biomedical Beat, where we go through the press releases for the investigators that we support, and write one- or two-paragraph, plain language, understandable, hopefully, descriptions of some of the advances. It's been growing for a little bit more than a year now, and the number of people who actually subscribe has increased.

Senator HARKIN. Let's take a look at that $3.2 million, huh?

Dr. LINDBERG. Yes, sir.

Senator HARKIN. All right.

Dr. LINDBERG. The price is good until midnight.

HUMAN MICRO BIOME PROJECT

Senator HARKIN. We'll see what we can do about that.

Let's see, what else did I want to go over here?

Dr. Collins, you mentioned the new effort called Human Micro Biome Project, trillion of microbes in the human gut, you went to talk about obesity and intestinal—could we also find out what causes irritable bowel syndrome and things like that, too? It seems to be an exponential rise up.

Dr. COLLINS. So, this Micro Biome opportunity is another example of something we couldn't have dreamed of doing as recently as 3 or 4 years ago.

You know, our bodies are both populated by microorganisms in various body cavities and orifices, some not proper to mention in a Senate hearing, and there are also, of course, many microorganisms in our skin. It's clear that we coexist with those organisms, happily most of the time, in fact it's clear they contribute to our health. But if something goes awry and the balance is off or you get the wrong microorganism in the wrong place, then one can result in an unfortunate disease situation.

Yet, we don't know nearly enough about this. We've been limited in our understanding of microbiology by what kinds of bacteria we can actually culture in the laboratory. It's clear, that's only a tip of an iceberg. There's lots of other microbes, particularly in our GI tract, that you can't grow. Yet, they're there, and many of them are probably helping us and some of them have the capacity to hurt us. So, how would we get at those?

Well again, the promise of being able to do very high throughput, very cheap DNA sequencing comes to mind, because these microbes have DNA also. DNA is their instruction book, just like ours. So, even if you can't culture them, you can determine what their DNA is by simply doing a—what we call a metagenomic experiment, where you make DNA from a whole collection of microbes and you read out the sequences and you piece together what must have been there.

Again, because this would have been prohibitively expensive until 3 or 4 years ago, it hadn't been approached in a very big way.

A very recent experiment that I think got everybody's attention about this, done by Jeff Gordon at the Washington University in St. Louis, relates to obesity. Where he was able to show—initially in mice, and then in people—that the particular collection of microbes in the gut have a lot to do with whether that mouse is going to be obese or not obese.

In fact, you can take an obese mouse and put the microbes into that animal that had previously been in a skinny mouse, and the fat mouse starts to get skinny too, without any other change. So, there's something going on there, in terms of an interaction between the host and the bacteria that live in their intestinal tract. That's been possible also now to show with people, that a change in body weight can be accomplished by a change in microbes.

Now, imagine what a wonderful circumstance that would be, if we could figure out how to help people lose weight or not gain weight, simply by altering their intestinal flora. It's not unimaginable that might not be the case.

So, we have, in fact, again as a collaborative effort involving lots of institutes, come up with a plan, which we hope will be funded as part of the Common Fund—because this is one of those that touches upon all of the institutes you see here and many that you

don't—to enable a really organized effort to try to characterize what bacteria are present in these various parts of the body. How variable are they from person to person? What happens when you take antibiotics for an ear infection? Does it just throw everything off? How long does it take it to recover?

If you looked at identical twins, do they have the same microbes, or are they different? If they're different, why are they different? Particularly, what happens with inflammatory bowel disease or with vaginitis or with a particular kind of dental problem like periodontitis, that changes those microbial flora in a way that we currently really don't understand, that might lead you into a pretty good idea about how to correct the situation.

So, it's very exciting. Again, another international opportunity here, because the Europeans are very interested in this and I think you're going to hear a lot about this in the course of the next 3 or 4 years as the amount of data we can generate really goes up very quickly. This instrument, this sensor that Dr. Pettigrew told you about, could, of course, be a way in which whatever we learn about microbes could be quickly translated into a diagnostic, yes, once you know what to put on that diagnostic in order to access what particular thing is there that you want to know about right away.

Senator HARKIN. Well, that's all well and good. I hope you don't mind if I remain skeptical.

Dr. COLLINS. Don't mind at all.

Senator HARKIN. I mean come on, look, I mean, calories in, calories out. More calories in, less calories out, it's stored, it's stored as fat.

Dr. COLLINS. We used to think it was just that simple. To first approximation it is, but clearly the microbes in your gut are a big part of your digestive process.

Senator HARKIN. It has to do with the rate of how fast you burn up your energy, too.

Dr. COLLINS. Also, whether you're really efficient at absorbing what you take in, or whether some of it doesn't actually get absorbed. That has a lot to do with what goes on in the distal small intestine, and particularly the colon, and the microbes apparently have a bigger part of that. I think we were all surprised. I was skeptical too, until I saw this paper in Nature from Dr. Gordon. It looks quite compelling.

It only takes a tiny change in your efficiency of absorbing what you eat over the course of many weeks to have a significant effect on what happens with body weight. It doesn't mean that it has to be this drastic difference based on what microbes are there. A little bit makes a big difference over the course of a long period of time.

Senator HARKIN. I, again, I remain skeptical. I just find that, it seems to me that we just need to change some diets and habits and what we consume as kids in this country, in terms of carbohydrates and fats and starches and sugars and everything else that we consume too much of. We get in these habits and habits are hard to break.

Dr. COLLINS. Senator, I think you're absolutely right. This may be a modification of that fundamental principle that might make it a slightly easier case for somebody who's really struggling, but you're basically correct.

Senator HARKIN. That is true. Some people have different rates of metabolism. People have to exercise and eat less than other people in order not to become obese. I understand that, I understand.

MACULAR DEGENERATION

I want to ask about macular degeneration. Dr. Berg, you talked about macular degeneration in a way—and I wrote this down—reverse damage. Is what you're doing, is it at the point of stopping it from progressing, or can you actually reverse the damage?

Dr. BERG. This is not something that we're directly funding. The idea is that it does not reverse the damage, but stops the progression.

Senator HARKIN. Yeah.

Dr. BERG. The way that the pathways contribute to the progression of a disease are understood, to some degree, you can block them with this RNA interference-based therapy.

Senator HARKIN. Where are we in that? I mean, are we in human trials right now?

Dr. BERG. Yes, the phase one trials were successfully completed, the phase two trials are underway now.

Senator HARKIN. It actually stopped the degeneration?

Dr. BERG. That's my understanding. The initial trials are just safety related, but they're into the phase two trials now and the expectation is that this therapy, if all goes well, will be on the market, I believe, in 2009.

Dr. LINDBERG. I think even before that, though, the eye guys have reported that, you know, once they've—well, first of all, the important thing is that a single gene could be seen as responsible for this disease, which was thought in the past to be one of these complex things that must be complicated, but wasn't.

So, once having found that that has to do with capillary growth, the ophthalmologists just reached out and took a syringe full of Avastin and injected it in the globe. If you do this every 10 days for four or five times, you know, metaphorically, they give you back your driver's keys, you know, that you can go from those big things to those small things and you can drive a car again. So I mean, it's a pretty enthusiastic kind of response.

Senator HARKIN. Fascinating.

Dr. COLLINS. This is really a wonderful success story and comes from several directions, Senator. So, basically, macular degeneration, particularly the wet type, does seem to be something that's gone awry, in terms of capillaries. But the treatment that Dr. Lindberg's referring to actually came out of the study of cancer, where we realized, particularly from the work of Judah Folkman, that cancer seems to have the ability to grow, particularly because it recruits blood vessels. Of course, if you can block the blood vessels, you can starve the tumor and it might be a very effective approach.

That's what this drug Avastin is all about, it's an antibody against a particular factor, VEGF, which is what blood vessels need in order to proliferate. So, you're blocking that proliferation. It's a very powerful scheme.

But, it turns out that this same strategy works quite nicely for this wet form of macular degeneration because, there again, your

goal is to try to block the proliferation of these blood vessels that are causing the blindness issue. In fact, there is a fragment of Avastin that's called Lucentis, I think it is, which was approved by the FDA for treatment, which is just as effective but I gather, has some economic disadvantages.

So, here we are in a circumstance where a disease that we considered to be both untreatable and probably not possible to understand, in the space of a short period of time, we've come a long way.

The mention of genetics has also been a big surprise. Most people thought this disease, which comes on in your 70s, 80s, or sometimes even 90s, was not going to have anything to do with genetics. But it turns out there are a couple of genes which play the major role, along with smoking. If you basically can put those together, you can make a very strong prediction about who's at risk. Here's a chance to do prevention. Coming back to our idea about focusing on preventing the disease, instead of waiting until it happens.

If we now know what the pathway is that causes risk here, which has something to do with inflammation, then perhaps by blocking inflammation in the eye, which we have drugs that are pretty good as anti-inflammatory agents, we might be able to—with those people at very high genetic risk, to prevent them getting the disease in the first place. The Eye Institute is investigating that vigorously right now.

Dr. LINDBERG. But Avastin's pretty cheap.

Dr. COLLINS. It is pretty cheap.

Dr. LINDBERG. It's an off-label use, of course, but, and I think the ophthalmologists are amazingly gutsy to do it. They impress me.

Dr. BERG. The potential advantage of the RNA-based therapy, is the same pathway. What this RNA molecule does, it blocks the expression, not of VEGF, but the receptor, what VEGF docks into. As I understand it, what the trials have indicated is it might be longer lasting, so you wouldn't need to get these injections as frequently.

RNA AND FLU VACCINE

Senator HARKIN. You mentioned RNA also, in terms of pandemic flu virus. I've had different people in my office talking about, you know, producing the vaccines. You're right, we really have to wait until we find out exactly what strain it is that is going from human to human. Once you do that, then you can develop the vaccine, but it takes a while to develop the vaccine, obviously, ape-based, long time. Then there was another process. Cell-based.

Then, someone came out and said, "Oh, there's an RNA-based method and it's even quicker than anything." But you were talking about it in terms of, excuse me, getting all these different strains and finding some RNA-based system of covering them all, but that was different than what I had heard. What I had heard, you'd wait until you found out exactly what the strain was, then you would develop an RNA-based vaccine to that exact strain and you could do it in just a couple months or something like that. What am I not understanding here?

Dr. BERG. Because we now have sequences of many flu strains, we can see which parts of the viral RNA genome are conserved. Those are things which presumably the virus can't change to avoid,

without damaging itself. Because RNA interference is so general, you can target the RNA molecules anywhere you want. We can go after regions in the viral genome which don't vary from strain to strain. This concept has the potential to be something which I was very skeptical about, sort of a universal flu vaccine.

Senator HARKIN. Universal flu vaccine. Is that being pursued right now? Is that——

Dr. BERG. It is. There's a company that's been developing it in partnership with Novartis (it originally started with an SBIR grant from NIH). Again, it's early stage, but——

Senator HARKIN. So how come they were talking to me about—again, I'm just, I don't know much about this, everyone on my staff does, but I was led to believe that RNA could only be used to develop a vaccine for a specific strain, not for a universal vaccine. That's why I don't, I'm having a hard time understanding this.

Dr. BERG. Right. This is a whole new world of therapeutics and, again, the macular degeneration example is the one that's most advanced. This requires a whole new pharmacology. We still don't know very much about how to deliver these RNA molecules as drugs.

Senator HARKIN. So it's possible——

Dr. BERG. It's possible.

Senator HARKIN [continuing]. To get a universal flu vaccine, no matter what strain comes out.

Dr. BERG. That's the promise. Again, this is very early——

Senator HARKIN. But again, should we be putting more energy and effort and money into that, or into building facilities that, when the strain comes out we can put people to work right away developing the vaccine on an RNA basis?

Dr. BERG. For the time being, I would say, you absolutely need to continue to invest in the technology to make the vaccine available. The whole concept of this technology is only a few years old. There are lots of potential problems, such as how do you deliver RNA molecules? How do you keep them stable enough so that they work? There are lots of hurdles to be overcome, but advances in any one area have the potential to impact the whole field.

Senator HARKIN. My gosh, if you could develop a universal vaccine, that would be the answer to everything.

Dr. BERG. Absolutely. We're investing, and NIAID is investing very heavily in moving this forward.

Senator HARKIN. When is Dr. Fauci here?

Mr. FATEMI. May 21.

Senator HARKIN. Anyone here talk to the Doctor, tell him I'm going to ask him that.

Dr. BERG. I will warn him.

Dr. COLLINS. I have a feeling he'll hear about this.

Senator HARKIN. Warn him I'm going to tell him, "Dr. Berg's got a different approach."

Dr. BERG. Well, they're the ones who are supporting it, so it really just stems from this discovery of RNA interference, which opened up this whole new approach and that's obviously an area where, if we could do it, it would have a huge impact.

NANOTECHNOLOGY

Senator HARKIN. Dr. Pettigrew, I didn't much get into it with you, but this whole area of nanotechnology that I know a little bit about, we hear it being applied in all different areas of physics and material sciences and things like that, nanotechnology, but I don't hear too much about it in health. Most of what I read about nanotechnology as to material sciences, physics, that type of thing, but—computers, but not too much in health. So what is there in nanotechnology that I don't know about? What implications does it have for health and health research?

Dr. PETTIGREW. Well, it's actually quite involved in health, and much of the technology that I refer to in my testimony regarding the ability to detect diseases at the cellular and molecular level would, in fact, involve devices that are constructed at the nanometer scale. As you know, a nanometer is a billionth of a——

Senator HARKIN. The delivery mechanism?

Dr. PETTIGREW. As a delivery mechanism, and also, as a mechanism for observing the response to a therapeutic intervention.

For example, we've talked several times now about breast cancer and heart disease and so forth. One might envision—in fact, there is considerable work already under way in this area, to develop a probe that consists of a nanometer-sized particle, which carries three components on this particle. The first component is a homing agent that delivers the particle to the specific target, such as the HER2 receptor in breast cancer. The second component on this particle would be an imaging agent that allows you to see that, in fact, it went there. It also allows you to see how much went there, and the size of the tumor, in the case of cancer. The third thing would be to deliver a therapeutic agent, such as a gene that codes for vascular cell death, apoptosis, which actually has been demonstrated in some early studies.

So, you'd have this one particle that is target-specific, goes directly to the target of interest, say a cancer cell, or the vascular supply to the cancer cell, as Francis mentioned about angiogenesis and the role that that plays, in which the goal is to destroy the antigenic activity.

The gene is delivered specifically, by way of this targeted nanoparticle, to the cells that make up the lining of these tiny blood vessels, kills them, and destroys the vascular supply.

So, I think that nanotechnology is very much involved. I don't know if you've had the NCI participate in the hearings yet, but when you talk with them, you'll hear about their large nanotechnology research effort aimed at developing just these kinds of probes. My Institute, as well, is very involved. We have a substantial part of our funding, is active in this, in this area. These devices are termed biosensors, in the sense that they send out a signal when they interact with the particular biologic process you're trying to discover.

Another example would be to identify tumors on the basis of the enzymes that they produce, such are protease, which lyses proteins. You have a structure that's constructed in such a way, and this is nanometers in size, that it has two components linked chemically

by a bridge. The two components are such that one emits light and the other one absorbs light.

When they're closely constructed, the emitted light is absorbed by the counter-component, but the bridge is constructed in such a way that is it lysed specifically by the enzyme that the cancer produces. So, when this nanostructure reaches the cancer, and is tailored to be lysed by a specific protease, that lyses, breaks these two components apart and, as a result of that, you can see it and you see the light.

So, the detection of light means that you've found the cancer. This allows you to identify cancer at an early stage, this is where the preemption comes in, is because you can identify it at the cellular stage. Also, monitor the response to various therapies. So——

Senator HARKIN. This is part of translating what you're doing into actual?

Dr. PETTIGREW. Yes. Yes. Absolutely. So again, just to emphasize, I mean, much of the work that's going on now in developing innovative new technologies that will allow you to identify disease early on, this happens at the nanometer scale, one. Then two, deliver therapy specifically targeted to that expression of the disease in that individual, also done by nanotechnology.

GENE THERAPY RESEARCH IN EYE DISEASE

Senator HARKIN. Anything else, Dr. Collins, about gene therapy—what was that dog's name?

Lancelot, the dog. I met Lancelot the dog a few years ago and Lancelot was blind and they did gene therapy and the dog sees. I understand that's now been done, replicated on a number of other dogs. I think the last I heard they were now going to primates.

Dr. COLLINS. Going to primates called people.

Senator HARKIN. Oh, I thought we were just going into——

Dr. COLLINS. So, there is a clinical trial about to get underway, which is supported by NIH. Yeah, this is a really fascinating story. So, the condition here is Lever's congenital amaurosis.

Senator HARKIN. That's it.

Dr. COLLINS [continuing]. Which causes blindness.

Senator HARKIN. Exactly.

Dr. COLLINS. In this case, different than macular degeneration, it's a degeneration of the retina.

Senator HARKIN. Right.

Dr. COLLINS. This particular version of it is caused by mutations in a gene called RPE65, which doesn't mean very much, but it turns out the briard dogs have this same genetic problem, which is why Lance was such a good model to try it out. I've also seen the films of these dogs before and after treatment, which are really dramatic——

Senator HARKIN. It's dramatic.

Dr. COLLINS [continuing]. Going from bumping into everything to clearly having a good grasp of what's around them through their corrected vision.

So, this is a circumstance where gene therapy injected into the eye, carrying in the gene therapy vector, the right version of this gene to make up for the fact that the one that the patient has is not working, shows a lot of promise. In fact, I don't know whether,

in fact, they've enrolled the first patients. This must be about the time where they were getting ready to do so, and I think I just saw last week, there's also a study getting underway in Europe for the same condition also using the same gene therapy vector. So, I think we all wait with bated breath to see if what worked so nicely for the dogs is going to work for people as well, with, I think, a good reason for optimism.

Senator HARKIN. That's great. That's great. That would be under probably the National Eye Institute I assume, right?

Dr. COLLINS. Yeah.

Senator HARKIN. But you, obviously know about it since it has to do with genes and everything.

Dr. COLLINS. Yeah, exactly, but Dr. Sieving could tell you even more.

Senator HARKIN. Exactly.

Well, thank you all very much, thank you again for your leadership, all that you're doing at NIH.

Does anybody have any last thing for the record, before we——

Dr. PETTIGREW. Yeah, I just wanted to comment on the earlier question regarding training for students.

Senator HARKIN. Yeah.

Dr. PETTIGREW. While I think it is more of a challenge to get high school students at the NIH, we do have two programs directed at undergraduate students, both on the NIH campus where we bring in a group of undergraduate students, and train them specifically in bioengineering, and we also have a program, in conjunction with the National Science Foundation where we establish 10 sites around the country at 10 universities, where students at the undergraduate level, and early graduate level, come and work specifically in these areas of new technologies.

Senator HARKIN. Mm hm.

Dr. PETTIGREW. We have a third program that we've recently created in partnership with the Howard Hughes Medical Institute, to develop a new training curricula, focusing specifically on team science and interdisciplinary sciences, as I mentioned before, which is very much one of the waves of the future, where you bring together scientists of multiple disciplines.

We think that these will be the scientists of the future, and that in order to really make that a reality, that the curricula that exists today need to be modified, so that the languages of these different disciplines—mathematicians, and biologists and physicists talk in different languages and know different things—are brought together and understand human biology and disease, as well as a physical science world, so that once they finish school, the can serve and function more effectively in a team science situation.

Dr. COLLINS. Senator, if I could——

Senator HARKIN. Yeah.

Dr. COLLINS [continuing]. Just as one final comment, express thanks from all of us, to you and Senator Specter for the leadership that you've shown through these years in supporting NIH. In my 14 years at the Institution, I've never seen more scientific opportunity, more excitement, more young scientists champing at the bit to jump in and solve problems that are going to have profound implications on human health. It is really a remarkable time.

Yet, we are caught in this dilemma where, we're not limited by ideas, we're not limited by talent, we're not limited by potential for transforming medicine, we're really limited by the ability to take the resources that we've got and try to stretch them as far as we can. We really appreciate the way in which you and Senator Specter have led this process to try to make it possible for us to do as much as we can.

This diabetes discovery that I'm so excited about, just in the last 2 weeks, opens up a whole new set of opportunities in terms of prevention and treatment——

Senator HARKIN. Sure.

Dr. COLLINS [continuing]. Yet when I look and see that we spend the equivalent of one latte per year, per American, on diabetes research—not a venti, mind you——

More like a grande—it does seem sort of discordant, we could do so much more.

Senator HARKIN. Well, thank you all very much, thanks, Dr. Collins. Well, it's been a great partnership with Senator Specter and with me, and over all of these years, and we've seen some great things happen, and right now we're really concerned about the budget crunch, and the fact that we've doubled the funding at NIH, but now it's been leveling off and it's going back, and we never, ever intended for that to happen. We wanted to get it on a higher plateau, and then keep going up. We're both very dismayed by this, and we're going to try to everything we can to get a better allocation this year for NIH.

But, that's just another battle we'll have to fight, I guess, on the budget.

But, I agree with you, there's just a lot of exciting things out there. I mean, this is why I really talked about these young people, getting young people enthused and excited about a career in science, and getting them when they're young. I think during that period when we were doubling it, I kept asking questions about it, because young people now see that they could have a career in research, and I don't want to destroy that, I don't want to have them say, well, maybe yes, maybe no.

Dr. LINDBERG. Now they're stranded.

Senator HARKIN. Yeah.

We've floated them out there, now they're stranded out there. So, hopefully we can fix that, with better budgets and that kind of thing.

Dr. LINDBERG. Many thanks for all you've done.

ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

NLM FACILITIES

Question. Dr. Lindberg, I understand that NLM faces increasingly stringent space constraints stemming from the continued expansion of its collections, the growing

need for computing infrastructure for storage, search and retrieval of electronic media and the successful implementation of its many important programs. Can you provide some examples of how space limitations affect the Library's ability to fulfill its many functions for information services, research and training?

Answer. Space limitations affect a range of NLM operations and services.

NLM's onsite space for new manuscript collections, such as the papers of eminent biomedical scientists and the records of important professional societies and foundations is at capacity. It is anticipated that the Library may be completely out of space for all collections, including printed books and journal volumes, films, pictures, and electronic collections, by 2010, even projecting a yet-to-be seen decline in hard copy publications. NLM serves as an archive-of-last-resort for the health community, provides access to materials that are not available elsewhere in the world and preserves materials that other health sciences libraries discard. Due to space limitations NIH no longer maintains on-campus training facilities used to teach NIH researchers and other staff to use NLM's search and retrieval systems. The rate of expansion NLM's National Center for Biotechnology Information (NCBI) has been partially governed by the speed with which NIH can locate and reconfigure office and work space for NCBI staff in other on-campus facilities.

NLM's Go-Local service provides consumers and physicians with links from Medline search results to facilities that provide related health care services within their geographic regions. Existing facilities support 17 Go-Local sites, which cover one-quarter of the U.S. population. Additional space would be needed for servers that would allow expansion of Go-Local to cover the entire U.S. population. Space is also one factor that could delay the addition of servers and storage devices needed to house the molecular sequences data key trans-NIH research initiatives, such as whole genome association studies and metagenomics projects.

Question. Can you tell us what steps NLM and NIH are taking to address these concerns and what more is needed?

Answer. NLM is implementing a number of steps to provide additional space for its collections and operations. NLM currently leases space in other buildings, both on- and off-campus. As of spring 2007, NLM leased approximately 33,000 square feet of space in other on-campus facilities and approximately 23,000 square feet of office space off-campus. These figures compare to 312,000 square feet of space in the two NLM buildings (Bldgs 38 and 38A). In coming months, NIH has arranged for NLM to take occupancy of additional on-campus space to house staff of the NCBI. In addition, NLM plans to lease off-campus space for the expansion of NLM's computer facilities. To make additional space for its physical collections, NLM also plans install additional compact shelving in building 38. This will require structural reinforcement of the building to support the additional load of more densely packed books and manuscripts.

Question. How cost-effective is it to lease additional space/facilities?

Answer. On campus, administrative space can be leased at a rate of approximately $19 per square foot, compared to approximately $37 off campus. Rental of on-campus space involves additional costs associated with moving NLM staff to the new site and relocating displaced NIH staff to other—typically off-site—facilities. Other costs must also be taken into account. In evaluating options for expanding its computer facilities, NLM found local expansion considerably less expensive than off-site locations due in no small part to the lower cost of electricity on campus.

Question. What is the status of plans to construct the new building at the National Library of Medicine for which planning funds were appropriated several years ago?

Answer. Architectural plans were completed in 2003 for a building that would provide additional space for Library collections and collaborative workspace for NLM's expanding research and development capabilities, in particular those of the NCBI. NIH did not request funding for construction in the fiscal year 2008 Budget.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

BASIC BEHAVIORAL RESEARCH

Question. Dr. Berg, over the past 8 years, this subcommittee and our colleagues in the other body have pressed the NIH to find or assign a home for basic behavioral research at your institute. The NIH has not responded to positively to this matter even though this same request was a recommendation of the National Academy of Sciences and of Director Zerhouni's advisory committee. It is also a part of the NIGMS statute. Basic behavioral research needs dedicated leadership at the NIH

in this important field of science. When will it be possible for NIH to respond favorably to this request?

Answer. Basic behavioral research, like basic biomedical research, is supported throughout the NIH, both in disease- and stage-of-life-specific institutes and in the institutes and centers with more general missions. An analysis performed by the working group of the Advisory Committee to the Director, NIH, indicated that nearly $1 billion in basic behavioral research is supported across NIH, including support within NIGMS. There is, and should be, basic behavioral research supported by each of the Institutes that relates to its mission.

The authorization language for NIGMS states: "The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more national research institutes or are outside the general area of responsibility of any other national research institute." In response to congressional inquiries and in keeping with this mission, NIGMS has initiated two programs recently. The first, "Collaborative Research for Molecular and Genetic Studies of Basic Behavior in Animal Models," is intended to facilitate research involving basic behavioral scientists and investigators with expertise in modern molecular biology and/or genomics. The second, "Predoctoral Training at the Interface of the Behavioral and Biomedical Sciences," will support institutional training grants that provide new scientists with rigorous and broad training in behavioral, biological, and biomedical sciences. These new programs reflect the potential high impact of integrating behavioral and biological approaches to advance fundamental understanding and yield new approaches to promoting human health and treating disease.

The NIH Office of Behavioral and Social Sciences Research (OBSSR) was established by Congress to stimulate research in behavioral and social sciences research throughout NIH and to integrate these areas of research across the NIH institutes and centers. Coordination across NIH is also enhanced by the establishment of the Division of Coordination, Portfolio Analysis, and Strategic Initiatives by the NIH Reform Act of 2006. NIGMS and the other institutes and centers are working with OBSSR and the new division to ensure that NIH supports a broad portfolio of basic behavioral research to further the broad NIH mission. This broad base of support provides a wide range of opportunities for behavioral scientists to find support for their research that is relevant to the NIH mission. In addition, basic behavioral research, just like basic biological and chemical research, that underpins the NIH mission at a deeper level, can find support at the National Science Foundation.

INFORMATION RESOURCES FOR HAWAIIANS

Question. Dr. Lindberg, last year you visited one of our native Hawaiian programs at Papa Ola Lokahi. I am most appreciative of the National Library of Medicine's continued interest in increasing access to health information and health resources for Native Hawaiians. What were your impressions of the Native Hawaiian programs at Papa Ola Lokahi?

Answer. An NLM team visited Hawaii in July 2006 and came away impressed with the effectiveness of Papa Ola Lokahi in working with Native Hawaiian communities and health providers.

Question. How can the National Library of Medicine and Papa Ola Lokahi work together to increase access to healthcare information in Hawaii?

Answer. The National Library of Medicine and Papa Ola Lokahi are working together in a variety of ways to improve access to healthcare information in Hawaii. Working with Papa, NLM has supported two pilot projects—one to strengthen the community library at Miloli'i so that residents have online access to health information; a second to install a computer in the waiting room of the Waimanalo Health Clinic so that patients can access health information. Both projects have made very good progress and are nearing completion. Also, with NLM support, Papa organized a one-day meeting in July 2006 to discuss needs and options for preserving and strengthening the collections of Native Hawaiian Health materials. The meeting was attended by various Hawaiian museum, archival, academic, and community organizations with an interest in this topic. NLM was pleased with Papa's work to arrange and conduct this meeting, and is exploring possible follow up. NLM has also provided support to Papa for improvement of Papa's web site, and, earlier, for participation of two Papa staff persons in NLM's Native American Internship Program. Additionally, Papa is represented on the NLM-supported Health Information Task Force of the National Congress of American Indians. And a Papa staff person was invited to participate in the NLM-sponsored Tribal Outreach Conference held in

July 2006 in Albuquerque, NM. NLM will continue its multi-dimensional relationship with Papa Ola Lokahi in order to enhance access to healthcare information throughout Hawaii.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

PUBLIC ACCESS

Question. Dr. Lindberg, please provide the following information on eligible articles deposited with NIH under the NIH Public Access Policy. Please include all articles that are eligible for deposit under the policy, including manuscripts and final published articles submitted by authors and publishers:

(1) The total number of articles that have been deposited with NIH since the May 2, 2005 implementation date and the overall percentage of deposits to date. Please describe how you arrived at the total number of eligible articles.

(2) The month-by-month deposits of articles, shown as a percentage of eligible articles available for deposit, and as a monthly total of the number of deposited articles from May 2005 to April 2007.

Answer. (1) Total articles deposited with NIH under the NIH Public Access Policy, May 2, 2005 to April 30, 2007

Articles deposited under the Public Access Policy: 6,196

Total articles eligible for deposit under the Public Access Policy: 142,000

Percent Deposited: 4.4 percent.

Using 2005 publication data as a baseline, we estimate that 71,000 articles per year (or 5,916 per month) should have been deposited as a direct result of the Policy. This is a conservative baseline because of a general upward trend in publication rates from year to year.

(2) The month-by-month deposits of articles, shown as a percentage of eligible articles available for deposit, and as a monthly total of the number of deposited articles from May 2005 to April 2007.

TABLE 1.—AVAILABLE ARTICLES BY MONTH, AS OF MAY 31, 2007

Month	Articles deposited [1]	Eligible articles	Percent of target
May 2005	110	5,916	1.9
June 2005	107	5,916	1.8
July 2005	186	5,916	3.1
August 2005	146	5,916	2.5
September 2005	146	5,916	2.5
October 2005	156	5,916	2.6
November 2005	143	5,916	2.4
December 2005	161	5,916	2.7
January 2006	208	5,916	3.5
February 2006	172	5,916	2.9
March 2006	175	5,916	3.0
April 2006	166	5,916	2.8
May 2006	231	5,916	3.9
June 2006	220	5,916	3.7
July 2006	160	5,196	2.7
August 2006	168	5,916	2.8
September 2006	252	5,916	4.3
October 2006	302	5,916	5.1
November 2006	317	5,916	5.4
December 2006	482	5,916	8.1
January 2007	746	5,916	12.6
February 2007	651	5,916	11.0
March 2007	639	5,916	10.8
April 2007	[2] 152	5,916	2.6
Total	6,196	142,000	4.4

[1] Articles that are approved for release in PubMed Central, including articles that may not actually be released until 12 months after publication, as specified by the author.

[2] Authors of articles submitted in April 2007 have only had a few weeks to review and approve them after conversion to the PubMed Central archival format. We expect the number of approved articles for April to rise in the coming weeks to the same level as for previous months, as authors have time to respond.

At the request of publishers, NLM deployed a mechanism in December 2005 (http://www.nihms.nih.gov/publishers.html#q2) to allow publishers to deposit author manuscripts on behalf of their authors. The welcome growth in deposits from September 2006 forward has been due mostly to a large publisher, Elsevier, beginning to use this system. As of April 2007, Elsevier is submitting all of its author manuscripts based on NIH funded research.

Author manuscripts need to be converted to an archival format for posting on PubMed Central. This conversion must be verified by the author. When author manuscripts are submitted by the authors themselves, the authors almost always complete this verification step. However, NIH is only able to post a portion of bulk deposits being made by Elsevier to PubMed Central, because many authors do not follow up with the necessary verification and approval. Author participation is voluntary under the policy.

In previous reports on the Policy, we counted the initial submissions of files as the number of manuscript deposited. (The actual number of articles that could be publicly released was slightly lower, but the difference was not significant as long as the majority of deposits were made by individual authors.) However, because of the large dropout rate associated with Elsevier's bulk deposits in recent months, it is more accurate to count as deposits only those articles that have the author's final approval for release in PubMed Central. These numbers include author manuscripts that may not actually be released until 12 months after publication, as specified by an author.

This more accurate measure of compliance applies to all of the articles reported in Table 1. As a result of this change in metrics, the deposits for 2005 and the first half of 2006 will be slightly lower than the corresponding numbers in earlier reports to Congress.

For reference, Table 2 shows the total number and percent of author manuscripts sent to NIH via bulk deposit, made by Elsevier between September 2006 and April 2007. The right column shows the number that received the author's final approval for release to PubMed Central and is included in Table 1.

TABLE 2.—ELSEVIER BULK DEPOSIT SUBMISSIONS, AS OF MAY 31, 2007

Month	Manuscripts sent to NIH via bulk deposit	Manuscripts approved for public release by authors	Percent
September 2006	77	52	67.5
October 2006	76	42	55.3
November 2006	204	120	58.8
December 2006	521	251	48.2
January 2007	711	398	56.0
February 2007	796	419	52.6
March 2007	810	389	48.0
April 2007	1,012	106	[1] 10.5
Total	4,207	1,777	(42.2)

[1] Authors of articles submitted in April 2007 have only had a few weeks to review and approve them after conversion to the PubMed Central archival format. We expect the number of approved articles for April to rise in the coming weeks to the same level as for previous months, as authors have time to respond.

We should note that Bulk Deposit is only one method by which publishers can submit content to PubMed Central. Under the Public Access Policy, two scientific societies have signed agreements to deposit all of their final published articles based on NIH funded research to PubMed Central. These PubMed Central (NIH Portfolio) agreements will result in 100 percent of their deposited articles posted on PubMed Central without author involvement.

Independent of the Policy, a number of journals routinely deposit their complete contents in the PubMed Central archive. Many, including the Proceedings of the National Academy of Sciences and the eleven journals of the American Society for Microbiology, have been doing so since 2000 or 2001, years before the Public Access Policy took effect. Authors who publish in these journals do not have to deposit their manuscripts based on NIH funded research under the Policy, because a copy of the journal's published article is already available to the public through PubMed Central. These articles were not included in the baseline total of articles eligible to be deposited under the Policy (71,000 per year or 5,916 per month) and, therefore, are not included in Table 1. Approximately 700 articles based on NIH-funded research come into PubMed Central each month from regularly participating journals.

SUBCOMMITTEE RECESS

Senator HARKIN. Well, thank you all very much, and thanks for taking the time to come down here today, and your expertise, and wish you the best, and keep on doing what you're doing.

May 21 will be our next NIH hearing.

Thank you very much. The subcommittee will stand in recess to reconvene at 2 p.m., May 21, 2007, in room SD–116.

[Whereupon, at 3:29 p.m., Monday, May 7, the subcommittee was recessed, to reconvene at 2 p.m., Monday, May 21.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

MONDAY, MAY 21, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 2 p.m., in room SD–116, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Cochran, and Stevens.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order.

I just thought that before we begin today's hearing I want to take a moment to offer my condolences to everyone, through you, at NIH over the recent passing of Dr. Steve Straus, the founding Director of the National Center for Complementary and Alternative Medicine. It's an enormous loss to science and to his many friends and colleagues at NIH where he worked for 27 years. We always knew that Steve was a man of great integrity and skill and dedication. That was apparent from his many scientific accomplishments.

But during his 2½ year battle with brain cancer we also witnessed his courage and his grace. He fought a valiant fight and was a teacher until the end. We were lucky to have him as NCCAM's founding director.

He and I had many, many conversations and meetings on alternative medicine, complementary medicine, where we're going and how we fold that in with other mainstream research. I think he's one of those people of whom we can truly say that he did make the world a better place.

So, this is the fifth of six hearings on the National Institutes of Health that the subcommittee will hold this year. We've heard from 13 Institutes so far. Today we'll hear from five more: the National Institute of Allergy and Infectious Diseases, the National Cancer

Institute, the National Center for Research Resources, the National Institute of Nursing Research and the National Center on Minority Health and Health Disparities.

I'll ask each Director to speak 5 to 7 minutes. In the spirit of how we've been doing this if I think of something while you're doing it I may even ask you a question at that time or—I excuse myself right now for interrupting. But we'll try to go through all of the testimonies and we'll just open up for general discussion after that.

I kind of like this format a little bit more than the formal one of sitting at a dais and that type of thing. I'd rather have more of a free flow of a discussion, sometimes even amongst you sitting across the table from me.

I think we learn a lot more and we get a better flavor for exactly what we're doing here. I know that C-SPAN and others pick this up. I look upon this as a way of also of teaching the public, getting information out to the public in a format in which they can get a better handle on just exactly what NIH is doing and what the different Institutes are doing.

So with that I'll start us here on my left. Dr. Anthony Fauci has served as Director of the National Institute of Allergy and Infectious Diseases since 1984. He received his MD degree from Cornell University Medical College. He has testified before this subcommittee many, many times over the years on everything from AIDS to pandemic flu to bioterrorism. I took over the Chair of the subcommittee in 1989. That was the first time I met Dr. Fauci.

So, welcome back, Dr. Fauci. All your statements will be made a part of the record in their entirety. Like I said if you could take 5 to 7 minutes or so, sum it up. I'd sure appreciate it.

SUMMARY STATEMENT OF DR. ANTHONY S. FAUCI

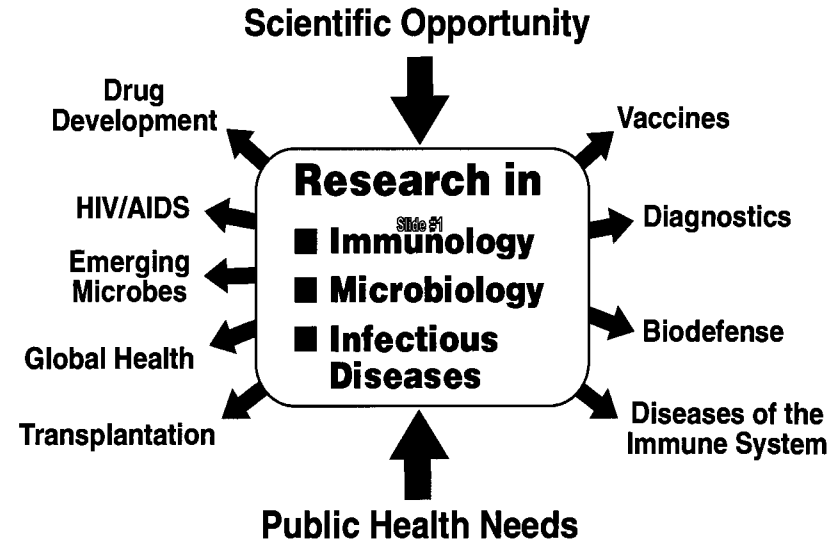
Dr. FAUCI. Thank you very much, Mr. Chairman and thank you for the opportunity to talk to you today a little bit about the activities of the National Institute of Allergy and Infectious Diseases.

I'm going to talk from some visuals that are right in front of you—right in front of you there.

Senator HARKIN. Okay.

Dr. FAUCI. I believe that's the top one. If you turn the page and look at the first slide.

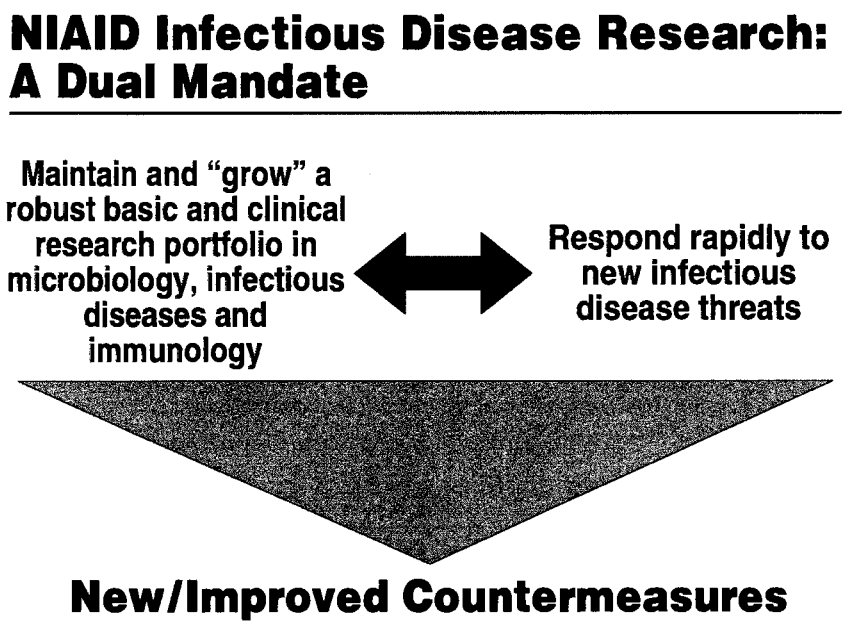
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)



I want to use that to tell you something that I know that you're familiar with. But for the sake of the record I will just mention very briefly what the mandate and the mission of the National Institute of Allergy and Infectious Diseases is. As you know it's responsible for the bulk of NIH research in the disciplines of immunology, microbiology and infectious diseases.

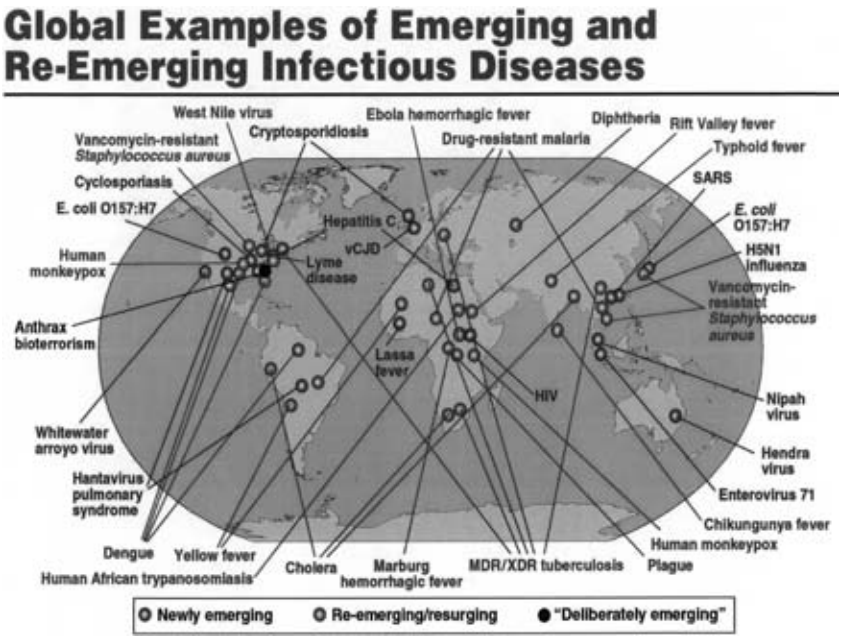
We're driven by two major issues. One is the scientific opportunity and the other is the public health need. You know about what we do from the much publicized issues such as HIV/AIDS, pandemic influenza and bio-defense. But we also have responsibility for emerging/re-emerging microbes, vaccinations and immunizations for adults and children, the development of antibiotics, vaccines as well as the study of diseases of the immune system, including the important issue of immunological tolerance, which has a great potential in many areas of medicine that go well beyond our Institute's mandate.

If you look at the next slide—I talk also here about what I call the dual mandate. Because in addition to all that we do, as every other Institute does, maintain a robust, basic and clinical research portfolio. For us it's microbiology, infectious diseases and the immune system. For Dr. Niederhuber, it's cancer and down the line. They each have what they do and what their Institute is responsible for.



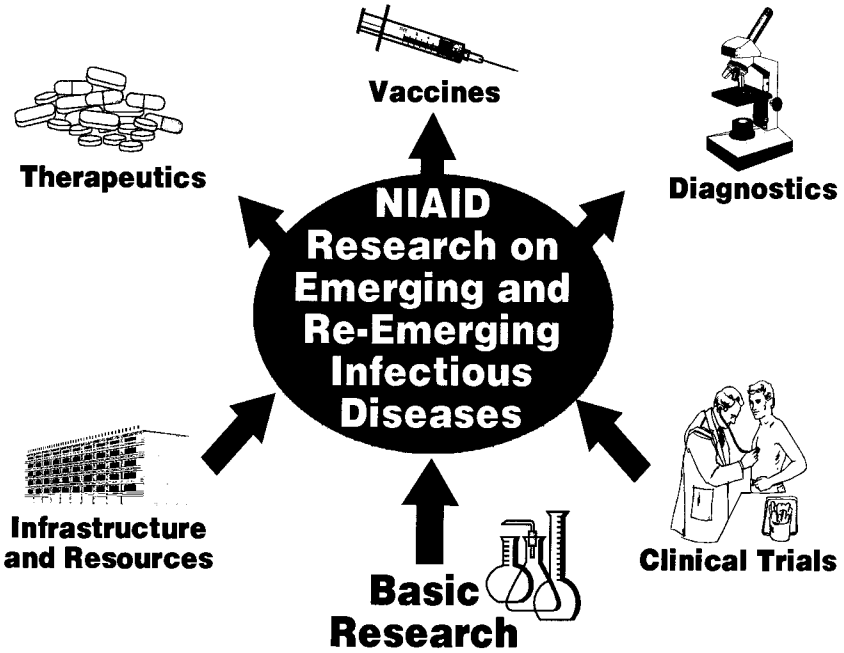
When I refer to our dual mandate I mean that we also need to be able to respond very rapidly to new infectious disease threats. You know we've discussed this at many hearings that we've had together on issues such as: HIV/AIDS, SARS, et cetera.

In fact if you go to the next slide. This is a slide I must have shown to you, Mr. Chairman, over the years since 1989 about 10 different times. The reason I can show you this—I hope without your getting bored, is that each year we add one, two and sometimes three, new emerging infectious diseases. In fact the print has gotten so small there that we're sort of running out of space. We started out with HIV/AIDS there, but you see there are many others that are emerging and re-emerging infectious diseases.



Of particular note this time is one that we've just recently added, which I hope we get a chance to discuss in the question period. That is extensively drug resistant tuberculosis, which is an issue that poses a significant threat to us. Also there are multiple drug resistant microbes like staphylococcus and enterococcus as well as things like the E. coli contamination of our spinach and our lettuce that was a major challenge just some months ago.

If you go to the next slide it really describes schematically, how we accomplish this. The NIAID research, for example on emerging and re-emerging infectious diseases is, as with all Institutes, based on a fundamental matrix of basic research which we hopefully then apply to the things that we need to do for the American public. In our case, it's the development of countermeasures, for example, in the forms of diagnostics, therapeutics and vaccines.



What I'd like to do in the next couple of slides is just go over with you some of the selected accomplishments which are also selected opportunities. So I'll go through them rapidly with you. If you look at HIV/AIDS, there has been this year, in addition to the great accomplishments of drugs that have essentially transformed the lives of HIV infected individuals. We know now that there have been a total, in a conservative estimate of about 3 million years of life saved in the United States on the basis of the anti-HIV therapeutic regimens that have been used.

Emerging/Re-Emerging Infectious Diseases: Selected Opportunities

HIV/AIDS

- New generation of anti-HIV drugs
- Expanded HIV vaccine trials
- New tools for HIV prevention, e.g. microbicides and circumcision

Malaria

- Mining genomic sequences of parasite and vector
- Averting and overcoming drug resistance
- Novel vaccine candidates

Influenza

- Development of new countermeasures for both seasonal and pandemic influenza, e.g. vaccines, therapeutics, and diagnostics

This year we have a couple of new drugs that are very exciting and will in fact, even improve that menu of drugs that we have available. In addition we have expanded HIV vaccine trials that we have embarked upon: one in collaboration with Merck and one with the Vaccine Research Center at the National Institutes of Health. In addition there are new tools for improvement such as the announcement that you probably heard of a few months ago about the protective effect of medically supervised adult circumcision for the prevention of HIV infection.

If you move on to malaria there have been some exciting new issues that have come up. For example, the sequencing of the parasite itself, and at least two or three of the vectors, namely the mosquitoes that cause it, allow us to get a greater insight into transmissibility, as well as drug resistance to the standard malaria antiparasitic drugs.

In influenza we're pleased to mention to you something that was announced just a short time ago, is that at our last hearing I mentioned to you that we were in the process of developing a pre-pandemic influenza vaccine. Just last month the FDA has approved that as an approved vaccine. We still need to make better vaccines for pandemic flu but we have at least one that's approved by the FDA.

UNIVERSAL INFLUENZA VACCINE

Senator HARKIN. That's not a universal?

Dr. FAUCI. No, no. We'll get to that, hopefully, in the questions. This isn't a universal—this is for the H5N1 bird flu.

Senator HARKIN. Specifically.

Dr. FAUCI. Specifically for the bird flu.

Then on the next slide I mention tuberculosis. I mentioned in my very earlier comments the real threat that we're seeing with this extensively drug resistant tuberculosis. NIAID has developed a strategic plan, very rapidly, which just this morning, at our National Advisory Council was presented to them for their final comments before we actually make it public. We'd be happy to provide that to you and your staff if you'd like it.

Emerging/Re-Emerging Infectious Diseases: Selected Opportunities

Tuberculosis

- Additional drug and vaccine candidates in clinical trials
- Development of point-of-care diagnostics
- Implementation of NIAID research agenda for XDR-TB

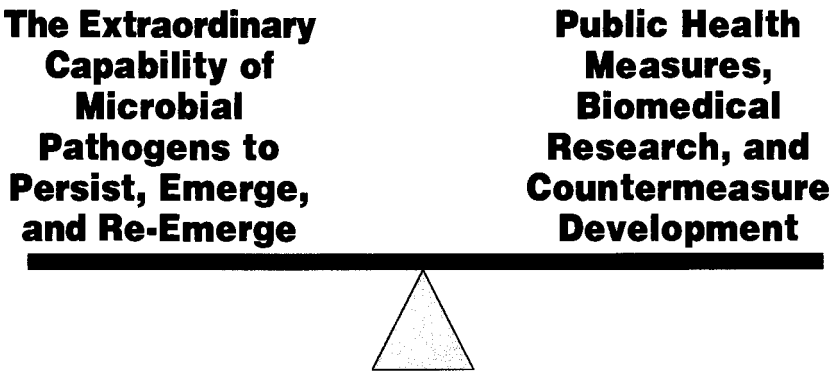
Potential Bioterror Agents

- Enhanced research infrastructure
- Application of basic research findings to the development of countermeasures

Then finally potential bio-terror agents, we've enhanced the infrastructure. Again a year or two ago I showed you the blueprints for the physical infrastructure that we were going to do. Several of those buildings are either near completion or actually up or—and operational such as the building on the NIH campus, building 33.

So if we go now to the last slide. I just want to close by saying that I've been talking to you about the threats of emerging and re-emerging infections and how the NIH research endeavor can meet these challenges, hopefully. I refer to it on this slide as a perpetual challenge because microbes will continue to emerge and re-emerge and nothing that we can do because of their evolutionary capability is going to allow us to completely eliminate the threat.

A Delicate Balance: The Perpetual Challenge



PREPARED STATEMENT

Dr. FAUCI. The best that we can do and I think it's something very important, is to maintain that balance by a very robust, research portfolio that can be wedded to our public health endeavors. We appreciate you and the committee for the support that you've given us over so many years. Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The fiscal year 2008 budget includes $4,592,482,000.

The mission of NIAID is to conduct and support research to understand, treat, and prevent infectious and immune-mediated diseases. Infectious diseases include well-known killers such as HIV/AIDS, malaria, tuberculosis, lower respiratory infections and diarrheal illnesses; naturally emerging or re-emerging threats such as pandemic influenza and SARS; and "deliberately emerging" threats from potential agents of bioterrorism. Preemptive medicine, in the form of vaccines and other prevention tools, is a major focus of the NIAID research portfolio in infectious diseases. Immune-mediated disorders include autoimmune diseases such as type 1 diabetes, lupus, and rheumatoid arthritis as well as asthma, allergies, and problems associated with transplanted tissues and organs. Here again, preemptive medicine is an important component of our research efforts, as NIAID extramural scientists work to predict, prevent, and treat immune-mediated diseases more effectively.

The NIAID mission has two distinct mandates. First, NIAID must plan and execute a comprehensive, long-term program of basic and clinical research on well-recognized endemic infectious and immune-mediated diseases. Second—and in this case distinctive among the NIH Institutes—NIAID must respond quickly with targeted research to meet new and unexpected infectious disease threats as they arise, often in the form of public health emergencies.

EMERGING AND RE-EMERGING INFECTIOUS DISEASES

Despite advances in medicine and public health such as antibiotics, vaccines, and improved sanitation, the World Health Organization (WHO) estimates that infec-

tious diseases still account for approximately 26 percent of all deaths worldwide, including about two-thirds of all deaths among children younger than 5 years of age. Moreover, the pathogens we face are not static, but change dramatically over time as new microbes emerge and familiar ones re-emerge with new properties or in unusual settings.

Influenza is a classic example of a re-emerging disease. Because circulating human influenza viruses continually accumulate small changes, a new vaccine must be made for each influenza season. When an influenza virus emerges that has undergone a major genetic shift such that the global population has limited natural immunity but the virus can be easily transmitted among people, a worldwide pandemic can result. Three influenza pandemics occurred in the 20th century, including the 1918 pandemic that killed more than 50 million people worldwide.

It is imperative that we take a preemptive approach to the possibility that a new influenza virus will emerge to cause a 1918-like pandemic. How well we do that, however, depends to a large extent on improving how we cope with seasonal influenza, which kills an average of about 36,000 people in the United States each year. Control of both seasonal and pandemic influenza requires development of and access to a sufficient supply of effective vaccines and antiviral drugs, effective infection control measures, and clear public communication. In this regard, NIAID research has directly laid the foundation for improved influenza vaccine manufacturing methods, new categories of vaccines that may work against multiple influenza strains, and the next generation of anti-influenza drugs. Certain of these goals will be accomplished through basic research projects intended to increase our understanding of how animal and human influenza viruses replicate, interact with their hosts, stimulate immune responses, and evolve into new strains. Other goals will be accomplished through targeted projects, such as a program to screen compounds for antiviral activity against influenza viruses.

Since last year, we have made substantial progress in influenza vaccine research. The inactivated-virus H5N1 vaccine currently stockpiled by the Department of Health and Human Services has been shown in NIAID-sponsored clinical trials to be safe and capable of inducing an immune response predictive of being protective against the H5N1 virus in healthy adults, children, and seniors. Although the vaccine dose required to induce this response is high, studies on enhancing the immune response to lower doses by employing immune enhancers called adjuvants are showing promising preliminary results. NIAID also is collaborating with industry to pursue several other vaccine strategies in addition to inactivated virus H5N1 vaccines. For example, trials of cold-adapted, live-attenuated H5N1 vaccine candidates are underway, as is a Phase I clinical test of a novel DNA H5N1 vaccine candidate developed at the NIAID Vaccine Research Center.

We also have made progress in antiviral drug and diagnostic test research over the past year. An NIAID program that screens both licensed drugs and new drug candidates—first in cell culture systems and then in animal models—has identified several promising anti-influenza candidates that are now being further developed in partnership with industry sponsors. These include FluDase, which binds host cell receptors to prevent viral entry; T–705, which inhibits replication of viral RNA; and Peramavir, which inhibits an influenza enzyme called neuraminidase. Research into influenza diagnostics is being vigorously pursued. For example, NIAID-funded researchers, working in collaboration with scientists at the Centers for Disease Control and Prevention, have reported encouraging results with a potentially revolutionary diagnostic device called the MChip, which is capable of quickly and accurately identifying many influenza viruses, including H5N1.

Tuberculosis (TB) is another emerging threat, especially with regard to new and dangerous drug-resistant forms of *Mycobacterium tuberculosis* that are being seen with increasing frequency. About one-third of the global population is latently infected with the TB bacterium. WHO estimates that 8.9 million TB cases occurred in 2004, as did 1.7 million TB deaths; active TB is especially common among people with HIV. Currently, about 20 percent of new TB cases are a multi-drug resistant form (MDR–TB), meaning that they are resistant to two common and inexpensive antibiotics and are thus far more difficult to treat than uncomplicated TB cases. However, an even more resistant form, called extensively-drug resistant TB (XDR–TB), has appeared. XDR–TB already accounts for about 10 percent of all MDR–TB cases, that is, two percent of all new TB cases.

The emergence of XDR–TB was not unexpected, but was a predictable consequence of imperfect compliance with the long and complex regimens needed to treat TB. We have long supported a large portfolio of research to develop new drugs, vaccines, and diagnostics for TB and to evaluate improved treatment and prevention regimens. As a result of that sustained effort, the "pipeline" of new countermeasures for TB is robust. At least nine new drugs are currently in clinical trials, including

SQ–109, a promising candidate being developed in a private-public partnership with Sequella, Inc. After a hiatus of 60 years in which no new TB vaccines were clinically tested, nine candidates are now in human trials, and at least ten more are in preclinical development. In addition, to ensure that the NIAID TB research program continues to contribute effectively to the global response to this increasing threat, the Institute has developed a comprehensive strategic plan for MDR/XDR–TB that will help guide our research efforts. .

Influenza and TB are just two of many emerging and re-emerging infections on which NIAID conducts research. Malaria, long a leading cause of death worldwide, has become even more problematic because of the emergence of drug-resistant malaria parasites and insecticide-resistant mosquito vectors. NIAID supports a large portfolio of malaria research that has generated many promising drug and vaccine candidates, some of which are now in clinical trials; this research is related to the President's Malaria Initiative, which was discussed at the December 2006 White House Malaria Summit. In addition, NIAID conducts research on many other less common, but nonetheless important tropical diseases such as leishmaniasis, trypanosomiasis, hookworm, and lymphatic filariasis, which exact an enormous toll worldwide.

HIV/AIDS RESEARCH

In the almost 26 years since it was first recognized, the acquired immune deficiency syndrome (AIDS) has become a global catastrophe. An estimated 39.5 million people worldwide are infected with HIV, the virus that causes AIDS. In 2006 alone, an estimated 4.3 million people were newly infected with HIV, and 2.9 million died of AIDS.

Although the global HIV situation remains grim, our government's investment in HIV research has generated many solid successes, and the healthy pipeline of new drugs, vaccines, and other prevention methods promises more successes in the future. Antiretroviral therapies made possible by NIAID-supported research have transformed HIV from an almost uniformly fatal infection into a manageable chronic condition. In this regard, a recent study concluded that since 1996 these antiretroviral medications have saved at least 3 million years of life in the United States alone. These life-saving therapies are now reaching the developing world: 1.6 million persons are now receiving antiretroviral therapy, more than half of them with support from the President's Emergency Plan for AIDS Relief (PEPFAR). In addition to these accomplishments, several new generation antiviral drugs that target HIV in novel ways are in the final stages of development.

Prevention efforts continue to be a major component of NIAID's HIV research program. We have improved our ability to prevent mother-to-child transmission. Research to develop topical microbicides capable of blocking HIV transmission during sexual contact is proceeding vigorously. And in December 2006, two NIAID-supported trials in Kenya and Uganda showed that medically supervised circumcision of adult males can significantly lower their risk of contracting HIV through heterosexual intercourse. The most powerful tool to prevent HIV infection would be a safe and effective HIV vaccine. NIAID is currently supporting 20 clinical trials of HIV vaccine candidates. Seven of these have moved beyond initial Phase I safety and immunogenicity testing. For example, in January 2007, a Phase IIb "proof of concept" trial of a non-replicating adenovirus vector modified to contain three HIV genes opened in South Africa. A related trial of the same candidate is ongoing in volunteers from North America, South America, Australia, and the Caribbean in collaboration with Merck pharmaceutical company. The NIAID Vaccine Research Center has also developed an HIV vaccine candidate that is currently being tested in Phase II trials, with an international Phase IIb efficacy trial set to begin later in 2007. Because of the enormous need for human testing of HIV drug, vaccine, and other prevention strategies, we recently reorganized our HIV/AIDS clinical trials network to make our clinical research capacity more efficient so that we can continue to meet evolving global AIDS research challenges. Additionally, NIH will contribute $300 million to the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria in fiscal year 2008.

BIODEFENSE RESEARCH

The possibility that terrorists will use a biological agent to mount an attack is a serious threat to the citizens of our nation and the world. Research to preempt and mitigate this threat is a key focus of NIAID, and complements our role in meeting the challenges of naturally emerging and re-emerging infectious diseases. Our strategic planning for biodefense research includes three essential pillars: infrastructure needed to safely conduct research on dangerous pathogens; basic research

on microbes and host immune defenses that serves as the foundation for applied research; and targeted, milestone-driven development of medical countermeasures to create the vaccines, therapeutics and diagnostics that we would need in the event of a bioterror attack. These efforts enhance not only our preparedness for a bioterrorism attack, but for naturally occurring endemic and emerging infectious diseases as well.

NIAID has undertaken a substantial expansion of biocontainment research facilities, which will greatly enhance our ability to safely and efficiently conduct research on infectious agents. For example, through its extramural program, NIAID is supporting the construction of two National Biocontainment Laboratories capable of safely containing the most deadly pathogens, as well as thirteen Regional Biocontainment Laboratories nationwide. Three intramural biocontainment labs—on the NIH campus, on the National Interagency Biodefense Campus at Fort Detrick in Fredrick, Maryland, and at the NIAID Rocky Mountain Laboratories in Hamilton, Montana—are either complete or well under construction. In addition to these facilities, NIAID has established a nationwide network of ten Regional Centers of Excellence (RCEs) for Biodefense and Emerging Infectious Diseases Research, which conduct research and development activities and provide training for future biodefense researchers.

The Institute's efforts have already yielded substantial dividends as described in our periodic progress reports, the latest of which was issued in January 2007. For example, new or improved vaccines and therapies against anthrax, smallpox and Ebola virus have shown great promise; among these is ST–246, a promising smallpox drug candidate that protects both rodents and nonhuman primates from lethal challenge.

NIAID also has been assigned the responsibility to coordinate research to develop countermeasures against a range of radiological and chemical threats. We have established eight Centers for Medical Countermeasures against Radiation and four Centers for Countermeasures against Chemical Threats; in addition, basic and applied research is moving rapidly. We continue to coordinate and collaborate on these important components of our national security with our sister Institutes at NIH as well as interagency partners, including the Department of Defense, Department of Energy, and Department of Homeland Security.

RESEARCH ON IMMUNE-MEDIATED DISEASES

Autoimmune diseases, allergic diseases, asthma and other immune-mediated diseases are significant causes of chronic disease and disability in the United States and throughout the world. NIAID-supported research in immune-mediated diseases has led to significant advances in our understanding of how to manage these diseases.

One promising strategy to treat and prevent immune-mediated diseases is the induction of immune tolerance. Immune tolerance therapies are designed to "reprogram" immune cells to eliminate injurious immune responses, such as those seen in autoimmune diseases, while preserving protective responses needed to fight infection. NIAID has established a comprehensive program in immune tolerance research, including basic research, preclinical testing of promising strategies in nonhuman primates, and clinical evaluation through the Immune Tolerance Network (ITN). In an important study of people with severe diabetes, the ITN has shown that the transplantation of pancreatic cells can improve blood sugar control, protect patients from severely low blood sugar, and, in a few cases, relieve patients of the need for insulin injections; unfortunately, insulin independence was not sustained in most subjects. Further research is underway to improve this promising procedure.

Last year, NIAID-supported scientists reported the identification of new ways to non-invasively assess the risk of kidney graft rejection by using gene-expression based biomarkers of immunologic activity present in urine. These investigators are now conducting a multi-center study to validate these approaches that potentially could allow physicians to predict, prevent, and treat kidney rejection more effectively.

NIAID remains committed to improving the health of children with asthma, particularly those who live in our Nation's inner cities. The NIAID-supported Inner City Asthma Consortium (ICAC) has undertaken two important efforts in this area. The ICAC is conducting the Urban Environment and Childhood Asthma (URECA) Study. Five hundred and fifty inner-city children have been enrolled at birth and will be followed prospectively during childhood. The goals of the study are to identify the immunologic causes of the development of recurrent wheezing, a surrogate

marker for asthma in children under three, and to monitor the development of food allergies in this patient population.

CONCLUSION

The research conducted at NIAID and at NIAID-sponsored laboratories encompasses a broad array of basic, applied and clinical studies. This research has resulted in tangible benefits to the American public and to individuals throughout the world. By supporting talented researchers and emphasizing a balance of basic studies and targeted research, we will continue to develop innovative interventions to prevent, diagnose, and treat the wide range of infectious and immune-mediated diseases that afflict humanity.

COORDINATION WITH CDC

Senator HARKIN. Would it be safe to say, Dr. Fauci that your Institute probably intersects with CDC more than any other Institute?

Dr. FAUCI. I would think that would be safe to say. Several of the other Institutes do interact with CDC. But since CDC is responsible for the disease surveillance of those precise diseases, those emerging infections, that we are responsible for the research that develop the counter measures. There's a natural marriage between our Institutions in working together.

COORDINATION WITH DEPARTMENT OF DEFENSE

Senator STEVENS. Dr. Fauci, we've put up a lot of money through the defense bill for similar endeavors. Do you coordinate with them?

Dr. FAUCI. Indeed we do, Senator Stevens. In fact, we have very robust collaborations with them. A couple of examples have been influenza, the bio-defense, the HIV and malaria as just four examples of things that we work very, very closely with the Department of Defense.

In fact, we have cooperative agreements with them. In our biodefense area we actually have a facility that's with them up at Fort Detrick. So the Department of Defense, NIH, NIAID interaction is very, very healthy.

Senator STEVENS. So there's not a redundancy there. You are keeping that coordinated, so it's not going to be.

Dr. FAUCI. It's complementary as opposed to redundant.

Senator STEVENS. Thank you.

Senator HARKIN. Now we turn to Dr. John Niederhuber, who became Director of the National Cancer Institute in September 2006. Also served as NCI's acting Director and Deputy Director. He received his MD from the Ohio State University School of Medicine and his research at the NCI has focused on the study of tissue stem cells as the cell of origin for cancer. Interesting.

Dr. Niederhuber, thank you very much for being here. You may proceed.

STATEMENT OF DR. JOHN E. NIEDERHUBER, DIRECTOR, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. NIEDERHUBER. Chairman Harkin, Senator Stevens and members of the staff, thank you for the opportunity to testify today on behalf of the National Cancer Institute and the National Institutes of Health.

Over the next few minutes, I would like to describe some of the progress NCI has made in cancer research along with some of the exciting opportunities we are pursuing.

For 2 years now we have seen unprecedented decreases in the actual number of cancer deaths nationally. That is remarkable news considering cancer is largely a disease of aging and as you know our country is not only growing older, its population is also growing.

Today's progress is occurring in no small part because researchers are coming to understand cancer's basic biologic processes. The sequencing of a human genome, a singular landmark in biomedical research, is providing a foundation for NCI's new Center of Human Cancer Genomics. Its mission is to systematically identify all important inherited and acquired genetic alterations that now contribute to a person's cancer risk and if cancer occurs, that cancer will behave. We are diligently working to understand these genetic changes and apply them to cancer prevention and to cancer treatment.

Consider if you will that under the microscope, diffused, large B-cell lymphoma tumors from different patients look the same. However, when subjected to gene expression analysis, they have distinct genetic signatures. These differences in their genetic signature predict prognosis and enable us to individually characterize a patient's cancer and match him or her with the best treatment. Importantly, this is not a futuristic technique. We are already beginning to apply this technology in clinical settings such as lymphoma, lung and breast cancer.

At the same time we are learning more about the mechanisms of a cancer cell including a small subset of cells within the tumor that drive the steps of invasion and growth. This subset of cells may enable the tumor to spread. Interestingly, these cells have stem cell like characteristics.

Evidence is building that these so called cancer initiators, or transformed tissue stem cells are the driving force behind many tumors, and are the basis for long term risk of cancer recurrence. Clearly these cells will be a necessary target for treatment of the future.

As we move toward an era of personalized medicine, advanced technologies will play a significant role in cancer prevention and preemption telling us in real time if a new drug treatment is reaching its target within the cell, if the novel drug is saturating that target, or if it is changing the function of the target. These early phase tests in patients will make go or no go decisions possible within hours, not within months for early cancer drug development, thus shortening development time and greatly decreasing cost.

We also realize, however, that most cancer patients have yet to see the benefits of our science. Too many patients lack the means, the mobility or even the language capacity to travel to a premier facility. It is clear that access to care will be one of the greatest determinants of cancer mortality in the years ahead.

Mindful of our mission to conduct research in all areas of science, including the behavioral sciences, such as how best to provide patient education and access to optimal care, NCI will in the next few

weeks launch the pilot phase of a community cancer centers program that if fully implemented will bring state of the art cancer care to patients in community hospitals across the United States. This program will encourage and foster the collaboration of private practice medical, surgical and radiation oncologists with the opportunity for close links to NCI's research and to our NCI designated cancer centers.

PREPARED STATEMENT

There is great cause for optimism in cancer science. But it must be tempered by an understanding of the hurdles we face. Cancer is a disease of staggering complexity with a singular name. Our progress is exciting. It is certainly encouraging, but we are continually challenged—challenged by our fellow citizens living with cancer to make faster progress.

Thank you for the opportunity to testify before the Subcommittee this afternoon.

[The statement follows:]

PREPARED STATEMENT OF DR. JOHN E. NIEDERHUBER

INTRODUCTION

I am most pleased to be before you today to report on the Nation's progress in cancer research. While there has been a steady decline in the cancer mortality rate (the number of cancer deaths per 100,000 people) since 1991, we now have the excellent news that—for the second year in a row—there has been a decline in the absolute number of cancer deaths. In 2003, there were 369 fewer cancer deaths reported in the United States than in 2002. In 2004 (the most recent year reported) the decrease was almost ten times greater, at 3,014 [Figure 1]. This decline is even more significant when you consider that cancer is largely a disease of aging, and our population is not only growing in numbers, it is aging at an even greater rate. Progress is, indeed, heartening, but our work is not done. Too many of our citizens—patients and families alike—continue to feel the pain and fear that come with the devastating news of a cancer diagnosis.

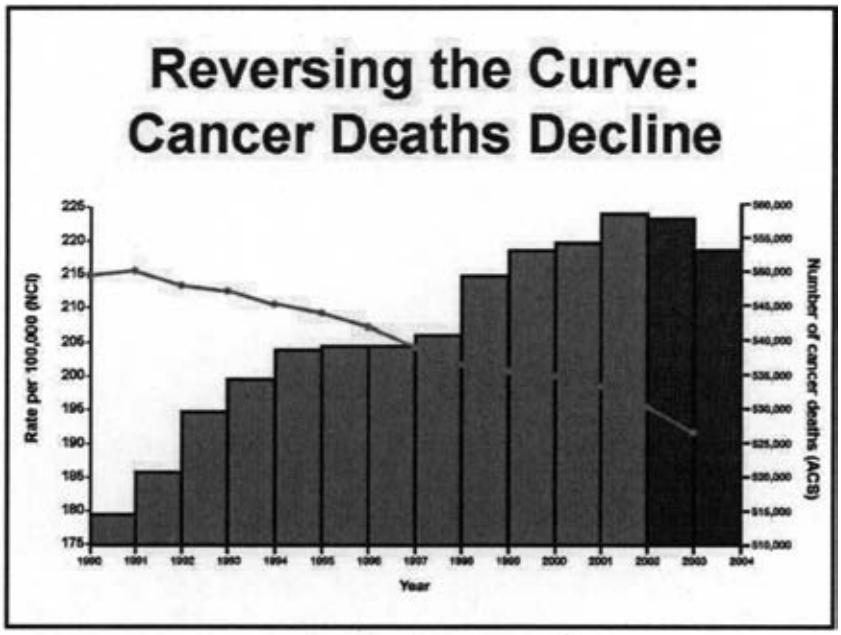


FIGURE 1.—*The green line represents the cancer mortality rate per 100,000 population. The bars represent the actual recorded number of cancer deaths in the United States.*

While we measure our progress against cancer in terms of patients treated and lives saved, that effort also has a measurable economic impact. It has been projected that even a 1 percent decrease in cancer mortality will result in a $500 billion benefit to the U.S. economy (Murphy, K. and Topel, R., Journal of Political Economy, 2006; 114(5), 871–904). In fact, such a benefit may ultimately be magnified many fold, because increasingly we recognize that cancer has become a model for developing our base of knowledge concerning many diseases. For example, the study of angiogenesis (blood vessel development) associated with tumor growth has been applied to greater understandings and treatment of macular degeneration, ischemic heart disease, diabetic wound healing, endometriosis and neurodegenerative illnesses. Furthermore, the unique capabilities of NCI's cancer researchers have been vital in other conditions. The identification of the AIDS virus and the development of assays to screen banked blood for the AIDS virus happened at the National Cancer Institute, where the current AIDS therapy regimen used around the world was also developed.

Today, the NCI is leading the way in identifying the genetic, molecular, and cellular mechanisms associated with cancer—research fronts that hold great potential to enhance research and research collaboration against other diseases, as well. Building upon the sequencing of the human genome and working in our newly developed "Center for Human Cancer Genomics," NCI is systematically identifying all the important inherited and acquired genetic alterations that contribute to cancer susceptibility. We are cataloguing genetic changes involved in the process of a normal cell becoming malignant, and we are applying this knowledge, in order to identify people at increased risk for developing cancer, prevent and detect cancer at its earliest, most treatable stages, and identify new targets for highly selective and specific therapeutic agents.

A RECORD OF REAL SUCCESS

The past year for cancer research and development has been one of substantial and heartening achievement. We are expanding both our knowledge and the technology tools to understand the mechanisms of cancer. Importantly, we are seeing scientific advances being rapidly applied to predict and preempt cancer.

—We reached an important public health milestone in June 2006, when the FDA approved a vaccine that prevents infection by the two types of the human papillomavirus (HPV) responsible for up to 70 percent of cervical cancer cases worldwide. We can all take great pride in the fact that our Nation's strong commitment to and investment in cancer research at NCI led to this approval.

—Researchers have begun to survey the human genome for DNA variants, to identify genes that predict risk for common cancers. Capitalizing on new knowledge of human genetic variation and technical advances in whole-genome scanning, The Cancer Genetic Markers of Susceptibility (CGEMS) project is currently targeting genes that increase the risk of prostate and breast cancer [Figure 2]. Work is beginning on a similar study for pancreatic cancer. These studies of large numbers of patients will be useful both for understanding causal pathways and for developing preventive interventions. DNA variants found to be associated with cancer risk will rapidly be made available publicly to the scientific community through the NCI cancer Biomedical Informatics Grid (caBIG?) database.

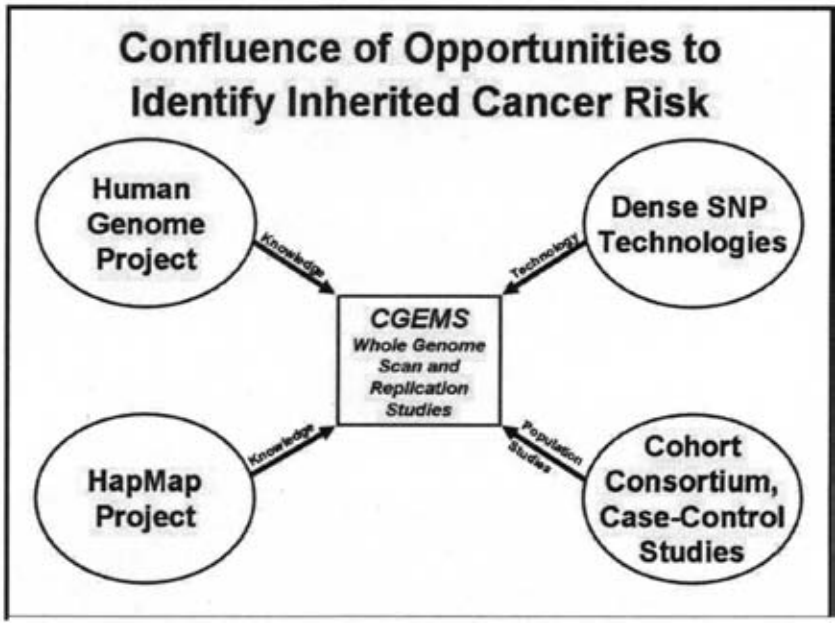


FIGURE 2.—*Previously developed technologies are used to analyze DNA specimens from large patient cohorts.*

—Genomic technology is already being applied to explain why some patients with diffuse large B-cell lymphomas (DLBCL) live longer and respond better to therapy than others [Figure 3]. Under the microscope, the DLBCL cancer cells from every patient look the same, but genetic differences have been shown to predict good versus poor prognosis. As a result of this research, it may be possible to determine which patients are most likely to respond to a specific treatment, thus sparing those patients unlikely to see a significant benefit the side effects of a failed treatment.

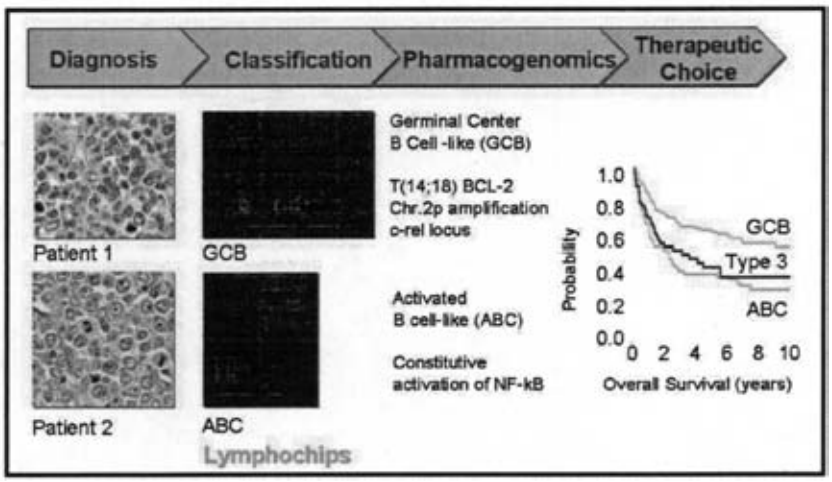


FIGURE 3.—*Previously developed technologies are used to analyze DNA specimens from large patient cohorts.*

DELVING DEEPLY INTO THE CANCER CELL ENVIRONMENT

Building on the success of the CGEMS project in identifying inherited genetic risks, the NCI and the National Human Genome Research Institute have launched a pilot phase of The Cancer Genome Atlas (TCGA), a collaboration designed to determine the feasibility of using large-scale genome analysis technology to identify important genetic changes involved in cancer. TCGA is currently studying lung, brain (glioblastoma), and ovarian cancers—which collectively account for more than 210,000 cancer cases each year in the United States.

Other initiatives are expanding our study of the cancer cell—and the networks and the cellular microenvironment that also appear to be significantly involved in tumor development and metastasis. These studies of molecular carcinogenesis are being conducted at the single-cell or the subcellular level, using high-resolution, three-dimensional electron microscopy. These technologies allow us to look within the nucleus to study differences in chromosome movement and location during stages of abnormal cell growth.

On another front, there is increasing evidence that cancer "stem cells" or "cancer initiator" cells are both the driving force behind many cancers and the basis for long-term risk. The presence of such cells, first demonstrated in acute myeloid leukemia patients, provides a different and exciting model with which to further explore cancer biology. NCI is establishing a group of scientists across the National Institutes of Health interested in embryogenesis and cancer stem cell biology, in order to advance the study of the underlying mechanisms in these processes.

ADVANCED TECHNOLOGIES ACCELERATE PROGRESS

It is clear that the area of advanced technologies development is absolutely essential and critical in creating tools for speeding up and enabling the discovery process. In addition to the genomic technology projects (CGEMS and TCGA), NCI is investing in the development of critical technology platforms in a number of other strategic areas, such as nanobiology, proteomics and computational biology.

Recognizing the key role of biospecimens in all of biomedical research, not just cancer research, NCI has led a pioneering effort to provide the first guidelines that standardize and enhance specimen collection and biorepositories. These guidelines have made it possible for NCI to develop a common biorepository infrastructure that promotes resource-sharing and enables data comparison among research laboratories, while also ensuring patient protection and ethical integrity.

We also believe that advanced imaging technologies will play a significant role in the prevention and preemption of cancer, as well as in making "go or no-go" decisions for early oncologic drug development. The NCI is working now in the aforementioned subcellular space, to be able to view—in real time—the interactions between drugs and cells and the resulting secondary functional changes. The NCI is

developing new targeted and non-targeted molecular imaging agents for use as lymphatic markers, angiogenic markers, and surrogate markers for drugs that enhance quantitative methods to measure early, real-time tumor response. These technologies are further examples of NCI initiatives that produce benefits that will be realized across multiple areas of biomedical research.

INTERAGENCY COLLABORATIONS

Addressing cancer requires work across institutional and sector boundaries, so members of the Department of Health and Human Services (DHHS) family of agencies, other federal offices, and the private sector can share knowledge and partner in the development of systems-based solutions. NCI has long been at the forefront of research and development of biomarkers for use in diagnosis and treatment for cancer. Now, a Biomarkers Consortium launched last year includes participants from the Foundation for the NIH, NIH, FDA, CMS, and private industry—with the goal of validating biological markers for a variety of diseases, including cancer. The first project approved by the Consortium is the evaluation of an imaging agent that detects an increase in cell metabolism characteristic of tumor growth. NCI is conducting trials in lung cancer and non-Hodgkin's lymphoma that use this ability to view cellular metabolism to monitor tumor masses for increased activity (cell growth) or decreased activity (cell death) during the early stages of anticancer treatment.

The joint NCI–FDA Interagency Oncology Task Force (IOTF), established in 2003 to enhance and accelerate the overall process of developing new cancer interventions, released two new guidance documents and a final rule intended to streamline the early clinical development of new drugs and biologics for cancer and other diseases. This has enabled the first-in-human "Phase 0" trial (a step before the classic Phase 1 level of drug study) that measures the activity of a new drug in a limited number of patients using a single, small dose of the study agent, prior to the traditional dose-escalation, safety and tolerance studies. Phase 0 will substantially compress drug development time.

TRAINING THE NEXT GENERATION OF CANCER RESEARCHERS

Cancer is one of the most exciting and innovative areas of medical research. It takes a superbly trained, highly effective workforce to make discoveries, to translate them into new interventions, and to put the improved knowledge base and cutting-edge tools to work for patients. NCI will continue to play an important role in developing the cancer research workforce in the United States and in other countries. We stand firmly by the Institute's commitment to provide unparalleled training opportunities for talented researchers from a wide variety of disciplines to advance their careers. In fact, many of the current programs at NIH had their origins in the NCI.

Of special significance are minority training programs, such as the Continuing Umbrella of Research Experiences (CURE), which begins with talented minority high-school students and continues progressively and selectively through long-term funding to qualified minority students interested in scientific, cancer research-related careers.

REACHING THE PATIENT AND COMMUNITY

NCI must continue to make progress for each cancer patient. Yet, the recent report on cancer deaths that showed a decrease in deaths nationally also confirms a troubling fact: Minority and low-income populations shoulder a disproportionate cancer burden and are not benefiting equally from important advances. We must bring the best science to patients, 85 percent of whom are treated in the communities where they live. With that obligation in mind, NCI is launching a pilot of the Community Cancer Centers Program (NCCCP). This pilot project will study how best to provide easily accessible, state-of-the-art, multi-specialty cancer care and earliest phase clinical trials research to patients in their communities. Through this program we will also learn best how to educate patients concerning risk, healthier living, screening practices, clinical trial participation, survivorship, and end-of-life issues.

This program is about bringing the newest science to patients where they live—a challenge that is more critical now than at any time in our history. Our nation's healthcare system faces many looming stresses, particularly in light of the fact that the first wave of baby boomers turns 65 in 2011. With the graying of a generation comes the need for a new way to confront the diseases of aging—and especially to anticipate what will be a marked increase in cancer incidence. That makes even more important our efforts to develop advanced technologies that will eventually

lead to the genomic and proteomic breakthroughs essential to enable us to preempt disease at earlier stages.

There is great cause for optimism, but an optimism that should be tempered by an understanding of the very real hurdles to progress we still face. These are challenges that we must address as a community. In doing so, the encouraging trends of decreasing death rates from cancer will become the rule, not the exception. We will learn how to deliver the best of our science to everyone—not just a few.

Senator HARKIN. Thank you, Dr. Niederhuber. Let's go on here unless you have a specific question right now.

Senator STEVENS. No.

Senator HARKIN. Dr. Barbara Alving was named as the Director of the National Center for Research Resources in April, although she served as acting Director before that. Her medical degree is from Georgetown University School of Medicine. Dr. Alving has published more than 100 papers in the areas of thrombosis and hemostasis.

Dr. Alving, welcome to the committee.

STATEMENT OF DR. BARBARA M. ALVING, DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES

Dr. ALVING. Thank you. Mr. Chairman, Senator Stevens, It's a great honor to discuss the mission and activities of the National Center for Research Resources today.

The research center is very different from the two ICs that you've heard about earlier. They are categorical. They're focused on specific disease areas, specific missions. The National Center for Research Resources, which is greater than a $1 billion center. Is really focused on providing the infrastructure and support to investigators and institutions throughout the country. That can really provide the support for studies in the categorical diseases.

CLINICAL AND TRANSLATIONAL RESEARCH

What we are focusing on at NCRR is clinical and translational research. By that, we're focusing on the ability to go from very basic studies, into preclinical studies, into clinical trials, and dissemination out into the public. The NCRR is very well situated for this.

For example, we have a division of comparative medicine that provides animal resources for the preclinical studies that are needed to test drugs before they go into clinical trials. We fund the eight national primate centers. I might add we also support Chimp Haven for the long-term retirement of those chimpanzees that have been involved in research.

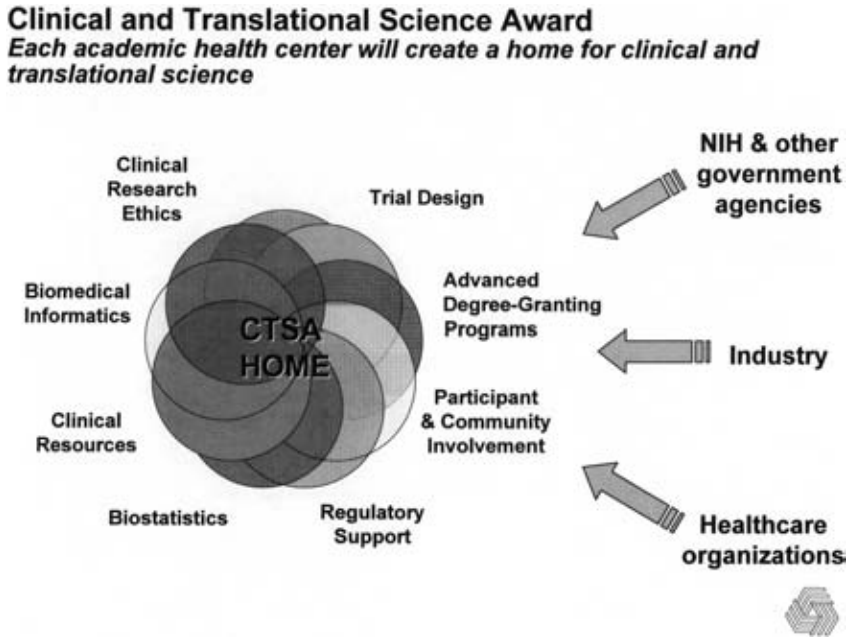
We fund biomedical technology resources that provide cutting edge research in new imaging techniques that can then be used in clinical trials.

We fund the General Clinical Research Centers that have been situated at academic institutions throughout the country to provide better ways to conduct clinical trials and the resources needed for biostatistics. What's very exciting is that this program of General Clinical Research Centers is now transitioning into a very large program known as the Clinical and Translational Science Awards.

In addition we fund outreach programs through our Science Education Partnership Awards that allow investigators to actually partner with museums to have public displays on, for example, re-

search opportunities, discussions of stem cell research, so that children throughout school systems can learn much more about the type of science, as well as the chronic diseases that are being studied in this country.

On the second slide here you see a little swirly area which represents a clinical and translational science award for an academic health center. As we have said, the General Clinical Research Centers that are funded throughout the United States are now going to be the academic health centers transitioning into receiving these clinical and translational science awards.

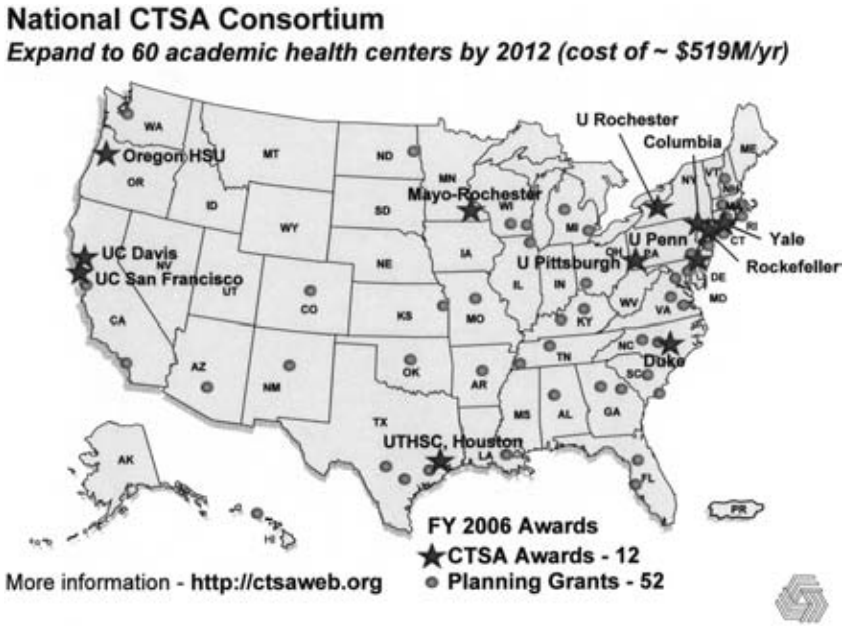


This means that each academic health center that receives such an award agrees to form a home for clinical and translational science. This will make all of our studies much more efficient, so that we can bring new research and new drugs out into the public much more rapidly and train a new generation of clinical and translational researchers. So they'll know how to interact with the FDA and they'll understand the rules. They will know how to develop better ways of doing clinical trials so that we can have more rapid accrual and less time delay and less expense.

Each of these academic health centers has agreed to form partnerships with the others, so this is really a consortium, and they will interact with industry as well as with other organizations such as Kaiser Permanente and the VA. These organizations are very rich in informatics and we want to bring interoperable informatics information systems throughout the country.

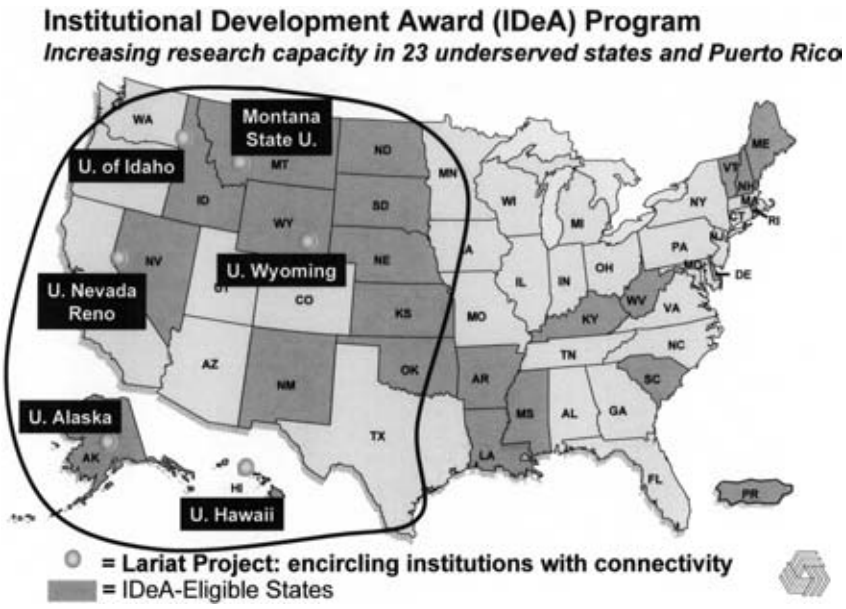
The third slide shows the United States in yellow. The little red stars show the first 12 CTSAs that have been awarded throughout the country. This was done in October 2006, along with 52 planning grants. By 2012, we hope to have 60 CTSA awards at a total

annual cost of $500 million per year. But we fund other large programs at NCRR, and we want to create a matrix of interactions with programs.



INSTITUTIONAL DEVELOPMENT AWARD

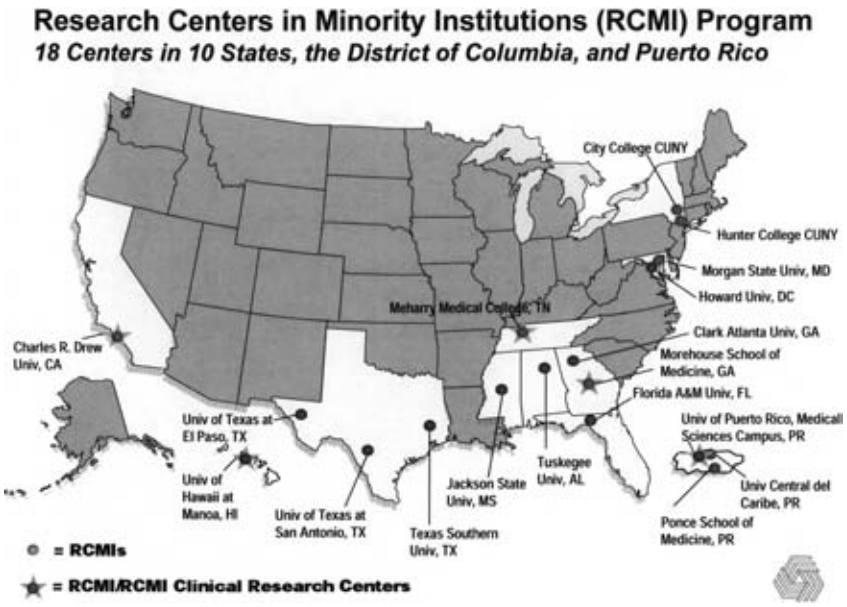
In the fourth slide you see the IDeA program. I think Senator Stevens is probably very well aware of this program. It is providing funding to 23 States and Puerto Rico that receive less—historically a lower amount of NIH funding. This is usually due because they have rural populations or small populations. These awards are allowing students from undergraduate colleges to have access to research training in some of the larger universities in these States.



We also realize they need to be connected because of their vast challenges of distance. So you see in the slide that shows the green States, those are the IDeA States red line which is Lariat. That's really a lasso to bring high speed information systems and fiber optic networks to six States that are very, very far apart that need to be connected. So through this Lariat project we've connected Hawaii, Alaska, Idaho, Nevada, Montana, and Wyoming. This provides the latest opportunities to conduct science through this high speed fiber optic system. It also has improved the economies of these States and allows the delivery of health care. We want to continue this in other areas.

RESEARCH CENTERS IN MINORITY INSTITUTIONS

If you go to the fifth slide to the map of the United States, you see another picture. You see the Research Centers in Minority Institutions. These are centers that include historically black academic health centers and Hispanic centers. These too, need to be linked up and have the latest opportunities.



We provide funding to these centers to conduct clinical research and training as well as basic research. What we're doing now is encouraging them and they are very eager to link up into this new clinical and translational science program. So we have Meharry talking with Vanderbilt. Morehouse is talking with Emory. Charles Drew is talking with UCLA. How can they form partnerships? How can they provide outreach to the communities?

MATRIX OF OPPORTUNITIES

Basically, at NCRR, we are now focusing throughout the center on translational and clinical sciences. We want to create a matrix of opportunities for this nationally, geographically and racially diverse matrix of academic health centers and other institutions. We want to include links to PHARMA, biotech, state and Federal agencies, as well as to CMS and the FDA, so that we can have a seamless interaction.

PREPARED STATEMENT

The whole result of this will be to provide better access to health care to our diverse populations. We're very aware of the increased amount of money going to health care. We want to make this much more efficient. We want to train the new generations of investigators who have to carry out this work.

Thank you for the opportunity to discuss this.

[The statement follows:]

PREPARED STATEMENT OF HON. BARBARA M. ALVING

Mr. Chairman and Members of the Committee: It is a privilege to present to you the President's budget request for the National Center for Research Resources (NCRR) for fiscal year 2008. The fiscal year 2008 budget includes $1,112,498,000. I appreciate this opportunity to discuss with you our vision of the future of health

and medicine and to share ways NCRR programs are transforming clinical and translational research.

The NCRR, which is one of the 27 Institutes and Centers at the National Institutes of Health (NIH), provides NIH-supported laboratory and clinical researchers with the infrastructure, tools, and training they need to understand, detect, treat, and prevent a wide range of diseases. With this support, scientists engage in basic laboratory research, translate these findings to animal-based studies, and then apply them to patient-oriented research. Through innovative programs and resources that transcend geographical boundaries, NCRR connects researchers with one another, and with patients and communities across the Nation. These connections bring together innovative research teams and the power of shared resources, multiplying the opportunities to improve human health.

TRANSFORMING CLINICAL RESEARCH

Given its mission and support to more than 30,000 basic and clinical researchers, NCRR has become the leader of the NIH Roadmap for Medical Research effort to energize the discipline of clinical and translational research. To remove the barriers identified by the research community, NCRR launched the Clinical and Translational Science Award (CTSA) program, which is a national consortium designed to more rapidly and efficiently facilitate the transfer of discoveries made in the laboratory into new treatments for patients. Through the CTSAs, academic health centers are developing centers, departments, or institutions for interdisciplinary teams that cover the complete spectrum of research from basic biology to clinical medicine. These academic homes also will train the next generation of researchers in translational and clinical research.

On September 30, 2006, we made the first CTSA awards to 12 academic health centers throughout the country. We will award the second group of CTSAs this fall. By 2012, the CTSA Consortium is expected to include approximately 60 CTSAs.

The impact of the CTSA Consortium will be far greater than the number of awards made. The Consortium will develop better designs for clinical trials, forge new partnerships with health care organizations, and expand outreach to minority and medically underserved communities. The CTSAs will focus on both types of translational research—ensuring first that basic discoveries are applied to the clinic and second that they are further translated into community practice. Improving clinical research informatics will be a prominent focus of the Consortium. Institutions are taking steps to prioritize their efforts to ensure that standards are developed, interoperability is enhanced, and communication resources are accessible to researchers and their patients.

To improve communication with the public and our stakeholders about our progress, as well as to foster collaborations within and beyond the Consortium, we recently launched the CTSAWeb.org site. I encourage you to visit the site and learn more about the CTSA Consortium. We also have started plans to evaluate the Consortium to ensure that the program spurs innovation, integration, inclusion, and dissemination.

Already, we are starting to see significant changes within and across the CTSA institutions. As a result of this effort, academic health centers are developing new curriculums, revamping their organizational structures, creating unprecedented partnerships with other medical and research disciplines, and generating medical advances. For example, the Institute for Translational Medicine and Therapeutics (ITMAT) at the University of Pennsylvania—a trans-institutional endeavor with the Children's Hospital of Philadelphia, the Wistar Institute, and the University of Sciences in Philadelphia—is leading clinical and translational research and fostering interdisciplinary science. Now with the CTSA award, ITMAT will also become the home to new centers in bioinformatics, personalized medicine, imaging, and chemical biology. At the same time, the University of Texas Health Science Center at Houston CTSA is encouraging participatory research by connecting with Hispanic communities on the border. By linking with NCRR's Science Education Partnership Award program in Houston, this CTSA is improving the public's understanding of the importance of clinical trial participation. As the CTSAs begin to work together, the benefits of the program will extend to the greater research community and ultimately be incorporated into clinical care.

I am pleased to report that this transformation is creating new energy and opportunities within NCRR and across the NIH. The CTSA initiative is further enhancing NCRR's long-standing investments in advancing translational research and providing new opportunities for community engagement. The addition of the CTSA Consortium to the matrix of NCRR programs is providing opportunities for increased cohesion and interaction throughout our entire research portfolio. Similarly,

the truly trans-NIH nature of the CTSA program is facilitating interactions among the NIH Institutes and Centers and helping to ensure that the benefits of the Consortium are realized across the full spectrum of medical research.

ADVANCING TRANSLATIONAL RESEARCH

Helping to propel the CTSA discovery engines are NCRR's translational research programs. Our readily available animal models and biomedical technology resources are fueling advancements in clinical care. We are exploring opportunities to enhance interactions among our translational programs and the CTSA Consortium to further capitalize on our research investments.

Animal models are the bridge between basic science and human medicine. The NCRR provides such models through specialized laboratory animals, research facilities, and training. Linking NCRR's animal resources with CTSAs will allow for more seamless translation from pre-clinical findings to clinical trials. This is already underway at two CTSAs, the University of California-Davis and the Oregon Health and Science University, which are connecting with the NCRR-supported National Primate Research Centers at their institutions. To provide researchers with easier access to animal models, and thus further accelerate translational research, we sponsored a workshop in 2006 to explore approaches to develop a resource that would enable researchers to find and use animal and other biological resources more efficiently. Based on stakeholder recommendations, we are planning to fund a comprehensive electronic catalog of animal model resources in fiscal year 2008.

Technologies are critical throughout all stages of biomedical research—from basic discovery to clinical application. The NCRR support for biomedical technology (BT) resource centers provides researchers with a broad spectrum of technologies, techniques, and methods. Across the nation, researchers depend on these centers for a wide variety of clinical and translational studies. For example, researchers at the University of Illinois are developing software to help analyze the motions of viruses, so that they can better predict the virulence of these organisms. At the University of Wisconsin-Madison, another BT resource center, researchers are using advanced nuclear magnetic resonance technologies to develop faster and more cost-effective methods for studying how biological systems work and respond to drugs. In the future, technologies developed at the BT resource centers may lead to discoveries that the CTSAs can translate into improved patient care.

ENHANCING COMMUNITY ENGAGEMENT

The launch of the CTSA initiative has further enhanced our appreciation of the need to actively engage not only the researchers but also the American public. Our programs are providing opportunities for people in underserved communities to participate and shape medical research. Our innovative science education programs are inspiring children to pursue careers in biomedical research and are increasing the public's understanding of medicine. By reaching out to new collaborators and strengthening our partnerships, NCRR is facilitating connections that are sparking new discoveries and maximizing the effectiveness of the matrix of NCRR programs.

NCRR has two successful programs that are creating new research opportunities for underserved communities. First, the Research Centers in Minority Institutions (RCMI) program increases the number of minority scientists engaged in biomedical research and enhances the research capacity and infrastructure at minority colleges and universities that offer doctorate degrees in health sciences. This program increases the number of minority scientists engaged in biomedical research and facilitates studies on minority health. Second, the Institutional Development Award (IDeA) program fosters health-related research and increases the competitiveness of investigators at institutions in 23 states and Puerto Rico, which have historically low aggregate success rates for grant awards from the NIH. The IDeA program provides workforce development, research opportunities, science education, and extends high-speed connectivity to IDeA institutions to facilitate research collaborations. For example, NCRR funded the Lariat Project to provide six states (Alaska, Hawaii, Idaho, Montana, Nevada, and Wyoming) with high-speed, fiber-optic network connections. This project has improved not only research capacity in these states, but also enhanced their economic development, higher education, and healthcare opportunities. To ensure these underserved communities have access to innovative research opportunities, we are exploring ways to facilitate partnerships with these communities and the CTSAs.

One of the many ways that community engagement is improving research is through a component of the IDeA program called IDeA Networks of Biomedical Research Excellence (INBRE) program. This program enables critical connections among different research institutions and facilities, as well as between mentors and

students. For example, the Montana INBRE brought together the seven tribal colleges within the state to conduct collaborative research projects. Today, these tribal colleges, which prior to the INBRE program had not interacted on research projects, are working together to identify research areas and collaborate with other undergraduate institutions within Montana.

Community engagement is synonymous with the NCRR Science Education Partnership Award (SEPA) program. By bringing together active biomedical and clinical researchers with educators, community leaders, and other interested organizational leaders, SEPA is stimulating public interest in health issues and encouraging young people to pursue careers in medical research. SEPA grantees currently collaborate with several RCMI and IDeA institutions and are beginning to make similar connections through CTSA community engagement activities. At Jackson State University, RCMI- and IDeA-funded researchers have partnered with the Jackson Public Schools through a SEPA grant to provide mentoring and research internships for students and professional development for teachers. Another SEPA project at the University of Utah, offers over 100 online activities, podcasts, and virtual labs on topics ranging from cloning to stem cells.

Innovative partnerships are providing the cohesion needed to ensure that the matrix of NCRR programs results in a maximum return on investment for all Americans. We are expanding our outreach efforts with the pharmaceutical industry, healthcare organizations and providers, and other Federal agencies, such as the Food and Drug Administration and the National Science Foundation. These collaborative partnerships will not only enable us to make research discoveries faster, but will ensure that these discoveries are quickly translated into improved patient care.

CONCLUSION

Through our matrix of programs and partnerships, NCRR expects to fulfill its charge to transform the practice of clinical and translational research and in turn, improve the future of health and medicine. The launch of the CTSA Consortium marks an exciting time in the history of NIH and for our Nation. It further enhances NCRR's long-standing investment in basic, translational, and clinical research. Our innovative programs and partnerships are maximizing our research investment to ensure that medical advances are reaching the people who need them.

Senator HARKIN. Dr. Alving, thank you very much.

Now we turn to Dr. Patricia Grady, who has served as the Director of the National Institute of Nursing Research since 1995. She pursued her graduate education at the University of Maryland, receiving a Master's Degree from the School of Nursing and a Doctorate in Physiology from the School of Medicine. Dr. Grady's scientific focus is primarily in stroke research.

Dr. Grady, welcome back to the committee.

STATEMENT OF DR. PATRICIA A. GRADY, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH

Dr. GRADY. Thank you, Mr. Chairman. I appreciate the opportunity to present to you, Senator Stevens and the staff, a brief description of some of the activities that are going on at the National Institute of Nursing Research.

The NINR supports clinical and basic research to establish a scientific basis for the care of individuals across the life span. NINR's research has contributed to improving the health of the American people for more than two decades. Our 20th anniversary provided an opportunity to look toward the future and update our strategic plan which formulates innovative ways to address the major health challenges facing our Nation, including the concurrent trends of an aging population, a growing racial and cultural diversity, an increasing reliance on technology and a rising demand for nurses.

In response to these and other challenges, you heard the Director of NIH call for a new kind of health care system. In the spirit of today's hearing I would like to briefly describe for you important

research that is preemptive and predictive and how that research is shaping our vision for the future.

The first preemptive example could have major implications for improving the lives of premature infants and their parents. Current practice during the birth of a pre-term infant is to clamp the umbilical cord immediately after delivery. However, delayed cord clamping has been shown to have certain advantages for the infant.

In a recent study, NINR supported investigators compared the effect of immediate verses delayed umbilical cord clamping. The results of this simple modification were very encouraging. Infants in the delayed cord clamping group had nearly a ten-fold lower rate of late onset infection and nearly a three-fold lower rate of brain hemorrhage. Each of these complications carries a high risk of disease, disability and death.

Another study tested the effect of a coping intervention for parents of pre-term infants, in which parents participated in a program about prematurity, infant behaviors and infant development. The effect of this program was dramatic. Parents demonstrated improved parenting behaviors and reported decreased stress levels. Moreover, the infants averaged 3.8 fewer days in the Neonatal Intensive Care Unit, which translated to a savings of roughly $5,000 per infant.

Developing preemptive strategies to reduce the risk factors for cardiovascular disease is another important research focus for us. A group of investigators tested a community based behavioral educational intervention to improve blood pressure management among young African American men. The intervention reduced blood pressure and subsequently reduced by half the incidence of left ventricular hypertrophy, a form of heart damage caused by high blood pressure.

We've also made strides in studying and preventing medical errors that continue to trouble our hospitals and clinics. For example, surgical sponges accidentally left inside patients can lead to complications ranging from infection to death. NINR investigators demonstrated that a radio frequency identification tag system for surgical sponges could quickly and accurately detect the presence of sponges retained at surgery. This is just one example of the type of innovative research needed to reduce the adverse health effects and significant cost implications associated with medical errors.

Investigators have also demonstrated a clear link between low nurse staffing levels and an increase risk to patients.

Senator HARKIN. What?

Dr. GRADY. Low nurse staffing levels and an increased risk to patients. Decreased nurse staffing levels are associated with increased mortality and morbidity, specifically, infections and other complications. These studies highlight the importance of the growing national nursing shortage upon the health of our population.

Finally, nowhere is the need for better preventive and preemptive efforts greater than in the minority communities and in other underserved populations. Recently scientists reported the first randomized controlled trial of a culturally tailored HIV risk-reduction program for Hispanic adolescents, a program that was successful in reducing risky behaviors for up to 1 year.

Another group of scientists developed an intervention that reduced stress and depression in low income single mothers, improving their ability to care for their children. Programs such as these are critical for reducing health problems in vulnerable communities and demonstrate the progress we have made already.

Let me now provide you with a few examples of new methods for predicting the needs of patients and for anticipating ways to proactively maintain quality of life for patients and their caregivers. One example of predictive illness management comes from NINR's research on the care of patients at the end of life. As you probably know, NINR is the lead institute at NIH for this important area of research.

One of our research teams characterized the functional decline in patients with specific illnesses in the last year of life. Trajectories range from—sudden, unexpected death to variations in illness and recovery, to steady and irreversible decline. This knowledge helps caregivers to better anticipate the course of illness, allowing the health team to tailor treatment strategies and improve quality of care.

Yet another study showed that minority patients who used spiritual coping are more likely to want aggressive care at the end of life such as life support, tube feeding or mechanical ventilation. Such findings can allow caregivers to better incorporate the culturally based needs and desires of patients and their families.

PREPARED STATEMENT

In conclusion, NINR is strongly committed to the NIH vision of a healthier Nation. We are proud of the important progress we have made toward this goal and we look forward to continued successes. We stand ready to address tomorrow's challenges based upon our 20 years of scientific accomplishments. Thank you, Mr. Chairman, Senator Stevens. I'd be happy to answer any questions that you or the Committee might have.

[The statement follows:]

PREPARED STATEMENT OF DR. PATRICIA A. GRADY

Mr. Chairman and Members of the Committee: I appreciate the opportunity to present the fiscal year 2008 President's budget request for the National Institute of Nursing Research (NINR). The fiscal year 2008 budget included $137,800,000.

INTRODUCTION

The mission of the NINR is to support clinical and basic research that establishes a scientific basis for the care of individuals across the lifespan—from management of patients during illness and recovery to the reduction of risks for disease and disability, the promotion of healthy lifestyles, promoting quality of life in those with chronic illness, and care for individuals at the end of life. NINR's research programs also place special emphasis on eliminating health disparities and on the health issues faced by the underserved.

NINR's research has contributed to improving the health of the American people for more than two decades. In 2006, NINR concluded the year-long observance of our 20th anniversary at NIH. During that period, we took stock of our scientific accomplishments, recognized our contributions to clinical practice, and launched a newly revamped web-site in support of our stakeholders. We also assessed the future role of nursing science in addressing the major health challenges of our Nation: an aging population; a growing racial and cultural diversity and the attendant health disparities; an increasing reliance on technology in health care settings; and a rising demand for nurses. Within this context, NINR developed a new, forward-looking Strategic Plan.

NINR's new 5-year Strategic Plan elucidates a unified framework for addressing the dynamic health care landscape. The Plan leverages key strengths of the NINR research community and focuses on areas of critical research opportunity including: Self-Management, Symptom Management, and Caregiving; Health Promotion and Disease Prevention; Research Capacity Development; Technology Integration; and End-of-Life. Pursuing this strategy, we seek to apply NINR's resources to the areas of public health which have the greatest needs, and in which NINR can have the greatest impact.

Allow me to briefly describe our programs within this framework, highlight recent accomplishments, and share our vision for the future.

NINR RESEARCH PROGRAMS

Self-management, Symptom Management, and Caregiving.—NINR's focus on the quality-of-life science continuum comprises three key research concepts: self-management, symptom management, and caregiving. Self-management science explores strategies that empower individuals to be more involved in their own health practices. Symptom management science focuses on biological and behavioral components of health and illness that improve the management of symptoms. Caregiving science addresses the quality-of-life dimensions experienced by care recipients as well as formal and informal caregivers across diverse health care settings.

Improving Care of Premature Infants.—According to the Centers for Disease Control and Prevention (CDC), half a million preterm infants are born in the United States each year, carrying a significant risk of death and disability, and often requiring care in a neonatal intensive care unit (NICU). In addition, their parents endure high levels of stress, anxiety, and depression (Miles, 1999; Singer, 1999, Wereszczak, 1997).

In one study, NINR-supported investigators assessed the effect of "immediate" (7 seconds) versus "delayed" (32 seconds) umbilical cord clamping on health parameters of preterm infants. Compared to the immediate clamping group, infants in the delayed group had nearly a 10-fold lower rate of late-onset septic infection, which carries a high risk of morbidity and mortality (IOM, 2006), and nearly a 3-fold lower rate of intraventricular hemorrhage, which carries a risk of developmental deficits (IOM, 2006).

Another study by NINR-supported investigators assessed the effect of an educational program on the psychological care needs of parents of preterm infants. Utilizing the Creating Opportunities for Parental Empowerment (COPE) educational program, parents were taught about prematurity, infant behaviors, and infant development. As a result, parents demonstrated improved parenting behaviors and reported decreased stress levels. Meanwhile, the infants averaged 3.8 fewer days in the NICU than controls, which translated to a savings of roughly $5,000 per infant (Melnyk, 2006).

Taken together, these studies demonstrate the significant potential benefits of combining a minor modification to a medical procedure at virtually no cost and an educational program during the care of preterm infants to improve health outcomes while reducing health expenditures. Their adoption into standard practice, and the exploration of additional approaches, could result in a more robust reduction in prematurity-related complications in early childhood, disability, death, and health care costs in excess of the $2.5 billion in estimated potential savings through the COPE intervention alone ($5,000 savings per infant multiplied by the estimated 500,000 preterm infants born in the United States each year).

Quality-of-life research directly impacts populations across the lifespan from the very early stages of life. In 2007, NINR plans to support research on symptom clusters in cancer and immune diseases, as well as biobehavioral research methods.

Health Promotion and Disease Prevention.—Within Health Promotion and Disease Prevention, NINR scientists explore dimensions of behavior, health in community settings, patient safety, and the biological factors useful in ensuring long-term positive health outcomes.

Culturally-tailored HIV/AIDS Intervention for Hispanic Youths.—According to the CDC, the incidence of acquired immune deficiency syndrome (AIDS) is up to three times higher among Latino adolescents than among their white counterparts (CDC, 2004). NINR-supported scientists tested a culturally-tailored HIV education program called "Cuidate! (Take Care of Yourself)" among Hispanic adolescents. Compared to controls, youths in the program were 34 percent less likely to report having had sexual intercourse in the past 3 months, 47 percent less likely to report having multiple partners across the follow-up period, and reported more consistent use of condoms. This study demonstrates the benefits of a customized, population-specific

intervention and highlights its potential to reduce health disparities if applied across a range of settings (Villaruel, 2006; Jemmott 1998).

In 2007 NINR plans to support research that incorporates an in-depth knowledge of cultural factors into HIV prevention studies among young people.

Research Capacity Development.—NINR is engaged in enhancing the research capacity of nursing science. NINR supports pre- and post-doctoral training through both individual and institutional training grants. NINR also supports Research Centers to establish and maintain hubs of research, such as the NINR Nursing Partnership Centers on Health Disparities, which bring together colleagues from research intensive institutions and minority-serving schools of nursing, with the goals of exploring health disparities research questions and training investigators from underrepresented populations.

In 2008, NINR will support academic research enhancement opportunities in minority-serving institutions.

Technology Integration.—NINR's focus on improving health care and quality of life encompasses the development, use, and adaptation of technologies. Functional technologies that assist patients and those that facilitate reporting of biological indicators of health and disease status form the framework of the technology integration program, including uses of technology for telemedicine, patient education, communication, and patient safety.

Radiofrequency Identification (RFID) and Patient Safety.—The Institute of Medicine (IOM) estimates the cost of medical errors to be over $37 billion annually; nearly half is associated with preventable errors; and, up to 98,000 deaths each year are attributable to medical errors (IOM, 1999). Currently, certain medical errors such as the retention of surgical sponges within patients after surgery persist. NINR-supported scientists have demonstrated that a radiofrequency identification (RFID)-tag system for surgical sponges accurately detected the presence of sponges retained at the surgery site after wound closure was simulated. If implemented into practice, this approach may not only contribute to the reduction of medical errors, but also decrease both the time spent in the hospital as well as heath care expenditures.

In 2008, NINR plans to support studies focused on stimulating technological strategies that improve health outcomes through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs.

End-of-Life.—The science of end-of-life explores research questions of this complex period for dying persons, family members, and both professional and informal health care providers. End-of-life scientists seek to understand not only biological aspects of dying, but also the needs of dying persons, including symptom relief, decision-making, advance directives, and palliative care. In addition, issues of culture, age, spiritual beliefs, and disease-specific considerations are included in research strategies.

Chronically Critically Ill and End-of-Life Care Preferences.—Patients who are or may become chronically critically ill may benefit from having advance directives in place should they lose the ability to communicate their preferences. NINR-supported investigators examined the frequency of documentation of advance directive choices of 1,128 patients hospitalized with a chronic critical illness. Results indicate that about two-thirds did not have an advance directive to document their care preferences, and may benefit from an educational program in end-of-life care and documenting their preferences.

CONCLUSION

NINR's dedicated investigators act on their clinical experience and insight to develop and test innovative solutions to the major health challenges facing our society. Equipped with a new Strategic Plan, we aim to sustain the pace of nursing science discoveries in the years ahead by bringing together innovation and determination within a strategic framework to improve clinical practice and patient care. With 20 years of research, NINR has garnered expertise for new opportunities to address tomorrow's challenges.Thank you, Mr. Chairman. I will be happy to answer any questions that the Committee might have.

Senator HARKIN. Thank you very much, Dr. Grady.

Now we turn to Dr. John Ruffin, who is the Director of the National Center on Minority Health and Health Disparities. He's led the effort at NIH to promote minority health and reduce health disparities for over 15 years and oversaw the development of the first Comprehensive Health Disparities Strategic Plan at NIH.

Dr. Ruffin, welcome to the committee. Please proceed.

STATEMENT OF DR. JOHN RUFFIN, DIRECTOR, NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES

Dr. RUFFIN. Thank you, Mr. Chairman, Senator Stevens. Today I'm here to give you a brief report on the progress the National Center on Minority Health and Health Disparities and the National Institutes of Health is making to promote the improvement of health among our Nation's racial and ethnic minority population. To advance research toward eliminating health disparities among all affected populations including the medically underserved, poor and rural populations.

Senator Specter, I'm sure you will recall the hearings that you and others convened in the late 1990s on minority health and health disparities. I participated in many of those hearings which ultimately led to the creation of the NCMHD. The release of the Institute of Medicine report entitled, "Unequal Treatment", came right on the heel of the Center's creation. That report, you will recall, was a vivid depiction of the state of affairs of the health care system and health among this Nation's diverse population.

Six years ago Congress established the NCMHD and gave us the authority to be the focal point at the National Institutes of Health for Minority Health and Health Disparities research. We took that authority seriously and have established the basis to fulfill our mission. There are a number of things that we know related to minority health and health disparities and then there are some unknowns that we continue to work toward understanding.

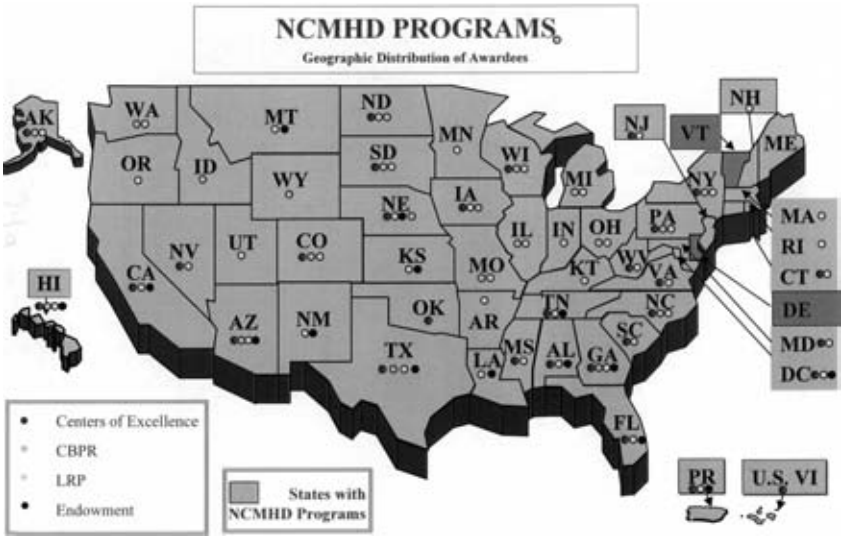
For example, what we have not yet uncovered is the cause of health disparities. We still do not know why racial and ethnic minorities and poor populations across this Nation continue to be burdened by diseases and conditions like HIV/AIDS, cancer, infant mortality, mental health and stroke, for example. What we do know is that there are multiple factors that contribute to disparities in health.

These are the types of issues that we are seeking to understand through our own research at the NCMHD as well as through the research efforts of the Institutes and Centers that my colleagues around the table spearhead, and other Institutes and Centers at NIH that are not represented here today.

Our approach to health disparities is multi-proned. Through research we study the diseases, the conditions, and the issues to gain insight into the core of the problem. To conduct research we have to have the capacity, the facilities and the workforce to carry out the studies. We also need to have the community involved, not only as research subjects, but actively engaged in planning and conducting research, translating the research results and—disseminating the information back into the communities.

To get at this, you, the Congress, statutorily mandated four initiatives that would set the framework for us to accomplish our goals in these areas. Those are our Centers of Excellence program, Research Endowment Program, Loan Repayment Program and the Community Based Participatory Research Program.

If you look at figure 1 the map, which I gave to you in the book there, you will note that geographically our programs are in every State except Vermont and Delaware. So we have set the foundation by implementing the programs that you mandated.



So what difference are we making to eliminate health disparities using this multifaceted strategy? If you look at the Centers of Excellence, much of the multidisciplinary research that we are conducting in communities across the country is being carried out through the Centers of Excellence Program that you authorized. We have funded 76 Centers nationwide since 2002.

Our research endowments have led to the establishment of educational and training facilities such as pharmacy and public health schools. We've helped approximately 17 institutions to build their competitive edge for health disparities research. In order to attract the best and the brightest to the health profession, we have made loan repayment awards to about 1,100 highly qualified doctorate level health professionals. An estimated two-thirds of the graduates have secured academic or research positions.

Imagine cutting edge biomedical research being led within our communities by members of the community. That's what our Community-Based Participatory Research Program is about. We launched this three-phase program in 2005. We received an overwhelming number of applications, approximately 180. Today we are supporting 25 grants under this program.

Mr. Chairman, our portfolio at the NCMHD is small in terms of dollars and numbers of programs, but that does not prevent us from fulfilling our mission. Collaboration is a large part of what we do within the NIH and with other agencies including my colleagues represented at this table.

Some of the initiatives within their health disparities portfolio that we have helped to support include: the Health Disparities Nursing Research Center for the National Institute of Nursing Research, the Bioethics Center at Tuskegee University with the National Center for Research Resources, research on autoimmune disease with the National Institute of Allergy and Infectious Diseases and the Vanderbilt-Meharry Comprehensive Cancer Center with the National Cancer Institute.

In conclusion, the NCMHD is making progress to predict and preempt disease through its Centers of Excellence and Community Based Participatory Research Program. We're building a culturally, competent workforce to deliver personalized medicine using the loan repayment program. Our Community-Based Participatory Research Program also embraces a critical element of medicine and that is the participatory aspect.

Overall, our contribution has heightened awareness about health disparities, has increased the Nation's capacity to conduct health disparities research, recruited, trained and attracted an increasing cadre of individuals to research careers on minority health and health disparities and germinated innovative and productive partnerships involving the community. But we have barely touched the surface. There is far more to be done.

PREPARED STATEMENT

The success of our health disparity effort, Mr. Chairman, depends upon our ability to further develop and sustain good models that we have all established. I thank you for the opportunity to brief you today.

[The statement follows:]

PREPARED STATEMENT OF DR. JOHN RUFFIN

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Center on Minority Health and Health Disparities (NCMHD) for fiscal year 2008, a sum of $194,495,000, which represents a decrease of $895,000 over the comparable fiscal year 2007 appropriation.

At the turn of the 21st century, the issue of health disparities was still a pervasive public health challenge. Racial and ethnic minority and medically underserved populations were suffering disproportionately from disease and death; individuals living in medically underserved communities in rural or urban cities were also experiencing similar disparities in health status and health outcomes; there was a national need for minority scientists in biomedical, clinical, behavioral, and health services research. There were very few racial and ethnic minorities in science, technology or engineering. This raised concern about the future of these fields and their potential to eliminate health disparities given the nation's changing demographics, and the projected significant increase of racial and ethnic minority populations.

This depiction of health in America was a part of the impetus for the creation of a national Center to address minority health and health disparities. Recognizing the gaps and the challenges, and understanding the promise of biomedical research, the Congress wisely established the National Center on Minority Health and Health Disparities (NCMHD) on the premise that through research, training, dissemination of information, and other programs, minority health would be improved, and health disparities would be reduced in the short-term and eliminated in the long-term. The NCMHD has embraced multiple partnerships as the guiding principle for understanding and addressing this national health crisis.

While the overall health of the American population has improved, sadly, health disparities have not declined. Nevertheless, within the past six years the investments of the NCMHD have positively impacted communities throughout this nation and globally. Our contributions have heightened awareness about the seriousness of health disparities; increased the nation's capacity to conduct health disparities research; recruited, trained and attracted an increasing cadre of individuals from health disparity populations to research careers on minority health and health disparities; and germinated novel and productive partnerships involving the community.

UNDERSTANDING HEALTH DISPARITIES

The Centers of Excellence program has become a leading force for research into various diseases and health conditions in health disparity populations such as HIV/AIDS, mental illness, obesity, diabetes, cardiovascular disease, stroke, infant mortality, and cancer. Collectively, these Centers have published more than 200 articles

on the priority diseases/conditions and issues related to minority health and health disparities among all racial and ethnic minority, medically underserved, and low-income populations. Leveraging of resources and expertise with other NIH Institutes and Centers and federal agencies, and among our grantees has fortified our capacity to conduct research into the most critical diseases and issues concerning disparities in health. Basic, clinical, social science and behavioral studies are examining the many factors that are believed to contribute to poor health in our communities. Understanding the cause of disparities in health is pivotal in determining and applying appropriate preventive, diagnostic, and treatment modalities.

Access to health care is a major health problem that potentially perpetuates health disparities. Those who have more resources are better positioned to benefit from costly new discoveries in science and medicine. An estimated 45 million Americans have no health insurance, most of them being racial and ethnic minority, rural, and low-income populations. A lack of access can delay timely medical care and increase the effects of disease without proper treatment. A study examining adherence to cervical cancer screening guidelines among publicly housed Hispanic and African-American women, found that only 62 percent of those sampled had received a screening for cervical cancer within the past year. 29 percent of the participants noted that no health care provider had ever notified them that they needed a screening test for cervical cancer. In this study, Hispanic and older women were far less likely to adhere to screening guidelines. The results prove the need for continued and increased efforts to ensure that medically underserved racial and ethnic minority women have access to cancer screening services. Understanding the complex nature of health disparities and the influence of socio-economic, biological, environmental, behavioral, and other factors, remains a research challenge that we must continue to examine through pioneering research.

TRAINING THE WORKFORCE: REMOVING THE BARRIERS

Access to health care is a multi-pronged problem that is complicated by the shortage of health professionals from underserved communities. Racial and ethnic minorities make up only 14 percent of the physicians in America. The NCMHD and its partners have been working to diversify and strengthen the science workforce through training. Two-year loan repayment awards have alleviated the financial burden of pursuing higher education for approximately 1,100 health professionals. These trainees with MD, PhD, DDS, and other doctorate level science degrees, engage in research, health promotion, and outreach activities in numerous disciplines to heighten awareness and deepen our understanding of specific diseases and conditions, and issues in health disparities.

Racial and ethnic minorities represent 64 percent of the current pool of NCMHD loan repayment awardees. An estimated two-thirds of the graduates have secured academic or research positions. The funding provided by loan repayments have helped to advance the careers of awardees and expose them to additional funding sources for their research activities. The program is slowly, but evidently achieving its mission to recruit and retain highly qualified health professionals in the workforce. In 2006, endowment funding supported the training of two Native American students completing the four-year Doctor of Pharmacy program at the University of Montana. This is a significant accomplishment because of the critical need to create permanent tenure track positions for Native Americans. At the University of Wisconsin at Madison, School of Public Health, the infrastructure established with NCMHD funding has helped to secure funds for a Health Disparities Research Scholars Training Program. This five-year training program will commence in Spring 2007 and it is anticipated that it will increase the number of researchers committed to health disparities. We will continue to enhance our focus on the recruitment and retention of individuals of health disparity populations to develop a culturally competent and well-trained workforce to address the burden of health disparities in our diverse communities.

CREATING THE COMPETITIVE-EDGE

The quality of health among health disparity populations, and the delivery of health care can be improved by training a diverse workforce that is representative of the community being served. However, in order to conduct innovative research, it is essential to have the right capacity such as the facility, faculty, students, and training programs. Notable progress has been made in developing research capacity at more than 40 academic institutions.

Having an endowed chair signals an institution's strength in a specific discipline. It is an incentive for a medical school to recruit and retain the most preeminent faculty in a given field, and adds credibility to its medical education program. En-

dowed chairs traditionally have been located at the most prestigious medical schools. NCMHD funding has established endowed chairs at three minority-serving institutions, Meharry Medical College, Morehouse School of Medicine, and the University of Hawaii. These endowed chairs are vital to building a critical mass of distinguished scientists in cancer, cardiovascular disease, diabetes, neuroscience, women's health, and Native Hawaiian health. This will place these institutions on the competitive edge to advance their study of minority health and health disparities in these fields. At Meharry, the endowed chair funds have helped to recruit a nationally renowned scientist to lead its Center for Excellence in Health Disparities Research in HIV/AIDS.

Research capacity in terms of physical infrastructure has increased considerably at several institutions after obtaining NCMHD funding. In some instances, facilities for health disparities research did not exist prior to NCMHD Centers of Excellence funding. Today, Charles R. Drew University has space totaling 8000 square feet, New York University 3,900 and Claflin University 3,403 square feet dedicated to conducting health disparities research. As a result, these institutions have been able to expand their research and training activities. The University of South Carolina-Claflin EXPORT Center recently erected a Molecular Virology Laboratory at Claflin University which houses state-of-the-art equipment for microscopic gene cell isolation and examination, where HIV viral load assays for example, can now be studied. The University of New Mexico houses the only School of Medicine in the state, and endowment funds have helped to establish the Institute of Public Health to address chronic health issues among low income and racial and ethnic minority populations.

VALUE OF PARTNERSHIPS

Our success in eliminating health disparities will ultimately depend on our ability to translate the lessons learned from our research endeavors, into usable tools and programs for the community. We have expanded our partnership base, and moved beyond the tradition of limiting partnerships to academic institutions, into domains where we can have the capacity to respond to health disparities in any form. We have continued collaborations NIH-wide, across the Department of Health and Human Services, and with other agencies such as the Department of Justice. Our efforts also have engendered unique partnerships between academia and the community; the community and local, state or federal agencies; research-intensive institutions and minority-serving institutions; and among NCMHD Centers of Excellence within a given state and state health agencies.

In partnership with the National Institute of Environmental Health Services, the private sector, universities and schools, molds and other allergens that may trigger asthma in children are being studied post-Katrina. In conjunction with the DHHS Office of Minority Health we mobilized our Centers of Excellence to respond to emergency health needs in the community and offer research opportunities at NIH for scientists after Hurricane Katrina. Today, the community is benefiting from electronic medical records, and telemedicine programs that are being incorporated into the health care infrastructure. In Oklahoma we have been able to reach more than 65,000 American Indians through a partnership of the Oklahoma Project EXPORT Center with nine tribes. The power and impact of our partnerships has touched the global community from state to state to places like Asia, Africa, Europe and the Caribbean where our students and faculty engage in research training.

IMAGINE THE FUTURE

We have begun to set the foundation through our research, training, capacity development, and outreach efforts to transform the health of this nation, but we have barely touched the surface. There is far more to be done. In three years, according to the Healthy People 2010 report, health disparities should be eliminated. However, the recent Midcourse Review of the report underscores the fact that not enough has been done overall to demonstrate any significant decline in health disparities.

Imagine a Nation where differences in health status and health outcomes no longer exist among populations. Imagine a nation where all Americans can lead a long and healthy life. Imagine a country where all Americans can access quality health care. Imagine physicians and health care professionals of all racial and ethnic backgrounds, in any specialty, practicing in every community across this country. Imagine cutting-edge biomedical research being led within our communities by members of the community. Imagine the discovery of solutions for critical diseases like diabetes, mental illness, cardiovascular disease, HIV/AIDS or obesity emerging from a community lab.

At the NCMHD we are cognizant that no single entity alone can solve the complex problem of health disparities. The sustainability and success of our health disparities efforts depends on strategic partnerships. We will continue to expand our network to address the diseases and issues that are already familiar to us, and examine new and emerging health disparities challenges in prisons, housing communities, or among our men. We must also be able to respond to health crises as they arise. Novel and multi-faceted strategies must be exercised and increased at the community, national and global level if we are to succeed in using the power of biomedical research to transform the health of racial and ethnic minority and medically underserved populations and eliminate the scourge of health disparities.

NCMHD PROGRAMS

Senator HARKIN. Thank you very much, Dr. Ruffin. I assume on this map you gave us, that CBPR, the green dot, is Community Based Participatory Research?

Dr. RUFFIN. That's correct, sir.

Senator HARKIN. We don't know how many are in each State. We just know there's something going on there, right?

Dr. RUFFIN. I think I can also tell you we've established 25 of those programs thus far. I think I have a map that I might be able to share with you that shows the distribution of those 25 programs.

Senator HARKIN. Tell me again what's that loan repayment program? How does that work?

Dr. RUFFIN. The loan repayment program is where we pay back the loans of individuals who go into health disparities research. These individuals get about $35,000 a year, principal and interest is paid as a repayment for those individuals to go into health disparities research. It is modeled a lot like the AIDS-Loan repayment program which many of you are familiar with, except in this case, our loans are given to not just MDs but to all health professionals.

Senator HARKIN. Would that be nurses too?

Dr. RUFFIN. Nurses, dentists, individuals in clinical psychology, sociology, all of the medical professions are eligible to apply for these loan repayment programs.

Senator HARKIN. Interesting. I have to find out more about that.

VACCINES

Dr. Fauci, I would like to talk a little bit about vaccines. As you know we have provided over $6 billion to HHS to prepare for a flu pandemic. A lot of that money is to develop both egg-based and cell-based vaccine capacity in this country. We've been through that many times.

But in the case of a pandemic even after spending this money, it will take us months to develop a vaccine that will be effective against the strain of flu that proves to be able to be transmitted from human to human. It will still take time.

UNIVERSAL VACCINE

Now, I've heard a lot about this idea of a universal vaccine. One that would be effective against all strains of flu, a vaccine that could be stockpiled now, made immediately available at the time of a pandemic or one that could be routinely administered to people giving them immunity in advance of a pandemic in certain areas.

I recently met with some people who were developing a DNA based vaccine that identifies proteins. It was very interesting to

me—that are common to all strains of flu. And I understand your Institute has supported some of this work. I just need to know more about this. Is there this possibility that we could get this universal vaccine that—since we identify proteins that are the same in all the different flus? Is this possible?

Dr. FAUCI. It is conceptually possible. I think over time it will be likely.

When you look at a flu virus the major components that we traditionally over the years have made vaccines against, have been the H and the N proteins that are on the surface. They stand for hemagluttinin and neuraminidase. That's the reason when you hear about flu—you name flus by the differences, H5N1, H3N2.

Now the good news is that the body makes a really good immune response against the H and the N. The bad news is that the H and the N change from influenza to influenza. Which is the reason why each season, to get a perfect match, most of the time you have to fine tune and tweak the vaccine a bit so that it's a little bit different than the one you did the year before to get optimum and maximum protection.

The concept that you're referring to, Mr. Chairman, is the idea of getting the components of the virus that don't change from strain to strain and season to season. Two of those proteins are the M2 or the matrix protein, and the NP or the nuclear protein. They don't seem to change from strain to strain. So then you—you ask the obvious question. If I was infected with seasonal flu 3 years ago, why am I not protected against the seasonal flu the next year or the year after?

The reason is the body does not make a very robust immune response against the M protein and the NP. So the strategy that we're working on with the people that you mentioned is to get those proteins and put them in a very immunogenic form. So that the body makes a very robust immune response that would cross over and help protect not only against this season's flu, but next season's flu and the year after.

Also, theoretically if you do it right, you could get a universal vaccine that would even be protective against a wide variation. The way we're seeing with the H5N1. Because the H5N1 that's circulating in birds in south east Asia right now, is very much different from the H3N2 that we all get exposed to every season. So that's the concept and the strategy of a universal vaccine.

The results that we're getting, preliminarily, in animal studies are really rather encouraging. Now you know in vaccine work it takes years to go from the concept to something that's in a bottle for people to use. But, I, myself am quite encouraged about that possibility.

Senator HARKIN. So you're funding research on this?

Dr. FAUCI. Oh, absolutely. We're funding research by our extramural grantees and contractors. We're collaborating with some of the pharmaceutical companies. For example Merck itself is working on a M2 vaccine. We're doing intramural research.

You mentioned the DNA approach. Where you can take the gene of any particular protein and code it for the protein that you want and essentially say I'm going to inject somebody with the DNA. That DNA will then cause the body to express the protein on a cell

that makes a good immune response. At the Vaccine Research Center under Dr. Gary Nabel, at the NIH, that's what we're doing with HIV. It's easily done also in influenza.

FUNDING INFLUENZA VACCINE RESEARCH

Senator HARKIN. Do you think we're putting enough resources into that on the balance of things? This is very promising.

Dr. FAUCI. It is very promising. It's very promising.

Senator HARKIN. It would be a big deal.

Dr. FAUCI. It would. It would. As you know I've always told you over the years you never ask a scientist if you put enough in. Enough is when you get the answer. We are putting a substantial amount. We are concerned as we all are with—when we have a flat budget will we be able to take advantage of some of the opportunities that would arise. So we have to be very careful in our prioritization. But we're putting substantial resources into it.

VACCINES AND AUTOIMMUNE DISEASE

Senator HARKIN. Two other things. I just want to ask one about vaccines and I want to ask about allergies.

Children get a lot of vaccines by the time they're three years old. I've heard estimates ranging from 18 to almost 30. Having a new grandchild myself last year, their parents are looking at all the shots that this kid is supposed to get by the time they're, well, 1 and then by 2. It was pretty darn close to 30.

I've heard a lot of concerns. That, you know—while each of these vaccines are very good in terms of saving lives, building immunity that maybe collectively, putting them all together could lead to autoimmune diseases later in life. I've heard a lot of this, read about it. So, again, I want to know, what kind of research is being—done on that aspect of all of these together effecting autoimmune diseases later in life?

Dr. FAUCI. It's obviously a good question because it is a matter of concern to some people. There have been studies done looking at retrospective data of children who get vaccinated as to whether or not there's this propensity to autoimmunity.

The basis of that concern, I think is the basis of why you really do want to vaccinate people because in people who have a genetic predisposition to autoimmunity, it is often triggered by an infection. We know that, for example with certain of the autoimmune diseases like lupus and rheumatoid arthritis and things like that.

So the question is mimicking the infection by a vaccine going to induce autoimmunity. The answer is in studies that have been pretty carefully done, no. But, importantly, the infection itself is a much more potent potential inducer of autoimmunity than is the vaccine that you give to somebody to prevent the infection.

So if we didn't vaccinate people and they actually got these infections that would be an even worse scenario. So if you're asking me, I can give the example: I have three children and they've gotten all the vaccinations. I feel very, very comfortable with having my children vaccinated with the menu of vaccines that are all recommended.

So, the concern is understandable. The research in the studies that have been done to see if there is a connection have all indicated that there is not.

FOOD ALLERGIES

Senator HARKIN. One last thing, allergies. A friend of mine in Iowa—we're just talking about kids and our kids, grandkids. It turned out that their little boy had developed severe food allergies.

You and I have talked about this before in previous hearings. Three hundred percent increase in the number of pediatric food allergy cases over the past 10 years. That's alarming.

Dr. FAUCI. Yes.

Senator HARKIN. What's going on? You know, what is happening out there?

Dr. FAUCI. To be honest with you, we don't know. There are some theories about that, but food allergy is something that we have now, we have had for some time. But even most recently based on the data you're talking about, are taking it very, very seriously.

Not only is food allergies—and certainly the recognition of and probably the reality of, more than just the recognition of are increasing. Not quite sure why that has occurred. I'm certain that there are factors that are not fully appreciated by us right now. But the thing that worries us is that some of these food allergies are more than just trivial. You can actually get anaphylaxis. One of the important ones, for example, is—is peanut allergies is really, really tough.

PEANUT ALLERGIES IN CHINA

Senator HARKIN. I've heard. Now tell me if I'm wrong on this. Have you ever heard this about kids in China eating a lot of peanuts there. But they don't get peanut allergies. But we get peanut allergies here. Have you ever heard such a thing?

You haven't heard that one?

Dr. FAUCI. I haven't heard that but I thought you were going to say that the Chinese were putting something in it that is toxic.

Senator HARKIN. No, it's just that China grows a lot of peanuts, like ours. The kids eat a lot of peanuts. But they have nowhere near the peanut allergies we have in this country. I was operating under the assumption that was factual data. I don't know.

Dr. FAUCI. I've not heard this.

Senator HARKIN. Look into that.

Dr. FAUCI. I certainly will. I certainly will.

RESOURCES FOR FOOD ALLERGIES

Senator HARKIN. But—again, with the 300 percent increase do we have enough resources going into that? It's our resources again.

Dr. FAUCI. It's the same answer to the question. We are doing a substantial amount. We could do more. Definitely.

Senator HARKIN. I'm told that NIH hosted an expert panel on food allergies in the spring of 2006. Last year. The participants developed a proposed road map to guide future research. But it has been a year now and I understand the road map still hasn't been approved. Give me an update on that, would you?

Dr. FAUCI. We met with that group in my conference room about 3 months ago. We walked away from that with them. They are quite satisfied with the portfolio that we've put together. With regard to a strategic plan that's almost a logistic thing, about getting a plan and a plan approved through the Department and what have you.

But the research that we're doing right now on food allergy, we've developed a very good relationship with the constituency groups on that. I have a lot of responses to that meeting that were very favorable.

Senator HARKIN. Well, alright. I just wondered what was happening there. I just—you can jump in anytime, just jump in if you have some things you want to cover. Go ahead.

COORDINATION WITH DEPARTMENT OF DEFENSE

Senator STEVENS. Tony, what about coordinating what you're doing with the other agencies? We're putting a lot of money in defense for investigation dealing with substances that might be used by terrorists for instance. Are you working with them too?

Dr. FAUCI. Yeah. There is a rather excellent coordination, Senator Stevens, between ourselves, the Department of Homeland Security and the Department of Defense. In fact, we feel very good about that. We were doing that—we've developed a good relationship with them.

Even antedating bio-defense because a lot of the things that they have done for force protection, malaria, and things like that, we have worked very closely with them. When the bio-defense issue arose following 9/11, we, in fact, strengthened our interaction with them. With the new Department of Homeland Security, we're even coordinating very nicely with them.

BIOLOGICAL, RADIOLOGICAL, OR CHEMICAL ATTACK

Senator STEVENS. That was going to be my next question because it just seems with the world wide impact of the terrorist movements that they're going to turn to substances one of these days. Are we prepared for that?

Dr. FAUCI. We are not totally prepared. I would be misleading you if I told you we're totally prepared for any biological, radiological, or chemical attack that we have. But since 2002, we have built up a rather robust research and development portfolio and have made some significant advances.

Obviously, you never know where, when or if a terrorist is going to strike in a biological, radiological, chemical way. But we have countermeasures now that we didn't have before. We were completely vulnerable to a smallpox attack. We had 18 million doses of smallpox vaccine in our reserve. Right now we have over 400 million. That's happened just over the past couple of years.

Senator STEVENS. That was my next follow up because it seems to me that we're doing a lot of research and prevention, but what about reaction to such events when they take place. That seems to be the area that we could be most effective.

Dr. FAUCI. Right.

Senator STEVENS. We can't immunize everybody against anything.

Dr. FAUCI. Sure.

Senator STEVENS. But we can get prepared for specific problems that might arise. Are we doing that?

Dr. FAUCI. We are. We are, Senator. I'll give you two examples that are actually very important examples.

You talk about treatment. We've never had any treatment for smallpox or pox viruses. There is a drug that we've helped develop with a pharmaceutical company called ST–246 which is very effective in an animal model against smallpox. You may have read in the newspaper about a military person who was getting vaccinated for smallpox with vacinea didn't fully realize that his child had eczema. When you expose the wound of a smallpox inoculation to a child with eczema, they can get an eczema vaccinatum which is a very terrible disease.

The child did get it accidentally, and doctors tried everything with the child and we brought this drug in. They treated the patient with the drug and the child has made a very remarkable recovery. So that's a—N equals one in medicine that doesn't mean anything, but this, I think, is an important indication that we now have an important drug.

We also have some antitoxins that we didn't have, for example against anthrax. We've developed the first Ebola vaccine that, I think is a very important advance.

Senator STEVENS. What about post exposure to nuclear. I heard the other day about something that would reduce the after effects of nuclear exposure.

Dr. FAUCI. Right.

Senator STEVENS. Is that really an accomplished fact.

Dr. FAUCI. What we are doing and we've had to partner with our colleagues from the cancer community, with the National Cancer Institute is to develop better versions of the drugs that are used on patients following a radiation to rescue bone marrow. For example, to allow the bone marrow to regenerate in a much more rapid and efficient way than it would to wait for it to normally respond. That's the main nuke-rad counter measure that we have.

Senator STEVENS. Are we stockpiling that?

Dr. FAUCI. Yes, we are. We have that in the National Strategic Stockpile.

NCI FUNDING

Senator STEVENS. Dr. Niederhuber, if I may? I was really—you know we doubled the research money for you in one period that Connie Mack and bipartisan effort. We did that over one period. I think it was a little less than 10 years. Are we going to look at a necessity to double it again in the next decade?

Dr. NIEDERHUBER. Well, living as we have for the past 3–4 years with a less than inflation budget has certainly taken its toll on the programs. If you calculate that up it's about a 12 percent decrease from where we might want to be at this point.

Senator STEVENS. Well, since you had 125 percent increase in the past years before that. Where do you think you'd stand if we hadn't done it?

Dr. NIEDERHUBER. Oh, I think we would be much worse off in the country as a whole. I think the increase that Congress, in its

wisdom, legislated and appropriated did a great job in this country in building up research infrastructure that was lagging. We built about $16 billion worth of new research space at our Research Universities across the country. I think that was badly needed.

Having come recently from the academic community we had some real pent up needs in the academic community. We were able to increase our faculties where we needed to in the biomedical research arena. So I think this was all, Senator Stevens, very needed.

The issue I think for us, as a country, has been that when you build up you need to keep moving with inflation in order to maintain what you've built. I think that's the issue that we are facing.

GENERATIONAL CANCER

Senator STEVENS. That's reasonable, I think.

Let me ask you a personal question. I had three generations of pancreas—pancreatic cancer ahead of me and I got prostate cancer. Now someone told me the other day that in all likelihood I had the same cancer. Is that possible that it migrated to my predecessors but didn't migrate for me?

Dr. NIEDERHUBER. Well, I don't think I would look at it quite that way, having been involved with managing and operating on patients with pancreatic cancer for most of my career, I think these are two separate diseases. They each have specific risk factors. I could share that with you.

Senator STEVENS. I just want to know what to tell my sons.

Dr. NIEDERHUBER. Well, I think the thing to tell your sons is that we're working hard to better understand the risk. What I was going to say that actually in July of this year our Center of Excellence in the National Cancer Institute focused on trying to understand risk in populations and risk for developing different cancers. We've just finished a whole genome scanning project in prostate and in breast and this July we'll launch one specifically in pancreatic cancer. So it's relevant to your question, Senator.

Senator STEVENS. Well, let me know will you?

Dr. NIEDERHUBER. I certainly will.

Senator STEVENS. What do I tell them—follow their grandfather, their great grandfather?

Dr. NIEDERHUBER. Live healthy, exercise, eat well.

ATTRACTING STUDENTS TO SCIENCE AND TECHNOLOGY CAREERS

Senator STEVENS. Which one should they be careful of? Anyway, let me ask you, Ms. Alving.

Are you familiar with Norm Augustine's report titled: "Rising Above the Gathering Storm", which discuses the problem of having enough students turning to the study of science and technology?

Dr. ALVING. Yes, Senator. We're very aware of this at NIH.

Senator STEVENS. But what are all of you doing about that? All of you have basic money, research money. I understand what you're doing Dr. Ruffin. That's very good.

We do the same thing by the way. We pay some of our staff who have high loans, before they migrate out to where they get paid more. So we have a little bit of a fund here. We can sort of entice them to stay a year or two longer. But are you doing anything about the concepts of trying to attract students into the areas so

that you're not the last of the breed in terms of scientists who are studying these things for us?

Dr. ALVING. Yes we are, Senator. I would say that NCRR is working very diligently on this. The other Institutes and Centers are working on this, as well, because across NIH we recognize this as a very large challenge. We also recognize——

Senator STEVENS. Let me interrupt you. Do you have internships for people in college to attract them so they'd be interested to go to graduate school? Do you reach out to people?

Dr. ALVING. Absolutely. For example, let's look at the IDeA program that I mentioned earlier. I personally visited Montana this last year and I saw how the investigators at the more research intensive universities are reaching out to the tribal colleges. So there are now research projects underway at the tribal colleges. The tribal students can go to the University of Montana and really envision research careers.

I remember one young man told his father he was going into biomedical research. He was Native American. His father said well, that's not what we do. But he said yes, this is what I do want to do.

So we are reaching out to students, I would say, of all ages, because to really attract students into research and into biomedical careers, you really have to get them at a very young age. In one of our SEPA programs, our Science Education Partnership Awards, one of our very fine investigators has developed a bus in Boston that actually is well equipped as a laboratory. It's even visited the NIH campus.

The bus goes throughout Boston. So it goes into the underserved areas. Students can get onto this bus, which is a traveling mobile lab, and learn about DNA and learn some of the simple experiments. In fact, I think this has been really replicated throughout many of the States.

So we're really attacking this, I think, at multiple levels. We're reaching out to the Hispanic community as well. And many of our very well funded researchers have very active programs where they serve as mentors and bring high school students into their labs. It's probably still not enough, but we're all very aware.

Senator STEVENS. If this Nation has a problem—the problem is the downward trend of our students who seek graduate education in science, technology, and engineering, which are very difficult areas of study. We've got to find some way to move out and give them incentives to continue.

CONGENITAL DEFECTS

I know I'm using my time. Dr. Grady, I just recently came about in connection with a relative. The problem of a defective heart valve which came from, they tell me, from what you mentioned, a problem at birth. Now what my question to you is have we any way to check this as people grow older? Whether they do have those defects that develop because of improper handling at birth?

Dr. GRADY. There are a number of tests that are now available where we can through imaging and other diagnostic tests tell very early on in children if there is a developmental defect.

Senator STEVENS. I'm talking about this person's almost 60. He was just determined—to have blood clots going to the brain. Suddenly they find out that was—escaped through some valves that have been defective since child—since birth. Now I—and he's had exams. He's been in the service. Why doesn't—why won't that show up on exams?

Dr. GRADY. Well, it turns out that many of us have problems, birth defects, congenital defects that we are really unaware of. Sometimes we die without being aware of them. But now that the life expectancy of the average American is longer, many of these things which would not have surfaced before are now surfacing.

Senator STEVENS. But how can we—can we discover them?

Dr. GRADY. Up until recently the imaging technology and the other technologies that we had were not able to. But we now have imaging technologies which have a very high resolution. You can tell things are happening in tissue that are structural and even metabolic disorders much earlier in life.

Senator STEVENS. Those valves could be discovered with the proper test?

Dr. GRADY. Yes. Very likely they could have been.

Senator STEVENS. Are we developing any indications that would lead people to take those tests?

Dr. GRADY. Actually there is a move on for people to do screening, whole body scans, et cetera and much higher technological screening early on in life. Some of these things, as we're all aware of, are not covered by insurance so people opt not to do them. But I think the technology is now becoming available and people's awareness that they should screen for things and that they should have check ups early is much higher. So hopefully, we'll be catching these earlier.

Senator STEVENS. We saw something that both the government and the insurers are not going to pay the cost of scans, particularly full body scans.

Dr. GRADY. That is currently the situation. There is a great deal of discussion, whether or not they should be available and for what particular conditions they would be most helpful.

MEDICAL SCREENING

Senator STEVENS. This is very disturbing. This person is now blind, partially. He's got tunnel vision because of those clots and had no idea that that existed. I was told it could have been diagnosed at any time prior to that if he had had the proper exposure to the scans. But I don't know how.

We've got all these systems. I don't know how we can get so that subjective to the people who need help, know that need help. Is that part of any of the studies we're making? How do we find out who needs this help?

Dr. GRADY. It is a problem in that we are trying to inform people. But we also have difficulty getting people to come in for screening exams which we know are helpful: mammography, breast cancer screening, and there are a number of other screenings that people do not necessarily take advantage of.

We are studying—we're funding a number of studies however, that look at what it takes to get people incentivized to come in for

screening. We have some very interesting information related to, you mentioned relatives, related to mothers and daughters. Daughters being more tuned into health prevention, getting mothers to come in, senior citizens and younger people, et cetera. So we're working on a number of techniques to incentivize people to come in for screening.

Senator STEVENS. I was told last week that there is now a system where you can go and have your—what your gene chain set out. They can compare that to the types of illnesses that come from these genes that you are determined to have and they can then give you a prediction on what you're going to suffer. I said why don't we all get that? They said, well, it's cost. That it's not available to the average income person today. Are we going to get to where we can get that for the average person?

Dr. GRADY. Well, it is true that it is not covered by insurance but also—we're not quite there yet where these tests are 100 percent accurate.

For some things such as stroke, we have developed and identified risk factors. We can weigh each one and there's a whole scale where you plug in your blood pressure, your age, et cetera. Then you can alter—what if your blood pressure came down a certain amount and you get a score which you can then program. If I alter my diet, if I lower my blood pressure, if I exercise more, that will reduce my chance of getting a stroke by *x* percent or so many points. So I think we are moving in that direction in some areas, but we're really not there yet.

Senator STEVENS. Maybe some of us don't want to know that's the problem.

Senator HARKIN. Do you have thoughts on what Senator Stevens just asked?

Dr. NIEDERHUBER. I was just going to comment that we—all of the Institute Directors were at a conference all day on Friday at the NIH and during that day we were talking about some of the latest technology coming online to do rapid sequencing. I believe, you can correct me, colleagues, if I'm wrong, but I believe the quote was that, "with this new technology today we can sequence half of our genome in 3 days at about $3,000."

So you can see how quickly within the next few years we will be approaching our goal of being able to sequence the entire genome of you as a patient within 3 or 4 hours for $1,000.

Senator STEVENS. Would it be cost effective for us to do that publicly?

Dr. NIEDERHUBER. Well, that's a very good question, Senator. I think that we all recognize in the science community that this information, this alphabet if you will, is the base of the information. We know that we have a lot more work to do in taking that code, if you will and understanding what that code means in terms of the proteins that our cells produce.

The changes in those proteins as they're produced and how they relate to what makes you function and you as an individual and your diseases and me, as an individual and my diseases. So we have a lot to build on. But that is like the periodic table of chemistry, if you will. It is the information based upon which we will

gain this kind of knowledge and this kind of understanding of the disease. It's a step, but a very important step.

GENOMICS

Dr. FAUCI. Can I add we should be careful though not to think that if you—if we, even if we get it inexpensively that if you get your genome and you look at your sequence, you're going to know exactly what's going to happen to you. That's—most diseases are multigenic. They rely a lot on interaction between the genetic factors and the environment.

So although you could get some probabilities there's still going to be the need for the broad, healthy things you need to do no matter what your genome is. So we spoke about that also.

Senator STEVENS. I said it was the last question. But I forgot this one.

END OF LIFE

Dr. Grady, you gave us this chart, tracking patient disability in the last year of life identifies opportunities to tailor interventions. We were told last year that in the last 2 years of the person's life they would probably spend as much money for health care as they've spent in all previous years. Are you suggesting here that there's some way to alter that?

Dr. GRADY. Your statement is true. What we are suggesting is that these are trends. So it's a very large population study but it gives parameters within which you can better be able to predict what a course of illness may be like. That doesn't mean it will necessarily be that way for each individual person, but it gives you parameters.

So it gives you a sense of what one could expect and hopefully to be able to better plan. It's an imperfect system when translated to single individuals but it does give the patient, the family, and the health care team some idea.

Senator STEVENS. Are you suggesting you think science can tell us when a disease is really terminal no matter what happens?

Dr. GRADY. We're still not there yet. It's very difficult. You can, as we all know, predict within some time frames. But still individuals are very different from person to person. So you have guidelines, but I would not be offering a finite timeline.

Senator HARKIN. Well, I want to pick up a little bit of what Senator Stevens just said this end of life care. I just wrote it down here. It's got to be more rational, caring and cost effective.

A lot of it is just irrational. The way it's administered. I don't know if it's more caring for a person to—to do expensive operations or anything like that knowing full well that the end of life is coming anyway than it is to just give him palliative care. Address yourself to that too.

Most—our health care system is not very good when it comes to palliative care—and then so a lot of people stay in acute care until they die. It just costs a fortune.

Dr. GRADY. It's very complicated, Senator, both Senators. What we found out so far—we've just scratched the surface.

What we've found out so far however that is disturbing is that some of the things that we could do we are not doing consistently.

For example, pain management. We know a great deal about pain management and our ability to handle pain in these stages of life. Yet, we find great disagreement between what the health team advises, what the patient says they want and what the family says that they think the patient wants.

So whether it's an intensive care unit setting or a hospice setting or chronic care setting, we find great disagreement. This is all within the therapeutic window of pain medication that could be administered that would be safe to administer. So that's one thing we know.

The other thing we have found is that—that many patients do not have advanced directives. They haven't really thought ahead. They haven't talked with their family, but even if they have many of the systems that we have are required. They basically are not allowed to withhold treatment, even if that is the patient's request.

So if in an emergency the ambulances are called or anything, it doesn't usually matter in practice if the person says no advanced measures.

Senator HARKIN. What would you think about that? I've never talked to Senator Stevens about this but this idea of having advance directives? People don't. They just don't think about it. Maybe when people get on Medicare that ought to be a part of when you qualify for Medicare that you ought to have a requirement that you have some kind of advance directive.

Dr. GRADY. Well if the person would have an opportunity to do that it would at least allow them to think about it. It would give the family some sense of where they should go and some guidance. It turns out the other studies we've done that look at the caregivers of terminal patients that the largest stress for them is reported to be that they didn't know what their family member wanted. They had to make a decision really acting in the dark by their report. That they felt was, by their report, almost as stressful as seeing the disability.

Senator STEVENS. But is that partly related to the liability factor of the caregiver in case another person—family member says you could have saved them and you didn't.

Dr. GRADY. There seems to be a great deal of anxiety about that.

Senator STEVENS. Well, I think, Senator Harkin is right. I think we ought to try to do something. I witnessed my first father-in-law after he had brought back to life. He was a minister and a grand man. He was in his mid 90s. I never heard him swear in his life, but he swore at the doctor that brought him back to life. He died about 2 months later and I think that is a very unfortunate thing. He did not have a directive. But there ought to be something to deal. Maybe we could tie to Medicare.

Senator HARKIN. I've thought about that. I hear this all the time. There is a liability problem there. People don't think about it. Families don't know what to do.

Senator STEVENS. I see my friend is here. I'm late for another appointment. So thank you very much, Senator.

Senator HARKIN. Thank you, Senator Stevens.

I want to follow up on one thing and that's on the nursing shortage.

Dr. GRADY. Yes.

NURSING SHORTAGE

Senator HARKIN. We had a hearing on global health a few weeks ago. We talked about the brain drain and other countries.

What's happening in other countries is a lot of their nurses especially in health care professionals are getting their degrees and that kind of thing. Then they come here, better paying jobs. We have a shortage of nurses here now so we started looking into this.

Well then, what did we find out? There's a shortage of nurses in this country. There's a demand for nurses. American Schools of Nursing last year turned away 42,866 qualified applications for baccalaureate and graduate programs due to a shortage of nurse faculty.

Dr. GRADY. That is correct.

Senator HARKIN. Now, we're in a real problem here.

Dr. GRADY. We are.

TRAINING NURSE FACULTY

Senator HARKIN. We need more nurse faculty. But if we don't have the slots for them, it seems to me pretty soon, they're going to start retiring and we're going to have fewer and fewer. I don't know.

Your Institute supports a lot of nurse faculty through research grants. So what role does your Institute play in increasing the number of nurses trained here in America, especially teaching nurses, faculty—teaching nurses? I don't mean just nurses that are out in the community, but I mean teaching.

Dr. GRADY. Senator Harkin, those are the nurses that we support in our training line. We have 7 percent of our budget devoted to training.

Senator HARKIN. 7?

Dr. GRADY. Yes, 7 percent, which is twice the NIH average. So we're dedicating a reasonable chunk of our budget to training. The people that we train are those individuals who become the teaching faculty. We train them to do research, but that's what faculty do on campuses of Schools of Nursing across our country.

So we have designed a number of programs to try to get these students in early. We work with the K through 12 programs. We work with the other graduates to encourage them to get doctorates. We also have what we call fast track programs so that they come into the baccalaureate program, come out with their Ph.D. without stopping.

Senator HARKIN. Thank you. What if you were advising us? If you could say here's what we're going to do. What would we do say; give us 3, 5 years. What would a 5-year plan look like to get more teaching faculty in this country?

Dr. GRADY. I think the 5-year plan would have some loan repayment, but I think that looking at loan repayment or service repayment. For example and this dates back to the older days, but we used to, if people had supported education that they would not have to pay back the loans, but they would pay back in service, teaching at schools as faculty, et cetera. I think maybe something of that sort.

Incentives to get people into the field earlier, I think there is a real sense and this is partly what we're working on internally is people are expected to get their advanced education but they're expected to work along the way because it is clinical profession. So we are trying to help design programs so that that is not necessary.

Believe it or not, many States require, in order to teach in a School of Nursing, that you have to have a Masters in Nursing and not just get your Bachelor's and then go on to a Ph.D. So there are a number of issues that we're working on. But it is safe to say that that the demand over the next 10 years is going up in excess of 20 percent. We're only supplying another 6 percent.

So we need programs that are attractive. We need programs to help retention. We have programs to help get people in but we need to figure out how to retain them. I think we need also to work on the quality of life issues such as loan repayment.

Senator HARKIN. Well, we need some advice. I mean if you turn away 42,000 last year. I assume the same will happen this year, maybe more.

Dr. GRADY. Yes. We are, as you had identified very astutely, expecting an increased retirement. It turns out that faculty in Schools of Nursing tend to retire earlier than later, 62 versus 65 or so on. So we really are getting a crunch from several directions. So we're hard pressed to try to design as many programs as possible to get people in and to make the field as attractive so that they will stay in.

NURSING RE-ENTRY

Senator HARKIN. Let me ask you this. I was amazed to discover in my State of Iowa a few years ago that there are a lot of nurses in my State, and I'm sure it must be true in other States. They went to nursing school. They became an RN. They were an RN for a while. They got married, started having families. They got out of nursing, raised their families. Kids are grown. They may not have been in nursing for 15, 18, 20 years. I was amazed to find out how many there were in my State.

So I began asking a few of them once I found out. In meeting people you never knew they were nurses. You meet them in other walks of life and find out they were a nurse. Would they ever think about going back into it. And they said, Oh, yes. But you know I don't, you know, have the wherewithal. It costs money to get retrained, go back to school. You know we're now in our late 30s, 40s. You know, yeah, if I had the ability or had the financial resources and stuff.

I just wonder if there's an untapped pool out there of nurses who may be in their late 30s, early 40s that would get back in if they had the wherewithal to do so.

Dr. GRADY. I believe there is, Senator. We've been talking with some of the schools about a re-entry program and with the AACN about re-entry programs. That is precisely what you're describing. To get people to come back in, if they have incentives.

You know it probably would not take a great deal of incentive. But to get people to think about it and to try to figure out some creative ways to get people back into the field. It is a wasted re-

source. Basically if people would like to come back to work, they have the background. I think it's an untapped resource.

Senator HARKIN. We ought to look—we ought to just see if there's some suggestions out there.

Dr. GRADY. I'd love to—we'd love to work on this, with you.

SUPPORT FOR WOMEN PURSUING PROFESSIONAL CAREERS

Dr. ALVING. The reason I'm nodding my head is that if you look at medical schools now, about 50 percent of the students in medical schools are women. We have a very big problem in this country in that there's very little support, child care support for example, for women who are trying to pursue professional careers. So this pertains to veterinarians, of whom 80 percent of the students are women, nurses and now physicians.

So I think we're going to have to think about some sort of ability to provide resources, child care, for those professional women. These nurses might not even drop out. They might stay in if they felt that their families and their children could have the appropriate type of child care.

Other countries have organized centers where they can, you know, provide day care. So that's another component of it. But I do support re-entry. I would also support it if they could only drop back to half time and not drop out, because once you drop out it's harder to re-enter. You lose confidence and that's a little bit more difficult.

Senator HARKIN. Interesting concept. I'm justified that the programs—programs for specified for certain groups like nurses. That's interesting.

Dr. RUFFIN. Senator Harkin, I think one of the areas too where we need to pay more attention is to our 2 year institutions around the country. This is an untapped resource to a great extent. I think that the attitude as it relates to 2 year colleges around the country has changed.

It used to be that the thinking was that individuals would go to the 2 year institutions to sort of bone up for the 4 year experience. That attitude is totally gone. We have great instructors now at these 2 year schools and good students at these 2 year institutions.

The problem is we're not bridging them. They're not transitioning to the 4 year institutions. We need more bridging programs that we can tap that vast resource of individuals who are at these 2 year institutions and begin to bridge them into our 4 year institutions in those challenging programs like nursing.

That's one of the areas that I think we need to concentrate on. It is a place where we need to visit that we haven't put much attention on.

Senator HARKIN. Very good. Dr. Niederhuber, let me ask you before I just turn to Senator Cochran.

I just wanted to ask you about clinical trials. Flat budgets for NCI over the past few years have taken a toll on clinical trials. When we finalized the fiscal year 2007 budget earlier this year, NCI was asking the cooperative groups that run cancer trials to trim their cost by 10 percent and reduce the number of open slots for patients by 3,000. Are those figures still accurate? I mean we did put some more money, as you know, in.

Dr. NIEDERHUBER. When we were trying to guess what that 2007 appropriation might be we were forced to ask everyone to do a worst case scenario. So they did work on a 10 percent cut. We actually, just the past few days, have been meeting together at NCI to put in place our funding program for the cooperative groups that are the bulk of the grants that support clinical trials research across the country, as you know.

It looks like it's going to be closer to a 5 percent decrease from last year. But that still translates into a decreased number of trials that will be open and a decreased number of patients that will go on trials as you understand.

One of the difficulties with this uncertainty in the budget for the clinical trials aspect of research, it's complicated to explain, but part of the support goes for infrastructure, bio-statistics and just the infrastructure people that have to be there. Another part of the budget is a bit of a guess in that we set aside resources that pay on a per patient basis. So as a patient goes on trial, that capitation gets allocated to cover part of those costs. It doesn't in any way cover the cost of a patient going on clinical trial. We're lucky in most trials if we come even close to 50 percent of the cost.

So, the problem the community at large is facing across the academic universities is not knowing exactly how that budget is going to grow or stay flat over the next few years. They have to be very careful on deciding to start a trial, get it up, and get it in place. That takes time and commitment. Not knowing for sure if the dollars are going to be there to support that trial in the second, third, and fourth years.

One of the things we do not want to do is to have to stop a trial in the middle. That would be a disaster. We just wouldn't want to do that. So I think that what I am seeing is that my community is being a little cautious in the number of trials they're willing to open up and willing to start because they can't predict down the road 2008, 2009, and 2010, what the resource flow is going to be.

Do you follow that? It's a complex issue. It's hard to explain a little bit until you get your hands into it.

Senator HARKIN. But you can assure that this 10 percent cut is no longer valid because of the——

Dr. NIEDERHUBER. It's not going to be that much in 2007. It's going to be closer to 5 percent.

Senator HARKIN. We need some kind of—I'll have to think about that a second. I have a question about pancreatic cancer, but I wanted to turn first to Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you very much for convening this hearing.

It is good to meet with the heads of the different Departments at NIH where you're undertaking very important research. We appreciate the hard work that all of you are doing.

We want to be sure that the budget request is as generous as it can be as well as the appropriations that follow. That when we approve a budget for this next fiscal year it reflects our genuine concern about doing the best we can do in developing research programs that will give us answers to problems relating to health and disease, infectious diseases, all the gamut of subjects that the Institute is working to help us understand.

PANDEMIC FLU AND OTHER INFECTIOUS DISEASES

I noticed that in Dr. Fauci's National Institute of Allergy and Infectious Diseases, you're doing a good bit of work in Avian flu and some other areas of that kind. I wonder what progress, if you can tell us is being made in coming up with new ways of dealing with some of those challenges of infectious diseases.

Dr. FAUCI. Well we have a very extensive portfolio in emerging and re-emerging infectious diseases, as you know. That is a major component of what we do. You mentioned pandemic flu and the concern that we have now because of the activity that is going on with bird flu particularly in south east Asia.

What's happened over the last year since I testified before the committee is some significant advances in that regard. We tend to link, Senator Cochran, our preparedness for seasonal influenza with that of pandemic. We feel as a group that we don't prepare well enough for seasonal flu. We have not advanced the vaccine technology for seasonal flu. The shots that you and I get every year that everyone else gets every year or should get every year, we haven't advanced that technology to the 21st century. We really need and we are not only re-looking at it but really transforming it.

For example, we make influenza vaccines now by growing them in eggs and then harvesting the virus in a very antiquated process which has great restrictions on scalability and the amount you can make. We've invested a lot of money to get the more up to date, 21st century methodologies for vaccine, either growing it in cells or doing recombinant DNA technology. We've made some significant advances in that regard.

I mentioned before you came in that the pre-pandemic influenza vaccine for H5N1 that we tested over the past couple of years has now been approved by the FDA as a licensed vaccine. What we need to do and are doing rather successfully is applying, for example, the technology of adjuvants, which is a substance which enhances the body's response to a vaccine so you can get away with a much lower dose and can scale up rapidly.

So I would report to you today that the work on emerging infections in general but in particular with regard to your question about pandemic flu is coming along very well.

HEALTH DISPARITIES

Senator COCHRAN. That's very encouraging. We appreciate the good work that you're doing. I noticed in one of my staff memos here that a recent report indicated that one of our counties in Mississippi has the highest mortality rate from breast cancer in the Nation. That stopped me. It's twice the national average in Madison County, Mississippi.

I wonder, we've talked about disparities. I think this might be something that the Research Centers in Minority Institutions program may be involved in. Dr. Alving, I think you'd know about that and can contribute something to our knowledge about what progress we're making at the National Center on Minority Health and Health Disparities.

Dr. ALVING. At the National Center for Research Resources we fund the RCMIs, or the Research Centers in Minority Institutions. We also work with Dr. Ruffin of the National Center on Minority Health and Health Disparities. I think also at the NCI there is a very big program in minority centers in cancer outreach.

I would wonder if there isn't a multi-factorial reason for this high mortality. The first question would be is it due to lack of screening. Second we would want to know that if there are women who have increased breast density which can also affect the screening results or the mammography. But I would really wonder about access to care and preventive measures.

As you know, the NHLBI funds the Jackson Heart Study in Mississippi, which is not only an observational study, but is dealing with ways of getting the participants used to the idea of preventive care and screening. We and the Research Centers in Minority Institutions are setting up a translational research network, with Jackson State as the data coordinating center, where we can do improved outreach and clinical trials in minority populations and also work collaboratively with my colleagues here at the table.

Senator COCHRAN. Let me ask Dr. Ruffin to comment on that too.

Dr. RUFFIN. Senator Cochran, I think that first of all what I would like to do is really congratulate the people in the State of Mississippi, if you're looking for an example of partnerships.

I just believe that whatever the disease area happens to be whether it's heart disease in the case of what we're doing with NHLBI or whether it's breast cancer or any of the other studies, whether we're talking about just getting the communities to participate in a clinical trial, I think there's a model in Mississippi that ought to be emulated. That is the ability of the institutions in the State of Mississippi to come together and work together.

We've got programs at the Center that are working. The one that you're referring to, the Center for Health Disparities in the State of Mississippi has brought all of the institutions there together. The University of Mississippi Medical Center, Tougaloo College, Jackson State and many other institutions come together to work on these issues. So I believe that irrespective of which disease we're talking about, because health disparities is a very complex issue, it deals with a whole plethora of different disease areas and you have so many experts there who are working on various aspects of this issue.

I think that by bringing these individuals together and everybody working together and understanding where their various strengths and weaknesses are, we're going to get an answer to a number of very important questions here.

Senator COCHRAN. Well, that's very encouraging and we appreciate your hard work and efforts in that regard. Now, you mentioned, was it Dr. Niederhuber or Dr. Fauci, did you have a role—do you have a role in this specifically?

INFORMATION DISSEMINATION

Dr. NIEDERHUBER. Dr. Niederhuber. Dr. N. is easier.

Senator, we as you might imagine at the Cancer Institute track very carefully the hot spots, if you will. We color them red. I don't know if that's significant politically or not but we know where

those hot spots are for various cancers. Some of those areas are industrial; others are what you would call rural.

Appalachia, if you go down through Appalachia we have very high incidence of certain kinds of especially female associated cancers. It's a multiple factorial problem. There's not one simple fix to this. Part of it has to do with education. Some of it has to do with socioeconomic status of those communities.

We look also very carefully at the environment and whether there are environmental relationships that we can pin to risk. We look at the genetic changes in the population to see whether there's a relationship with the genetic background or inherited genetic patterns in those communities that relate to this risk as well.

We're looking at all aspects of it. It's a very complicated issue. Certainly an awful lot of it though has to do with education and an opportunity or access to science, to care.

As I mentioned in my opening statement before you arrived, Senator, we're launching in the next few days actually, 10 pilot centers across the country that are specifically targeted at rural communities. Not universities, but in community environments around community hospitals and probably about 100 to 250 bed facilities. The purpose of those pilots is to try to learn as much as we can about what we're going to need to do to bring the latest of our science, the latest of our discoveries directly to those people.

We know that 85 percent of patients with cancer get the care for their cancer in the community where they live. They don't leave the community. They don't travel to M.D. Anderson in Houston or to Memorial Sloane Kettering or to Duke University or wherever. They stay right at home for a variety of reasons. Part of it has to do with age and the dependency on the family for support and care. That's just what's happening in this country.

We have to understand that better. We have to understand how we're going to get our science, our discovery to people where they live.

Senator COCHRAN. It's very interesting. Well, we thank you for the good work that you're doing. We appreciate your being here at the hearing. We look forward to continuing a close relationship with you as we go through the mark-up process. Thank you.

CANCER SPORE'S PROGRAM

Senator HARKIN. Thank you, Senator Cochran. As I said, Dr. Niederhuber, pancreatic cancer, number four killer among cancers. Once it strikes, very little hope. Senator Stevens had talked a little bit about that. It's one of the few cancers for which mortality rates are virtually the same today as they were 30 years ago. So that makes the work of the three pancreatic cancer SPOREs so important, the Specialized Programs of Excellence.

Dr. NIEDERHUBER. Absolutely.

Senator HARKIN. I understand that NCI is considering changes to the SPORE program that could have a significant impact on pancreatic SPOREs. Could you tell me about your plans in that area?

Dr. NIEDERHUBER. Actually, I think that the changes that we have been making, Senator, have actually strengthened the program. We have been working very hard to keep as much resources,

financial resources into this program as we have had in the past. So we've been scraping to do that.

When I came onboard I looked at some of the struggles and some of the problems. Having come from the academic community and having been Cancer Center Director and knowing a little bit from the outside about the issues that this SPORE program has and how difficult it is to bring the basic scientist together with the clinical scientist. It's not an easy accomplishment for any university to build one of these programs, one of these collaborative efforts.

So I began working directly with the currently funded leadership of the SPORE program across all of the diseases. Some of the things that we decided to do together, collectively, was one to have them come in separately.

Senator HARKIN. Individualized.

Dr. NIEDERHUBER. We would have the lung cancer programs all coming in at the same time but then not being able to come back in for 2 or 3 years for funding. That didn't make a lot of sense to any of us. So we've changed that structure around. We've put in place three separate times a year when anybody who comes together and creates a SPORE program in breast or prostate or pancreatic cancer. They have the resources to put into this and to compete for one of these grants. They can come in September/October or January/February or in the springtime.

They also now have the opportunity, if the study section who reviews that application doesn't give it quite the score to get funding, a score level, they then have the opportunity to immediately respond to that, revise their application and come right back in. That was not something that existed before.

I met with the SPORE PIs about 3 weeks ago at the American Association of Cancer Research meeting in Los Angeles, since they were mostly all there. We had a special opportunity for them to come and sit with me. I reviewed with them the funding plan we have put in place so that they could understand the resources and how the resources were being distributed. They could see the same detail that I have.

I think they really appreciated that. It was the first time that anybody had been that open and shared with them the details of funding. We talked about the future. We talked about some innovative things that we might do with the program that might further enhance the SPORE program.

So I think we have a very collegial working relationship with the research community that's committed to putting these grants together and to keeping them going. The goal is the best science.

Senator HARKIN. I understand but again I think there's some concern that the pancreatic cancer SPOREs will get squeezed out.

Dr. NIEDERHUBER. No. You're talking to a person who's spent his whole life doing pancreatic cancer surgery. So, I'm very committed to being sure we continue that.

PANCREATIC CANCER

Senator HARKIN. One last thing.

Dr. NIEDERHUBER. I'm hopeful that there will be other Institutions that will feel they have the resources, academic, and intellec-

tual resources, to come in. If we get another good application that number is not frozen at three, we'll fund the best we can get.

Senator HARKIN. Ok. One last thing. Pancreatic cancer is so bad because there's no early detection.

Dr. NIEDERHUBER. Correct.

Senator HARKIN. Once you've found out and we all assume we've all had friends die of it. I just had one recently within the last couple of years who was my back seat guy when I flew in the Navy. Literally within, probably, 9 months he was dead.

Dr. NIEDERHUBER. Six months to a year.

Senator HARKIN. I've had others say the same thing. By the time you detect it, it's too late. What kind of hope can you give us? What kind of research is going on for some kind of early detection, methodology for pancreatic cancer?

Dr. NIEDERHUBER. If you remember in my opening presentation I highlighted that. Our genome-wide scanning that we are doing to look at large cohorts of patients to determine what genetic changes may be present in their genome, in their code of DNA, what changes they may carry with them that predict. For example we studied breast first, then prostate. We've learned quite a bit from that.

We've had, I think, over the past 3 months, six papers I believe it is. Don't quote me for sure on that number. But I think it's six papers in Nature which is one of the leading journals as a result of that work in both prostate and breast. So in July of this year we will begin the same kind of study in pancreatic cancer.

I am a person very interested in pancreatic cancer. I'm very excited about that because I think that's the first step in getting the kind of background information we need in terms of what changes may exist in your genome that says you've got a greater risk over your lifetime of developing this kind of cancer. It's a huge step for me, I think, in what we need to know. It will be a great foundation to build on. I hope that out of that we will get some clues of what kind of, we call them biomarkers, to look for in this particular cancer.

TUBERCULOSIS

Senator HARKIN. Thank you very much. Dr. Fauci, I'm hearing more and more about drug resistant tuberculosis. I just had a question on it this weekend from someone. How big is the threat and how prepared are we to deal with it?

Dr. FAUCI. It's a growing threat, Mr. Chairman that we're concerned about. As you know, TB is a very, very important global problem. One third of the world's population is infected with tuberculosis, not sick with it, but infected with it.

Senator HARKIN. One-third of the world's population is infected with tuberculosis.

Dr. FAUCI. One-third of the world's population is infected with tuberculosis, right. We get about 8 million new cases a year with 1.3 to 1.6 million deaths. Twenty percent of all of the tuberculosis active cases are multiple drug resistant. It means that it's resistant to the standard drugs that we use. But we do have alternative drugs. Ten percent of that 20 percent have what we call extensively

drug resistant tuberculosis or XDR as it's referred to. It's a growing problem.

We are ratcheting up very aggressively our tuberculosis portfolio to address the issue of drug resistance. We just, as I mentioned earlier, put together a strategic plan that I presented to my National Advisory Council this morning. Then we will be formalizing that plan. It is a real serious problem.

It was first brought to the attention of the scientific community from about 54 cases that were identified in South Africa, of which an astounding 52 died. That's a very, very high rate. The reason it is likely because they were also co-infected with HIV. It isn't just confined to people with HIV.

But when you say extensively drug resistant you mean that the standard INH and rifampicin, the drugs that you usually give. It's resistant to them. It's resistant to the fluoroquinilones and it's resistant to at least one injectable third-tier tuberculosis drug like amikasin and drugs like that. So it's a very serious problem.

In some cases it is completely non-curable. So we have to work really fast to get other drugs into the pipeline. But importantly to make the right diagnosis because you get drug resistant TB by not properly treating regular TB, and you don't properly treat it because you don't diagnose it early enough. Then when you do, people don't come back for follow-up because they start to feel better right away. So we need to have a good screening process and a very sensitive diagnostic. All of that is part of our strategic plan that I was talking about a moment ago.

MULTIPLE DRUG RESISTANT AND EXTENSIVELY DRUG RESISTANT TB

Senator HARKIN. I think most people would be alarmed to find out tuberculosis which we thought was in the Dark Ages has come back so strongly. I had not known that 1 out of 3, 30 percent. That's alarming.

From the figures that you gave me it's about—you say about 20 percent are multiple drug resistant.

Dr. FAUCI. Ten percent of that 20 percent are extensive.

Senator HARKIN. So 2 percent are resistant to anything.

Dr. FAUCI. Right. Exactly.

Senator HARKIN. Is that in just a certain area of the world? Is that confined to a certain area?

Dr. FAUCI. Thirty-seven countries now have extensively drug resistant tuberculosis. There are a few cases we have in the United States that have been taken care of and contained. The problem is very serious in southern Africa. Interestingly we have a considerable number of cases in the Eastern European bloc countries and even in Korea. But there are 37 countries worldwide that have extensively drug resistant tuberculosis. That's reported.

But given the fact that most of that one-third of the world's population is in the developing world in areas in Asia and India and China and in Africa. That's where you don't likely get the medical care to get the diagnosis to get it treated. So it's a problem that's probably underestimated. So I'm telling you it's 20 percent and then there's 10 percent of 20. It's probably an underestimate as to what's really going on. It's a serious problem.

Senator HARKIN. Is it highly transmissible?

Dr. FAUCI. Well, it's transmissible like any tuberculosis. You need close continued contact and it's aerosolized droplets that contain the tuberculosis bacillus.

Senator HARKIN. Anthrax.

Dr. FAUCI. Yes.

Senator HARKIN. Recent estimates have said we need to be prepared for an anthrax attack. HHS has stockpiled anthrax vaccine and antibiotics. The problem with antibiotics is that they have to be administered shortly after any kind of attack or event. I've heard that there are other therapeutics that could target the toxins released by the anthrax bacteria and therefore could be effective even after the onset of symptoms.

Dr. FAUCI. Correct.

ANTHRAX ANTIBIOTICS AND ANTI-TOXIN

Senator HARKIN. Tell me more about that.

Dr. FAUCI. Sure. We started a program right at the point of a few months after the anthrax attacks here in our capital. One of the concerns we had is that we have very, very good antibiotics for anthrax. In fact, the clinical trial was done among Senate and House staff when they were given Ciprofloxacin following known exposure.

In fact it's very interesting. Some of you may not know that when they did blood test screening of antibodies that many of the people who just did perfectly well because they took Ciprofloxacin or doxycycline. Actually you have proof that they were exposed, which means that if they did not take the antibiotic they very likely would have gotten sick. So the people who took the antibiotics did the really, the right thing about taking the antibiotics. I say that because we have good antibiotics.

But what we are concerned about is, remember, several of the postal workers here in the city who were misdiagnosed initially. Then when they finally had the right diagnosis and were put on Ciprofloxacin, they were so advanced in the disease that the circulating anthrax toxin was the thing that killed them as opposed to the replicating anthrax bacillus.

So, what we've done and we've been rather successful at it is to develop antibodies against the toxin itself. So if you have the antibiotic, prevents the replication of the bacteria, but the anti-toxin neutralizes the circulating toxin which is the thing that actually caused the death of several of those people. So we do have it. Some of it is already in the stockpile and we're working on even better ones.

Senator HARKIN. I was not aware of that.

Dr. FAUCI. Yeah, yeah, it's true.

Senator HARKIN. You actually have it in the stockpile now.

Dr. FAUCI. We have an order for it through Bioshield.

Senator HARKIN. Again this would be effective even after I become symptomatic—after the symptoms arise. You could target that? You say you're working on others, you mean there's——

Dr. FAUCI. There are multiple—there are three major toxins and we have antibodies to all of them. One of the ones, the lethal toxins that are the ones that we're most concerned about. We have now molecular biological techniques where we're trying to make

monoclonal antibodies against. Monoclonal antibodies in anybody you actually code and manufacture to make only the response against a particular toxin you're worried about.

Senator HARKIN. How certain are you? I mean, what's the success rate if you had 100 people who became symptomatic with anthrax and you gave them this vaccine? What's the survival rate?

Dr. FAUCI. It depends when you get it. I have to tell you being an infectious disease person and having taken care of a lot of people who have advanced septicemia and shock. Once a person goes into the toxic septicemia of endotoxic or other types of shock the salvage rate of those individuals is very low.

So I think even with an anti-toxin, if given early enough, before you have a lot amount of accumulated toxin, it would probably increase the salvage rate and decrease the morbidity and mortality significantly. I can't put a number on it for you because the clinical trial has not been done. So it would be folly for me to say, oh it's a 90 percent, 80 percent. We just don't know. We just don't know.

Senator HARKIN. How soon?

Dr. FAUCI. I hope we never have to test it.

Senator HARKIN. How will you know? How will you ever know?

Dr. FAUCI. We'll know when we have another attack.

Senator HARKIN. That's about the only way.

Dr. FAUCI. We have animal models which have worked very, very well in the animal models. But again we always be careful—if you tell me based on the animal model would I project that it would be a success I would say yes. But I have to be very cautious because there's a big leap between a successful animal model and what works in the human.

CANCER STEM CELLS

Senator HARKIN. I've got to go but a couple of things I wanted to cover. Cancer stem cells. There's an idea that within a tumor there are cancer stem cells are really the driving force. That if we could just figure out how to get to those stem cells and target those that we would have a better success rate in curing cancer. What can you tell me about that?

Dr. NIEDERHUBER. Well, it's a very exciting area of research. It is not a totally new concept. It's really an old concept. But it has come back in just the past few years.

An example, Senator Harkin, a year ago at the AACR, the big national research meeting, there were maybe 20, 25 papers. This year there were over 225 papers at the meeting. So it just shows you how the community has become excited and interested in this concept.

So we know that within our tissues, the normal tissues of our body there are cells that are responsible for regenerating those tissues. Let's take the lining of the intestine, the colon, for example. We know that there are what we call tissue stem cells that have a certain division property that allows them to regenerate that lining of the colon.

So the concept is that the genetic changes that occur that lead to a cancer may have to occur in those cells, in those tissue stem cells, in order for the cancer to become a significant lesion—to have the property or potential for invasion and the potential for spread.

In the tumor the bulk of the tumor cells don't carry that kind of genetic imprint.

It's like thinking of the cell as an orchestra. Some of the instruments that give that orchestra in that cell the properties of being stem like in character are in a subpopulation of the tumor, maybe 1 percent, maybe as much as 2 percent of the tumor. The bulk of the cells in the tumor don't have that set of instruments playing at that particular moment.

We think we're doing a good job of getting rid of the bulk of the tumor but what gets left behind is that one percent of cells that can lie quiescent in the tissues of the body for a number of years. Those of us who practice oncology over the years have been always puzzled by seeing a patient with breast cancer seemingly cured 15 years or so later coming back with the disease seemingly everywhere. It may be part of the explanation of this.

So without question we need to learn more about these cells. We need to learn what gives them resistance to the therapies that we use. We know that they have certain properties that can pump drugs that get into the cell immediately back out of the cell. So there are a lot of things that are—that make them more difficult to target. Maybe we haven't been specifically targeting them in the ways that we need to.

Some of the new research is showing pathways that are unique to those cells. That is, signal pathways within the cell and potential ways to target them that are unique. So I think you'll see over the next few years a lot more research going on that is trying to get at that population of cells, better characterizing it and better targeting it for therapy.

NATIONAL PRIMATE RESEARCH CENTERS

Senator HARKIN. Thank you very much. I have a couple of last questions for Dr. Alving. This subcommittee has been very supportive of the primate centers. We included report language in a lot of our past bills, so I was disappointed to see in your budget request that your plans cut the funding for the centers by $1.7 million for a total of $72.3 million. What's the reason for that cut in the primate centers?

Dr. ALVING. This was in the congressional justification estimate and now the fiscal year 2007 joint resolution, which was a higher change from the CJ. But what we have had to do and what we are doing throughout the NCRR is to look at where we can best put our resources.

We are actively working with the primate centers to better manage the consortium. We're saying that they need to work together as a consortium in managing their animal facilities and in managing the breeding of the animals. We're very supportive of the work and they also are working with the CTSAs. So if we have improved funding we will be able to put more money into that program.

Senator HARKIN. Your budget request cut that funding.

Dr. ALVING. This was according to the amount of money that we had allocated as we went across the budget. We will put this money back in. We also are committed——

Senator HARKIN. So, if we—I mean, excuse me for interrupting. So if we do better than the President's budget will you put that money back in?

Dr. ALVING. Yes. Yes, we will.

Senator HARKIN. Ok.

Dr. ALVING. But also realize, Mr. Chairman, that we are working on building up our CTSAs and that's another challenge in NCRR. As we are building the primate centers, we'll be working with the CTSAs. For example, two of our CTSA awardee institutions, Oregon and UC Davis have primate centers. Those primate centers are working in that consortium as well.

But we are very supportive of the primate centers. They're doing excellent work. I visited four out of eight of them. We want to work with them as a consortium to support them.

GCRC TRANSITION INTO CTSA

Senator HARKIN. Ok. Well we'll try to put some more money in there for it. It's not that big. One last question on the CTSAs. As you say you're building them up, but what happens to the General Clinical Research Centers? I guess they're going to be folded into them or something like that?

Dr. ALVING. There will be a transition into the Clinical and Translational Science Awards. For example, of the first 12 CTSA awards that were provided, 16 General Clinical Research Centers were included. Those have become part of the CTSAs.

We're also emphasizing pediatrics in the CTSAs. For example, at the University at Pennsylvania, two General Clinical Research Centers were folded into that CTSA award, one from the Children's Hospital of Pennsylvania, one from the University of Pennsylvania. Now they are absolutely working together.

Senator HARKIN. So you can assure me there will be no diminution of training researchers the next generation in translation and clinical research because of this new structure.

Dr. ALVING. What we're really building is the training of the clinical researchers because the GCRC program never included training. So this is a big component of the new CTSAs.

Senator HARKIN. Thank you. Any last things from anyone else that I didn't touch on or that you wanted to express yourself on before I gavel this closed here? I thought it was a very good hearing. I think we got a lot out and a lot of good information.

Again, I thank you all very much for your leadership in all these various areas. I just hope that we can get a little bit better budget than what the President requested. We will. We'll get better than what the President requested. And now we're looking ahead to see how we can repair some of the damage of the last few years. The 12 percent or 13 percent that we've come down in NIH over the last 4 or 5 years and we've got to get it back up again. But that's our problem. We'll see if we can do better on that.

So with that, thank you very much. We have one more group from NIH and we haven't scheduled a hearing but I assume it won't be this week and it won't be next week because we're not here. So it will be sometime in June we'll have the last set of hearings.

ADDITIONAL COMMITTEE QUESTIONS

So I thank you very much and we will keep the record open for any questions that other Senators who weren't here today have for you that they might submit in writing.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

FOOD ALLERGIES AND ANAPHYLAXIS

Question. Dr. Fauci, children who have had atopic dermatitis, also known as eczema, are more likely to have severe food allergies and asthma. Has the NIAID considered the possibility of funding a complementary initiative, perhaps in coordination with the NHLBI, on atopic dermatitis as it relates to asthma and food allergy?

Answer. The National Institute of Allergy and Infectious Diseases (NIAID) is committed to supporting research to better understand the relationship of atopic dermatitis (AD) to asthma and other allergic diseases, particularly food allergy. At this time, the NIAID is supporting several studies in this area. The Consortium of Food Allergy Research is conducting an observational study of the development and loss of tolerance to foods in a cohort of 400 children, ages three to twelve months, at a high risk of developing food allergies, including children with AD. The study will correlate biological markers and immunologic changes associated with the development of peanut allergy and the resolution of allergies to egg and cow's milk, and evaluate genetic and environmental influences on these food allergies.

Another NIAID-sponsored program, the Immune Tolerance Network, is conducting two clinical trials related to food allergy and AD. The first will determine whether feeding a peanut-containing snack to young children at risk of developing peanut allergy will prevent development of this allergy. The subjects are children between 4 and 10 months of age with AD and/or allergy and they will be followed until they reach 5 years of age. The second clinical trial is enrolling children with AD who are between the ages of 18 and 30 months and at high risk for developing allergies. This trial will determine whether oral administration of cat, grass, and house dust mite allergens will prevent the development of allergy to these and other allergens and asthma in these children.

The NIAID Inner-City Asthma Consortium is conducting the Urban Environment and Childhood Asthma (URECA) observational study, which will assess antibodies to milk, egg white, and peanut in infants at risk for developing allergic diseases, including asthma, allergic rhinitis, and AD. The study will look for a correlation between food allergies and the onset of asthma later in life.

Lastly, the NIAID currently collaborates with NHLBI on two initiatives related to asthma. One of these, Immune System Development and the Genesis of Asthma, includes a grant which studies the relationship of AD to asthma.

Question. What plans does NIAID have to encourage research applications on anaphylaxis? Has the NIAID considered the need for clinical studies of emergency room treatment for anaphylaxis?

Answer. To address the problem of anaphylaxis, the NIAID is pursuing two major approaches: expanding support for research on the causes, treatment, and prevention of allergic diseases, including food allergies and food-allergy-induced anaphylaxis; and supporting national and international conferences that will disseminate new knowledge and promote a more cohesive approach to the diagnosis, prevention, and clinical management of anaphylaxis.

Expanding research

—The Report of the NIH Expert Panel on Food Allergy Research discussed food-induced anaphylaxis in detail and emphasized the need to study the pathogenesis of severe food allergy.

—The NIAID-funded Consortium of Food Allergy Research is conducting an observational study of the natural history of food allergy, which is expected to provide new information about severe allergic reactions and anaphylaxis. In addition, the Consortium is conducting a clinical trial focused on severe food allergy, which will use increasing oral doses of egg to treat patients with severe egg allergies.

—The NIAID has just announced a new initiative, Exploratory Investigations in Food Allergy, which encourages studies on severe life-threatening food allergy.

Supporting national and international conferences

—The NIAID, in partnership with the Food Allergy and Anaphylaxis Network (FAAN), a patient advocacy group, convened meetings in 2004 and 2005 to establish clinical criteria to identify cases of anaphylaxis with high precision, review evidence on the most appropriate clinical management of anaphylaxis, and outline research needs in this area. Participants included experts and representatives from professional, governmental, and lay organizations. The proceedings of these symposia were published in the March 2005 and February 2006 issues of the Journal of Allergy and Clinical Immunology.

The NIH Expert Panel on Food Allergy Research considered the need for clinical studies of emergency room treatment for anaphylaxis and presented its recommendations as part of its report.

Question. Does NIAID make information available to health professionals about the best approaches to treating food allergy?

Answer. The Consortium of Food Allergy Research was initiated in 2005 to develop new approaches to treat and prevent food allergies. As such, one of the goals of the Consortium is the development, implementation, and dissemination of educational programs for children, their parents, and pediatric health care workers. In addition, the Consortium supports preclinical research, observational studies, and immune-based clinical trials for treatment or prevention of food allergies.

To ensure that the information on diagnosis, prevention and management of anaphylaxis is developed and widely disseminated to the medical community, NIAID, in collaboration with FAAN and the American Academy of Allergy, Asthma and Immunology, is organizing a series of meetings. These are scheduled to begin in July 2007 and will develop evidence-based guidelines for the diagnosis and management of food allergy, including anaphylaxis.

TOBACCO-RELATED RESEARCH

Question. Dr. Niederhuber, in March, you told NCI's Board of Scientific Advisors that the Tobacco Control Research Branch has been cut by $6.5 million between fiscal year 2004 and fiscal year 2007. Are those numbers still correct? If so, can you tell us how cutting back on this type of research will affect our ability to prevent tobacco-related cancers?

Answer. The Tobacco Control Research Branch (TCRB) budget was $19.2 million in fiscal year 2004. We are still in the process of making final funding decisions, but the current estimate for fiscal year 2007 is $12.7 million, which is a reduction of $6.5 million from fiscal year 2004. Part of the reduction during the period between fiscal year 2004 and fiscal year 2007 was due to the expiration of some tobacco control research initiatives. However, additionally, the period following the doubling of the NIH budget has resulted in very difficult choices in terms of setting priorities and implementing funding decisions. The NCI Executive Committee and advisory boards have worked diligently to conduct strategic priority setting and decision making related to the scientifically appropriate distribution of resources. In order to pursue new and emerging opportunities in cancer research, we must make choices about which programs and research initiatives come to an end.

In terms of planning for the future, scientists in TCRB are currently working on several new research concepts in response to the 2006 NIH State of the Science Conference, "Tobacco Use: Prevention, Cessation and Control," and other priority setting reports. NCI will use these concepts to develop and redirect initiatives in tobacco control research in the future.

NCI's research efforts in the prevention and control of tobacco use are premised on three fundamental facts: all tobacco products are hazardous; there is no safe level of tobacco use or ETS exposure; and the only proven way to reduce the burden of disease and death due to tobacco products is to prevent their use and to assist those who use tobacco products to quit. Further progress in reducing tobacco use is an important challenge facing the public health, medical, and policy communities.

The Tobacco Control Research Branch (TCRB) maintains a diverse portfolio of research and dissemination activities. Most noteworthy are the following:

—Transdisciplinary Tobacco Use Research Centers (TTURC). The TTURCs are a collaboration between NCI, NIDA, and NIAAA to study tobacco use control and addiction research spanning diverse areas ranging from molecular biology, genetics, neuroscience, and epidemiology to imaging, primary care, behavioral science, communication, health policy, biostatistics, economics, and marketing. Collaborative research across disciplinary boundaries permits scientific exploration of the complex and interactive determinants of tobacco use.

—Testing Tobacco Products Promoted to Reduce Harm is a program which funds multidisciplinary research on the interplay of behavior, chemistry, toxicology,

and biology to determine the cancer risk potential of reduced-exposure tobacco products.

—Smokefree.gov is a state-of-the-art Web site developed by NCI in collaboration with the Centers for Disease Control and Prevention (CDC) and the American Cancer Society (ACS). It offers science-based tools and support to help smokers quit. Smokefree.gov complements the National Quitline Network that has established a new state-supported national telephone number so smokers in every state have access to information and proactive smoking cessation counseling.

—The Health Disparities Network is a unique endeavor to understand and address tobacco-related health disparities by advancing science, translating scientific knowledge into practice, and informing public health policy. In partnership with the Pennsylvania State University, core scientific activities are focused on methodology, treatment/cessation, prevention, translation/community, and policy. The formation of the network fills a void by establishing a mechanism to bring together an ethnically diverse group of researchers representing different disciplines and interests to answer multiple questions related to the research agenda in health disparities and explore optimal mechanisms for translating research into practical and effective community strategies.

MINORITY HEALTH

Question. Dr. Ruffin, if the Subcommittee were able to provide additional funding for the Center over the President's budget request, what would be your top priority for how to spend it (e.g., health disparities research vs. research capacity-building and infrastructure), and why? Please be as specific as possible.

Answer. The fiscal year 2008 President's Budget request of $194.5 million will support NCMHD's highest priority research activities. However, if the NCMHD were to receive any additional funding over the President's budget request, those funds would go towards research capacity-building specifically in the area of training. Having a strong and culturally diverse workforce is vital to the ability of NCMHD to fulfill its mission to improve minority health and eliminate health disparities. NCMHD would place additional emphasis on recruitment and retention at every level of the pipeline.

First, NCMHD would strengthen the retention component of the NCMHD Loan Repayment Program in order to keep more individuals from health disparity populations interested and involved in health disparities research, as well as attract young investigators from these populations to the biomedical research field in general.

Second, NCMHD would be to further develop the capacity of our Centers of Excellence to enhance their capability in conducting research into the multi-factorial issues associated with health disparities. The research efforts of these Centers contribute significantly in enhancing the nation's understanding of health disparities, and offer the training and professional research environment required for the workforce to study minority health and health disparities issues.

FOOD ALLERGIES

Question. Dr. Fauci, during the hearing, you indicated that the "roadmap" which was developed by the leading food allergy researchers and experts in immunology after they met in March 2006 is still in the process of being approved. When will it likely be released?

Answer. In March 2006, the National Institute of Allergy and Infectious Diseases (NIAID), on behalf of the Secretary of the Department of Health and Human Services, convened the NIH Expert Panel on Food Allergy. The Expert Panel met to review current basic and clinical research on food allergies and develop recommendations for enhancing and coordinating research activities concerning food allergies. The recommendations have now been posted on the NIAID website at http://www3.niaid.nih.gov/healthscience/healthtopics/foodAllergy/ReportFoodAllergy.htm.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

NATIVE HAWAIIANS AND CANCER

Question. Dr. Niederhuber, Native Hawaiians have a much higher mortality rate from cancer than other residents of the State. What efforts has the National Cancer Institute taken to understand cancer in Native Hawaiians?

Answer. The National Cancer Institute (NCI) continues to support research to find the causes of cancer health disparities and to develop effective ways to improve cancer outcomes for Native Hawaiians. Among these continued efforts are: enhanc-

ing surveillance of Native Hawaiian populations to document the extent of cancer health disparities and monitor progress in improving cancer outcomes in these communities; empowering Native Hawaiian communities to participate in setting cancer research goals and priorities; assuring access to community-based health care that is culturally and linguistically appropriate; supporting infrastructure for Native Hawaiian communities that promotes cancer awareness, supporting research education and training in cancer prevention and control research by Native Hawaiian researchers, and supporting the development of evidence-based information and interventions to improve cancer outcomes in Native Hawaiian communities.

Community Networks Program

Two of NCI's Community Networks Programs continue to address Native Hawaiian populations: 'Imi Hale—Native Hawaiian Cancer Network, and WINCART: Weaving an Islander Network for Cancer Awareness, Research and Training. These five-year grants, engage in cancer education, community-based participatory research and training targeted specifically to the Native Hawaiian population.

The Native Hawaiian Cancer Network, 'Imi Hale, is located in Honolulu, Hawaii and collaborates with key partners at the community, state, and national levels to provide support systems and expertise to: (1) provide a core organizational infrastructure; (2) increase utilization of proven interventions to reduce disparities; (3) increase the number of Native Hawaiians participating in community-based research to reduce cancer health disparities through recruitment, training, and mentorship; (4) promote research that focuses on the spectrum of issues relevant to cancer health disparities, with an emphasis on developing interventions that can be used in and by Native Hawaiian communities; and (5) provide evidence-based information on reducing cancer health disparities to decision and policy makers at the community, local, state, and Federal levels.

WINCART

WINCART aims to: (1) identify multilevel barriers to cancer control among Pacific Islanders; (2) improve access to and utilization of existing cancer prevention and control services for these communities; (3) conduct community-based participatory research; (4) increase the number of Pacific Islander researchers through training, mentorship, and research projects; (5) sustain community-based education, training, and research activity through government and organizational collaborations; and (6) disseminate research to aid in the reduction of health disparities among Pacific Islander communities. Research activities focus on obesity, tobacco, cancer screening, survivorship, and recruitment of Pacific Islanders into clinical trials. The Network works with the NCI-supported Cancer Information Service to develop culturally and linguistically appropriate educational materials.

NCI SURVEILLANCE OF CANCER HEALTH IN NATIVE HAWAIIAN POPULATIONS

NCI continues to strengthen the Surveillance Epidemiology and End Results (SEER) Program which has expanded its surveillance coverage and activities to capture 70 percent of Native Hawaiians and Pacific Islanders in the surveillance network. These include cancer surveillance, behavioral risk factor surveillance, health information and health services data, and epidemiologic data. This expansion is critical to uncovering the extent of the cancer problem and monitoring progress in eliminating cancer disparities in Native Hawaiian and Pacific Islander communities.

CANCER IN PACIFIC ISLAND SUBPOPULATIONS

The NCI also recognizes the dramatic disparities found in many Pacific Island subpopulations, including rural Native Hawaiian populations. Through the Minority Institution/Cancer Center Partnership Program, NCI supports a research partnership between the University of Guam, and the Hawaii Cancer Research Center to address the cancer research needs of Guam and adjoining Islands.

Through the Cancer Information Service, NCI supports efforts to provide NCI products, resources and services, including promotion of the Clinical Trials Education Series and clinical trials to individual hospitals in Hawaii approved through the American College of Surgeons Commission on Cancer (ACoS). In addition, CIS provides professional training in cancer and cancer clinical trials throughout Hawaii, raises awareness among Kauai Community College (KC) nursing students about cancer clinical trials, and promotes access and dissemination of NCI cancer clinical trials resources. These efforts have improved screening rates among Hawaii's medically underserved populations.

NURSING

Question. Dr. Grady, could you discuss the funding rates of the NINR compared to other institutes at the NIH? What percentage of nursing studies are co-funded with other institutes? What are your impressions of co-funded studies?

Answer. NINR, like the rest of NIH, calculates success rates by dividing the number of research project grant (RPG) applications selected for funding in a given fiscal year by the total number of RPG applications reviewed during that year. In fiscal year 2006, NINR had a success rate of 18 percent, slightly lower than the overall rate of 20 percent for NIH as a whole. NINR has historically had success rates lower than the NIH average; however, success rates can and do fluctuate from one year to another based on both the number of applications received and the overall NINR budget. In fiscal year 2006, NINR chose to devote about 72 percent of its budget to the support of RPGs.

In fiscal year 2006, approximately 7 percent of NINR-supported research grants were co-funded by one or more of the other NIH Institutes and Centers (ICs). However, co-funding is only one aspect of NINR's overall collaborative effort across NIH. In today's increasingly complex, interdisciplinary research environment, NINR views trans-NIH collaborations as an important part of its research mission. In addition to co-funding research, other such efforts include: co-sponsoring new research initiatives with other ICs, leading the NIH effort in end-of-life research, and maintaining leadership roles in trans-NIH activities such as the NIH Pain Consortium, Public Trust Initiative, and Roadmap. Greater collaboration with other ICs increases both the visibility of nurse scientists in the greater research community and trans-NIH awareness of research areas traditionally associated with nursing science, such as symptom management and disease prevention. Interdisciplinary collaborations also provide our own investigators with opportunities to expand the breadth of their work into areas of research not previously associated with nursing science.

NIAID AND NATIVE HAWAIIANS

Question. Dr. Fauci, in your testimony, you indicate that autoimmune diseases, allergic diseases, asthma and other immune-mediated diseases are significant causes of chronic disease and disability in the United States and throughout the world. With respect to asthma and lower respiratory disease, Native Hawaiian adults have a much higher prevalence of asthma compared to other adults in Hawaii—71 percent higher than the total State prevalence. How can the NIAID contribute to a greater understanding of the asthma among Native Hawaiians?

Answer. Native Hawaiians, along with other minority U.S. populations, have higher asthma prevalence. A recent Centers for Disease Control and Prevention report indicates that the prevalence of asthma in children in Hawaii, is among the highest in the Nation. The National Institute of Allergy and Infectious Diseases (NIAID) welcomes research grant applications focusing on the causes of increased asthma prevalence and morbidity. While the NIAID is not currently supporting research that investigates asthma in Native Hawaiians, the Institute is actively supporting research in other groups who have high asthma prevalence and morbidity.

One of the Institute's initiatives is the Inner City Asthma Consortium (ICAC), which aims to identify the causes for increased asthma prevalence and morbidity and develop effective management approaches in urban, minority children populations.

Additionally, the NIAID and the National Heart, Lung, and Blood Institute (NHLBI) co-sponsor the "Immune System Development and the Genesis of Asthma" program, which supports research on changes in immune function that occur early in life and lead to the development of asthma.

Information gained from these studies will enhance our understanding of the mechanisms of increased asthma in specific populations. We hope that this understanding can be extended to Native Hawaiians and can lead to measures of prevention and therapy that will ameliorate this significant health problem.

DENGUE FEVER

Question. Dr. Fauci, in 2001, Hawaii experienced an outbreak of dengue fever that lasted 8 months, in which over 1,500 people experienced severe sickness. Worldwide, dengue fever kills approximately 25,000 each year, and it is estimated that there are between 50 million and 100 million cases of dengue fever illness each year. Given the impact of this disease on my constituents, what efforts has the NIAID taken towards vaccine development?

Answer. The National Institute of Allergy and Infectious Diseases (NIAID) is currently supporting several research projects to develop a safe and effective vaccine against dengue fever. Development of a dengue vaccine is challenging because of several factors, chiefly, the requirement that a dengue vaccine be tetravalent, that is, simultaneously protective against all four dengue serotypes. Researchers at the NIAID have developed components of a tetravalent dengue vaccine that are undergoing clinical testing. Other efforts to develop a vaccine against dengue fever include support of the following research projects:

—Preclinical and clinical development of a recombinant subunit vaccine against the 4 dengue serotypes (Hawaii Biotech, Inc., Aiea, HI): Additional formulation studies and toxicology testing are currently ongoing in preparation for a Phase I clinical trial planned for 2008.

—Preclinical development of live attenuated vaccine against the 4 dengue serotypes (InViragen, LLC., Mount Horeb, WI): Extensive safety and efficacy testing is currently being conducted in different animal models in preparation for a Phase I clinical trial.

—Development of a microneedle array system for delivery of a DNA tetravalent dengue vaccine in the skin (Cyto Pulse Sciences, Glen Burnie, MD): This vaccine is currently being tested for immunogenicity in different animal models, and the microneedle array will be tested in human volunteers for safety.

—Development of dengue virus replicon system to measure dengue virus neutralizing antibodies in the serum (Integral Molecular, Philadelphia, PA): This assay will be evaluated using serum samples of patients who are hospitalized with dengue fever in Nicaragua.

—Recombinant envelope protein domain III as a candidate subunit dengue vaccine (University of Texas Medical Branch, Galveston, TX): The long-term goal of this project is the development of a candidate subunit vaccine that induces neutralizing antibodies for all four flaviviruses that cause dengue fever.

Question. When may we expect to have an effective product?

Answer. The candidate vaccines listed previously are moving through the product development pipeline. However, the challenges facing the development of a safe and effective vaccine are still significant. The timeline for a vaccine product to be manufactured for use in the United States depends upon a manufacturer successfully completing late-stage clinical trials, including a Phase IV population effectiveness trial and submitting the results to the Food and Drug Administration for licensure. This can be a lengthy process and can extend several years after clinical trials have been completed.

Question. Which other States may be affected in the near future?

Answer. According to the Centers for Disease Control and Prevention (CDC), there is a small risk for dengue outbreaks in the continental United States. However, the epidemic in Hawaii in 2001 serves as a reminder that many states in the United States are susceptible to dengue epidemics. In particular, states in southern and southeastern United States, where the Aedes aegypti mosquito is found, are at risk for dengue transmission and sporadic outbreaks (http://www.cdc.gov/ncidod/dvbid/dengue/index.htm).

Question. What impact, if any, could global warming have on the spread of dengue-carrying mosquitoes?

Answer. Environmental events, such as climate shifts, weather changes, and deforestation, can affect infectious diseases, particularly vector-borne diseases such as dengue virus. High temperatures, in combination with favorable rainfall patterns, could prolong the disease transmission season in places where the virus already exists or expand the ranges of the mosquito vectors to places where the disease is not usually found, such as Hawaii and the southern region of the continental United States.

TERRORISM PREPAREDNESS

Question. Dr. Fauci, the NIAID has been assigned the responsibility to coordinate research to develop countermeasures against a range of radiological and chemical threats. You describe how the Centers for Medical Countermeasures against Radiation coordinate activities with interagency partners, including the Department of Defense, Department of Energy, and Department of Homeland Security. Could you describe ongoing research of medications that would provide protection against radiation in the event of a small nuclear weapon or a dirty bomb?

Answer. The National Institute of Allergy and Infectious Diseases (NIAID) is currently evaluating multiple compounds, including many drugs that are licensed for other indications, for use as countermeasures to combat the effects of an incident involving release of radioactive material. This research is part of the NIAID radi-

ation and nuclear countermeasures program, which is guided by the NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Radiological and Nuclear Threats.

Examples of specific NIAID-supported research initiatives include:

—Research on all elements of radiation injury and the development of products that can be licensed and included in the Strategic National Stockpile.

—Programs to screen candidate compounds for use as radiation countermeasures. These programs have tested 40,000 compounds and identified 52 for further evaluation.

—Development of improved forms of the chelating agent diethylenetriaminepentaacetic acid (DTPA). A chelating agent is a compound that binds to a radionuclide and facilitates and accelerates its elimination from the body.

—Research on 29 candidate drugs that exhibit activity against a broad range of radionuclides that might be used in radiological dispersion devices or "dirty bombs", including several that currently lack effective treatment approaches, such as Strontium 90 and Cobalt 60.

Research to develop medical countermeasures to treat radiation injury remains in the early stages of development; significant research and pre-clinical testing is needed before we will have candidate products developed to treat radiation injury that can move forward for licensure.

QUESTION SUBMITTED BY SENATOR ARLEN SPECTER

OVARIAN CANCER

Question. Dr. Niederhuber, as you are aware, there is currently no early detection method for ovarian cancer. Because of this, more than 75 percent of women diagnosed with ovarian cancer die within five years of being diagnosed. If we were to find these cancers early, the mortality rate falls dramatically to about 15 percent. And, ovarian cancer is not alone; similar statements could be made for pancreatic cancer. Please share NCI's strategy for fiscal year 2008 regarding early detection research, such as biomarkers, for cancers like ovarian and pancreatic, where the incidence numbers are smaller than, say, breast or prostate cancer, but the mortality rates are much higher.

Answer. NCI launched the Pancreatic Cancer Cohort Consortium (PanScan), which is conducting whole genome scans of common genetic variants in 1,200 pancreatic cancer cases and 1,200 controls from 12 cohorts to identify markers of susceptibility to pancreatic cancer. The promising genetic variants (single nucleotide polymorphisms (SNPs) identified will be validated by testing data from participants in a pancreatic cancer case-control consortium. It is anticipated that SNPs that are highly likely to be markers for genetic variants related to pancreatic cancer risk will emerge from this analysis as they have in similar studies on prostate and breast cancers, and lead to further studies of gene-gene and gene-environment interactions with pancreatic cancer risk factors. It is hoped that the PanScan will lead to identification of not only susceptibility genes but early markers for disease. This would be particularly useful for pancreatic cancer which is usually diagnosed at an advanced stage.

There are also several projects being conducted on ovarian and pancreatic cancer in NCI's Early Detection Research Network (EDRN). Scientists are conducting research to enhance early detection of ovarian cancer. EDRN plans to screen serum DNA from larger cohorts of early ovarian cancer patients and controls collected by the EDRN- and SPORE-funded clinical centers for validating the optimized panel of genes for early detection and risk assessment. There are also a number of similar studies to discover biomarkers for the early detection of pancreatic cancer.

NCI launched a unique program in September 2006, the NCI's Clinical Proteomic Technologies Initiative (CPTI). CPTI represents a highly-organized approach to apply proteomic technologies and data resources to support the discovery of biomarkers for the early detection of cancer and to monitor therapeutic outcomes. CPTI will advance the field of clinical cancer proteomics through the development of an integrative team framework that networks multiple research laboratories to permit large-scale, real-time exchange and application of existing and newly developed protein measurement technologies, biological resources, and data dissemination. Efforts will include refining and standardizing technologies, reagents, methods, and analytic platforms in order to ensure reliable and reproducible identification, quantification, and validation of proteins from complex biological mixtures; and evaluating

new technological approaches to identify proteins that occur during cancer development.

In December 2005, leaders from NCI and the National Human Genome Research Institute (NHGRI) launched The Cancer Genome Atlas (TCGA) Pilot Project, a comprehensive effort to accelerate understanding the molecular basis of cancer, and was the result of a "blue-ribbon" committee of the nation's leading scientists. Cancer includes more than 200 different diseases, each with a set of genetic changes that results in uncontrolled cell growth. The purpose of the Cancer Genome Atlas pilot is to test the feasibility of completely sequencing and cataloging the full range of genetic defects in 3 tumor types—brain (glioblastoma), lung and ovarian cancers, leading the way to a better understanding of all cancers.

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you all very much. The subcommittee will stand in recess.

[Whereupon, at 4:10 p.m., Monday, May 21, the subcommittee was recessed, to reconvene at 10 a.m., Friday, June 22.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

FRIDAY, JUNE 22, 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Reed, Specter, and Cochran.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF RUTH L. KIRSCHSTEIN, M.D., ACTING DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services will come to order. This is the last of our six hearings we have had on the National Institute of Health. We have heard from 18 Institutes so far, today we will hear from five more. The National Center for Complementary and Alternative Medicine, the National Institute of Dental and Craniofacial Research, the National Institute of Environmental Health Sciences, the National Eye Institute, and the National Institute of Child Health and Human Development.

I want you all to know, I've really enjoyed the informality of these hearings. This is just like we've had all of the other ones, actually. When I first came on this committee in 1985, Senator Weicker, had sort of established this process of having these kinds of hearings. I thought they were very informative, and this is the way we have done it. I kept thinking, up until the mid-1990's I wanted to re-institute, reinstate that again.

I found that these hour and a half or 2 hour hearings that we have had, for me, it's like being in class again. I get to learn a lot of things I didn't know about, and it's extremely informative, not just for me, but for our staffs on both sides, and people right here. I think we get a little bit more in-depth knowledge of what each of the Institutes are doing, what we're looking ahead for, and I think it gives us a better idea of, perhaps, where our allocations

of money ought to be going. So, it has been great to get into little bit more in depth than we have had.

I just want to say a few words about the fiscal year 2008 budget that we marked up yesterday, by the way. We proposed a $1 billion increase for NIH. This will allow NIH, for the first time since fiscal year 2005, to plan on increasing the average cost of new grants by 3 percent. I know that's not big, but it's better than what we have had, and it will provide the full-blown committed level for non-competing grants for the first time.

We also increased the common fund by 10 percent. We've set aside the full amount to continue the National Children's Study, and provided additional support for young investigators. I know Senator Specter and I both wish we could have done more for NIH, and who knows, when it goes to conference, maybe we will even do more. We don't know, but we'll do as much as possible.

I want to thank both Senator Specter and Senator Cochran for their support of NIH, and for this proposal that we have, that we passed yesterday in full committee.

With that, I will yield to my colleague, and good friend, Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you very much, Mr. Chairman. Thank you, ladies and gentlemen for coming in today. The work of this subcommittee is well known, and our vigorous advocacy for NIH, and is even better known for our success in raising the funding level through the efforts of Senator Harkin, Senator Cochran and others on this committee.

When I take a look at the complementary alternative medicine line, my recollection is it was $7 billion before my wife told me how important it was. I shared that information with Senator Harkin. We have talked about the change of the gavel being seamless—it doesn't matter who is there. Senator Cochran has been a member of this subcommittee longer than either of us has—and as chairman and ranking member of the full committee, and has given tremendous support to these efforts.

I wanted to come by to send my personal greetings to you. I regret that I have commitments in Pennsylvania today. Friday is the day when we try to take care of the home front, except Senator Harkin who works 7 days a week, so he schedules hearings on Friday morning. You can shoot a canon through the Senate and the House today and have no risk of hitting anybody. Except for Senator Harkin and Senator Cochran. So, I'm going to excuse myself, but my staff will stay and report to me of the preceding, and I will be following it very closely.

Senator HARKIN. Thank you very much, Senator Specter, have a good weekend.

Senator Cochran, did you have a statement?

STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, I'm pleased to join you and Senator Specter to welcome our panel of witnesses to the committee today. We appreciate the opportunity to continue our review

of the fiscal year 2008 budget request for the National Institutes of Health.

Today, we have five representatives of different Institutes conducting research to talk about their requests for the coming year, and we appreciate the participation of this panel in hearing and discussing with us your plans for the coming year.

The National Center for Complementary and Alternative Medicine has provided, for the last 7 years, a foundation of scientific research in the emerging area of alternative medicine and therapy. Dr. Stephen Straus served as the Institute's first Director. We convey our condolences to the NIH family for the recent loss of Dr. Straus. A great deal was accomplished under his leadership to further our understanding of alternative therapies, and their role in integrating medicine.

Also, the role that dental health plays in ones overall well being has received more attention recently. The death of a 12-year-old child in Maryland due to a dental infection raised awareness of the importance of good dental care. I am co-sponsoring legislation—the Children's Dental Health Improvement Act of 2007—with Senators Bingaman and Cardin, which seeks to provide disadvantaged children with better access to dental services. The work being done by the National Institute of Dental and Craniofacial Research is important to improving dental health for all Americans.

We're learning that a number of conditions afflicting our population are connected to environmental factors. It's important that we extend our resources from simply treating existing diseases, to identifying ways to prevent them. As we learn more about the impact the environment has on different disease processes, we're better positioned to identify prevention measures. The work in this area through the National Institute of Environmental Health Sciences is very important, and I look forward to hearing about recent advances in this research.

In my State of Mississippi, diabetes is a very challenging situation, presents a very challenging situation. There's been a big increase in the prevalence, and this causes many complications to the health of our citizens. What was once thought to be an adult disease is occurring now more often in children, as we see numbers of overweight and obese young people increase. Progress in this area is very important to me. We have more diabetes as a percentage of our State's population than any other State in the union. So, progress in this area could help a significant number of people.

I'm not going to go through the list and talk about every Institute that is represented here today, but issues like infant mortality, the National Children's Study being done at NIH through the National Institute of Child Health are uncovering disparities which need our attention, and your suggestions as to what we can do about this in terms of national policy and funding priorities.

Dr. Zerhouni has testified before this committee on a number of occasions, in March, he talked about the medical advances resulting from NIH-supported research, and we are aware of the importance of our continuing to be generous in the appropriation of funds for these activities—translating basic science, knowledge into improved and lifesaving therapies is very challenging, but it is very important as we work to improve the work being done by our Fed-

eral Government agencies. I appreciate the hard work all of you are turning in, and your dedication to ensuring that NIH is successful in these important areas of inquiry.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran.

Let's just go from left to right. I would like to ask each of you, all of your statements will be made a part of the record in their entirety. I would just like to ask if each of you would just please speak for five to seven minutes, and we'll just go from left to right, then we'll just open it up for kind of general discussion at that point in time.

First I will introduce Dr. Ruth Kirschstein who I don't really need to introduce very much, I'll do it anyway. She has served as Acting Director of NCCAM since August 2006. I want to join with Senator Cochran in expressing my condolences on Dr. Straus' passing. He fought that brain cancer for a long time, it kept coming back, and right up until the end, just did an outstanding job of leading that Institute.

But, Dr. Kirschstein's career at NIH spans 33 years. In 1974, became the first woman to serve as the Institute Director, head of the NIGMS, and her positions also included a 2-year period as Acting Director of all of NIH, and I remember we worked together at that time. In 2002, I had the great pleasure of surprising her by renaming the National Research Service Awards, as the Ruth L. Kirschstein National Research Service Awards.

Dr. Kirschstein, welcome back, as we have for so many years, back to the committee, and please proceed as you so desire.

SUMMARY STATEMENT OF DR. RUTH L. KIRSCHSTEIN

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman, Senator Cochran, and Senator Reed. I want to thank you also for providing us with the opportunity today to discuss NCCAM's vision for the future, and to tell you how much we at NIH are grateful for your ongoing support, and thank you for your efforts on behalf of the health of the American public. Today as Senator Harkin has said, I'm here as the Acting Director of the National Center for Complementary and Alternative Medicine. I'm delighted to be back, and to see you once again.

I have some material from NCCAM, which I want to provide to you, I think some of you have a strategic plan, but just in case, since NCCAM was established by Congress, thanks to your vision, Mr. Chairman, the Center has built a global scientific research enterprise, for the study of complementary and alternative medicine.

The progress that has been made in understanding the scientific basis of CAM is greatly attributable, as you said, to the leadership of Dr. Stephen Straus, NCCAM's founding Director. And I want to thank you and your staff for your kindness in postponing the hearing on the day of his funeral, and to thank the staff for attending the funeral.

INTEGRATIVE MEDICINE

Today, we know that many Americans are using CAM modalities in an effort to promote health and well-being, and to preempt disease, and that it is driven largely by consumer demand for com-

plementary and alternative medicine. Integrative medicine is rapidly becoming the major force-shaping healthcare in the United States.

Integrative medicine makes use of both conventional and complementary therapies to address all aspects of health and wellness. In addition, we know well, that better communication between patients and their medical practitioners is absolutely vital to ensure well-coordinated, comprehensive and safe care.

In NCCAM's pursuit of rigorous science to understand complementary and alternative medicine, is the foundation that will build the evidence to facilitate the adoption of integrative medicine in our society. Our efforts to study and understand CAM continue to grow, and in the past year we have launched three new activities, a new program to assess the potential of community-based, primary care research networks, which will increase our knowledge about the efficacy and the cost-effectiveness of CAM modalities, as well as the safety of the approaches.

We're also studying the mechanism of action underlying manipulative and body-based practices, such as chiropractic. We're developing innovative tools and technologies to study the biologically based aspects of mind body intervention.

Our overall strategy is to support a diverse portfolio of basic translational and clinical studies. The study of acupuncture is an example of this approach. Clinical studies have demonstrated the potential of acupuncture for a number of conditions, such as osteoarthritis, and the basic and translational research using state-of-the-art neuroimaging technology has now elucidated mechanisms of brain function that have direct relevance to pain relief.

Advances of similar importance are beginning to emerge in other areas. In the last year alone, NCCAM supported-research has demonstrated the potential of CAM for addressing a number of conditions, and I would like to give you a few examples.

The spice turmeric, which has long been important as a component of Ayurvedic medicine, is being used in the treatment of many inflammatory disorders. Preliminary evidence shows that turmeric contains specific compounds that may have anti-arthritic activity. This suggests potential ways in which turmeric may be used, and could yield insights into the mechanisms of arthritic disease.

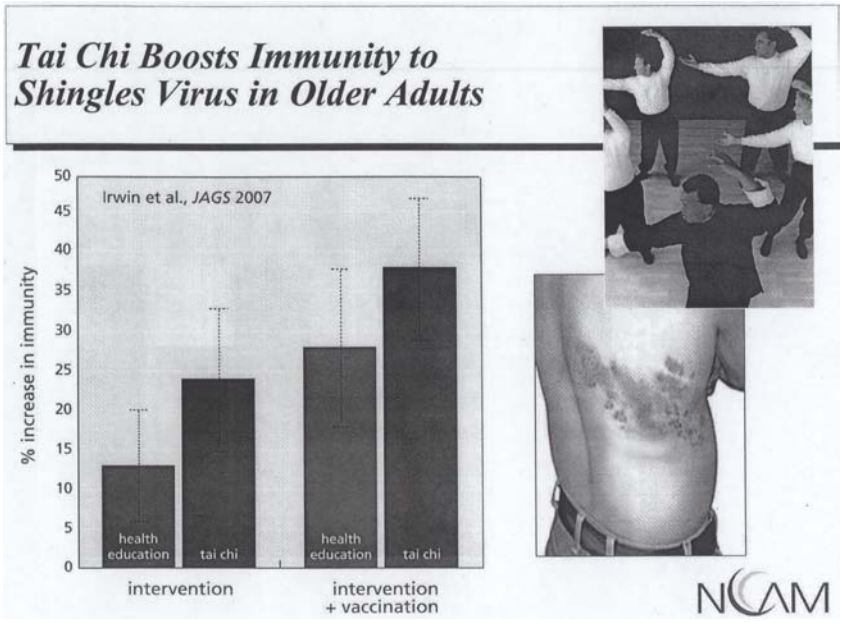
In another example, we have supported studies of the herb Ginkgo Biloba. This is a popular dietary supplement that is purported to promote brain health. Our studies in animal models of Alzheimer's disease have found that ginkgo reduces both the formation of the specific brain abnormalities that are also seen in humans, as well as preventing the paralysis seen in these animals.

These studies of animal models are very important, and will serve as leadership into the hypothesis that is now being tested in a large clinical trial of Ginkgo—the prevention of dementia. This trial is supported, not only by NCCAM, but by a number of the other institutes.

A very recently recognized clinical trial which you have referenced in your folders relates to Tai Chi, which is a traditional Chinese form of exercise. This modality may help older adults avoid getting shingles by increasing their immunity to the

varicellis osta virus, and enhancing the body's immune response to the vaccine.

Shingles, you know, affects the nerves, and causes pain and blistering in adults. There is a picture (Figure 1) of that in your folders. Shingles is caused by the same virus that causes Chicken Pox in children. Tai Chi combines aerobic activity, relaxation and meditation, and the combination of the shingles vaccine and Tai Chi out does the vaccine alone. This study was supported by the National Institute on Aging and NCCAM.



RESEARCH TRAINING

But in addition, Senator Harkin alluded to the importance of research training. NCCAM mandate to train the next generation of CAM researchers. This must involve collaborations between CAM practitioners, and experienced scientists, and it's absolutely fundamental to our approach to research training and career development.

Since its inception, NCCAM has increased the percentage of funds committed to research, training and career development from 1.3 percent in 1999, to 8.3 percent in fiscal year 2006.

OUTREACH

Now, the other, and third, component of our mission, is to provide authoritative, evidence-based information on CAM. We have a growing communications program that distributes information in English and Spanish, and in both print and electronic form, and includes CAM on PubMed, which is a database developed in partnership with the National Library of Medicine. It indexes more than 470,000 articles related to CAM.

We have an online continuing education program that offers information on a variety of topics, to help professionals and to the public. In addition, this year, we have a new patient provider educational initiative to encourage communication between patients and physicians about CAM use. The program, which is outlined in two pieces of paper in your folder (exhibits A&B), is called, "Time to Talk," to ensure physicians talk to their patients, and that patients talk to their physicians about the use of CAM. It will ensure safety and integrated health care. We look forward to building on NCCAM's foundation of scientific accomplishments in 2008. We will include new activities, such as the partnership with the Centers for Disease Control and Prevention to support the first national, population-based survey, assessing CAM use among the United States' pediatric population. This survey will help to fill an important information gap, and help NCCAM to set additional priorities.

TIME TO TALK. ASK your patients about their use of complementary and alternative medicine.

Ask

Did you know that almost two-thirds of people aged 50 and older are using some form of complementary and alternative medicine (CAM)? According to a recent survey[1] less than one-third of those people talk with their providers about CAM use.

What is complementary and alternative medicine (CAM)?

CAM is a group of diverse medical and health care systems, practices, and products that are not currently considered to be part of conventional medicine. CAM includes such products and practices as herbal supplements, meditation, chiropractic manipulation, and acupuncture.

Why should I ask my patients about their CAM use?

- Most patients do not proactively disclose use of CAM to their physicians.
- Patients with chronic and acute medical conditions—including cancer, diabetes, back pain, and depression—turn to CAM in large numbers.[2]
- As more patients use CAM therapies, you need a full picture of all conventional and CAM practices they are using so that you can effectively manage their care.

How can I find the time to discuss CAM with my patients?

- Include a question about CAM use on medical history forms.
- Ask your patients to bring a list of all therapies they use, including prescription, over-the-counter, herbal therapies, and other CAM practices.
- Have your nurse, nurse practitioner, or physician assistant initiate the conversation.

With so little information available about most CAM therapies, what can I tell my patients?

- You can refer your patients to credible, Federal resources to get evidence-based information and patient education materials. You do not need to know everything about all CAM treatments.
- Rigorous scientific research on CAM is taking place at major academic and medical institutions throughout the United States.

Federal Resources for Providers

National Center for Complementary and Alternative Medicine at the National Institutes of Health
nccam.nih.gov

CAM on PubMed
Journal citations specific to CAM:
nccam.nih.gov/camonpubmed/

Online Continuing Education Series
Video lectures available for CME/CEU credits:
nccam.nih.gov/videolectures

Resources for Patients

National Center for Complementary and Alternative Medicine
nccam.nih.gov
Toll-free clearinghouse: 1-888-644-6226

MedlinePlus
medlineplus.gov

[1] Survey by AARP and NCCAM

[2] Barnes P, Powell-Griner E, McFann K, Nahin R. CDC Advance Data Report #343. Complementary and Alternative Medicine Use Among Adults: United States, 2002. May 27, 2004.

NCCAM

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE
National Institutes of Health U.S. Department of Health and Human Services

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TIME TO TALK. TELL your doctor about your use of complementary and alternative medicine.

Tell

Did you know that almost two-thirds of people aged 50 and older are using some form of complementary and alternative medicine (CAM)? According to a recent survey[1] less than one-third of those people talk with their providers about CAM use.

What is complementary and alternative medicine (CAM)?

CAM is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. CAM includes such products and practices as herbal supplements, meditation, chiropractic manipulation, and acupuncture.

Why tell your health care providers about CAM use?

- Giving your health care providers a full picture of what you do to manage your health helps you stay in control.
- Some CAM approaches can have an effect on conventional medicine. Talking to your health care providers about CAM use will help ensure coordinated and safe care.
- Talking to your providers about CAM use helps them to be fully informed and your partners in health care.

Tips for talking to your health care providers about CAM

- When completing patient history forms, be sure to include all therapies and treatments you use. Make a list in advance.
- Tell your health care providers about all therapies or treatments—including over-the-counter and prescription medicines, as well as herbal and dietary supplements.
- Don't wait for your providers to ask about your CAM use. Be proactive.
- If you are considering a new CAM therapy, ask your health care providers about its safety, effectiveness, and possible interactions with medications (both prescription and nonprescription).

[1] Survey by AARP and NCCAM

CAM Resources from the National Institutes of Health

National Center for Complementary and Alternative Medicine
nccam.nih.gov or 1-888-644-6226

MedlinePlus
medlineplus.gov

NIH Office of Dietary Supplements
www.ods.od.nih.gov

National Cancer Institute Office of Cancer Complementary and Alternative Medicine
www.cancer.gov/cam

NCCAM

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE
National Institutes of Health U.S. Department of Health and Human Services

Finally, we are also launching a new initiative to examine the potential influence of genetic variation on the likelihood of response to selected CAM interventions.

With these, and other studies, NCCAM will continue to provide leadership in the research area.

PREPARED STATEMENT

Thank you, Mr. Chairman. I thank Senator Specter, Senator Cochran, and Senator Reed for your continued support. I would be pleased to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF DR. RUTH L. KIRSCHSTEIN

Mr. Chairman and members of the committee: I am pleased to be here to present the President's fiscal year 2008 budget request of $121,268,000 for the National Center for Complementary and Alternative Medicine (NCCAM).

In the 7 years since it was established, NCCAM has built a global enterprise of scientific excellence and leadership in research on complementary and alternative medicine (CAM). NCCAM-supported studies, carried out at more than 260 institutions, encompass the wide range of CAM practices and have resulted in more than 1,500 scientific papers published in peer-reviewed journals. The progress that has been made by the research community in understanding the scientific basis of CAM is, in large part, attributable to the leadership of Stephen E. Straus, M.D., NCCAM's director from 1999 to 2006. Under his leadership, CAM research has been established as a legitimate field of scientific inquiry that is laying the scientific foundation for the emerging discipline of integrative medicine.

This effort continues. In the past year, NCCAM has launched studies to: (1) develop innovative tools and technology for studying biologically based and mind-body interventions; (2) assess the potential of community-based primary care research networks to increase scientific knowledge about the safety, efficacy, and cost effectiveness of CAM; and (3) increase scientific understanding of the mechanisms underlying manipulative and body-based practices.

NCCAM'S ROLE AND THE CHANGING NATURE OF MEDICINE

Large numbers of American health care consumers are using CAM modalities in an effort to preempt disease and disability or promote health and a sense of well-being. Despite the relative paucity of information about the effectiveness and safety of these uses, Americans are de facto personalizing medicine through approaches that often require their active ongoing participation in a diverse variety of health practices and behavior change approaches.

Driven largely by consumer demand for CAM, integrative medicine—which can be defined as a health care approach that makes use of all appropriate evidence-based disciplines, therapies, and health care professionals to achieve optimal health and healing—is rapidly becoming a major force shaping health care systems in the United States and around the world. At the same time, studies continue to show that open communication between conventional medical practitioners and their patients about CAM use is uncommon. Such communication is vital to ensure well-coordinated, comprehensive, and safe care.

The ultimate goal of NCCAM is to inform, through science, the discipline of integrative medicine. Thus, NCCAM's mission is to support rigorous research intended to fill the CAM knowledge gap; train CAM researchers; and disseminate authoritative information regarding CAM to the public (only one in three of whom consult their physicians about their CAM use), and to physicians and other health care professionals who rarely ask patients about CAM use.

BUILDING THE EVIDENCE BASE OF INTEGRATIVE MEDICINE

Because CAM interventions are widely used by the public, NCCAM supports a diverse portfolio of basic, translational, and clinical studies. The benefits of this strategy are well illustrated by the example of acupuncture. Clinical trials supported by NCCAM have documented the efficacy and safety of this widely used CAM practice in many but not all conditions studied. More recently, basic and translational research employing state-of-the-art neuroimaging technology has led to important insights into the mechanisms of action for acupuncture's effects, and has elucidated mechanisms of brain function that will have direct relevance to other approaches to pain relief.

Advances of similar importance are emerging in other areas of CAM research. As is the case with acupuncture, clinical and preclinical information fills gaps in knowledge about a number of CAM practices and builds a fuller understanding of what CAM can offer. Whether a study's result is positive or negative, we expand our knowledge not only about the tested therapy, but also learn more about the condition it is supposed to treat. Several examples from the past year illustrate this point further:

—*Arthritis*.—As the U.S. population ages, the need for better, safer, and more effective treatments for arthritis increases. Through basic studies, NCCAM-supported investigators determined that extracts of the spice turmeric, an important component of Ayurvedic medicine that is used in the treatment of a number of inflammatory disorders, contains specific compounds with anti-arthritic activity, as well as others that can inhibit this activity. This research suggests

the need for further investigation of the potential of turmeric, points toward ways in which its use might be optimized, and yields insight into the mechanisms of arthritic disease.

—*Neurodegenerative Diseases*.—Ginkgo biloba is a dietary supplement widely used for its purported beneficial effects on brain function. NCCAM-funded investigators studying it in an animal model of Alzheimer's disease found that it reduces both the formation of the specific brain abnormalities seen in humans, and the resulting paralysis seen in the animals. These experiments lend support to the hypothesis that Ginkgo biloba may be useful in slowing the progression of Alzheimer's disease. That hypothesis is being tested in a large clinical trial of Ginkgo biloba for the prevention of dementia, supported by NCCAM and several other NIH Institutes.

—*Yoga for Chronic Low Back Pain*.—Chronic low back pain is prevalent and has few treatment options. NCCAM supported researchers have concluded a randomized clinical trial studying the effectiveness of yoga, exercise, or a self help book in improving back function and decreasing chronic low back pain. The results of the trial demonstrated that yoga was more effective and produced longer-lasting pain relief than exercise or the self-help book.

—*Menopause and Black Cohosh*.—Given concerns about the use of hormone replacement therapy to treat symptoms of menopause, many women have turned to the dietary supplement black cohosh for relief, although evidence supporting this approach has been scant. In 2006, a clinical trial supported by the National Institute on Aging and NCCAM failed to show relief of menopause-associated symptoms by treatments containing black cohosh. Two other large clinical trials of black cohosh continue.

TRAINING THE NEXT GENERATION OF CAM RESEARCHERS

The rigorous basic, translational, and clinical research required to understand integrative medicine must involve collaborations between CAM practitioners and experienced scientists. This multidisciplinary approach is the fundamental tenet of NCCAM's strategy in support of research training and career development. Since its inception, the Center has increased the percentage of funds committed to research training and career development—from 1.3 percent in fiscal year 1999 to 8.3 percent in fiscal year 2006—to support research training, career development, and educational opportunities. Recipients of CAM doctoral degrees are now among those eligible for National Research Service Awards, as well as for the NIH-wide loan repayment program.

DELIVERING AUTHORITATIVE INFORMATION

NCCAM is recognized as a source of authoritative, evidence-based information on CAM. Information on CAM treatments, herbs and dietary supplements, advice for consumers, research results, and clinical trials are available in English and Spanish in print and electronic form. In 2006, NCCAM's website, cited by Prevention magazine for "Best Alternative Medical Information," had more than 2.6 million visitors. CAM on PubMed, a database developed in partnership with the National Library of Medicine, now indexes more than 467,000 articles related to CAM. NCCAM's online continuing education program offers information on a variety of topics to the public and health professionals. Of particular note is a new patient/provider education initiative—"Time to Talk"—that encourages informed and open communication between patients and physicians about CAM use, to ensure safe, integrated, personalized and participatory care.

GOING FORWARD

NCCAM will build on the foundation of scientific accomplishment and leadership that it has established during its first 7 years. Specific new activities planned for fiscal year 2008 include the following:

—Working in partnership with the Centers for Disease Control and Prevention, NCCAM will support the first national, population-based survey assessing CAM use among the U.S. pediatric population. This study will fill an important information gap in knowledge of CAM use in children and help NCCAM and the broader scientific community in establishing pediatric CAM research priorities.

—A new initiative will examine the potential influence of genetic variation on the likelihood of response to selected CAM interventions. This phenomenon, an important factor in the variation observed in responsiveness to conventional medicine, will be examined through linking new basic research to ongoing clinical trials, maximizing the value of the investment in both.

—A multidisciplinary workshop will bring together scientists from a broad range of the physical, social, and biological sciences to explore novel methodologies for clinical research of complex CAM approaches that make up whole medical systems.

Through these and other activities, NCCAM will continue to provide leadership in establishing the emerging discipline of integrative medicine. Thank you, Mr. Chairman. I would be pleased to answer any questions that the committee may have.

Senator HARKIN. Thank you very much. That last point, I want to follow up on in open questions on this.

Now we'll move to Dr. Lawrence Tabak, who became Director of the National Institute of Dental and Craniofacial Research in 2000, received his D.D.S. in dentistry from Cornell, his Ph.D. in Biology from Sunni at Buffalo. He's also one of the co-chairs of an effort to promote inter-disciplinary team science at NIH.

Dr. Tabak, welcome.

STATEMENT OF DR. LAWRENCE A TABAK, D.D.S, Ph.D., DIRECTOR, NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Dr. TABAK. Thank you, Mr. Chairman. I would like to thank you, Senator Cochran, and Senator Reed, for providing us with the opportunity to discuss our vision for the future, and of course, I want to thank each of you for your steadfast support of the National Institutes of Health.

This morning I would like to discuss the NIDCR strategies to address the many complex diseases and conditions that fall within the mission of our Institute. I hope you have these materials. If not, I would just give them to you.

As you can see, in the first figure, Figure 1, that I provided, complex diseases are those resulting—if I could refer you to Figure 1 of the handout that I've provided to you, complex diseases and conditions are those that result from an interplay between and among one's genes and environment, infectious agents and behavior, societal issues and the unknown.

Figure 1. Solving the "Puzzle" of Complex Diseases and Conditions

Genes
Behavior
Diet/Nutrition
Infectious agents
Environment
Society
???

National Institute of Dental and Craniofacial Research

EARLY CHILDHOOD CARIES

One good example of a complex disease is early childhood caries, and if I could refer you to the next figure, Figure 2, you can see that in this condition, primary teeth can be decayed down to the gum line. This is a condition that is found disproportionately amongst underrepresented minority children.

Figure 2. Early Childhood Caries

Raul Garcia, Boston University

Fluoride varnish is an effective approach to preventing ECC in very young, high risk children

Increasing the number of fluoride applications decreased the percentage of children with ECC

The results provide additional rationale for early preventive oral health assessment

Weintraub, *et al.* J Dental Res 85:172, 2006

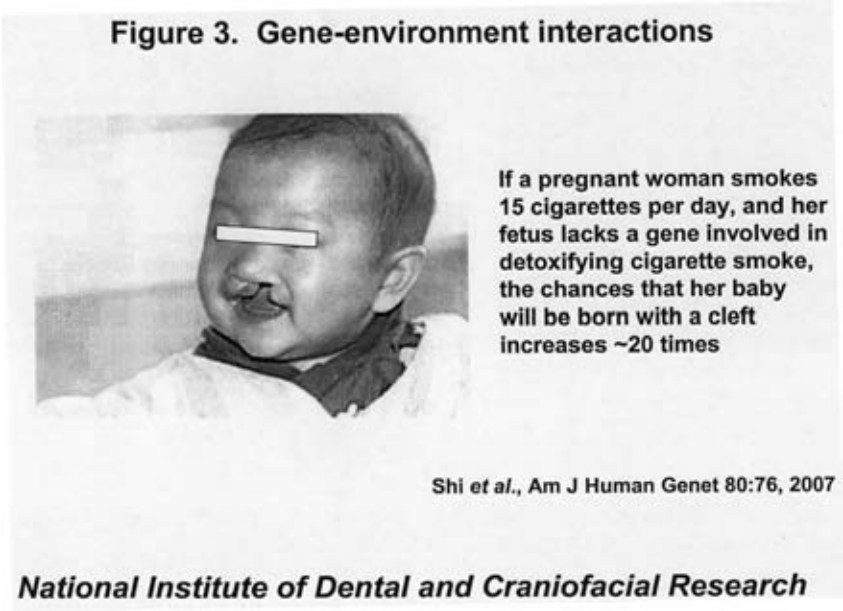
National Institute of Dental and Craniofacial Research

NIDCR supports a research centers program to reduce oral health disparities, and we presently have 5 centers based around the country. What is unique about these centers is that they are embedded within their communities. What is needed to overcome conditions such as early childhood caries, are inexpensive, simple and culturally acceptable interventions.

One such example is the use of a fluoride varnish, which has been worked on in a study conducted by the center at the University of California, San Francisco. What they have shown is that this approach can be highly effective in preventing early childhood caries in the very young, and in children at greatest risk.

SMOKING, GENETICS, AND CLEFT PALATE

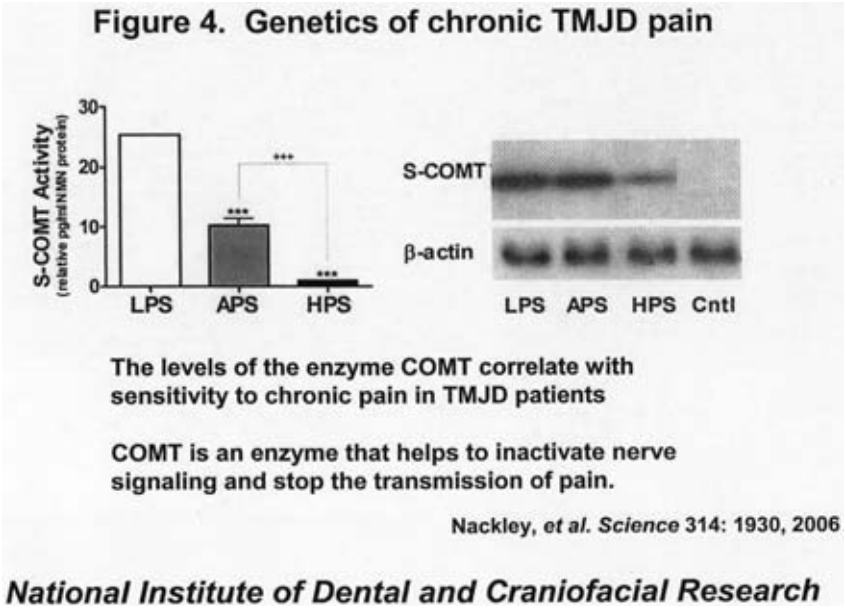
If I can refer you to the next figure, Figure 3—gene-environment interactions, are typified by recent studies, which are summarized in this figure, conducted by NIDCR-supported investigators at the University of Iowa, together with colleagues at NIEHS. This work showed that babies of European ancestry—up to 25 percent of them, and up to 60 percent of babies of Asian history lack a gene. That is important in detoxification of cigarette smoke. If a pregnant woman smokes 15 cigarettes a day, and lacks this important factor, the chances of her baby clefting increases 20-fold.



CHRONIC PAIN

NIDCR scientists at the University of North Carolina are slowly unraveling the genetic basis of chronic pain by studying patients with temporomandibular muscle and joint disorder. If I can refer you to Figure 4, differences in susceptibility to pain correlate with the levels of a particular enzyme, the so-called COMT enzyme. On the left-hand portion of this figure, you see individuals who have

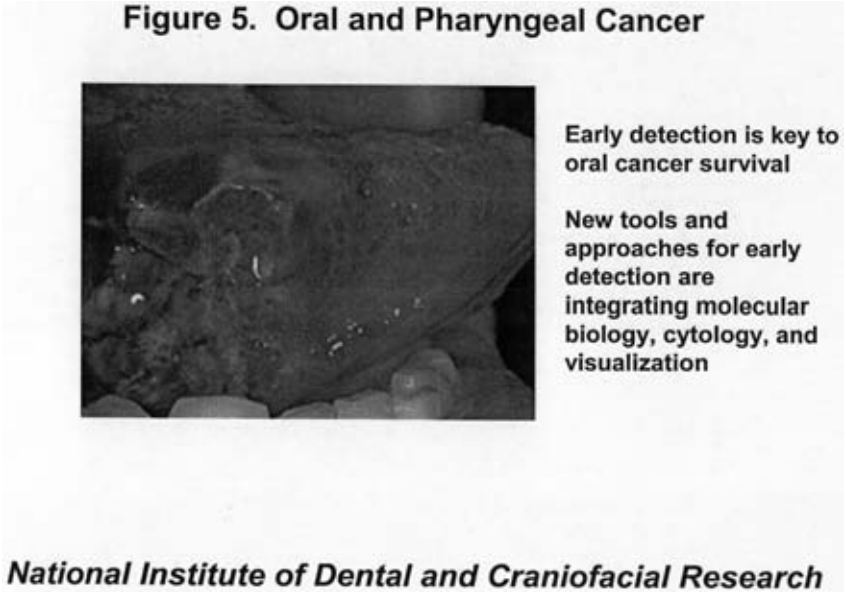
low pain sensitivity and very high levels of this enzyme. Then at the far end, those which have the highest pain sensitivity have very low levels of this enzyme. This makes sense because this enzyme is involved in the transmission of pain and this enzyme is involved in breaking down the transmitters of pain. So, if you have large levels of this enzyme, you are less susceptible to painful activity.



What's very, very important about this is, for the first time we're beginning to understand the true biological basis for diseases and conditions, such as TMJ, which heretofore had proved very enigmatic. We now understand the real biological basis for these diseases and conditions. By unraveling the molecular basis, we have an opportunity for early detection and diagnosis, as well as potential interventions in the future.

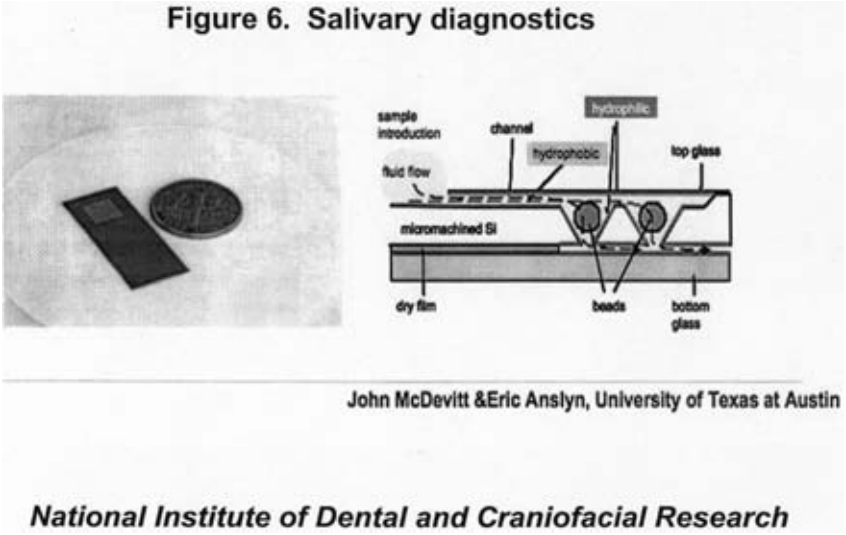
ORAL CANCER

If I can refer you to the next figure please, Figure 5. You see an example of an oral cancer. Oral cancer kills. The best hope is to detect cancer at its earliest stage. NIDCR has invested in a comprehensive tool kit of complimentary diagnostic approaches that will lead to bio-markers with both diagnostic and predictive value. An exciting advance in bio-markers research has been the use of saliva as a diagnostic fluid.



SALIVARY DIAGNOSTICS

If I can refer you to the final figure, figure 6. On the left you see a lab on a chip, which currently is the size of a U.S. dime. This lab on a chip can already analyze multiple markers simultaneously, including the genetic signatures that are associated with oral cancers. What we have done is married the expertise of bioengineers with the knowledge of oral biologists and what is in saliva to create this program. Ultimately we will be able to use saliva to measure a wide range of bio-markers. It doesn't take too much imagination to see that if we can shrink the size of that lab on a chip from the size of a U.S. dime down to the size of a pinpoint, we would have the opportunity to place that device in the mouth, so that we could have the opportunity for real-time surveillance, constantly. Of course, this is the ultimate goal with this program.



PREPARED STATEMENT

I appreciate the opportunity to tell you about these few exciting new approaches to address the many complex diseases and conditions that affect oral, dental, and craniofacial tissues. This is a time of tremendous scientific opportunity for oral health research, and of course, I would be pleased to answer any questions that you have.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. LAWRENCE A. TABAK

Mr. Chairman and members of the committee: I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health (NIH). The fiscal year 2008 budget request for NIDCR is $389,722,000.

FACING THE FUTURE: INTEGRATIVE APPROACHES TO ADVANCE PUBLIC HEALTH

Innovation has long been the great engine of progress in American life, including the tremendous progress made in improving the Nation's oral health over the last half century. From the tube of fluoridated toothpaste in the medicine cabinet to the high-resolution digital X-ray unit in the dentist's office, scientific innovations have helped more people than ever keep their teeth for a lifetime.

The Nation's oral and craniofacial researchers stand on the threshold of even greater innovations to improve the lives of millions of Americans. No longer must they attempt to understand health and disease one gene and protein at a time. Today, they can click the computer mouse on their desks and call up vast databases of biological information. In essence, thousands of pieces to the biological puzzle are now on the table. If we meet the challenge to integrate the pieces—intentionally blurring in the process the lines that have defined the traditional research disciplines—great progress can be made in understanding the molecular underpinnings of oral and craniofacial health and disease. This year, I would like to offer a few of the many examples of how integrative science will lead to greater innovation. I'd also like to highlight how this innovation ultimately will lead to more personalized dentistry and medicine in which treatment can be tailored to a patient's specific disease and healthcare needs.

CRANIOFACIAL CONSTRUCTION AND RECONSTRUCTION

The human face has been celebrated in art and literature since time immemorial and rightfully so. It is among the body's most distinctive structures and, is also one of the most developmentally complex structures of nature. Tremendous progress has been made in recent years in unraveling the genetic programs that are activated in the embryo to produce the face and the skull. Similar progress has been made in pinpointing which genes can go awry to produce a cleft lip and/or palate.

But much work remains. We must decipher the developmental programs that give rise to the various craniofacial tissues, hard and soft. By knowing how the craniofacial complex is assembled, it will be possible to better reassemble tissues that are damaged, either at birth or due to injury later in life. Exciting research is under way to explore the viability of regenerating damaged bone, teeth, and soft tissues with stem cells, novel biomaterials, and growth-promoting proteins. NIDCR-supported researchers recently reported success using stem cells to engineer a replacement root/periodontal complex that could support a porcelain crown and provide normal tooth function in studies with mini pigs. Other investigators are well on the way to creating a replacement gum tissue that can be produced in sufficient quantity to repair large oral defects.

The developmental programs will be helpful not only in treating craniofacial abnormalities but in preventing them. This year, for example, a team of NIDCR grantees determined that women who smoke during pregnancy and carry a fetus whose DNA lacks both copies of a gene involved in detoxifying cigarette smoke substantially increase their baby's chances of being born with a cleft lip and/or palate. About a quarter of babies of European ancestry and possibly up to 60 percent of those of Asian ancestry lack both copies of this gene. This finding reinforces in a concrete, personal way the public health message that women, especially those who are pregnant, should not smoke.

HEAD AND NECK CANCER

The NIDCR also has made a major investment in promoting integrative approaches to head and neck cancer. Our intent is to move beyond the current imprecise clinical definitions of these tumors, which are generally based on their appearance and patterns under a microscope. We need to examine the genetic hard drives of these tumors' cells to understand their abnormal and often deadly behaviors. This work already is taking place. NIDCR scientists have compiled comprehensive profiles of proteins expressed in some head and neck cancers. This information should help in developing true biomarkers with diagnostic and prognostic value.

NIDCR-supported scientists are also developing new and exciting visualization tools and approaches to improve diagnosis of oral cancer. One such tool being tested is called the VELscope®. It is a simple hand-held device that emits a cone of blue light into the mouth, which excites various molecules within the tissue, causing the tissue to absorb the light's energy and re-emit it as visible fluorescence. Because changes in the natural fluorescence of healthy tissue generally are different from those indicative of developing tumor cells, the VELscope® allows dentists to observe telltale differences.

In a recent follow-up study, the scientists reported that the VELscope® performed extremely well in accurately and rapidly delineating the real borders between tumor and healthy oral tissue during biopsies in the clinic. Intriguingly, 19 of the 20 examined tumors in the study had fluorescence changes that extended in at least one direction beyond the clinically visible tumor. These extensions, which are undetectable to the unaided eye and thus would likely not be excised, extended up to an inch beyond the visible lesion. Leaving these abnormal cells in the mouth increases the chance of other tumors arising over time. The instrument was developed as one component of an integrative approach to oral cancer detection and treatment that combines cytology, molecular biology, and staining to improve early detection. This finding and others will allow practitioners to gain a better molecular characterization of developing tumors, providing the intellectual basis for more personalized treatment and a future in which fewer people will undergo disfiguring surgery to fight the disease and/or die from these cancers.

SALIVARY DIAGNOSTICS

Other diagnostic tools are under development as well. The NIDCR is a national leader in development of the use of saliva as a diagnostic fluid. Several Institute grantees are working to develop tiny automated machines, which can rapidly and precisely perform many diagnostic functions that previously required painful needle sticks. One group recently fabricated the first disposable, low-cost, miniaturized di-

agnostic platform that can process small amounts of saliva, amplify its DNA and detect the levels of genetic sequences of interest. Work is proceeding to ultimately create a fully functional hand-held instrument for everyday use to detect conditions ranging from oral cancer to cardiovascular disease to AIDS.

TEMPOROMANDIBULAR MUSCLE AND JOINT DISORDERS

Integrative approaches are proving productive in our ongoing efforts to understand temporomandibular muscle and joint disorders, or TMJDs. Previously, NIDCR-supported scientists found that different sets of common sequence variations in the COMT gene correlate with low, moderate, and high susceptibility to chronic pain. This finding makes good biological sense. The COMT gene encodes an enzyme that helps to inactivate nerve signaling compounds and stop the transmission of an unpleasant sensation. The scientists recently showed that each of these sets of sequence variations changes the resulting structure of the corresponding messenger RNA. When a gene is expressed, it is copied into messenger RNA which, like an order form, contains the information to produce a specific protein. The scientists determined that the genetic variations that correlate with high sensitivity to pain produce messenger RNA with long, rigid loops in their structure, which reduces the rate of COMT protein synthesis and thus slows the nerve's ability to turn off an unpleasant sensory signal. The likely result: those with the "sensitive" variations will personally experience the sensation of pain longer and possibly more intensely.

Such findings are particularly exciting because these studies could not have been conducted just a generation ago. Not enough was known about the basic mechanisms of pain. But as more of the biochemical pieces to the puzzle are found in the years ahead, great progress in controlling pain will be possible, and the NIDCR will help in leading the way for all those battling chronic pain conditions, including TMJDs, to find relief through a more accurate diagnosis and more personalized care.

DENTAL DISPARITIES: RIGOROUS SCIENCE, PRACTICAL RESULTS

It now has been 7 years since the U.S. Surgeon General issued the report Oral Health in America. As many will recall, that report pulled together for the first time the stark statistics of the Nation's "silent epidemic" of tooth decay and other oral diseases among its minority and underserved populations. The reasons for these disparities are complex, but two facts were indisputable in the report: Many oral diseases are either preventable or easily controlled, and new strategies are needed to ensure that all Americans are aware of and ultimately benefit from the latest research advances.

To meet this need, the Institute established five Centers for Research to Reduce Oral Health Disparities in 2001. This approach allows scientists to assemble multidisciplinary research teams that lend a greater wealth of expertise to understand and address the complex elements underlying oral health disparities at the community level. Building on the knowledge and evidence amassed by the initial health disparities centers, the Institute has begun preparations to re-compete its center grants with a specific public health aim. That aim is to assemble a more seamless investigative team structure that can take a well-defined clinical issue and with the participation of a community-based population, test the effectiveness of promising interventions on a wider scale. This approach holds considerable promise to yield rigorous science, participatory research with those in underserved communities, and a significant reduction in oral health disparities.

PRACTICE-BASED RESEARCH NETWORKS

The Institute awarded grants in early 2005 that established three regional practice-based research networks, or PBRNs. Their mission is to create networks of practicing dentists and dental hygienists with their patient populations to participate in clinical studies on a variety of pressing everyday issues in oral healthcare. In 2006, the PBRNs were enlisted to investigate an important emerging health issue. Millions of Americans currently take a type of drug called bisphosphonates, typically to ease cancer-related pain or to prevent osteoporosis. But recent reports indicate that newly formulated bisphosphonates can cause in some people a debilitating thinning of the jawbone called osteonecrosis. What remains unclear is the prevalence of this unwanted side effect and, more importantly, who precisely is at risk. A few years ago, NIDCR would have lacked the clinical infrastructure in place to investigate these and other related questions. The PBRNs have changed the equation. The NIDCR has rapidly organized the needed studies to investigate the problem and will provide in the near future more meaningful data for the millions of Americans at risk.

Traditional research approaches have produced extraordinary benefits to the Nation's public health. But we now face a new scientific frontier, and new possibilities confront our researchers. These opportunities require novel approaches that fall under the rubric of integrative science. From this coordinated approach to science, the biological complexity before us will give way to simplicity and once unimaginable public health advances in which personalized health and medicine become a reality.

Senator HARKIN. Thank you very much, Dr. Tabak.

Next, we will turn to Dr. David Schwartz, Director of the National Institute of Environmental Health Sciences. He has been Director since 2005, earned his M.D. from the University of California, San Diego, and his Ph.D. degree from Harvard School of Public Health. But most importantly of all, he spent the better part of 12 years at the University of Iowa. Is that about right?

Dr. SCHWARTZ. Very formative years.

Senator HARKIN. His own research focuses on environmental lung diseases. Dr. Schwartz, welcome to the committee.

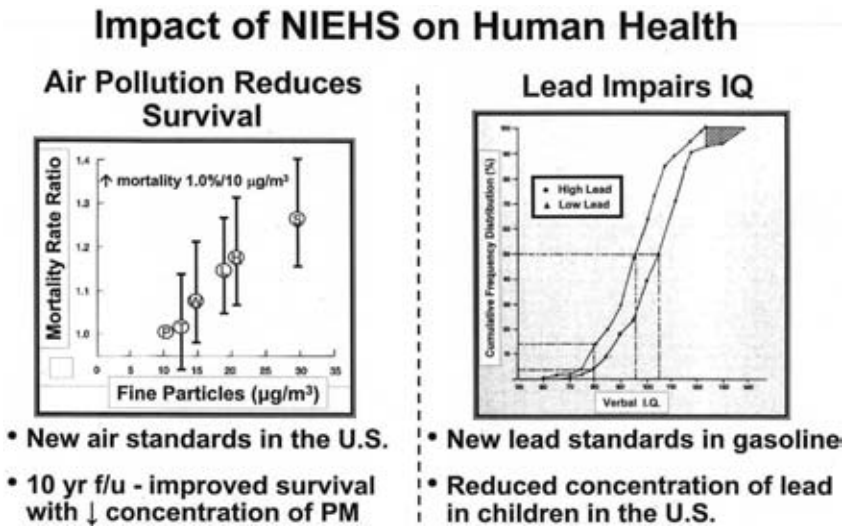
STATEMENT OF DR. DAVID SCHWARTZ, M.D., DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH AND SCIENCES

Dr. SCHWARTZ. Thank you very much, Mr. Chairman, Senator Cochran, and Senator Reed. It's a pleasure to be here, thank you for providing us the opportunity to discuss our collective vision for the future of medical research.

I do have a handout that may be of help to the members of the committee.

Just by way of introduction, NIEHS protects the Nation's health by understanding the role of the environment, in terms of the development and also the distribution of disease in society. Our view is, understanding the causes of disease will provide the types of insights that are absolutely necessary to preventing disease in society. That's the focus of the Institute. The work of NIEHS in the past has improved the average length and quality of life by looking at disease etiology, and also prevention of exposures that are relevant to disease etiology.

If you look at the second page of the handout, Figure 1, I will give you two examples of work that has been done in the past at NIEHS that exemplifies this approach. The two examples focus on air pollution and lead exposure. NIEHS funded a very important study called "The Six City" study, that focused on air pollution and identified air pollution as a major cause of morbidity and mortality, especially as related to heart and lung disease.



In the graph on the left-hand panel, the letters on the graph refer to the six different cities that the study was done in. You can see very clearly, as you move from left to right, that the level of air pollution increases, and the mortality, and also the morbidity, from lung and heart disease increases.

As a result of this very compelling research, new standards were adopted by the EPA under the Clean Air Act, which changed the standards in the United States for air pollution. As a result, there have been marked decreases in the level of air pollution, but marked improvements in morbidity and mortality related to air pollution exposure.

The second example is an example of collaborative work between NIEHS and the National Institute of Children's Health and Human Development. On the right-hand side, the second figure on the second page shows a very striking relationship between the concentration of lead in the blood of children, and IQ. The higher the lead levels, the lower the IQ. This research resulted in the elimination of lead in gasoline, and subsequently resulted in improvements—substantial decreases—in the concentration of lead in the blood of children around the United States.

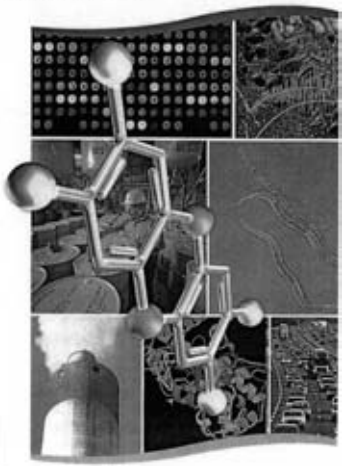
STRATEGIC PLAN

If you look at the next page of the handout, figure 2, between 2005 and 2006, shortly after my arrival at NIEHS, we developed a strategic plan, and our strategic plan lays out a very clear vision—to prevent disease and improve human health by using environmental sciences to understand human biology and human disease. Embedded in this plan, we have several challenges that face us, that keep us focused on our mission—our mission focusing on specific exposures and diseases that are relevant to those specific exposures.

NIEHS Strategic Plan 2006-2011

www.niehs.nih.gov/external/plan2006/home.htm

Vision: ***Prevent disease and improve human health by using environmental sciences to understand human biology and human disease***



Challenges:

1. Prioritize relevant diseases and exposures
2. Integrate scientific disciplines
3. Empower people and society with knowledge to improve environmental choices and live healthier lives

Transparency and Accountability

If you look at page four of the handout, Figure 3, we have developed 7 specific goals that help keep us on track in terms of the development of research priorities at NIEHS that are consistent with our strategic plan. So, although we've made a lot of progress in each one of these goals, and we've implemented programs in each one of these goals, I just want to tell you about three distinct programs.

Implementation of Strategic Plan

Goals and Progress:

1. Clinical research
   Clinical Research Unit, and Head off Environmental Asthma in Louisiana
2. Basic mechanisms in human biology
   Support investigator-initiated research (> 20% success rate)
3. Integrated environmental health research
   New programs in translational research
4. Global and community-linked research
   Global Environmental Health Workshop
5. Next generation of environmental health scientists
   Training and career development (high school, college, and early careers)
6. Partnerships across disciplines and agencies
   NIH Institutes, Roadmap, CounterAct, EPA, CDC, and FDA
7. Personalized measures of exposure, response, and genetic susceptibilities
   Exposure Biology Program of the Genes, Environment and Health Initiative

HEAD-OFF ENVIRONMENTAL ASTHMA IN LOUISIANA

The first program is called the HEAL Program. It stands for Head-off Environmental Asthma in Louisiana, and it's based on in fact that children moving back to New Orleans are at very high risk for the development of asthma, as a result of exposure to a contaminated environment—the molds and the bacteria that have overgrown many of the environments in New Orleans as a result of Hurricane Katrina.

This is a collaborative project, and it's a community-based project. The community is very, very involved in this project, and the Department of Public Health is very involved in this project, as is Tulane University. It's a collaboration between NIEHS and the National Center on Minority Health and Health Disparities, and also the Merck Childhood Asthma Network. It represents a public/private partnership, in addition to a collaboration within NIH. Again, the project is focused on an intervention program, and studying that intervention program to see if we could reduce the burden of airway disease in these children that are at very, very high risk of developing and exacerbating their underlying airway disease.

TRAINING AND CAREER DEVELOPMENT

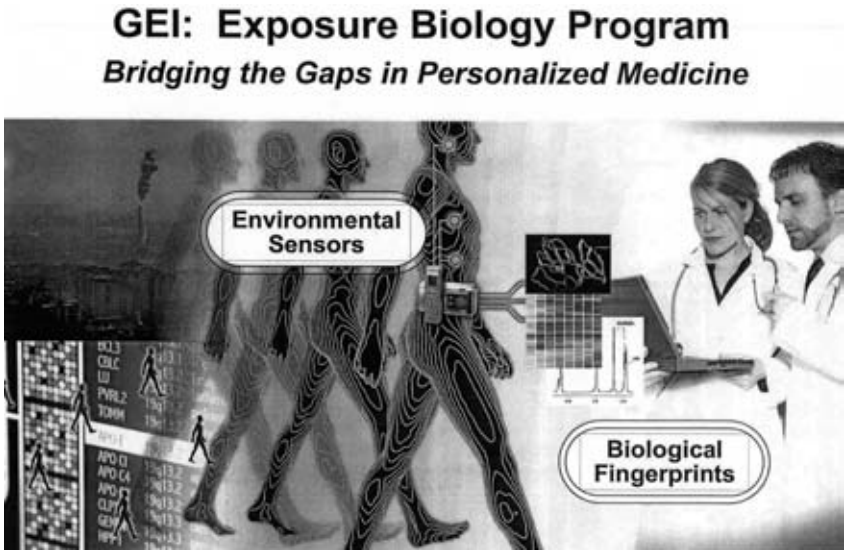
The second area of development that I want to highlight is in training and career development. We've revitalized our training—in fact, our training programs now go all the way from high school through college, including training for foreign scientists. The training reaches out to minority students, as well as physicians-scientists—two very important groups that are underrepresented in the NIEHS portfolio—and also focuses on new investigators to help them develop a focus in environmental sciences and have an opportunity for research in environmental sciences.

EXPOSURE BIOLOGY PROGRAM

The third area I want to highlight is the development of personalized measures of exposure, very similar to what Dr. Tabak was talking about, in terms of these miniaturized exposure measurements and biological response indicators, that are very important in terms of identifying how much someone has been exposed to, and how biologically responsive someone is to that exposure.

If you look at the next page of the handout, Figure 4, you can see that we've developed a program called the Exposure Biology Program that is part of the Genes, Environment, and Health Initiative. This new initiative is supported by all institutes across the NIH, and is led by me and Francis Collins and at NHGRI. The overall goal of the Exposure Biology Program is to develop personalized sensors of exposure, and also, biological response indicators. Step back for a second, and consider how we're able to precisely measure genetic variation across the human genome and how crude our tools are to measure individual differences in terms of environmental exposures—and you realize very quickly that this program is essential to be able to look at the interaction between genes and environment, in terms of the risk of developing disease. After all, for the foreseeable future, our main way of preventing

disease will be to intervene in the environment, not to intervene genetically.



So, it's essential that we understand this relationship between genes and environment, as a way of understanding risks related to human health. Outgrowths of the Exposure Biology Program might include specialized wrist bands or smart shirts that could alert a person, or a physician, to an exposure that could be detrimental to an individual's health.

OPPORTUNITIES

If you turn to the last page of the handout, Figure 5, as we look forward, we're focused on three main opportunities. First, as I mentioned, through the Exposure Biology Program, we're developing these personalized measures of exposure and response indicators.

Second, we're focusing on a number of new research programs on complex diseases, such as asthma and neurodegenerative diseases and arthritis, that are caused by both genetic and environmental factors. We believe very strongly that the environment will be very helpful in identifying the genes that are important in terms of the risk of developing disease.

The third aspect that we're focused on is populations that are exposed to high concentrations of toxins, such as arsenic, or high concentrations of air pollution, so that we can reduce the burden of disease in these populations and improve health.

PREPARED STATEMENT

So, I want to thank you for your attention. I look forward to your questions, and I would yield to my colleagues, and look forward to the informal discussion that we will have following everyone's formal presentation.

[The statement follows:]

PREPARED STATEMENT OF DR. DAVID SCHWARTZ

INTRODUCTION

Lives saved by environmental health research can be counted in millions. By the Environmental Protection Agency's (EPA) estimates on air pollution alone, the Nation's commitment to cleaner air will prevent 23,000 premature American deaths; 1,700,000 new asthma attacks or aggravation of chronic asthma; 67,000 new cases of acute and chronic bronchitis; 22,000 respiratory-related hospital admissions; and 42,000 cardiovascular hospital admissions (EPA 410–R–99–001) by the year 2010. The commitment to new air standards arose from NIEHS-supported research on air pollution such as the Six-Cities Study which revealed important associations between air pollution and mortality from respiratory and cardiovascular disease.

Air pollution is only one example of the public health impact of environmental health research. Studies on adverse effects of lead, much of it funded by NIEHS, revealed lead-associated decrements in the IQ scores of young children, as well as increased tendencies by affected children to aggressive behaviors. It was these types of neurobehavioral problems that led the Nation to ban sources of lead contamination, a move that has led to a 78 percent decrease in average blood lead levels in

this country (JAMA, 272:284–91 (1994)) and a corresponding improvement in the health of our children. Further NIEHS-supported research involving adults found that long-term exposure to lead is associated with an increased risk of high blood pressure (hypertension), kidney problems and cataracts. Reduced lead levels in the environment are expected to translate in the future into a decreased incidence of hypertension, kidney failure, and cataracts among the elderly.

NIEHS-supported researchers have made other recent discoveries with high potential for public health impact. Some examples include identification of a novel biological mechanism that controls airway tone and could be targeted for the treatment of asthma; discovery of important mechanistic linkages between exposure to inhaled particulate matter and cardiovascular disease; new insight into regulatory mechanisms within the brain that affect learning and memory; and identification of the structural basis of errors in DNA synthesis that may result from environmental stress and have profound effects on a variety of human diseases, including cancer.

As these examples illustrate, environmental health science can exponentially return its investments on improvements in a wide spectrum of diseases and disabilities. Operating on multiple molecular and cellular pathways, environmental agents can track these complex molecular pathways that lead to chronic diseases such as cancer, birth defects, hypertension, and neurological disorders. Because environmental agents often operate early in the disease process, they can be useful for identifying very early events in disease, suggesting ways to diagnose and remedy diseases before they progress. The challenge now is to develop techniques needed to assess environmental exposures as they operate at the level of individual health. This will require the development of sensitive devices that can assess the environmental exposures to which individuals are exposed in their daily lives. Ideally, these small, specialized, wearable sensors would measure environmental exposures, as well as the actual biological changes that arise as early markers of response in environmental agents. Such devices would allow scientists and physicians to access the more dynamic, real-world exposures of the American population and would provide information that could be useful to identify very early events in disease, suggesting ways to diagnose and remedy diseases before they progress.

Many of NIEHS' recent achievements have been possible because of powerful tools used to study events at the genetic and molecular level that would have been impossible ten years ago. With so many promising avenues to explore, NIEHS developed a new strategic plan, New Frontiers in Environmental Health Sciences and Human Health (www.niehs.nih.gov/external/plan2006/home.htm) that focuses on three major challenges and seven specific goals to prevent disease and improve human health by using environmental sciences to understand human biology and human disease. Steps to implement the Strategic Plan have led to research in exposure biology (personalized measures of exposure), epigenetics (inheritance not based on the sequence of DNA), comparative genomics (use of model systems to understand the biological effects of environmental exposures), translational research (integrating basic and applied sciences to understand the effect of the environment on human health), and focused training and career development programs to expand the workforce in environmental sciences. Our success will be measured in the disease and suffering that we are able to prevent.

EXPOSURE BIOLOGY PROGRAM

The Exposure Biology Program, a component of the larger Genes, Health and Environment Initiative at the National Institutes of Health (NIH), was created to develop tools to precisely measure the exposure to chemical/biologics, dietary changes, physical activity, psychosocial stress, and addictive substances and subsequently assess the effect of these exposures on human health. This program will produce noninvasive tools that can be used to track exposures critical to human health. While new technology will be developed, this program will also borrow and re-engineer tools from other fields that have focused on measuring various component of the environment. Possibilities include the use of molecularly imprinted polymers that show promise in identifying antibodies, enzymes, and animal tissues or cells; small labs-on-a-chip that can be made through recent advances in silicon and glass micromachining; and the use of nanoparticles in biomolecular sensors. These technologies would be combined with new techniques to assess co-modifiers of response such as diet and physical activity. As these technologies are incorporated into large-scale epidemiological studies, much of the background "noise" obscuring our ability to identify environmental components of disease will be reduced. Furthermore, the program is soliciting researchers to develop these new tools in ways that can also provide insight into the molecular underpinnings of disease response, thus identifying therapeutic targets for intervention.

One exciting outgrowth of this project will be in the area of personalized and participatory medicine. The sensor technologies developed through the Exposure Biology Program are envisioned to be small, portable devices that can measure actual exposures to environmental agents, as well as monitor diet, physical activity, heart rate and respiration. An example would be a device that could alert an individual with asthma to dangerous air pollution levels. Another example would be a device that could determine harmful pesticide levels and cross-reference this information with an individual's own genetic risk profile for neurodegenerative diseases like Parkinson's disease. Alternatively, data derived from such sensor devices could be used by physicians to tailor treatment and prevention strategies based on actual exposure risks. The strategies could range from altering the environment or modifying behavior through disease risk education to selecting pharmaceutical treatments that would more accurately target the underlying molecular changes resulting from environmental exposures.

EPIGENETICS—BEYOND THE SEQUENCE OF DNA

The field of epigenetics is uniquely related to environmental health sciences. Epigenetics refers to a modification of gene expression that does not involve a change in gene sequence; rather, a sometimes slight modification of DNA or its associated proteins or sugars that can dramatically change gene function, sometimes into subsequent generations. Almost all known factors causing epigenetic change are from the environment, diet, or supplements. Epigenetic mechanisms are being linked to multiple illnesses, including cancer, cognitive dysfunction, and respiratory, cardiovascular, reproductive, autoimmune, and neurobehavioral diseases.

Recently, NIEHS developed a program in epigenetics that supports research to understand how the epigenome is affected by environmental exposures and how this ultimately affects human health. This field is particularly promising in identifying how early life exposures can generate disease outcomes later in life. One purpose of this program is to identify critical windows of susceptibility to epigenetic changes, particularly during pregnancy, early life, and puberty. The fruits of this research will help us develop biomarkers of early exposure, as well as identifying possible therapeutic strategies to prevent disease later in life.

CLINICAL AND TRANSLATIONAL RESEARCH

In the summer of 2007, NIEHS will complete construction of its first clinical research unit that will be used to study how human subjects respond to a variety of environmental stressors. This facility will foster integrated, interdisciplinary research opportunities between our basic and clinical scientists to speed the translation of knowledge from bench to bedside. NIEHS' Office of Translational Research is also focusing on taking discoveries from our basic and population-based studies and translating them into research findings that have direct relevance to human health and disease. New integrative research programs are designed to promote an interdisciplinary approach to focus environmental sciences on important human health conditions. Two examples are the extramural DISCOVER (Disease Investigation through Specialized Clinically Oriented Ventures in Environmental Research) Program and the intramural Director's Challenge. The approach being taken in these programs is to closely integrate basic, mechanistically driven laboratory research directly with patient-oriented research to speed the translation of the environmental health sciences into clinical and public health applications. Awards made under both the intramural program and the DISCOVER Centers will be for multiproject, interdisciplinary programs to understand the etiology, pathogenesis, prognosis, and epidemiology of disease processes such as respiratory diseases, cancer, or neurodegenerative diseases.

WORKFORCE TO MEET NEW CHALLENGES

The much greater complexity of research techniques and the new focus on human health and disease requires a new, specialized workforce. The new environmental health workforce must be increasingly collaborative and must have skills to work across multiple research disciplines. NIEHS is refashioning its training program in order to produce researchers with the skill sets needed in the future. For promising high school and college students, the Short Term Educational Experiences for Research (STEER) program provides needed support for attracting and developing this next generation of environmental health scientists. NIEHS and NHGRI developed a collaborative training program for pre- and post-doctoral students in environmental genetics. The Outstanding New Environmental Scientists Award (ONES) program is a new way to recruit talented young independent researchers into environmental health science research. These programs complement existing training

programs and, in concert, will help develop a workforce that can meet the many demands of environmental health research.

SUMMARY

The opportunities within environmental health sciences are greater than ever. New programs initiated this past year will produce a more sophisticated understanding of the environmental components of disease, as well as a better knowledge of how individuals vary in their response to exposures. This information will enhance our ability to develop personalized approaches that can decipher an individual's actual exposures, their individual risks for adverse effects from these exposures, and ultimately lead to a customized strategy for reducing these risks and circumventing undesirable health outcomes. This more extensive understanding of environment-disease associations will, in the aggregate, lead to improved intervention and therapeutic strategies that can lessen the disease burden of our citizens. I would be happy to answer your questions.

Senator HARKIN. Thank you very much, Dr. Schwartz.

Now, we'll turn to Dr. Paul Sieving. He became Director of the National Eye Institute in 2001, received his M.D. and a Ph.D. in biomedical engineering from the University of Illinois and conducted research focused on retinal conditions, such as retinitis pigmentosa.

Dr. Sieving, welcome to the committee.

STATEMENT OF DR. PAUL A. SIEVING, M.D., Ph.D., DIRECTOR, NATIONAL EYE INSTITUTE

Dr. SIEVING. Thank you, Senator Harkin and congratulations on saying retinitis pigmentosa. That's a big word as are many of the words we use in medicine, but these words have very important implications for disease and health of the American people. As Director of the National Eye Institute, it's my privilege to tell you, to report to you today on some of the remarkable advances that are happening in vision research.

We are at a precipice in medicine as I've heard my colleagues also report, where we're really able now to move from basic research into the phase of improving health. In my case, the eye health of the American people. It's a very exciting time. With the support of the United States Congress our vision scientists are developing treatments to prevent vision loss and, even more remarkably, in some cases to partially restore sight for some common eye diseases, including age related macular degeneration that affects the older age population. Conditions that affect children, such as amblyopia, start in childhood, but the vision loss can persist for a lifetime.

I think all of us can understand and appreciate that the loss of sight really affects people in a fundamental way. It threatens independence. It is socially isolating, we can't look at one another. It affects the quality of life. The number of the eye diseases that we suffer actually increase with age. They strike later in life. As the American people live longer and the baby boom generation ages, unfortunately, we can expect an increasing prevalence and incidence of some of these conditions that are related to aging.

AGE-RELATED MACULAR DEGENERATION

I would like to focus my comments on one storyline of remarkable success involving age-related macular degeneration or AMD. This is a condition in which central vision is affected. You look at the person sitting across from you and his or her face dissolves into

a blur. It's difficult to see the face of a friend. It's difficult to read a book. Obviously driving a car, that privilege is lost. Even simple things, such as cooking, those simple tasks become very difficult.

But, the last 2 years have been a watershed time for AMD, both in terms of new treatments, remarkable new treatments and genetic factors that are now coming online. Over the past 2 years, attention to a particular molecule called vascular endothelial growth factor, just about as big a word as retinitis pigmentosa. Vascular endothelial growth factor or VEGF is a molecule that was pursued quite vigorously by the cancer research community for many years. It turns out that abnormal blood vessel growth is also involved in one of the severe forms of age-related macular degeneration, causing abrupt loss of central vision. Now, over the past 2 years, an anti-molecule, anti-VEGF, administered to the eye, injected into the eye, literally, can stabilize the vision. In some cases, even improve reading ability somewhat.

Senator Cochran, you mentioned the incidence of diabetes in your State. Diabetes is a problem of blood vessels that also involves the blood vessels in the eye, as you alluded to, and causes a condition called diabetic retinopathy, a blood vessel problem in the eye. So, this same molecule, the VEGF molecule is involved and anti-VEGF therapy is now being tried for diabetic retinopathy. We can hope that that will be successful. But, we need to intervene at an earlier course of disease.

I would like to go over some old ground that I have presented here to this committee previously, called the Age-Related Eye Disease Study, in which prevention was the focus. This was an NEI sponsored study. It ran for 7 years. It focused on the daily use of antioxidant vitamins and minerals.

After work, hard experimental work with some 4,000 individual subjects, participants, it was found that this approach delayed the onset to serious vision loss and advanced macular degeneration, delayed that by about 25 percent. That is a remarkable success. So, that if this dietary intervention could be fully utilized by the American people who need treatment, we could anticipate over the next 5 years, it would rescue the vision of some 300,000 people. In that study, the AREDS study, is now in a second phase of AREDS2, testing other dietary components, such as DHA or omega-3 fish oils.

But, let's move back even one step further. So far we've talked about treatments and prevention, but we can actually go right to the root causes of AMD by looking at the genetic factors that predispose us, literally sitting around this table, to have AMD in later ages. Now, we have suspected for many years that genetic factors play a role in developing AMD and just 2 years ago, in April 2005, 26 months ago, the NEI-supported researchers identified the first gene that predisposes to developing AMD in a large population. One gene, first time in history, a remarkable event. In the intervening 26 months, four additional genes have been found. So now, there are five genetic risk factors that are contributing, we believe, about 75 percent of the risk for those of us around the table to ultimately develop AMD.

These genes are also surprising in their molecular theme, their biological theme. They're in the immune system of the body, the

complment cascade. The first factor was complment factor H. Another gene was complment factor B. These are components that operate normally in the body's immune defense against microbial infections. The way we think about it is, it's suboptimal control of this very vigorous defense system in the body. A normally protected pathway in which suboptimal control leads to chronic inflammation of the tissues of the retina and ultimately causes AMD to develop.

This gives us then the first handle on something that, in fact, we can take to the American people from this very basic genetic study. That is the recognition that the environmental factors, as my colleague next to me has just mentioned, and lifestyle factors play on this genetic background to further increase the risk of us developing AMD.

EYEGENE

This, my mentioning of these four or five genes for AMD are just part of the genetic story that is now rapidly evolving. There are some 450 genes that have been found to cause eye disease. These diseases include cataracts, glaucoma, strabismus, retinal disorders, corneal opacities, eye motility problems. With this wealth of genetic information, the Eye Institute, over the past 2 years, has a developed a collaborative national network of research laboratories to support genetic testing.

We are calling this eyeGENE. You can go to Google and type in "NIH eyeGENE" and come up with a few pages on it. It is a consortium of 20 universities across the country that participates actively, with oversight, and setting directions to make available genetic information, both to research, to move the research along to appropriate conclusions. At the same time, as a corollary to provide genetic direct information to families. The research group is really quite excited about that. We will have a centralized registry for research data mining. We will have a secure blood collection for research, a research repository. EyeGENE is now receiving samples from physicians across the country.

So, what I have given you is what I think is a very exciting story of treatment for macular degeneration, genes for macular generation, the ability to provide information to all of us before we are, literally, patients. So that, perhaps, we can avoid becoming a patient for these conditions. I think this is in the tradition, as I'm hearing, already down the table of real opportunities for personalized and certainly, ultimately, participatory medicine. The first time in history, I think, we are really making tremendous progress. So, it is a rich and rewarding opportunity for us to move forward.

PREPARED STATEMENT

With that, thank you for the opportunity to testify. And, I will certainly be pleased to answer questions.

[The statement follows:]

PREPARED STATEMENT OF DR. PAUL A. SIEVING

Mr. Chairman and members of the committee: I am pleased to present the fiscal year 2008 President's budget request for the National Eye Institute (NEI). The fiscal year 2008 budget includes $667,820,000 in the President's request.

As the Director of the NEI, it is my privilege to report on the many research opportunities that exist to reduce the burden of eye disease.

AGE-RELATED MACULAR DEGENERATION

The loss of sight affects us in fundamental ways, threatening independence, mobility and quality of life. Most eye diseases strike later in life. Thus, as life expectancy has increased and the baby boom generation ages, more Americans are becoming susceptible to vision loss and blindness. One such disease, age-related macular degeneration (AMD), is the leading cause of legal blindness. Based on published study data, 8 million older-age Americans are at high risk to develop advanced AMD. AMD causes a progressive loss of central vision, making it difficult to read, recognize faces, drive a car, or perform even simple tasks that require hand-eye coordination.

ANGIOGENESIS AND AMD

Angiogenesis is the term used to describe the growth of new blood vessels. Angiogenesis plays a crucial role in the normal development and maturation of tissues. It also plays a role in many diseases, including eye diseases such as diabetic retinopathy, retinopathy of prematurity and advanced AMD. In advanced AMD, new blood vessels grow abnormally beneath the retina. These abnormal blood vessels leak blood and fluid, producing scarring and severe vision loss.

NEI-supported researchers have established that a protein called vascular endothelial growth factor (VEGF) plays an important role in triggering angiogenesis in AMD and diabetic retinopathy. Thus, VEGF is an important target for drug development. Two anti-VEGF therapies have recently been approved by the FDA for the treatment of AMD. More recently, NEI-supported researchers have found that in animal models, combination therapies that control diverse elements of angiogenesis can completely inhibit some forms of abnormal blood vessel growth. Anti-VEGF therapies are also being evaluated in clinical trials for diabetic retinopathy. NEI and NIH have invested considerable resources in understanding and controlling angiogenesis. That investment is already paying handsome dividends.

DISEASE MECHANISMS IN AMD

Another critical area in developing treatments of AMD is to identify the causes and mechanisms of the disease early in its pathology. Researchers have long held that AMD can result from the confluence of genetic predisposition and chronic exposure to environmental risk factors, such as diet and smoking. In this scenario, a gene or genes contain subtle variations that hamper cellular function but may not necessarily cause disease directly. However, years of cumulative environmental insult can further strain the underlying genetic predisposition and trigger disease.

On the genetic side of the equation, NEI-supported investigators have identified common variations in four genes that are associated with AMD and may account for 75 percent of the risk of developing AMD. Two of these genes—complement factor H (CFH) and complement factor B (BF)—contain instructions to encode proteins that help regulate the body's immune defense against microbial infections. This defense, called the complement system, provokes inflammation, a common response to foreign pathogens. It is thought that certain variations in these genes result in suboptimal control of the complement system and cause chronic inflammation. Chronic inflammation may damage tissues of the retina and could lead to AMD.

Chronic inflammation is thought to play a role in many other common diseases beyond the eye, such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, kidney disease, stroke, and atherosclerosis. Although the cells, tissues, and molecular events in these diseases are diverse, they may share some common disease mechanisms that present an opportunity to cross pollinate findings from diverse research areas.

The genetic discovery of the possible role of inflammation and the immune system in AMD is a watershed moment. We have now uncovered a possible central disease mechanism that may lead to a better understanding of this major disease and the development of therapies that prevent vision loss. We now hold the possibility to learn an individual's risk vulnerability well before the disease is detectable clinically, and to intervene effectively, thereby preempting the disease process at its early stages.

PUBLIC HEALTH AND PREVENTION

Another critical and fruitful area of research is the development of public health strategies to prevent or delay AMD. Several epidemiologic studies, published in the 1990s, found evidence to suggest that diets rich in leafy green vegetables, which contain antioxidants, might be associated with a reduced risk of AMD. To leverage these findings, the NEI initiated a large, multi-center prospective study and clinical

trial called the Age-Related Eye Disease Study (AREDS). Data from the AREDS study, published in 2001, found that over a 5-year period, a daily formulation of antioxidant vitamins and minerals (vitamins C, E, beta-carotene and zinc with copper) delayed the onset of advanced AMD by 25 percent.

An estimated 8 million older-age Americans are at high risk to develop advanced AMD and vision loss. Of these 8 million, 1.3 million will develop advanced AMD within 5 years. However, now with the successful AREDS treatment, 300,000 of these individuals could be rescued from severe vision loss associated with advanced AMD over a 5-year period. This simple and relatively inexpensive dietary intervention offers to the American public a valuable intervention to prevent severe vision loss and to reduce the need for more aggressive and expensive therapies.

On the heels of this success, the NEI launched AREDS2. One of the primary objectives of AREDS2 is to determine whether oral supplementation with lutein and zeaxanthin and/or omega-3 long-chain polyunsaturated fatty acids will further decrease the progression to advanced AMD or formation of cataract. Previous NIH-funded studies have found high concentrations of these nutrients in the macula of the eye. Moreover, several studies have found an inverse relationship between dietary intake of these compounds and AMD. AREDS2 could result in a more effective but still inexpensive treatment regimen to prevent severe vision loss.

GENOMIC MEDICINE

AMD research is but one example of genomic medicine, the effort to diagnose and treat patients at the molecular level. Over the past 15 years, NEI-supported researchers have identified more than 450 genes that are involved in various eye and vision diseases. Considerable progress has been made in understanding the resultant disease mechanisms, and treatments are now beginning to emerge. As genomic medicine progresses, we must grapple with the obvious opportunity and challenge of genotyping individuals with eye disease and delivering therapies that are specifically tailored to the individual patient. This personalized approach to medicine is vital to improving the health of all Americans.

The NEI initiated eyeGENE to address this issue. EyeGENE is an organized national network of research laboratories to support genetic testing for individuals with eye diseases. As testing services are not routinely available, the diagnostic information from eyeGENE will directly benefit such patients and families. The initiative will significantly aid vision research through a centralized registry that can be used to locate individuals who may wish to participate in clinical trials for new therapies. eyeGENE fills a critical research need that will advance the field. It includes a secure research blood collection and a centralized research repository of disease phenotype features which coupled to genes that cause disease will allow for the creation of the large datasets necessary to identify novel genetic risk factors and other epidemiologic questions. Programs like eyeGENE will drive genomic research and become the necessary fabric for individuals to benefit from advances in genomic medicine.

ADDITIONAL ADVANCES

Recently, a number of developments have added further excitement to the field of vision research. The NEI is supporting projects that address the possible restoration of vision in blinding retinal degenerative diseases by building on recent advances in cell transplantation and precursor cell biology, including the use of bone marrow stem cell transplantation, and on "re-engineering" the production of light-sensitive proteins in retinal neurons.

Research will continue in efforts to control angiogenesis in a number of eye diseases, and will include the conduct of clinical trials in this area. In support of this research is the Diabetic Retinopathy Clinical Research Network (DRCR.net). This collaborative network, supported by the NEI, is dedicated to facilitating multicenter clinical research on diabetic retinopathy, diabetic macular edema and associated conditions. The DRCR.net supports the identification, design, and implementation of multicenter clinical research initiatives focused on diabetes-induced retinal disorders. Principal emphasis is placed on clinical trials, but epidemiologic outcomes and other research may be supported as well. The DRCR.net was formed in September 2002 and currently includes more than 150 participating sites (offices) with more than 500 eye care providers throughout the United States. The success of this new model for bringing improved treatments for diabetic retinopathy more rapidly to patients is dependent upon the active participation of clinical research centers across the United States, as well as the participation of the patients they treat.

Program plans for fiscal year 2008 include pursuing the research finding of several genes involved in Leber's Hereditary Optic Neuropathy, a genetic disease that

frequently results in a substantial loss of central vision. The development of animal models carrying these mutations could lead to successful gene-based therapy for this disease. Research will also pursue remarkable new findings about how the activity of certain brain cells allows us to perceive a stable view of our surroundings despite constant head and eye movements, as highlighted in NEI's strategic plan. This research will help us to understand better the neural control of eye movements and associated disorders, and may have applicability in other sensory systems.

Senator HARKIN. Thank you Dr. Sieving.

Now, we'll end with Dr. Duane Alexander, served as the Director of the National Institute of Child Health and Human Development since 1986. As I understand, you were there since 1968, is that right?

Dr. ALEXANDER. That's right.

Senator HARKIN. Received his M.D. from Johns Hopkins University, some research specializes in developmental disabilities. Welcome, again, back to the committee. Dr. Alexander, please proceed.

STATEMENT OF DR. DUANE F. ALEXANDER, M.D., DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Dr. ALEXANDER. Thank you, Mr. Chairman. I'd like to join with my colleagues in thanking you and the committee members for holding this hearing, and for your many years of strong support for the NIH that's allowed us to do what we've accomplished.

Since the National Institute of Child Health and Human Development was established nearly 45 years ago, our scientists have made discoveries that have improved the health and well being of children and adults.

For example, our research has contributed largely to the Nation's 70 percent reduction in infant mortality rate over that span of time, and 93 percent reduction in transmission rate from mother to child of the AIDS virus, the near elimination of five major causes of mental retardation, successful treatments for infertility, an effective intervention for reducing a major cause of premature birth, and many other benefits.

Our current research agenda builds on its past discoveries, addresses some of our country's and the world's most crucial health needs, and moves us closer to predicting or pre-empting diseases and conditions such as infertility, birth defects, disability from limb loss and infant mortality from premature birth.

FERTILITY PRESERVATION

One area of our current focus is fertility preservation for women facing cancer treatment. The chemotherapy and radiation used to treat cancer can irreparably damage the body's reproductive tissues, and render both men and women infertile.

Males may have the pre-treatment option of storing their frozen sperm for later use, but no comparable option currently exists for women. Eggs seldom survive the freezing and subsequent thawing process required for storage. However, our scientists are developing new techniques to protect the egg during the freezing, thawing and maturation process. When a woman who has had chemotherapy or radiation is ready to start a family, these follicles can be thawed and then cultured. The resulting eggs could be fertilized, and implanted in the uterus to establish a pregnancy.

PREVENTING DISABILITY

Preventing disability by newborn screening is another current emphasis for the Institute. It allows us to predict whether an infant has one of hundreds, literally, of genetic or metabolic disorders by testing a single drop of a newborn's blood, and treating the condition as soon as it's identified, preempting the infant's early death, or a lifetime of mental retardation or physical disability.

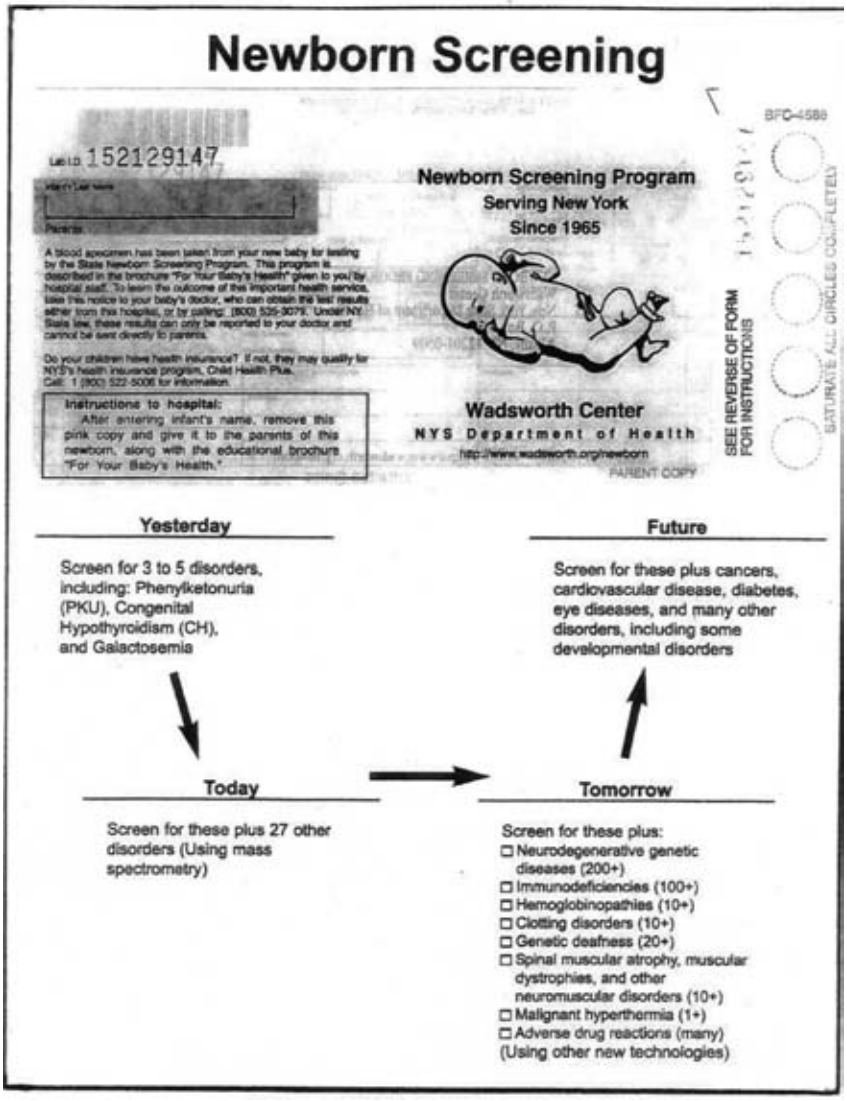
The screening and treatment, developed in large part through NICHD research, now is provided universally in the United States, but only for a few disorders.

One such disorder is congenital hypothyroidism. It occurs once about 3,000 births, affecting 1,300 children every year in the United States. Without treatment, the child with congenital hypothyroidism will suffer irreparable brain damage within months, and require a lifetime of special care.

However, as a result of our research, children with congenital hypothyroidism are now routinely identified at birth and given treatment immediately. One thyroxin pill daily spares them from the brain damage that would otherwise result, thus eliminating congenital hypothyroidism as a significant cause of mental impairment. The cost of treatment is just a few pennies a day. The lifetime amount of dollar savings is about $140 million a year, and the human suffering prevented is priceless.

NEWBORN SCREENING

An NICHD initiative to develop the technology to markedly expand newborn screening to hundreds of conditions is being funded in fiscal year 2007, and will expand in 2008 by establishing a national network to pilot test these new successful treatments. This is a card (Exhibit A) that they use in New York State newborn screening program. Each State runs its own program, and determines which conditions it screens for. You can tell from what's listed here that we have moved in just the last year from a system which screened for 3 to 5 conditions only, to where a majority of States are now using tandem mass spectrometry to screen for 30 disorders, and we're working with other technology developments using micro array chips, luminex beads, or others to markedly expand this to literally hundreds of genetic disorders, immunodeficiency diseases, muscular dystrophies, and other conditions.



NECROTIZING ENTEROCOLITIS

Another cause of infant mortalitym, that NICHD is attacking is necrotizing enterocolitis (NEC). We have made major advances against other causes like respirator, distress syndrome, severe jaundice, meningitis or sudden infant death syndrome, but NEC is a continuing problem. In 40 years, we've really made little progress against this condition. It causes death or disability by destroying the intestines of premature infants, and it attacks about one-tenth of all infants under 1,500 grams.

Our efforts have identified some potential treatments. One is epidermal growth factor, which in mice and rats is highly protective against NEC. Another human study, has demonstrated that interleukin-10 in breast milk is highly protective.

These and other potential treatments for NEC are going to be tested in a special initiative, launched by NICHD, about to be published, and funded in 2008.

MEDICAL REHABILITATION

As our country's armed forces return from stations abroad, and as the Nation's population continues to age, increased attention is needed on medical rehabilitation, to prevent immobility and dependence. Among the initiatives in the NICHD portfolio is developing mechanical limbs that allow for better comfort at the socket and improved mobility. Advances in this area can be particularly helpful to veterans who have lost limbs in combat.

One exciting new finding from this research is a new type of prosthetic arm, that connects in a way that allows the amputee to use it simply by thought—thinking about using the arm stimulates the chest muscles that are tied into it to contract with relative ease, and move the arm with greater speed and precision.

Researchers hope to use similar technology to restore natural movement and sensation to the limbs of individuals paralyzed by injury or stroke.

PREPARED STATEMENT

Mr. Chairman, committee members, I would like to thank you again for your continued support of our research, as we try to understand disease, and improve the health and well-being of men, women, children and future generations. I'll be pleased to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF DR. DUANE F. ALEXANDER

Mr. Chairman and members of the committee: I am pleased to present the fiscal year 2008 President's budget request for the National Institute of Child Health and Human Development (NICHD). The fiscal year 2008 budget includes $1,264,946,000.

With continuous support from this committee, the NICHD has made significant discoveries that have improved the health and well-being of children and adults. For instance, in the 45 years since the NICHD was founded, our research has been largely responsible for a decline in infant mortality of more than 70 percent, a 93 percent reduction in the rate of mother-to-child transmission of the AIDS virus, the elimination of five major causes of mental retardation, successful treatments for infertility, an effective intervention for reducing a major cause of premature birth, and many other benefits. Our scientists around the country are grateful to this committee for providing the opportunity to pursue research in these areas.

The Institute's research agenda builds on the discoveries from the last decade, addresses some of our country's and the world's most critical health needs, and moves us closer to major breakthroughs against diseases and conditions such as infertility, birth defects, infections, limb loss, premature birth, and maternal death.

PRESERVING FERTILITY FOR WOMEN FACING CANCER TREATMENT

The chemotherapy and radiation used to treat cancer can irreparably damage the body's reproductive tissues and render men and women infertile. Males may have the pre-treatment option of storing their frozen sperm for later use, but no comparable option currently exists for women. Eggs seldom survive the freezing and subsequent thawing processes required for storage. Currently, the only option for women facing the prospect of such infertility is in vitro fertilization and long-term

storage of the embryos, which tolerate freezing. However, this option is not always suitable. Young women with cancer may be forced to forego having their own children in order to receive life-saving treatment. The NICHD's new Fertility Preservation Research Program seeks to develop treatments to preserve fertility among patients with cancer or environmental risks for infertility. Building on current research, such as using a gelatin mixture to surround the follicle containing the egg, our scientists will be developing new techniques to protect the egg during the freezing, thawing, and maturation process. The goal is to allow a small section of the ovary to be removed and frozen for later use. When the woman is ready to start a family, the frozen follicles could be thawed and then cultured. The resulting eggs could be fertilized and implanted in the uterus to establish a pregnancy.

PROTECTING OUR CHILDREN AS WE TREAT THEIR ILLNESSES

The Best Pharmaceuticals for Children Act (BPCA)—enacted by Congress to increase information about the safety, usefulness, and dosage of medications for infants and children—is an important part of the nation's ongoing effort to assure that our treatments for children do not harm them. As we have learned, children's immature body systems and metabolic rates make pediatric clinical trials essential for studying the impact of widely prescribed drugs on children and infants. Within its work on the BPCA, the NICHD, in consultation with the Food and Drug Administration, identifies and prioritizes drugs for pediatric clinical study. The NICHD collaborates with manufacturers and academia in designing and implementing preclinical and clinical studies of drugs that are widely used or integral to the care of children with specific medical conditions. Currently 29 studies are under way evaluating drugs to provide information for labeling to guide pediatric use.

PREVENTING DISABILITIES THROUGH NEWBORN SCREENING

Imagine being able to know if an infant has one of hundreds of genetic or metabolic disorders by testing a single drop of a newborn's blood. Imagine being able to treat the condition as soon as it is identified, sparing that infant an early death or a lifetime of mental retardation or physical disability. This screening and treatment, developed in large part through NICHD research, now is provided universally in the United States for a few such disorders. For example, the National Newborn Screening and Genetic Research Center reports that congenital hypothyroidism (CH) occurs once in every 3,000 births, affecting 1,300 children each year in the United States. Without treatment, an infant with CH will suffer irreparable brain damage within months and require a lifetime of special care. Because an NICHD grantee developed a screening test for the disorder in the 1970s, children with CH are now routinely identified at birth and treatment begins immediately. One thyroxine pill daily spares them from the brain damage that would otherwise result, thus eliminating CH as a significant cause of mental impairment. The cost of treatment: a few pennies a day; the lifetime net dollar savings: $140 million each year; the human suffering prevented: priceless.

Currently, the number of conditions for which newborns are screened varies widely from state to state. The March of Dimes notes that nearly all of the 4.1 million American infants born each year undergo screening for some disorders, and about 5,000 are diagnosed with an abnormality. Treatments exist for the conditions for which we now screen, as well as for others for which screening is not yet possible. To remedy this situation, the NICHD is funding a series of contracts to develop gene-based technologies that can identify hundreds of rare genetic disorders in a single test. In addition, the Institute will fund new projects to spur research on new treatments for potentially screenable disorders. Examples of conditions in these categories are Spinal Muscular Atrophy, the leading genetic cause of infant death, and Fragile X Syndrome, the leading inherited cause of mental retardation. Expanded efforts in fiscal year 2008 will include creating a multi-site newborn screening translational research network to test the most promising new screening technologies and experimental treatments in collaboration with state newborn screening programs.

REDUCING ANOTHER CAUSE OF INFANT MORTALITY: NEC

Through research led by the NICHD, one cause of infant mortality after another has yielded to treatments based on new discoveries. Respiratory distress syndrome, severe jaundice, meningitis, and Sudden Infant Death Syndrome cause far fewer deaths today. One remaining problem is necrotizing enterocolitis (NEC). This condition affects 10 to 12 percent of infants weighing less than three pounds, and about 30 percent of those affected will not survive. NEC attacks and destroys their intestines. Unfortunately, its incidence and mortality rate have not changed in 40 years.

Now, new NICHD studies give hope that prevention or effective treatment can become a reality. One study in mice demonstrated that epidermal growth factor, administered orally, was highly protective against NEC. Another study, in humans, demonstrated protection against NEC from interleukin—in breast milk. These and other potential therapies will be tested in a new NICHD initiative on NEC to be launched in fiscal year 2008.

DEVELOPING IMPROVED PROSTHETICS

As the country's Armed Forces return from stations abroad, and as the nation's population continues to age, increased attention is needed on medical rehabilitation. The Institute's National Center for Medical Rehabilitation Research is a leader in such efforts and provides a Federal focal point for research in this important field. Among the initiatives in the Center's portfolio is developing mechanical limbs that allow for better comfort and mobility. Advances in this area can be particularly helpful to veterans who have lost limbs in combat. One exciting new finding from this research: an amputee can move and have functional use of a prototype prosthetic arm simply by thought. Thinking about moving the arm stimulates the chest muscles to contract. Microprocessors in the arm read the nerve signals sent by the chest muscles, and movement flows with relative ease and greater speed and precision. Researchers hope to use similar technology to restore natural movement and sensation to the limbs of individuals paralyzed by injury or stroke.

HELPING DEVELOPING NATIONS OVERCOME DISEASE

Every 30 seconds, malaria takes the life of a child somewhere in the world. The mosquito-borne disease kills more than one million people each year and severely sickens millions more in developing countries, crippling economic growth. It is one of the world's leading health concerns. Researchers at the NICHD's Laboratory of Developmental and Molecular Immunity—in partnership with researchers in the Malaria Vaccine Development Branch of the National Institute of Allergy and Infectious Diseases, and the Biotechnology Unit of the National Institute of Diabetes and Digestive and Kidney Diseases—may have a solution.

These researchers have developed an experimental vaccine that stops the spread of malaria, mosquito by mosquito. The vaccine eliminates the parasite responsible for malaria from the digestive tract of a malaria-carrying mosquito after it has fed on the blood of a vaccinated individual. Future bites from this mosquito then no longer transmit the disease. If it is proven safe and effective, the vaccine could free entire geographic regions from this destructive disease.

The NICHD's research investments to improve health in developing nations go beyond laboratory benches. The Institute supports the Global Network for Women's and Children's Health Research, an initiative devoted to addressing the leading causes of illness and death in pregnant women and their infants in developing countries. This year one network study, a randomized double blind clinical trial conducted by birth attendants in rural India, demonstrated that giving women a single dose of misoprostol, a uterine muscle constrictor, just after delivery nearly eliminated the incidence of severe post-partum hemorrhage, a leading cause of maternal mortality in developing countries worldwide. India immediately took action to make misoprostol treatment available as standard care throughout the country, and other nations are doing the same. This one simple and cost effective intervention will save the lives of millions of women throughout the developing world.

Mr. Chairman and members of the committee, I would like to thank you for your continued support of the Institute's research as we strive to understand disease and improve the health and well-being of men, women, children, and future generations in the United States and around the world. I will be pleased to answer any questions.

Senator HARKIN. Dr. Alexander, thank you very much.

It's hard to know where to begin, but thank you all very much for excellent testimony. Very pointed, very to the point. We might as well start where we started with Dr. Kirschstein.

RESPONSE TO COMPLEMENTARY AND ALTERNATIVE MEDICINE

I'm very interested in what you mentioned about looking at genetic variations, and I want you to just tell me a little bit more about that, because it seems to me, every time we talk about people who have had an experience with a complementary or alter-

native medicine approach, were over the counter or something like that. Sometimes it seems to work for some people, and it doesn't for others. So, why does it work for some, and not for others? So, maybe there is some genetic variation there that allows for something to be done, and is therapeutic, but on the other hand, for someone else it isn't. Is that what you're looking at?

Dr. KIRSCHSTEIN. That's what we plan to look at. We know that that's true, also, for the use of more conventional drugs. We know that the people respond differently to drugs, and that there are times when the dose has to be cut, or they actually have to substitute one drug for another. We don't have that knowledge about these complementary materials, particularly the biologically based ones that people have been using on their own that they can purchase in various stores. This is what we want to take a look at, now that we know so much about the sequencing of the genome and the variation as to what could be happening. We're going to launch studies to that effect. We have not started as yet.

NATIONAL ADVISORY COUNCIL ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

Senator HARKIN. I see. I just want to cover one other thing with you, Dr. Kirschstein, and that is the structure of the advisory council.

Dr. KIRSCHSTEIN. Yes, sir?

Senator HARKIN. Here's the law that set it up.

First of all, you know we had it first as the Office of Alternative Medicine, and then we changed it to NCCAM, and when we changed it to NCCAM in 1998, many people were disappointed in how the structure of the advisory panels had been set up previous to that. So, we wrote into law certain guidelines, put it right into the law. Of the 18 appointed members, 12 shall be selected from among the leading representatives of the Health and Scientific Disciplines, relative to the activities of the NCCAM. Particularly, representatives of the health and scientific disciplines in the area of complementary and alternative medicine members shall be practitioners licensed in one or more of the major systems with which the Center is involved.

Then it says, "Six shall be appointed by the Secretary from the general public and shall include leaders in the fields of public policy, law, health policy, economics, and management. Three of the six shall represent the interests of individual consumers of complementary and alterative medicine."

I understand that earlier this week you named six new members to the advisory Council. I've had concerns about this going clear back to 1991. As you know, as I said, I just read to you that 50 percent of the Council's non-staff members should be licensed CAM practitioners. Three, as I mentioned, from the consumer population. I don't believe that statute has always been met, and I want to ask you, where do we stand now with these additions to the panel? If you don't know that, you can respond to me later on.

Dr. KIRSCHSTEIN. I will expand on the question for the record.

[The information follows:]

NATIONAL ADVISORY COUNCIL ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

Question. The statute for the National Center for Complementary and Alternative Medicine (NCCAM) stipulates that at least half of the members of NCCAM's Advisory Council, who are not ex officio members, shall include practitioners licensed in one or more of the major systems with which the Center is concerned, and at least three individuals representing the interests of individual consumers of complementary and alternative medicine. How close is NCCAM coming to meeting the law?

Answer. There are several factors that influence the composition of NCCAM's National Advisory Council:

—NCCCAM's mission encompasses a diverse body of research. The scope of NCCAM's research includes all organ systems and medical/scientific disciplines, as well as a range of CAM modalities and practices within the four major CAM domains or systems (manipulative and body-based practices, biologically based practices, energy medicine and mind-body medicine) as well as the whole medical systems of which they are a part. The collective expertise of NCCAM's Advisory Council, which is responsible for second-level peer review of the grant applications that NCCAM receives, must reflect this diversity.

—Regulation of and licensure to practice any medical or CAM discipline is within the purview of the states, and requirements vary widely. For example:

  —All states license chiropractors.

  —All states license medical doctors and most include within the medical licensure standards degrees obtained from schools of osteopathy.

  —Most states have some form of licensure for practitioners of acupuncture and/or oriental medicine and practitioners of massage therapy.

  —A large majority of states do not have any specific form of licensure for practitioners of naturopathy or homeopathy.

  —Specific licensure does not exist in any state for many of the CAM disciplines involved in research grant applications reviewed by NCCAM's Advisory Council. Of these disciplines, many can be legally practiced for health care purposes by or under the auspices of licensed medical providers, such as allopathic physicians, doctors of osteopathy, or licensed mental health care professionals, and always within the legal framework and limitations of their licensed discipline.

Table 1, attached, lists the current NCCAM Advisory Council members, their areas of CAM and/or medical/scientific expertise, and their research and professional interests relevant to their service on the council. The table illustrates how the composition of the Advisory Council reflects the need to simultaneously address relevant statutory requirements, and to ensure appropriate scientific and CAM expertise needed to carry out its charge.

The terms of four Council members listed in Table 1 (Calabrese, Ezzo, Manyam, and Pickar) expire in 2007. Those members are slated to be replaced by six individuals whose appointments are in the final stages of completion. Table 2 lists the areas of CAM, medical/scientific expertise, and the research and professional interests relevant to the Advisory Council for the pending new members.

NCCAM will continue to assure that it has an appropriately qualified and balanced Advisory Council, as required by statute, that permits the Center to support the highest quality of scientific investigation of CAM, such as the examples highlighted in my testimony before the Subcommittee.

TABLE 1.—NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE—MEMBERSHIP, EXPERTISE, AND RESEARCH/PROFESSIONAL INTERESTS

Member degree(s)	Institution location	CAM expertise	Medical/scientific expertise	Professional/research interests and activities
Lori Alvord, MD [1 2]	Dartmouth Medical School, Hanover, NH	Native American Medicine.	Surgery	Integrative medicine. Health services research on patterns of care for Native Americans.
Stephen Barnes, Ph.D.[1]	U Alabama at Birmingham, AL	Botanicals/natural products. Pharmacognosy	Biochemistry Pharmacology Toxicology	Botanical research. Research on diseases of aging and chronic disease prevention.
Carl Calabrese, ND, MPH [2 3]	National College of Natural Medicine, Portland, OR.	Naturopathy	Clinical research	Clinical research on CAM natural products.
Sheldon Cohen, Ph.D.[1]	Carnegie Mellon, U Pittsburgh, PA		Psychology Mind-body medicine Psychosomatics	Role of stress, coping, and social support in health and weal-being. Psychoneuroimmunology.
Fabio Cominelli, MD, Ph.D.[1]	U Virginia, Charlottesville, VA	Gastroenterology Cell biology	Inflammatory bowel diseases Mucosal immunology	
Silvia Corvera, MD	U Massachusetts Medical School, Worcester, MA.		Endocrinology	Type II diabetes and metabolic syndrome.
Jeaneette Ezzo, Ph.D., MsT, MPH [2 3]	James P. Swyers Enterprises, Takoma Park, MD.	Massage therapy	Epidemiology Biostatistics	Systematic reviews evaluating CAM evidence base. Health policy—breast cancer advocacy.
Joan Fox, Ph.D.	Case Western Reserve, University, Cleveland, OH.	Reiki	Cell biology	Cardiovascular disease; mechanisms of action of mind-body practices affecting cardiovascular disease.
Marjorie Gass, MD [1 2]	U. Cincinnati, Cincinnati, OH		Obstetrics and Gynecology	Women's health. Osteoporosis, menopause.
Ted Kaptchuk, OMD, LAc	Harvard Medical School, Osher Institute, Boston, MA.	Asian medicine Acupuncture		Acupuncture. Clinical and basic research on the placebo effect and its implications for practice and research methodology.
Bala Manyam, MD [3]	Hindu University of America Odessa, FL	Ayurveda	Neurology	Research on movement disorders. Ayurvedic herbal medicine approaches to Alzheimer's disease.
Joel Pickar, DC, Ph.D.[2 3]	Palmer College of Chiropractic, Davenport, IA.	Chiropractic	Physiology	Neurophysiology of chiropractic manipulation.
Bruce Redman, DO	U of Michigan, Ann Arbor, MI	Osteopathy	Clinical trials	Immunotherapeutic approaches to treatment of cancer.
Danny Shen, Ph.D.	University of Washington Seattle, WA		Pharmacokinetics Pharmacology Toxicology	Herb-drug interactions.

TABLE 1.—NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE—MEMBERSHIP, EXPERTISE, AND RESEARCH/PROFESSIONAL INTERESTS—Continued

Member degree(s)	Institution location	CAM expertise	Medical/scientific expertise	Professional/research interests and activities
Frank Torti, MD, MPH [1]	Wake Forest U School of Medicine Winston Salem, NC.		Oncology	Cancer biology. Antioxidants and cytokines.
Stephanie Vogel, Ph.D.	U of Maryland Baltimore, MD		Immunology Microbiology	Mechanisms of immune defense.

[1] The appointment of these six individuals was announced on June 21, 2007.
[2] Public member.
[3] Terms expire in 2007.

TABLE 2.—NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE—EXPERTISE AND RESEARCH/PROFESSIONAL INTERESTS OF MEMBERS PENDING APPOINTMENT

Pending	CAM expertise	Medical/scientific expertise	Professional/research interests and activities
1 [1]	Naturopathy		Integrative oncology.
			Cancer Prevention.
			Public policy.
2 [1]	Osteopathy		Osteopathic practitioner.
3 [1]	Chiropractic	Clinical trials	Research on CAM treatments for low back pain, neck pain, asthma, infantile colic, and headache.
4	Acupuncture	Psychiatry	Practice of acupuncture.
5 [1]	Qi Gong	Biochemistry	Cell biology.
	Tai Chi	Biophysics	Research on mechanisms of action of qigong and acupuncture.
		Cell biology	Teaching of Oriental Medicine.
6		Internal medicine	Cardiovascular Disease.
		Cardiology	Epidemiology of cardiovascular disease in African Americans.
		Epidemiology	Epidemiology and preventive medicine.

[1] Public member.

Dr. KIRSCHSTEIN. I do know we have tried very hard to fulfill the law. We submit two names for each spot on the advisary council. We have been in discussion with the people who have worked on this, and we are always working to improve the submissions for the advisory council.

On the other hand, we need a very balanced advisory council, because we need individuals who can take a look at things like the genetic variation studies that we will be setting up. So, this is a challenge to us, and we're going to work hard to meet it.

Senator HARKIN. I appreciate that, Dr. Kirschstein, could you please get to my staff within the next week or so, the rundown of the members, the six that have been appointed, I want to know how close we've come to meeting the law?

Dr. KIRSCHSTEIN. Yes, sir, I will do that.

Senator HARKIN. I'm still concerned about that.

Dr. KIRSCHSTEIN. I will work with you on it.

Senator HARKIN. I appreciate that. It's something, as you know, I've been hot on this for a long time.

Dr. KIRSCHSTEIN. Yes.

CAM AND INFLAMMATION RESEARCH

Senator HARKIN. I don't mean to let up on it.

It's interesting that you mentioned in your written statement—I read it last night—but you mentioned something about the use of turmeric as an anti-inflammatory thing. Is that investigation ongoing right now?

Dr. KIRSCHSTEIN. Yes, sir. It is an investigation ongoing right now, and some preliminary data have indicated that it has anti-inflammatory effects, and possibly anti-arthritic effects, therefore we are planning to expand those studies.

Senator HARKIN. I've always asked a lot of doctors—if you look at my hands and look at my two little fingers, there's little bumps on the last thing of that digit—do you know what that's called?

Dr. KIRSCHSTEIN. I have one called——

Senator HARKIN. What's that called?

Dr. KIRSCHSTEIN. Osteoarthritis.

Senator HARKIN. What is that called? Aheberden's nodes, but it's only because it comes to the little fingers and the thumbs, basically

where it affects—there was a Scottish doctor that found this, and it's prevalent among people from that area of the world—Scotland, Ireland, it happens to be where my ancestors come from. But, a very painful, arthritic conditions.

It's interesting, because you know, I've been interested in complementary and alternative medicine for a long time. I was in Iowa last fall in the campaign and what do you do during the campaign? You shake a lot of hands. Well, these can be very painful, can you imagine shaking hands with this? It was so painful, I couldn't even stand to shake hands.

I just happened at that time to have dinner with a couple of doctor friends of mine, brothers, Dr. Neil Sahai and his brother Sabash, they're from India. They have a medical practice in Webster City, Iowa, and they invited me over for dinner, great family. Their mother was there, and the best Indian food I've ever had in my life. So, I went there for dinner, just as a social thing, I know them. I was complaining about my hands hurting. I had arthritis in my fingers, and Neil Sahai, Dr. Sahai said, "Well, I think I may have something to help you from India, we've got this, something called turmeric."

Well, I'd kind of heard of that as a spice before, and so he asked me to take two of these every day for a month, and just see if it had any effect, and I didn't change any other thing I did in my life. I changed nothing in terms of my eating habits or sleep, basically went on as I've been going, except I started taking this turmeric every day, and after about 30 some days or something, I just had no problem, and I have no more pain left in my hands at all. I take turmeric every day now. Now, is that the reason for it? I don't know. All I can tell you, I didn't change anything else. It's interesting, when I read your testimony last night I thought, "Oh my gosh," I thought maybe it was just mental stuff with me, I didn't know what was going on. It was amazing, I had to have that happen.

Dr. KIRSCHSTEIN. Maybe next year or the year after, the permanent Director of NCCAM will be able to tell you the answer.

Senator HARKIN. Well, it's just interesting that you're interested in that, and looking at it. Anyway, I didn't mean to get into my own health thing or anything like that.

Well, I have a lot more questions, but Senator Cochran, I would yield to you for another 5 or 10 minutes, and then I'll come back.

Senator COCHRAN. Mr. Chairman, one thing that could have helped your hand is you quit running for President, you don't have to shake as many hands.

NATURAL RESEARCH PRODUCTS

Senator HARKIN. That's a good point.

Senator COCHRAN. I think it's very interesting, to hear the testimony this morning. I've enjoyed the opportunity to hear your remarks about the different areas of inquiry the National Institutes of Health is engaged in, and your areas of expertise.

I remember, too, in connection with dietary supplements, there's a growing popularity among American people in these kinds of things, and at our University of Mississippi, there's a natural prod-

ucts center that has been established, and it's been working now for some time, exploring health beneficial uses of natural products.

It all started, frankly, with an idea someone had for undertaking marijuana research, and it's the only place in the country that I know about where the Government actually encourages the growing of marijuana, and testing and analysis, and trying to figure out what the medicinal properties might be that can be useful, and that has expanded now to include a lot of other areas of inquiry. It's become an international center for research and exchange of information, and we're very proud to host that in our State in Mississippi.

I just wonder if the National Institute has had any connection or correspondence, communication with people down there who are working in these areas.

Dr. Kirschstein, do you know of any connection or exchange of information?

Dr. KIRSCHSTEIN. We have a great deal of contact with the people down there, indeed we support research at the University of Mississippi on natural products botanical center, and we just—there was recently a meeting there which we helped support, so we're very active in that area, sir.

CAM AND PEDIATRIC POPULATIONS

Senator COCHRAN. I know that one area of interest is in alternative medicine for children. I know I grew up in a family that didn't believe in taking medicine. My mother always said, "If you eat right, you don't have to take medicine, you'll be healthy." If you exercise and do all of these right things. Of course I've learned later that it's probably the genetic properties we were born with have an awful lot to do with good health, too, and disposition towards disease and illness.

How important is it for us to concentrate on education in these areas of factual information that could be helpful, at least, to reducing anxieties, contributing to unnecessary use of medicines, if we can change the mindset by just improving the level of knowledge and understanding and appreciation of what the facts are? What really does matter in good health, for children, particularly?

Dr. KIRSCHSTEIN. It's extremely important. Dr. Alexander, of course, can expand on this. But one of the reasons we are doing this survey with the CDC is to determine how extensive the use of complementary and alternative practices is in children. We know that their parents are using a great deal of this, and therefore some of them, of course, are giving similar treatments or modalities to their children. We really don't have good follow up on that, and we need to begin to do some research, being very mindful that the child is not just a little adult—there are differences between children and adults. We must be sure that we are protecting our children at the same time, and that we know what we're giving them.

The other part about education is that what we know, Senator Cochran, is that people, consumers, of complementary medicines and alternative medicines, when going to the regular practitioner, their doctors do not tell them that they are using the alternative or complementary products, and vice versa. The doctors do not ask them. As a result, the communication about all of the materials

that an individual is using does not get transmitted. That is why we have started these new campaigns—education in this field, just like in all medical fields—is very important.

PRETERM BIRTHS

Senator COCHRAN. Thank you. I know, Dr. Alexander mentioned in his testimony the problem of premature births. I think the statistics that we have show that this has increased by 30 percent, just in the last 20 years. That is a substantial number, it's now the leading cause of newborn death. What factors, do you think, are the cause, or can be attributed to the pre-term births? What do we do in terms of national policy or education to improve on these numbers?

Dr. ALEXANDER. This is a real puzzle to us, Senator Cochran, because there's no question about these statistics. The change, the increase in premature birth is real. It's also accompanied by an increase in low birth weight, not unexpectedly.

After many years in which this declined, it has now started to go up again, and the trend has persisted in spite of our efforts to reverse it. So, people talk about a variety of things that may be contributing to it. One of the first things people talk about is the increased prevalence of assisted reproductive technology—invitro fertilization, and other efforts to assist people who are infertile to have children. For a variety of reasons—sometimes because multiple fetus pregnancy is established—two, three, four, fetuses—all of which tend to increase the likelihood of prematurity. We have now, 1 to 2 percent of our population born as a consequence of assisted reproductive technology. So, as that has increased, the likelihood of prematurity has increased. What we're trying to do here with the obstetric community is encourage, when people do IVF, only to put one embryo back, and to establish a pregnancy with a single embryo, rather than two, three, four, five, as has been done in the past to increase the likelihood of establishing the pregnancy. That is one tactic.

In addition to that, there probably is a factor of increased efforts to save very, very low birth weight babies, so that babies that might have been classified previously as still births, now are classified as live births, and are entered as babies who are live births, and thus contribute to infant mortality, whereas previously they would have been considered stillbirths because they were so small, that no efforts were made to help them start breathing or start a heart rate. That is another factor.

But, there are others that we just don't understand. We're in the process of working with the Office of the Surgeon General to put together a report on prematurity that was called for by the Preemie Act that the last Congress passed. So, we're involved in that, and we hope through our very intense examination of that, which follows on the work of an Institute of Medicine committee focusing on prematurity, we will learn some more useful routes to pursue to try to get at this question of what is causing the increase, and what can we do to reverse it?

Senator COCHRAN. Thank you. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran.

TEMPOROMANDIBULAR JOINT/MUSCLE DISORDERS

Dr. Tabak, I think you and I talked about this a long time ago. That included report language, for many years, on TMJ, and you mentioned it briefly. We discussed it several years ago again. Very briefly, could you tell what advances have been made recently in the area of TMJ? On the muscle and joint disorders? Are you doing some research on regenerating damaged bone and tissue, but just again, give me a couple of minutes on that.

Dr. TABAK. Surely, and thank you for the question.

We've actually done quite a bit in this area. The most important thing is that we are now attracting researchers with different talent sets to study this enigmatic set of diseases and conditions. We have finally been able to attract geneticists, neurologists, neuroscientists, individuals who are able to look at the entire system, as opposed to the very specific joint.

By bringing in these additional people with their expertise, we're beginning to get a much more balanced view of this complex, and probably heterogeneous, set of diseases and conditions. The work that you alluded to, work related to replacement of diseased joints, is ongoing. We have a very extensive bioengineering program, which makes use of advanced material development. The materials are not stagnant, they are typically impregnated with so-called growth factors, similar to those that Dr. Sieving spoke to you. These growth factors can help inform the surrounding cells as to what they should be doing to facilitate regeneration and regrowth. So, we're really looking at this at all levels.

A final point that I will make is that we recently funded a longitudinal study at the University of North Carolina termed OPERA, which is looking at individuals before they even develop symptoms of temporomandibular joint/muscle disorders. What we're doing in this prospective longitudinal study is collecting a large amount of data—including biological samples—so that as the individuals within the cohort begin to develop symptoms and evidence of disease, we will have already banked materials. Once and for all we can begin to get insight into the very earliest stages of the disease, so that we can begin to pick out those people in the community who are most at risk. I think that's going to be a very important adjunct.

We have programs to look at the very earliest stages of the disease. We have programs looking at the disease as it currently exists, and then we have the programs at the end stages, where we are recreating the joint for those individuals who have had extensive joint destruction.

Senator HARKIN. Very good, I'll keep on top of this. We've been on it for several years, and I'm really interested in, again, pushing this ahead and advancing the early detection of that, and intervention on that program.

AUTISM

Dr. Schwartz, let's talk a little bit about autism. You didn't really cover that in your testimony, but we just had a hearing on that, and it was the first hearing we've had on this committee just looking at autism.

Anyway, you look at it, autism is almost epidemic right now. The increases over the last 2 years have been phenomenal, and the number of kids diagnosed with autism. Again, we're looking at things like, we know the earlier you get to it, there are certain interventional-type programs you can do that can lessen the effects of autism later on.

But, still, kids have autism. We don't know whether it's genetic or environmental, and it seems to be, in taking with CDC, maybe it's some genetic, maybe some environmental. Maybe the two feed off of each other. I'm wondering, what are you doing in your Department, what are you doing, looking at any environmental aspects of autism? Any correlative types of things that deal with autism and the environment?

Dr. SCHWARTZ. I agree with you entirely. I think a very important area of health research in the United States, with the changing patterns of disease. It looks like environment is playing an important role in terms of increasing the risk of developing disease, the patterns of disease, the severity of disease, or the type of disease that children are presenting with. Because we recognize that, we have been working in a very focused way to address this issue of autism. In fact, we've increased our funding from 2006 to 2007 from $1.8 million to $3.5 million in the area of autism.

We have a new study that we are funding at the University of California in Davis, UC Davis.

Senator HARKIN. Just stop right there a second. Okay, tell me again, how much you're spending this year, on autism?

Dr. SCHWARTZ. In 2007, $3.5 million.

Senator HARKIN. That's all you're spending on looking at environmental aspects of autism? Is that what you're saying?

Dr. SCHWARTZ. That's correct.

Senator HARKIN. Out of $637 million?

Dr. SCHWARTZ. That's correct. As I said, we have doubled the amount from 2006 to 2007.

Senator HARKIN. Okay, but I'm just wondering why we haven't been doing more before that. I'm always interested when people tell me they've doubled, or something's gone up by 100 percent, I always try to remember, and remind people that zero to 1 is an infinite increase. So, it depends on where you're starting from.

Dr. SCHWARTZ. In the climate of a flat budget, we have increased the investment in this area, because we recognize the importance of this. So, let me just tell you the things we're doing, and that we're planning to do, because I think it really gets at your questions which are, what will our investment be over the next several years, and how seriously do we take this disorder?

AUTISM RESEARCH

In terms of the $3.5 million, we just initiated a very large, prospective study of children at risk of developing autism to try to identify the factors that pre-date the development of autism to understand the biological signals, and also the genetic factors, as well as the environmental exposures, that are related to the development of autism.

That's one thing. The second thing is that we're working with the Centers for Disease Control to make their panel of exposure meas-

urements, which constitutes about 150 biological exposure measurements, available to these long-term epidemiological studies to try to understand whether pesticides in the blood, or solvents, or metals in the blood are related to the risk of developing autism in these populations that have already been established.

The third thing that we have done is we recently helped develop a conference with the Institute of Medicine focusing on the environment and autism. Dr. Alexander was involved in that conference. Dr. Insel, Director of the National Institute of Mental Health, was also involved in that conference, and we identified several areas of potential collaborative activities in the area of autism that we want to pursue further. So, we're currently in discussions with the National Institute of Mental Health—one other thing, we are newly supporting this year are the Autism Centers of Excellence. One of those Centers will be supported by NIEHS. That will be in the 2008 budget, so that is not counted in the $3.5 million.

Now, one of the areas we're developing in collaboration with the National Institute of Mental Health is to take our Environmental Health Science Centers and when they are co-localized with the Autism Centers of Excellence, we will provide extra support for those two areas of expertise, to collaborate effectively on how the environment is affecting autism.

Senator HARKIN. Okay. In a recent issue of Discover Magazine, I think there was a cover story on autism, yes, and it had an interesting map. This was of the State of Texas, and it had a map of the State of Texas, like three maps. One showed the number of reported cases of autism in young children. I think it was, maybe, 10 years ago. I could be off on that, but some time ago. The next map showed the use of, by county by county, it was a map of the counties of Texas. I think it was EPA data showing the amount of, levels of, I don't know if they were carcinogenic, but of different compounds in the environment that was, sort of, toxic. It had a lot to do with, I think, petrochemicals. It had a lot to do with pesticides, herbicides, a whole panoply of things, a whole bunch of things.

Then, the next map showed the increase in the rate of autism. You overlay that map and it is just amazing. It's just about the same. So again, this is your department, right?

Dr. SCHWARTZ. That is correct.

Senator HARKIN. It seems to me that you really ought to be really pushing the envelope on this to try to find these kind of patterns and getting more scientists involved and getting more grants. I don't know what the rate or what the kind of proposals that are coming in that actually get through the peer review process. I would be interested in knowing what percentage or how many of the peer reviewed client proposals that come through, requests that come through to study the environmental aspect of the impact on autism. How many of those are being granted?

Dr. SCHWARTZ. A great question.

Senator HARKIN. Is it 15, is it 20?

Dr. SCHWARTZ. We can provide that information to you.

[The information follows:]

SUCCESS OF NIEHS AUTISM GRANT APPLICATIONS

The NIEHS received eight research applications for projects focusing on autism in fiscal year 2006. Three of the proposals, or 37.5 percent, were funded. This percentage is substantially higher than the success rate of the overall NIEHS portfolio and demonstrates the Institute's commitment to autism research as a program priority.

Dr. SCHWARTZ. It is more than 20 percent. It's probably 30 or 40 percent. I think we are looking at this as a challenge and also an opportunity for the field of environmental sciences.

THIMEROSAL

Senator HARKIN. Are you looking, there was for some time this thought that Thimerosal was a leading cause. Medical professionals and researchers said that that's not the case. CDC basically testified that they did not think there was a correlation there, but there's other thoughts that it's the amount of vaccinations that are given to kids before the age of 2. Now, it's like 25 or 26 or something like that.

Do you know, Dr. Alexander?

IMMUNIZATIONS

Dr. ALEXANDER. If you add all the diseases together and the number of immunizations you get for each one of them, that's about the right ballpark.

Senator HARKIN. Somewhere between 20 and 30. I know my grandson, they're just wrestling with that right now, but this is something relatively new. I mean new in the last 20 years or so. We never did that before.

Dr. ALEXANDER. But, there's been no thimerosal in any of these vaccines for the last 5 years.

Senator HARKIN. Not the thimerosal, I'm just saying maybe it's the number of these and the cumulative effect it has. As you said, these are not just little adults. Everything is different in a baby and you're talking about giving between 20 and 30 immunizations between, before they're 2-years-of-age. There's some thought that maybe just the accumulation of that may have some affect on autism.

NATIONAL CHILDREN'S STUDY

Now again, I don't know and I don't know if any research is being done into that either through you or through you.

Dr. ALEXANDER. Let me tell you something that is about to be done. It's a payoff benefit from the National Children's Study that you made reference to earlier. NIEHS and EPA and CDC are joined with the NICHD and many other institutes in the planning for this study. One of the things that will be looked at as a key outcome is autism. With a prevalence of six per thousand, we will have 600 kids and 99,000 controls. So, we will have information on these children including DNA from both parents and the child and siblings, we will have prenatal exposures of the mom to a large number of environmental factors and toxins and substances and so forth. We will be sampling the child from birth with umbilical cord blood etc. and we will be following the environment that the child lives in, measuring environmental exposures. We will measure the

vaccinations and immunizations the child gets, the whole course of their medical history.

Senator HARKIN. Are you talking about the children study?

Dr. ALEXANDER. Yes.

Senator HARKIN. That longitudinal study?

Dr. ALEXANDER. Right, and that will be providing us with this information that there is no other source to get. It will all be obtained prospectively and we'll be able to analyze, not just one thing at a time, but we'll be able to analyze gene-environment interactions, the interactions between different environmental exposures and each other, and we will be able to look at that in relationship to family history.

You made reference earlier with Dr. Kirschstein as to whether there were genetic variations and susceptibility to things, this is one of the things we'll be able to look at in the National Children's Study with validity, because it's collected prospectively, and we have a large sample size of 100,000 children 200,000 parents.

Senator HARKIN. Okay, since we're on that—as you know, I've been a strong supporter of that, and we put the money in this year to continue that again. Where are we on this children's study? How far along are we in terms of identifying, fitting that 100,000 pool?

NCS STUDY PLAN

Dr. ALEXANDER. Okay, with the funding that you provided this year, the $69 million that you added to the appropriations for 2007, we will be recruiting the first one-third of the 105 sites around the country who will be conducting the study. Those will be funded by September 30. That is $32 million of the funds that you provided. The 7 Vanguard centers that have been funded for the last year and a half to start some of the piloting for this study will be funded with about $20 million this year to markedly expand their efforts and get them ready, so that they can start to actually enroll subjects for the study, for the pilot phase by July 2008.

The following year, another third of the sites will be added, then the following year, another third. So, we will be actually starting the actual recruitment of the full study cohort in 2009, with a pilot cohort from the Vanguard sites in July 2008. We also will be using the funds to set up the sample repository center, the laboratories that are going to be doing the analyses, the informatics and data collections systems, all of which will be electronic, so that those funds are going to be put to good use in 2007.

Senator HARKIN. Well, that is encouraging, and we need to move ahead as aggressively as possible, and I would like to know from you if the funding levels are adequate to move it as aggressively as possible? I know these things—some of these things take time, and no amount of money can move some of these things, because you just have to set up the structures, and have to identify the people and that kind of thing. But I would like to know whether or not we can move more aggressively on that.

AUTISM RESEARCH

But I want to make the point that we shouldn't, Dr. Schwartz, that we—both Dr. Alexander—that we shouldn't have to just wait

10 or 15 or 20 years to get data and information from the children's study.

Dr. ALEXANDER. We will have all of the kids with autism diagnosed by age 3, so we don't have to wait 15 years. We'll be doing those analyses as quickly as we can have the data available.

Dr. SCHWARTZ. That is precisely why we're funding focused studies on the environment and autism today.

Senator HARKIN. Yes, that's my point, we can't just wait.

Dr. SCHWARTZ. We initiated a cohort study in October 2006—that's $1.5 million each year to support a study that focuses on children at very high risk of autism, and looks at environmental causes of autism in relation to the development of the disorder.

Senator HARKIN. When you say environmental, that also might include immunizations?

Dr. SCHWARTZ. Absolutely, absolutely. Also thimerosal.

Senator HARKIN. But we don't use thimerosal any longer.

Dr. SCHWARTZ. So we do have studies. The thimerosal question is not completely a moot issue, and we have studies that are looking at the relationship between mercury and brain damage in primates and in animal models, and we're still in the process of doing that research.

Senator HARKIN. I thought it was a well-known fact that mercury in the bloodstream does affect the brain.

Dr. SCHWARTZ. It does affect the brain. The question is, does it affect the brain in terms of the risk of developing autism.

Senator HARKIN. I don't know the answer to that question, obviously. Okay, I just, again, need to keep—I want you to keep us up to speed, and keep my staff up to speed on what your Institute is doing in this area of autism.

Dr. SCHWARTZ. We can provide you that information.

[The information follows:]

NIEHS AUTISM RESEARCH

NIEHS is actively investigating possible environmental factors in autism risk, including studies of gene-environment interaction. These are some of the projects being funded:

—The NIEHS Center for Children's Environmental Health and Disease Prevention Research at the University of California (UC) Davis is building on its earlier finding of immune dysfunction in autism and is currently focusing on the interplay of immune, genetic and environmental factors in autism susceptibility.

—NIEHS is expanding support for continuation of enrollment in another large, ongoing study at UC–Davis (CHARGE) to provide the ability to detect gene-environment interactions in distinct subgroups of children.

—An epigenetic study of genes implicated in autism and their interactions with neurotoxicants is also being conducted at UC–Davis.

—NIEHS is funding a promising project at Johns Hopkins to develop a sensitive biomarker for the immunotoxic effects of mercury (and use it to compare families with and without autism).

—NIEHS helped to plan and conduct the recent Institute of Medicine workshop on *Autism and the Environment: Challenges and Opportunities for Research* to examine the most promising scientific opportunities for improving the understanding of potential environmental factors in autism.

—The NIEHS is contributing funding for the Autism Centers of Excellence. Some funds are being committed in fiscal year 2007, and a larger investment is planned for fiscal year 2008.

—NIEHS plans to fund a new 5-year prospective cohort study of pregnancies at high risk for autism beginning in fiscal year 2008.

—NIEHS is a contributor to the National Database for Autism Research (NDAR). The initial phase is focused on developing a clinical module which will serve as

a data repository for the ACE investigators. The plan is ultimately to expand the NDAR to other investigators and other types of autism research beyond clinical research. NIEHS contributed $250,000 in fiscal year 2006.

ASTHMA RESEARCH

Senator HARKIN. Asthma—more and more kids getting asthma, it's amazing. But tracking with autism, what is going on? Why are so many kids getting asthma today, what's happening?

Dr. SCHWARTZ. Asthma is a classic example of a disease that is clearly increasing in prevalence, and our genetics are not changing to alter the risk of developing the disease, so the environment is contributing substantially to the risk of developing asthma. Environments like the environment in New Orleans, environments that are heavily contaminated with micro-organisms, are risky, environments for the development of airway inflammation. That is one of the reasons that we're studying that population very carefully, to try to identify ways in which we can intervene to decrease the risk of asthma.

Senator HARKIN. I can't tell you how many people I've talked to in the last several years that come up to me and, in different settings, and have said, "You know, I've never had allergies before I came to Washington, DC." That, a lot of people say that. There's something happening around here, I don't know what it is.

Dr. SCHWARTZ. There's a very interesting process that's occurring. There's definitely an interaction between airway inflammation that is caused by environmental pollutants, and the risk of developing allergic responses in the body. We're spending $40 million a year on our asthma portfolio. So, this is something we're actively engaged in to try to understand how these air pollutants are altering——

Senator HARKIN. When you say asthma, that's allergies also, right?

Dr. SCHWARTZ. There is a non-allergic form of asthma as well. Individuals who work in the hog industry can develop asthma caused by microbial contamination alone without any allergic response. They develop the same exact symptoms and signs of asthma that someone who has allergic asthma.

HEALTH EFFECTS OF NOISE

Senator HARKIN. One other area I want to cover with you, Dr. Schwartz, before I leave you here is, you didn't cover it in your thing, and I want to know if your Institute covers this—noise. Noise, the environmental aspects of noise, and what it is doing to kids today, and all of us. The noise levels we're subjected to all of the time, whether it's jet aircraft, automobile noise, just the noise around, is phenomenal. Kids with those plugs in their ears, listening to their iPods, and you don't know what volume you've got them cranked up to, but I suspect the volume—the more the volume gets cranked up, the more they lose their hearing. They keep cranking it up all of the time. So, talk to me about what your Institute is doing in looking at the environmental aspects of noise, and its effect. Its behavioral effect, not just the effect on loss of hearing, maybe neurobiological types of effects it might have on an individual, are you looking at that?

Dr. SCHWARTZ. We have a relatively small portfolio in terms of noise, and the portfolio that we have in relation to noise relates to occupational or excessive environmental exposures to noise.

The Dr. Battey's institute.

Senator HARKIN. The National Institute on Deafness.

Dr. SCHWARTZ. They're looking at the pathophysiologic effects of noise.

Senator HARKIN. That's what he's looking at. I'm just talking about the environmental aspects, and how that impacts. Are you coordinating with them on that?

Dr. SCHWARTZ. Any time we have an opportunity to, we do. I don't know the specifics, and I can get that specific information back to you, in terms of what studies are being supported by NIEHS, and what studies are coordinated with the other institutes. I just don't have that information for you.

Senator HARKIN. Well, give us some information on what you're looking at in terms of noise, and what kind of research you're doing in terms of the effect of noise on our bodies, on our physiological things, and what happens with behavioral aspects of noise.

Again, I read these articles in Science magazine, I read about certain thoughts that a lot of this noise is causing people to behave in odd ways. Maybe altering brain patterns and brain waves. I don't know. I'm just saying there's some bits and pieces, some research in different places going on about this, and I don't know who, among all of your institutes out there, covers this. If it's not you—I don't know if it's Dr. Battey or not. I would like to find out that answer. But it seems to me it is an environmental aspect.

Dr. SCHWARTZ. I'll get you that information.

[The information follows:]

RESEARCH ON THE HEALTH EFFECTS OF NOISE EXPOSURE

Environmental noise is certainly a ubiquitous exposure and one that is understudied. A recent review[1] of the published literature underscores the difficulty of conducting this research. Both active coping strategies employed by noise-exposed people as well as subconscious physiological adaptation to noise complicate the ability to perform good studies. Furthermore, clinical expression of these stress reactions in the form of symptoms can take many years to occur. In reviewing the existing work, the authors state that:

"The evidence for effects of environmental noise on health is strongest for annoyance, sleep and cognitive performance in adults and children. Occupational noise exposure also shows some association with raised blood pressure. . . . The effects of noise are strongest for those outcomes that, like annoyance, can be classified under 'quality of life' rather than illness."

That said, the authors also recognize that "the interaction between people, noise and ill-health is a complex one," and that further study is needed. It may be that adaptation to noise carries its own health costs, or that noise can combine with other physiological or chemical stressors to lead to greater health impacts than noise exposure alone.

NIEHS has funded research in the past on effects of noise (with or without concomitant ototoxic chemical exposure) on hearing loss. Current research applications on noise exposure resulting in hearing loss are typically assigned to the National Institute on Deafness and Other Communication Disorders. NIEHS has also funded research looking at effects of noise-induced stress on intestinal disease and presence of reactive oxygen species in rats. No specific noise-related solicitations are planned in the current budget, but investigator-initiated grants would be welcomed and carefully considered. In addition, noise is an exposure category proposed for study in the

[1] Stansfeld SA, Matheson MP, 2003. Noise pollution: non-auditory effects on health. *British Medical Bulletin* 68: 243–257.

National Children's Study, for which NIEHS has been a contributor of both funding and expertise through the planning phase.

Senator HARKIN. I'd like to kind of know who's looking over that.

AGE-RELATED EYE DISEASE STUDY

Dr. Sieving, you mentioned the AREDS Study. It showed that certain supplements, beta-carotene, Vitamin C, and E, and Zinc can slow the progression of AMD, macular degeneration. Well, okay, so that's useful once a person has been diagnosed with AMD, is that right? But how about before? Is there any evidence that these can help prevent a person from getting AMD in the first place? Also, direct yourself to the use of lutein, I don't know if you mentioned that or not, but is there not some scientific evidence that lutein acts as a preventative, or is there not?

Dr. SIEVING. Those are very interesting questions. As you have stated, the first AREDS study explored anti-oxidants, principally, Vitamins A, C, E, and some minerals. The design of the study—when you don't know what the answer will be, you have to design a question that will get you the first phase of it, and the first phase of the answer was to look at the conversion from early stage AMD to later stage AMD, and it was found that these factors—anti-oxidants—were effective in slowing, retarding that progression.

Senator HARKIN. When you said delay, by 25 percent, delay for how long? 1 year? 2 months? 5 years?

Dr. SIEVING. That would be the perspective you and I would have as the person taking it, in terms of delaying, or decreasing the conversion from one State to another. That is a population statement. So it is slowing the conversion rate. The actual delay in time is the more difficult question to get at.

Senator HARKIN. You're saying the 25 percent of the population had a delayed onset?

Dr. SIEVING. That's correct, yes.

Senator HARKIN. I still don't know how much of a delayed onset, or did it just vary?

Dr. SIEVING. The slope, as you look at time. The proportion of individuals who went on to develop AMD over this 5-year interval was about a 25 percent reduction. So, one can think in terms of years of putting off the conversion for some individuals. The study was not sensitive at the level of asking, is it going to help people who have not yet been identified or diagnosed with some early stage of AMD.

Senator HARKIN. Now, are these helpful in preventing, how about lutein?

Dr. SIEVING. The question of lutein is the subject of the next phase of this called AREDS 2. It's lutein, zeaxanthin and the fish oil, omega-3 fatty acid or fish oil, DHA. So, we hope that we will have an answer in a few years on your question of lutein.

[The information follows:]

LUTEIN RESEARCH

NCCAM has funded an exploratory study at the Johns Hopkins University to investigate the effects of lutein, an antioxidant that is part of the carotenoid family, to address retinitis pigmentosa, which is an eye disease that causes loss of night vision and peripheral vision, and, possibly blindness. Currently, NCCAM has no ongoing research on lutein.

Dr. SIEVING. There is the expectation, at least, in part of the practicing community of physicians, ophthalmologists, that lutein is beneficial in retarding the conversion to active vision loss from advanced AMD, and that's the reason for doing the study.

Senator HARKIN. Dr. Kirschstein, do you know if NCCAM is doing anything in that area?

Dr. KIRSCHSTEIN. I do not know. I will check on it, but I don't think so. I think Dr. Sieving, the Office of Dietary Supplements may also be doing some things, and of course, anything that they fund, would be in conjuction with NCCAM, or other ICS. They do not have the authority to fund grants.

GENE THERAPY

Senator HARKIN. Good point. Well, and also—I understand that more dogs have joined Lancelot.

Dr. SIEVING. Nearly 50.

Senator HARKIN. Nearly every year, I keep hearing they're now going to move into primates. And then I heard recently they were actually going to start doing this gene therapy in humans, where are we?

Dr. SIEVING. Well, I'm pleased to tell you, on the international world scale, we have crossed your threshold of moving it to people. There are four groups internationally, two in this country, one in France, one in England, considering the question of whether gene delivery into people will restore vision, will do something beneficial for vision. And the first of the groups to accomplish this is in London at the Institute of Ophthalmology. A scientist by the name of Robin Ali, who, I think it would now it would be 3 months ago, had done the injections of this gene construct called RPE 65, in two individuals to my knowledge. Looking forward in future attempts over the next 2 months, we can expect similar experiments to be done in Senator Specter's home State at the University of Pennsylvania. That study has been funded by the American people through the NIH National Eye Institute, and we will have a second opportunity to see whether there is benefit to doing this gene therapy in people.

Senator HARKIN. So again, just to make sure I understand this, a couple of people have already been, already agreed to undergo this gene therapy in London? This year you will have some more people who will be willing to undergo this, here in the United States?

Dr. SIEVING. That is correct. Just for the others around the table, the condition that is being treated is a form, a genetic form, of childhood blindness. In this case, the absence of an enzyme, genetic absence of an enzyme called RPE 65, the lack of that enzyme prevents the retina from responding to light, and hence, the individual has no vision, and is blind. When that was done in Lancelot, who you met, that dog has this RPE 65 deficiency, and by injecting the gene construct into that dog, the dog can now nearly play Frisbee with you, and can certainly walk the halls of Congress and look at you. That is an extremely exciting possibility.

As I think about opportunities to move forward on an experimental basis, on gene delivery as a concept in medicine, this is a designer circumstance to try.

Senator HARKIN. So, the first humans in the United States will be at the University of Pennsylvania, is that what you said?

Dr. SIEVING. Yes, it's a consortium between Pennsylvania and Florida.

Senator HARKIN. How many, do we know?

Dr. SIEVING. It will be a handful. The question the first time through is, one can think of this on two planes, one can think of the people who could potentially benefit, we hope they do, and it will be a small number. On the other side, this will be a big advance, like a moon shot to get a person to the moon—this is a big advance for the concepts and the validity of gene therapy, if these experiments are successful.

So, we're hoping.

Senator HARKIN. So, will this be publicized? I mean, I would be interested in finding out how soon after a person—and I don't even know the process, how many injections they have to have?

Dr. SIEVING. One.

Senator HARKIN. Just one? Just one? I thought it was a pattern you had to go through.

Dr. SIEVING. No, the delivery of genetic material is courtesy of a virus, an adenor virus. Once that virus introduces the gene into the cell, it persists there. In the case of Lancelot, Lancelot had one injection, now some 5 years ago, and this dog is still seeing. So, it would be one injection.

Senator HARKIN. How soon after that injection would we know whether or not it worked?

Dr. SIEVING. Well, in the mouse, the biology in the mouse says that within 60 days or fewer, the transfer of the gene into the cell and the activity in the cell can make this protein. So, it should be short order, it should be on the order of weeks to months.

Senator HARKIN. But you don't know when this is going to happen.

Dr. SIEVING. We have a good idea of when it will happen.

Senator HARKIN. Is it this summer?

Dr. SIEVING. We expect this summer. Obviously, for something like this, we are helping to take a close and careful look at the safety, getting the trial started, and the first outcome of the study will be announced as a safety outcome. If, in fact, the individual recovered some form of vision, that would be a bonus, and quite a delightful bonus.

Senator HARKIN. That's very informative. I appreciate that. We will be following that.

Dr. SIEVING. We will keep you informed, obviously.

Senator HARKIN. We'll follow that very closely.

READING FIRST

Dr. Alexander, I know time is running out, and I have to leave here in a few minutes, but I just wanted to go over one thing with you.

NICHD's involvement in a program called Reading First, a lot of congressional interest in this area. Education's Inspector General found the Department officials mismanaged the program, steered school contracts to publishers they favored away from others, flagrantly ignored Federal laws on maintaining local and State con-

trol of school curricula. Not me, that's the Inspector General of the Department of Education said that, and we've been looking into it.

As to be expected, the Education Inspector General focused mainly on the activities of the Education Department employees, but a former NICHD researcher named Reid Lyon also played a huge role in how Reading First was implemented. Lyon, a reading specialist, was the Chief of the Child Development and Behavior Branch under you. According to one news article, he said he spent more than half of his time between 2002 and 2004 on Reading First. E-mail showed that he frequently advised the Reading First Director Mr. Chris Doherty on how to run the program. He wasn't simply offering general advice, there were detailed discussions about how particular districts were using Reading First grants. We also know that Dr. Lyon wrote on numerous occasions to Margaret Spellings, the current Secretary of Education when she was Domestic Policy Advisor at the White House on this program.

Now, again, I can understand that an NIH researcher who's an expert on reading might occasionally be called upon by the Department of Education to offer some expert advice when they're called upon. But, I don't expect someone like that to spend more than half of his time trying to advise another agency on how to run their programs, it doesn't smell right, there's something wrong there.

Now, again, I know that Dr. Lyon is no longer there, he now works for a for-profit education company. That's fine, if he wants to be an advocate for that, that's what he should be. So, I would hope that the Chief of the Child Development and Behavior branch would have other things to do than like this.

So now, again, we have a replacement coming up. Has that replacement been named yet?

Dr. ALEXANDER. Yes.

Senator HARKIN. Oh, you do have a replacement?

Dr. ALEXANDER. For Dr. Lyon, as chief of that branch? Yes. Dr. Peggy McCardle. She's been in there as branch chief for almost 2 years.

Senator HARKIN. Two years? I didn't know that. Is this person spending more time, spending half his time on Reading First?

READING FIRST SCIENCE

Dr. ALEXANDER. No, I think she's spending virtually no time on it. Dr. Lyon's time when he was involved with this, was when he was on detail to the White House, and was not in charge of the branch. Basically, that was turned over to Dr. McCardle on an acting basis. I have no direct knowledge on what Dr. Lyon's interactions were, specifically. I know that he was called upon frequently by the Reading First program, and the Department of Education in other areas as well, for advice on the scientific basis for different types of approaches to reading instruction. The legislation related to Reading First required that the programs have demonstrated efficacy in a scientific fashion, of their effectiveness in being able to result in children learning to read in an effective way.

Much of the question that came to Dr. Lyon, in my understanding, was in terms of whether programs that were proposed for use in Reading First were, in fact, scientifically validated, research-based programs, and the advice that he provided was evaluating

the quality of the science that was done in evaluating those programs. Sometimes it was very weak science, weak to none. Other programs have been very thoroughly and rigorously evaluated, and to my knowledge, and what we really have the authority and authorization to do, was to provide information and advice as to the scientific validity of these programs. How rigorously have they been evaluated for their effectiveness as a teaching method? That was a requirement in order for them to be funded as part of Reading First.

So, that was the nature of the interaction, to my knowledge.

Senator HARKIN. Well, I know that, because I was very much involved in writing that law.

Dr. ALEXANDER. You were, indeed.

Senator HARKIN. In the other hat I wear on the other committee, and I had been following this very closely with my staff, and a number of these programs in a certain State were scientifically valid, they were passed, the scientific reviews and all of that. But a funding pattern emerged, that when these programs were evaluated and it all came down, that they had to use this one program, this one certain program, all of these things seemed to trace back, in many ways, to Dr. Lyon.

I thought that was an odd situation, that someone from NIH would be so heavily involved in trying to choose one over the other, when they were basically scientifically validated, and saying, "Well, yeah, they may be scientifically valid, they may all meet the scientific requirements, but this one is best." That is not—that was never, that should never have been his job.

That's sort of water over the dam, but I just, again, I hope that we don't go through that again. It was kind of disturbing to me to see that that had happened, and that is why I asked the question about the new replacement, which I didn't know was there, and how much they were spending. Like I said, I don't mind if they're called upon for expert advice, I mean, that's fine—that is what they should be doing. But it seemed like he went overboard in being involved in how this was being run.

SPINAL MUSCULAR ATROPHY

The last thing I wanted to cover with you is SMA. As you know, I've been very much involved with this ever since I first learned its leading genetic cause of death in small kids, and then how much we were looking at it, and you and I talked about this before, on SMA, and I've talked to Dr. Landis about it, also. I talked about this with Dr. Landis just a few weeks ago, there's some breakthrough work that NINDS is doing in this area.

But, you have funded, as I understand, two small grants on SMA in the past few years. Since it is a leading genetic cause of death to infants and toddlers, I think I would have expected that NICHD would take a larger role than it has thus far, so I'm just wondering, where are you in SMA research in the coming year?

Dr. ALEXANDER. Well, last year, we funded four grants, or parts of four grants, focusing largely on improving newborn screening, and developing the capability for doing newborn screening for the disorder, and we additionally funded two grants that came in, in response to our program announcement for developing new thera-

peutic approaches to disorders that could potentially be diagnosed by newborn screening.

The best progress we have to report is that in one of the grants, Dr. Tom Pryor at Ohio State has, in fact, developed a very successful approach to newborn screening for SMA. With the technology that he has, he's gotten samples from the filter paper blood spots like I just handed out to you, several hundred with SMA, several hundred carriers, and several hundred normals. They have 100 percent success in diagnosing every case of SMA, 100 percent success in identifying every carrier, 100 percent success in determining unaffected individuals.

He's also developed a methodology for incorporating this onto the luminex-bead system, which is one of the systems we're testing for new applicability. The SMA community is so excited and enthusiastic about this, that they've actually petitioned the Secretary's Advisory Committee on screening of infants and children for genetic disorders for inclusion of this in newborn screening regimens.

So, we are very excited about this approach, we think this is probably going to be the one that can be incorporated, it can be done in a very cost-effective way, and that we will have the newborn screening, and as the SMA advocacy groups point out, all of the evidence is that it is essential to begin treatment at birth, or as close to birth as possible. Because the moms protect the fetus during development, these babies are pretty much okay at birth. If we can get the treatment to them, and have an effective treatment, that is going to be key.

We also have two grants that are working on new treatment methodologies for this. There are two different approaches—one is to increase the production of a protein that doesn't work very well, another is to try and skip a codon, that is, blocking the formation of the normal proteins, so that we produce more normal protein. We're testing both of these, and we're hopeful that we're going to have, not just the prenatal diagnosis methodology, but a treatment methodology as well. That is where we are.

Senator HARKIN. That's good. That is good news. So that is what is going to be happening in the future.

Dr. ALEXANDER. Yes, we will continue with that.

Senator HARKIN. Now, I can't leave that without—one thing leads to another, don't you know? I learned about SMA and I get to learning about causes, and I meet with families, well then I start thinking about Fragile X Syndrome also, which is another one. Now I find out that's a leading cause of mental retardation, genetic cause of retardation. So, then I'm wondering, where are you going in that?

NEW APPROACH TO NEWBORN SCREENING

Dr. ALEXANDER. Similar story, we're working on newborn screening. We funded a grant several years ago, to develop and evaluate newborn screening for this condition, with the support of parents and advocacy groups. The test that we thought was going to work, didn't, another one that we thought was going to work didn't, we're now on a third approach to the newborn screening. This one looks like it's going to work, but we're still in the final testing for that.

That is the essential component for that grant, in order to be able to diagnose this in newborns.

In terms of therapy, we're farther away from that than we are, probably, with SMA. Although different approaches are being tried, we have nothing that looks real promising right now. But, the parent and advocacy groups still say we want to diagnose this in newborns, if at all possible, because we would like to be able to plan for these children, we'd like to intervene as early as possible with ancillary kinds of treatments, and we would like to know for our family planning purposes whether we have this problem, because these kids are often not diagnosed until 3, 4, 5, 6 years of age, and there's often another child born by then.

Senator HARKIN. Doesn't that, doesn't that gene just go through one parent or the other?

Dr. ALEXANDER. Yes, the mother.

Senator HARKIN. Okay, that's good information, that's good information. Okay, any last things before we all get out of here and go to lunch, or something like that? I want to thank all of you for coming down, it's been a good session. As I said, I always learn a lot of things at this, it's like being in class again.

So, I thank you very much. Thanks for all of your leadership, Dr. Alexander. Thanks for the SMA work you're doing, we appreciate that. You're going to get back to me on some of this stuff.

ADDITIONAL COMMITTEE QUESTION

There will be an additional question which will be submitted for your response in the record.

[The following question was not asked at the hearing, but was submitted to the Department for response subsequent to the hearing:]

QUESTION SUBMITTED BY SENATOR TOM HARKIN

DOWN SYNDROME

Question. An estimated 350,000 Americans have Down syndrome. Yet the fiscal year 2008 proposed budget calls for spending just $13 million on research concerning this condition—down 43 percent from the fiscal year 2003 level of $23 million. Why has funding for Down syndrome research declined so dramatically?

Answer. The senator's funding figures for NIH-supported research on Down syndrome are correct. Although NICHD has the scientific lead on this issue, a number of other Institutes and Centers also contribute resources to address this condition. However, due to the competitive nature of the peer review process, the number of successful applications proposing research on Down syndrome has decreased, and thus funding contributed by ICs to such research has decreased.

However, research on Down syndrome is an important part of NIH's research portfolio. In fact, to facilitate research on Down syndrome across the NIH, NICHD took the lead in pulling together a working group of these ICs in 2006. NICHD, NINDS and NIA form the steering committee for the group, which has been meeting regularly with the goal of producing a NIH research plan for Down syndrome in the fall of 2007. In addition to compiling the NIH-funded research in this area, literature reviews are being conducted so that new research is complementary and not duplicative. The working group sponsored two major scientific meetings, in March 2007 and July 2007, to get input from that community, as well as from national constituency organizations representing individuals with Down syndrome and their families. Input on the plan, which will address strategies for basic and clinical research on the genetics of Down syndrome, its developmental consequences, and its impact on cognition and synaptic function, will be actively sought prior to its publication.

CONCLUSION OF HEARINGS

Senator HARKIN. So, thank you all very much, that concludes our hearings.

[Whereupon, at 12:07 p.m., Friday, June 22, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2008

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

NONDEPARTMENTAL WITNESSES

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

PREPARED STATEMENT OF THE ACADEMY OF RADIOLOGY RESEARCH

This statement is submitted on behalf of the Academy of Radiology Research, an alliance of 23 scientific and professional societies with a membership of more than 40,000 radiologists, imaging scientists, and allied professionals. The Academy is also supported by national organizations representing more than 100,000 radiologic technologists.

In addition, I am also representing the Coalition for Imaging and Biomedical Engineering Research (CIBR). CIBR is a permanent coalition of radiology, imaging, and bioengineering societies; imaging equipment and medical device manufacturers; and patient advocacy groups. What unites all of these diverse groups is the common recognition that new imaging and biomedical engineering techniques and technologies can transform medical science and produce dramatic improvements in the detection, diagnosis, and treatment of a broad range of diseases and conditions.

The purpose of my statement is to urge the Appropriations Committee and Congress to make an investment this year that will foster innovation in imaging and produce a new revolution in medical science and health care driven by technology development. Recognizing the significant budgetary challenges we face at present, it is critical that the Federal Government take full advantage of the scientific opportunities that offer the best prospects for improving the capability of physicians to diagnose and treat a broad range of diseases and conditions. Imaging is one such area of scientific opportunity. For that reason, we request that the committee increase the appropriation in fiscal year 2008 to $350 million for the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the newest Institute at the National Institutes of Health and the primary home for basic research in imaging at the NIH.

The NIBIB is not the sole home for imaging research at the NIH. Indeed, the National Cancer Institute was the primary supporter of imaging in the years before the NIBIB was established. With strong support from NCI Director John E. Niederhuber and leadership from Dr. Dan Sullivan, the NCI Cancer Imaging Program continues to grow and push the boundaries of knowledge. I hope that the committee will support the growth of NCI initiatives in areas such as imaging as a biomarker for drug development, the development of new image-guided ablative therapies, and computer-assisted methods of combining imaging and other clinical data.

While the extramural community strongly supports imaging research programs at the NCI and other Institutes, the NIBIB is the Institute charged with developing new imaging techniques and technologies with broad clinical and research applications. Investing in the NIBIB yields dividends for all of the other Institutes in the form of new tools for studying the specific diseases that constitute the missions of

those Institutes. It also pays large dividends for patients, who will benefit from new imaging techniques that improve medical care and reduce the need for more invasive, painful, and expensive procedures.

A good example is the first grant made by the NIBIB in 2002—a Bioengineering Research Partnership award to a multi-institutional group led by Dr. James Duncan of Yale University. With this support from the NIBIB, Dr. Duncan and his team have been developing new, image-guided surgical techniques for treating patients with certain, severe forms of epilepsy. The results have been dramatic. A patient who has undergone this surgery recently told the House Medical Technology Caucus that the number of seizures she suffered daily dropped from more than 30 to zero. After years enduring a severe disability that affected virtually every area of activity, she was suddenly given her life back.

As with many imaging research projects, however, the longer-term payoff will be much greater. This research is producing data from the brain that is helping scientists to understand brain structure and function in general. Moreover, this new information about the brain will improve our understanding of Parkinson's Disease, autism, Alzheimer's Disease, dementia, and other disorders. Finally, the techniques developed with this grant could have much broader applications, such as the use of imaging to guide cancer therapy to destroy tumors or to deliver drugs to precise locations in the brain in order to treat a variety of neurological disorders. Thus, a project to improve the lives of epilepsy patients will eventually produce new treatments for many more people with a range of neurological disorders. This is typical of NIBIB and imaging initiatives.

The NIBIB, is different from other Institutes. As NIBIB Director Roderic I. Pettigrew has observed, "In other Institutes they utilize tools. In this Institute, we discover tools." These tools are used by investigators at the other Institutes both to improve our understanding of disease processes and as a principal component in new therapies. Optical imaging, for example, is an emerging technology that uses light waves to produce high-quality images. Based on early research, the use of optical imaging to diagnose and treat breast cancer appears to be especially promising. This technology may allow physicians to investigate large sections of tissue rapidly for cancerous growths, to guide surgery to remove tumors, and to scan effectively for additional disease. As optical imaging develops, physicians and scientists will have a new tool with applications to a wide spectrum of diseases. It also promises to be safer and less expensive than earlier technologies.

The last Congress overwhelmingly approved the National Institutes of Health Reform Act of 2007, which called for a renewed emphasis on trans-NIH research and a special focus on research at the nexus of the physical and life sciences. NIBIB is well positioned to make good on Congress's intent in both areas. The NIBIB, by its nature, is perhaps the most collaborative and interdisciplinary of all the Institutes and Centers at the NIH. In its first years, the NIBIB has pioneered collaborative projects with other Institutes to develop new techniques with applications to specific diseases. NIBIB is also NIH's most prominent "bridge" to the physical sciences. Three examples clearly illustrate NIBIB's unique collaborative roll.

IMAGE GUIDED INTERVENTION

Despite its prominence in modern-day medicine, surgery remains in a relatively primitive state. Although improvements in surgical techniques abound, costs are high, invasive procedures are still the norm, and surgeons continue to rely on pre-operative images. Significant improvements to the current state of surgery are well within our reach. Highly exacting image-guided intervention could potentially minimize invasiveness, greatly reducing patient recovery time and the costs associated with it. With the acquisition and use of real-time (moving) 3D images, surgeons will move far beyond pre-op images to observe blood flow patterns, identify clot risks and "see" brain, nervous and electrical functions during surgery. Other advances bridging nano and imaging technologies together could permit surgeons to visualize and operate at the cellular level. In general, with additional research, surgical tools will be smaller, less expensive, and easier to manipulate.

The field of image-guided interventions is at a critical juncture. The NIBIB leads the Interagency IGI Group, a trans-agency special interest group including representation from seven Federal agencies as well as 13 NIH Institutes and Centers. The need to support further research and development in IGI was documented at a January 2006 retreat of the Interagency IGI group. NIBIB-support has already led to major advances in this area and the Institute is poised to lead the technological advances that will revolutionize IGI in the future.

IMAGING AT THE POINT OF PATIENT CARE

Medical imaging is critical for quality health care. Yet, sophisticated imaging services remain widely unavailable to many patients in small clinics and hospitals in rural and low-income communities. The development of low cost, portable imaging devices could extend point of care , modern diagnostic imaging techniques to millions of underserved Americans. Recent advances in miniaturization of electronic hardware and improved software may allow the development of widely available low-cost ultrasound devices to diagnose complications of pregnancy, hemorrhage associated with trauma, renal obstructions and other significant medical conditions. Similar advances in optical imaging may herald wider access to optical probes capable of early detection of cervical cancers. Additionally, advances in the electronic transmission of images can allow specialists located thousands of miles away to evaluate these point of care images and prescribe appropriate clinical treatment for millions of underserved patients.

Reduction of health disparities through new and affordable medical technologies is an explicit goal in NIBIB's Strategic Plan, and the Institute was established with this as one of its primary research initiatives. NIBIB has been a steady proponent of this research and recently launched a new initiative to develop low-cost imaging subsystems which attracted the attention of the Gates Foundation, as low-cost technologies are mutual priorities for both organizations. NIBIB is also spearheading the creation of a network of point-of-care research centers. Given NIBIB's strategic priority for developing low-cost imaging technologies, its leadership in this field, and its focus on point-of-patient-care technologies, NIBIB is ideally suited to lead a new major program to bring the benefits of advanced imaging technologies to all Americans.

TISSUE ENGINEERING

The rapid development of transplant medicine along with the aging of the baby boomer generation have caused increased demand for tissues and organs far exceeding the available donor organs. As of May 2006, there were over 90,000 people on the waiting list for donor organs. Many of these individuals will die before a suitable organ can be found. By providing tissues and organs "on demand," regenerative medicine will improve the quality of life for individuals and reduce healthcare costs. A recent report by the Department of Health and Human Services (2020: A New Vision—A Future for Regenerative Medicine http://www.hhs.gov/reference/newfuture.shtml) underscores the need for a cohesive Federal initiative in this area. The NIBIB is poised to lead this initiative into the future.

Tissue Engineering is the cornerstone of regenerative medicine. It involves the growth and engineering of living, functional, tissues and organs. The long-range goal of tissue engineering is to use these tissues and organs to restore, maintain, or enhance function lost due to age, disease, damage or congenital defects. Tissue engineering has already seen some spectacular human successes, including nearly-complete regeneration of a severed finger and a functional bladder grown ex-vivo, as well as animal studies where motor function has been largely restored in a rat with a damaged spinal cord. Despite these successes, much still needs to be done to better understand why tissue regeneration starts and stops and to develop technologies to grow and preserve larger quantities of tissue.

Clearly tissue engineering is an emerging multidisciplinary field at the interface of the life and physical sciences. Thus, it is no surprise that NIBIB exerts a leadership role in the Multi-Agency Tissue Engineering working group for the President's National Science and Technology Council. Given its pivotal role in this area, NIBIB requires additional resources to fund the science necessary to accelerate advances in this critical area of biomedical science.

The current budget proposals for fiscal year 2008 do not measure up to the scientific opportunities in imaging. To be sure, these are stringent budgetary times. In such circumstances, the unique collaborative role of NIBIB offers the valuable potential for synergies with other NIH Institutes and other agencies of government that will stretch the value of scarce research dollars and expand the translational potential of the joint studies that are undertaken. Surely this is what Congress had in mind when it placed so much emphasis on breaking down the barriers separating the various Institutes, and disciplines at NIH. The NIBIB can only realize its vast collaborative and translational potential if it grows at a reasonable rate. As the newest of the NIH Institutes, it did not share in the doubling of the NIH budget that ended just as the new century began.

Failure to invest adequately in the NIBIB will have at least two negative consequences. First, scientific opportunities to improve diagnosis and treatment of a wide range of diseases will be, at best, delayed and could be lost. NIBIB Director

Rod Pettigrew has proposed a program of "quantum" projects designed to produce major breakthroughs in health care and medical science. Without additional resources, this initiative will surely be postponed or scaled back. Moreover, advanced research in other Institutes aimed at specific diseases will be set back by the delay in developing leading-edge imaging techniques that enable advanced research.

Second, it will discourage the large group of researchers who have been attracted to the NIH for the first time. Scientists in fields such as physics, mathematics, and computer science have been drawn to the NIBIB as a home for research that ties together the physical and biological sciences. Congress clearly sees such interdisciplinary research as the future of biomedical science, but that future could be delayed significantly if top scientists are discouraged from even submitting applications because funds are not available to support good research.

For these reasons, I hope that the committee will increase the 2008 appropriation for the NIBIB to $350 million and consider a multi-year plan to build toward a budget that will enable the Institute to fulfill its collaborative mission.

The Congress created the NIBIB in 2000 to be different from the other Institutes. It is different because its primary mission is technology development. It is different because it does not focus on a single disease or organ system; instead, it is charged with developing new technologies with broad applications to many diseases and conditions. It is different because its foundation in the physical sciences separates it from the Institutes based on the biological sciences.

To a significant extent because of these differences, the NIBIB represents the future of interdisciplinary, team-driven biomedical science that is changing health care. I hope that the Congress will provide the resources needed to fulfill its promise.

PREPARED STATEMENT OF THE AIDS ACTION COUNCIL

I am pleased to submit this testimony to the members of this committee on the importance of increased funding for the fiscal year 2008 HIV/AIDS portfolio. Since 1984, AIDS Action Council has worked to enhance HIV prevention programs, research protocols, and care and treatment services at the community, State, and Federal level. AIDS Action's goals are to ensure effective, evidence-based HIV care, treatment, and prevention services; to encourage the continuing pursuit of a cure and a vaccine for HIV infection; and to support the development of a public health system which ensures that its services are available to all those in need. On behalf of AIDS Action Council's diverse membership, comprising community-based HIV/AIDS service organizations, prevention services, public health departments, and education and training programs, I bring your attention to issues impacting funding for fiscal year 2008.

Despite the good news of improved treatments, which have made it possible for people with HIV disease to lead longer and healthier lives, stark realities remain:

—There are between 1.1 and 1.2 million people living with HIV in the United States.

—Half a million HIV positive people in the United States do not receive regular medical care including treatment for their disease.

—Between 200,000 and 300,000 people in the United States do not know that they are HIV positive.

—There are at least 40,000 preventable, new HIV infections each year. Approximately half of these infections occur in youth aged 13–24

—Between 14,000–16,000 people die from HIV related causes each year.

—While African Americans comprise only 12 percent of the United States population, they account for approximately half (49 percent) of those infected with HIV/AIDS and 70 percent of new HIV infections each year.

—HIV was the #1 cause of death for Black women, aged 25–34, in 2004 the most recent year we for which have data.

—According to a CDC study released in 2005, 46 percent of urban African American men who have sex with men (MSM) were HIV-positive.

—70 percent of HIV positive people depend on Federal programs to receive HIV treatment, care, and services.

The Federal Government's commitment to funding research, prevention, and care and treatment for those living with HIV is critical. Despite this commitment, we are not doing enough. We need more prevention, more treatment and care and more research to slow and eventually reverse this epidemic.

AIDS Action Council concurs with many in the HIV community that increased support for HIV care and treatment, research, and prevention are critical. The community has come together under the umbrella of the AIDS Budget and Appropria-

tions Coalition with the community funding request for the HIV domestic portfolio for fiscal year 2008. The numbers requested represent that community work. These requests have been submitted to the committee.

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, administered by the Health Resources and Services Administration (HRSA) and funded by this subcommittee, provides services to more than 533,000 people living with and affected by HIV throughout the United States and its territories. It is the single largest source of Federal funding solely focused on the delivery of HIV services. CARE Act programs have been critical to reducing the impact of the domestic HIV epidemic. Yet in recent years, CARE Act funding has decreased through across-the-board rescissions. The rescissions in fiscal year 2005 and fiscal year 2006 that were executed on all non-defense and non-homeland security discretionary spending during the final negotiations of the bills had a devastating impact on the HIV/AIDS portfolio in general, and on the Ryan White CARE Act in particular.

Now in its 17th year, the Ryan White CARE Act was reauthorized by the 109th Congress. The changes made by reauthorization, combined with the late enactment of fiscal year 2007 funding, has created the potential for crisis within the CARE Act. It is AIDS Action's hope that this subcommittee will recognize and address the true funding needs of the care programs within the domestic HIV/AIDS portfolio and make significant increases in all aspects of the HIV funding portfolio.

Five new jurisdictions were added to Ryan White CARE Act's Title I as transitional grant areas (TGAs), but no new funding was added for the Title I grantees in fiscal year 2007. Some of the services provided under Title I include physician visits, laboratory services, case management, home-based and hospice care, and substance abuse and mental health services. With the new reauthorization these services will be even more dedicated towards funding core medical services and to ensuring the ability of patients to adhere to treatment. These services are critical to ensuring patients have access to, and can effectively utilize, life-saving therapies. AIDS Action along with the HIV/AIDS community recommends funding Title I at $840.4 million.

Title II of the CARE Act ensures a foundation for HIV related health care services in each State and territory, including the critically important AIDS Drug Assistance Program (ADAP) and Emerging Communities Program. Title II base grants (excluding ADAP and Emerging Communities) was the only program to receive an increase from $331,000,000 in fiscal year 2006 to $406,000,000 in fiscal year 2007 for a total increase of $75,800,000. AIDS Action along with the HIV/AIDS community recommends funding for Title II base grants at $463.4 million.

The AIDS Drug Assistance Program (ADAP) provides medications for the treatment of individuals with HIV who do not have access to Medicaid or other health insurance. According to the National ADAP Monitoring Project, approximately 96,404 clients received medications through ADAP in June 2005. The President recommends an increase of $25.4 million for the critical AIDS Drug Assistance Program (ADAP) in his fiscal year 2008 budget. However this amount is far too low. AIDS Action along with the HIV/AIDS community recommends an increase of $232.9 million for ADAP for fiscal year 2008. This request is derived from a pharmacoeconomic model to estimate the amount of funding needed to treat ADAP eligible individuals in upcoming Federal and State fiscal years.

Title III of the Ryan White CARE Act awards grants to community-based clinics and medical centers, hospitals, public health departments, and universities in 22 States and the District of Columbia under the Early Intervention Services program. These grants are targeted toward new and emerging sub-populations impacted by the HIV epidemic in urban and rural settings. Title III funds are particularly needed in rural areas where the availability of HIV care and treatment is still relatively new. AIDS Action, along with the HIV/AIDS community, requests is an increase of $87,800,000.

Title IV of the Ryan White CARE Act awards grants under the Comprehensive Family Services Program to provide comprehensive care for HIV positive women, infants, children, and youth, as well as their affected families. These grants fund the planning of services that provide comprehensive HIV care and treatment and the strengthening of the safety net for HIV positive individuals and their families. AIDS Action and the HIV/AIDS community request is an increase of $46,400,000.

Under Part F, the AIDS Education and Training Centers (AETCs) are the training arm of the Ryan White CARE Act; they train the healthcare providers, including the doctors, advanced practice nurses, physicians' assistants, nurses, oral health professionals, and pharmacists. The role of the AETCs is invaluable in ensuring that such education is available to healthcare providers who are being asked to treat the increasing numbers of HIV positive patients who depend on them for care. Additionally, the AETCs have been tasked with providing training on Hepatitis B

and C to CARE Act grantees and to ensure inclusion of culturally competent programs for and about HIV and Native Americans and Alaska Natives. However no funding was added for additional materials, training of staff, or programs. AIDS Action and the HIV/AIDS community request a $15.3 million increase for this program.

Also under Part F, Dental care is another crucial part of the spectrum of services needed by people living with HIV disease. Unfortunately oral health is one of the first aspects of health care to be neglected by those who cannot afford, or do not have access to, proper medical care removing an opportunity to catch early infections of HIV. AIDS Action and the HIV/AIDS community request a $5.9 million increase for this program.

AIDS Action and the HIV/AIDS community estimate that the entire Ryan White CARE Act portfolio needs $2,794,300,000 for fiscal year 2008 to address the true needs of the over 1 million people that the Centers for Disease Control and Prevention (CDC) estimates are living with HIV in the United States. The fiscal year 2007 funding that was allocated was just over $2 billion ($2,112,000,000). This is a significant shortfall from the actual needs of people living with HIV.

The Minority AIDS Initiative directly benefits racial and ethnic minority communities with grants to provide technical assistance and infrastructure support and strengthen the capacity of minority community based organizations to deliver high-quality HIV health care and supportive services. HIV/AIDS in the United States continues to disproportionately affect communities of color. The Minority AIDS Initiative provides services across every service category in the CARE Act and was authorized for inclusion within the CARE Act for the first time in the 2006 CARE Act reauthorization. It additionally funds other programs throughout HHS. AIDS Action and the HIV/AIDS community request a total of $610 million for the Minority AIDS Initiative.

The Housing Opportunities for People with AIDS (HOPWA) program, administered by the U.S. Department of Housing and Urban Development (HUD), is another integral program in the HIV care system. Stable housing is absolutely critical to the ability of people living with HIV to access and adhere to an effective HIV treatment plan. Stable housing plays a key role in HIV prevention; lack of housing is a known risk factor for HIV. Although HOPWA is not part of the Labor, Health and Human Services Appropriations bill, AIDS Action urges all Appropriations Committee members to support this critical program. AIDS Action requests that $454,000,000 should be appropriated to the HOPWA program for fiscal year 2008.

According to CDC estimates contained in the agency's December 2005 HIV/AIDS Surveillance Report, 956,019 cumulative cases of AIDS have been diagnosed in the United States, with a total of 518,037 deaths since the beginning of the epidemic. As funding has remained essentially flat for more than 6 years, new infections also have stubbornly remained at the level of 40,000 per year. Dr. David Holtgrave, chair of the Johns Hopkins Bloomberg School Department of Health, Behavior and Society, has convincingly shown that there is a strong correlation between the lack of funding increases and the failure to reduce the number of new HIV infections. Therefore, AIDS Action Council estimates that the CDC HIV/AIDS, STD, and TB prevention programs will need $1,597.3 million in fiscal year 2008 to address the true unmet needs of prevention in HIV/AIDS, STDs, and TB.

Research on preventing, treating and ultimately curing HIV is vital to the domestic control of the disease. The United States must continue to take the lead in the research and development of new medicines to treat current and future strains of HIV. Primary prevention of new HIV infections must remain a high priority in the field of research. It is essential that NIH continues its groundbreaking research to secure a prevention vaccine and continue to research promising treatment vaccines that may help HIV positive people maintain optimal health. Research on microbicides [gels, creams or other substances that prevent the sexual transmission of HIV and other sexually transmitted infections (STIs) when applied topically] for vaginal and anal sexual intercourse is also critical. Continued research on new medications for drug resistant strains of HIV is also critical. Finally, behavioral research to increase knowledge of sexual behavior and research to help individuals delay the initiation of sexual relations, limit the number of sexual partners, limit high-risk behaviors related to alcohol and substance use and move from drug use to drug treatment are all critically important. NIH's Office of AIDS Research is critical in supporting all of these research arenas. AIDS Action requests that the National Institutes of Health AIDS portfolio be funded at $3.2 billion for fiscal year 2008 an increase of $300 million over fiscal year 2007.

HIV is a continuing health crisis in the United States. On behalf of all HIV positive Americans, and those affected by the disease, AIDS Action Council urges you to increase funding in each of these areas of the domestic HIV/AIDS portfolio. Help

us save lives by allocating increased funds to address the HIV epidemic in the United States.

PREPARED STATEMENT OF THE ALPHA-1 FOUNDATION

Agency Recommendations:

1. NIH: The Alpha-1 Foundation requests an allocation in the budget to enable the NIH, NHLBI to focus additional research leading to a better understanding of Alpha-1, including improved management and therapeutic approaches. The Foundation observes that much can be learned by studying the biology of Alpha-1, a human model of environment-gene interaction, which will inform Chronic Obstructive Pulmonary Disease (COPD) and liver cirrhosis, both of which are major public health concerns. The Foundation requests cooperation between NHLBI, NIDDK, NHGRI, and other institutes to enhance targeted detection, raise public awareness about Alpha-1 and provide appropriate information to health professionals. The Foundation recommends achieving these goals through use of the NHLBI Rare Lung Diseases Consortium and the COPD Clinical Research Network.

2. NIH: The Foundation commends NHLBI for their national launch of the COPD Awareness and Education Campaign titled "COPD Learn More Breathe Better" and recommends that NHLBI continue to enhance its portfolio of research and education on the fourth leading cause of death in the United States, Chronic Obstructive Pulmonary Disease (COPD), including genetic risk factors such as Alpha-1 Antitrypsin Deficiency.

3. NIH: The Alpha-1 Foundation notes that the severe adult-onset lung disease caused by Alpha-1 stems directly from the protein secretion abnormality in the livers and lungs of affected individuals. Alpha-1 has also been shown to be a risk factor for hepatitis C and B infection. The Foundation requests that NIDDK collaborate with NHLBI, NCI and other institutes to enhance its research portfolio, encourage detection, raise public awareness and provide appropriate information to health professionals. The Foundation encourages the use of the NIDDK Cholestatic Liver Disease Consortium to achieve these goals.

4. NIH: The Foundation notes that given the link between environmental factors and the onset of Alpha-1 related COPD, the committee encourages NIEHS to develop research initiatives to explore gene environment interaction research and develop support for public private partnerships.

5. CDC: The Foundation requests that CDC develop a program to promote early detection of Alpha-1 so that individuals can engage in preventative health measures and receive appropriate therapies which significantly improve their health status. The Foundation requests a public private partnership to actively support Alpha-1 targeted detection efforts that utilize public and professional education regarding chronic obstructive lung disease, both genetic and tobacco related.

DISCLOSURE

Title: Rare Lung Disease Clinical Research Network Grant #1 U54 RR019498–01

Principal Investigator: Bruce C. Trapnell, M.D., University of Cincinnati Medical School

Dates: 09/01/03 through 08/31/08

Total Costs—$5,520,790

The Foundation receives a small percentage of this grant as the coordinating center.

Thank you for the opportunity to submit testimony for the record on behalf of the Alpha-1 Foundation.

THE ALPHA-1 FOUNDATION

The Alpha-1 Foundation is a national not-for-profit organization dedicated to providing the leadership and resources that will result in increased research, improved health, worldwide detection and a cure for Alpha-1 Antitrypsin (Alpha-1) Deficiency. The Foundation has built the research infrastructure with private investment, funding over $28,000,000 in grants from basic to social science, establishing a national patient registry, tissue and Biobank, translational laboratory, assisting in fast track development of new therapeutics, and stimulating the involvement of the scientific community. The Foundation has invested the resources to support clinical research uniquely positioning ourselves for a perfect private public partnership. There is a lack of awareness of the insidious nature of the early symptoms of the lung and liver disease associated with this genetic condition by both medical care providers

and the public. It is our hope that the Federal Government will leverage the Foundation's investment with support for a national Alpha-1 targeted detection program.

ALPHA-1 IS SERIOUS AND LIFE THREATENING

Alpha-1 is the leading genetic risk factor for Chronic Obstructive Pulmonary Disease (COPD) and is often misdiagnosed as such. Alpha-1 afflicts an estimated 100,000 individuals in the United States with fewer than 5 percent accurately diagnosed. These are people who know they are sick and as yet have not put a name to their malady. Although Alpha-1 testing is recommended for those with COPD this standard of care is not being implemented. In addition, an estimated 20 million Americans are the undetected carriers of the Alpha-1 gene and may pass the gene on to their children. Of these 20 million carriers, 7–8 million may be at risk for lung or liver disease.

The pulmonary impairment of Alpha-1 causes disability and loss of employment during the prime of life (20–40 years old), frequent hospitalizations, family disorganization, and the suffering known only to those unable to catch their breath. Fully half of those diagnosed require supplemental oxygen. Lung transplantation, with all its associated risks and costs, is the most common final option. Alpha-1 is the primary cause of liver transplantation in infants and an increasing cause in adults. Alpha-1 liver disease currently has no specific treatment aside from transplantation. The cost to these families in time, energy and money is high and often devastating. Alpha-1 also causes liver cancer.

Alpha-1 is a progressive and devastating disorder that in the absence of proper diagnosis and therapy leads to premature death; in spite of the availability of therapeutics for lung disease and preventative health measures that can be life-prolonging. It is estimated that untreated individuals can have their life expectancy foreshortened by 20 or more years. Yet early detection, the avoidance of environmental risk factors and pulmonary rehabilitation can significantly improve health.

ALPHA-1 AND COPD

As the forth leading cause of death, COPD is a major public health concern. Data indicates that not all individuals who smoke develop lung disease leading many to conclude that COPD has significant genetic and environmental risk factors. As the most significant genetic risk factor for COPD, Alpha-1 has much to tell us about the pathogenesis of lung disease. Discoveries and advances made in Alpha-1 will impact the larger 12–24 million individuals living with COPD.

DETECTION

The Alpha-1 Foundation conducted a pilot program in the State of Florida where we garnered the knowledge and experience necessary to launch an awareness and National Targeted Detection Program (NTDP). The goals of the NTDP are to educate the medical community and people with COPD and liver disease, alerting them that Alpha-1 may be an underlying factor of their disease; and stimulating testing for Alpha-1. This effort will uncover a significant number of people who would benefit from early diagnosis, treatment and preventative health measures.

The Foundation distributes the American Thoracic Society/European Respiratory Society (ATS/ERS) "Standards for the Diagnosis and Management of Individuals with Alpha-1 Antitrypsin Deficiency" to physicians, nurses and respiratory therapists. Additionally, health care practitioners and the COPD community are being targeted through press releases, newsletter articles and various website postings.

The national implementation of the NTDP is enhanced through the 7 Clinical Resource Network Centers of the National Heart, Lung, Blood Institute of the National Institutes of Health; 51 Foundation affiliated Clinical Resource Centers; large pulmonary practices and various teaching hospitals and universities. The NTDP also employs a direct to consumer approach targeted to people with COPD.

The Alpha-1 Foundation's Ethical Legal and Social Issues (ELSI) Working Group endorsed the recommendations of the ATS/ERS Standards Document which recommends testing symptomatic individuals or siblings of those who are diagnosed with Alpha-1. Early diagnosis in Alpha-1 can significantly impact disease outcomes by allowing individuals to seek appropriate therapies, and engage in essential life planning. Unfortunately, seeking a genetic test may lead to discrimination against individuals who have no control over their inherited condition. The absence of Federal protective legislation has caused the ELSI to recommend against population screening and genetic testing in the neonatal population. The Foundation is encouraged that the House has passed the Genetic Information Nondiscrimination Act of 2007 out of committee and may soon take this measure up on the House floor.

The Alpha-1 Coded Testing (ACT) Trial, funded by the Alpha-1 Foundation and conducted at the Medical University of South Carolina offers a free and confidential finger-stick test that can be completed at home. The results are mailed directly to the participants. The ACT Trial has offered individuals the opportunity to receive confidential test results since September 2001.

ALPHA-1 RESEARCH

The Alpha-1 Foundation believes that significant Federal investment in medical research is critical to improving the health of the American people and specifically those affected with Alpha-1. The support of this subcommittee has made a substantial difference in improving the public's health and well-being.

The Foundation requests that the National Institutes of Health increase the investment in Alpha-1 Antitrypsin (AAT) Deficiency and that the Centers for Disease Control and Prevention initiate a Federal partnership with the Alpha-1 community to achieve the following goals:

—Promotion of basic science and clinical research related to the AAT protein and AAT Deficiency;
—Funding to attract and train the best young clinicians for the care of individuals with AAT Deficiency;
—Support for outstanding established scientists to work on problems within the field of AAT research;
—Development of effective therapies for the clinical manifestations of AAT Deficiency;
—Expansion of awareness and targeted detection to promote early diagnosis and treatment.

PREPARED STATEMENT OF THE ALZHEIMER'S ASSOCIATION

Chairman Harkin, ranking member Specter and members of the subcommittee, thank you for the opportunity to submit testimony regarding funding for key programs that address the enormous demographic and economic impact that Alzheimer's disease presents to our society.

Last month, the Alzheimer's Association released a comprehensive report indicating that Alzheimer's is much more pervasive than we thought. The report confirms that more than 5 million people in the United States are living with Alzheimer's disease today, including 200,000 or more under the age of 65. This is a 10 percent increase from previous estimates, but it is only the tip of the iceberg. By mid-century, as many as 16 million Americans will have the disease. We will see half a million new cases of Alzheimer's this year alone. That means someone in America is developing Alzheimer's disease every 72 seconds!

The report also sheds new light on dramatic shift in mortality among Americans. A diagnosis of Alzheimer's is a death sentence and death rates for Alzheimer's a rising dramatically, up nearly 33 percent in just 4 years while other leading causes of death—heart disease, stroke, breast and prostate cancer—are declining. Alzheimer's is the seventh leading cause of death for people of all ages and the fifth leading cause of death for people age 65 and older. The absence of effective disease modifying drugs, coupled with the aging of the baby boomers, makes Alzheimer's the health care crisis of the 21st century.

Alzheimer's already costs the Nation $148 billion a year. Medicare alone spent $91 billion on beneficiaries with the disease in 2005 and Medicaid spent another $21 billion. By 2015 those two programs will be spending more than $210 billion just on people with Alzheimer's. The disease is also overwhelming health and long term care systems: 25 percent of elderly hospital patients, 47 percent of nursing home residents, and at least 50 percent of people in assisted living and adult day care have Alzheimer's or another dementia.

The impact of Alzheimer's on American families is just as devastating. Today at least 10 million family members provide unpaid care. In Iowa, these caregivers are providing nearly 81 million hours of care a year; in Pennsylvania, almost 375 million hours. Nationwide, the work Alzheimer caregivers are doing is valued at nearly $83 billion and consumes 8.5 billion hours annually.

Alzheimer's disease is exploding into an epidemic that will undermine all of our best efforts to control health care costs, assure access to quality care, and protect the retirement security of generations to come. This is the reality of Alzheimer's disease. It is not a pretty picture. But it is a picture that we can change. Today, there is real hope that we can get Alzheimer's under control, that we will find the ways to prevent millions from ever getting the disease, and that for those who do get it; we can change it from a death sentence to a manageable chronic illness.

Today, the Alzheimer research community can report genuine, tangible, quantifiable hope for effective prevention and treatment of Alzheimer's disease. Within the next 3 years, it is very likely that we will have disease-modifying drugs that could fundamentally change the nature of Alzheimer's. If we succeed, for millions of Americans, a diagnosis of Alzheimer's disease will no longer be a death sentence but the beginning of a manageable chronic illness.

The drugs being tested are very different from the ones now on the market. Current drugs treat the symptoms of Alzheimer's but leave the underlying disease untouched. While they do help some patients temporarily, the predictable progression to death continues along the cruel path we know too well. The new drugs are designed to attack the disease directly. Results to date are very encouraging. These drugs are safe. Patients tolerate them well. And they appear to show significant positive impact, slowing the progression of the disease. Higher doses or combination drugs might arrest the process completely. One of the drugs currently in clinical trials could go to the Food and Drug Administration for review as early as this fall.

The other exciting news is that scientists are rapidly gaining knowledge about genetic and other risk factors of Alzheimer's disease, and developing techniques to detect early changes in the brain well before symptoms appear. These discoveries will let the medical community identify persons at risk of Alzheimer's, diagnose presymptomatic disease, and begin treatment in time to prevent development of dementia altogether.

All of this good news is the direct result of your decision to double funding for the National Institutes of Health. The influx of resources moved Alzheimer research from a backwater of obscurity to perhaps the single most visible, most competitive, and most exciting field in the neurosciences. This is the key to drug discovery. Drug development does not start or end with pharmaceutical companies. It begins at NIH-funded laboratories at academic health centers, where scientists uncover the molecular basis of disease, identify treatment strategies, and develop the research methods and techniques that make clinical investigation possible. Clinical trials depend on the expertise of NIH-funded investigators, and many require direct NIH funding because the drugs under investigation are not protected by patent.

The emphasis on the fundamental role of NIH funding is critical because there is still so much work to be done. We are right to be excited about treatments that attack the amyloid plaques, one of the primary hallmarks of Alzheimer's disease. But they will not likely be the complete answer. Like cancer and heart disease, Alzheimer's is a complex puzzle. Solving it will involve multiple strategies. There are already a number of other potential targets for intervention—including the chemical basis of the tangles in the brain that are the other hallmark of Alzheimer's, the relationship between heart and vascular disease and Alzheimer's, the connection to Type 2 diabetes, the role of nerve growth factors, and the interaction of environment, life style choices, and genetics in the development of disease.

If science can validate the prevailing wisdom about amyloid, and if researchers can refine these other theories, then every major pharmaceutical company will begin bringing new drugs into human clinical trials. That will not happen, however, unless Congress provides the funds to sustain the Alzheimer research enterprise. Despite its devastating consequences, research on Alzheimer's disease remains seriously under-funded.

In 2003, annual NIH funding of Alzheimer research peaked at $658 million. The scientific community is living off the results of that investment, but we now risk losing that momentum. Since 2003, there has been a slow, steady decline in funding—down to $643 million this year and even less if Congress approves the President's fiscal 2008 budget request. In constant dollars, the drop is devastating—a 14 percent decline in overall funding at the National Institute on Aging (NIA) alone.

This is happening at a time when the scientific opportunities have never been greater. There are more highly promising avenues of inquiry to explore than ever before. And researchers now have research tools at their disposal, involving genetics and imaging, that can help get better, quicker answers. But scientists cannot use those tools without adding funds to existing projects.

The slow down in funding is already having an impact in the Alzheimer research community. NIA is funding less than 18 percent of the most highly rated investigator-initiated projects it receives—down from a 30 percent success rate in 2003. What is more, the first-year grants that are awarded are funded at 18 percent below the level recommended by NIA's own independent review panels. There are no inflationary adjustments in the out-years or for existing projects. This means that most scientific opportunities are left on the table, and the successful ones are being seriously under-funded. It also means that some of the most promising clinical trials—the way to translate basic research findings into effective treatments—will be delayed or scrapped altogether. Conversations within the Alzheimer research commu-

nity confirm that we are at risk of losing a generation of scientists, young investigators who are either choosing less traditional careers or are leaving research altogether. These brilliant minds are our greatest resource, and we should be applying them to our most difficult problems. Only money will bring them back.

These budget cuts are not just killing research projects. They are killing the minds of millions of Americans. And they are killing our chances of getting health care spending under control. If we let the disease continue on its current trajectory, in less than 25 years Medicare will be spending almost $400 billion on 10 percent of its beneficiaries—those with Alzheimer's. That is almost as much as we are spending in the entire Medicare program for all beneficiaries today.

We can cut that spending dramatically—saving over $50 billion annually—within just 5 years of even modest breakthroughs that would delay the onset of Alzheimer's and slow its progression. And we can also save millions of families from devastation. Within 20 years of a breakthrough, there would be 3.7 million fewer cases of Alzheimer's in the United States than there are today—in spite of the rapid aging of the baby boomers. And among those who would still develop the disease, most would never progress beyond the mild stages of the disease and could continue to live productively with their families in the community.

We cannot win this fight against Alzheimer's without an all-out commitment from Congress and from every relevant part of the Federal Government—especially NIH and the Food and Drug Administration (FDA). The Alzheimer's Association is working closely with all these agencies to maximize our mutual efforts within the limits imposed by existing law and resources. We are proud of our longstanding partnership with the National Institute on Aging and the tremendous commitment of Dr. Richard Hodes and his dedicated staff. We are also gratified by the response of the Food and Drug Administration to our Effective Treatments Initiative, to increase its focus on Alzheimer's and to bring patients and caregivers into the drug review process.

Mr. Chairman and subcommittee members—we are in a race against time. With every year that passes, we risk losing that race. The Alzheimer's Association respectfully requests that you provide sufficient resources for NIH in the fiscal year 2008 Labor/HHS/Education Appropriations bill so that funding for Alzheimer research can be increased by $125 million. The Association also seeks continued support for proven programs that are serving hundreds of thousands of Alzheimer families, including $1 million for the 24/7 Alzheimer's Call Center and $12 million for the Alzheimer's Disease Matching Grants to States Program administered by the Administration on Aging. Services provided by the Call Center include access to professional clinicians who provide decision-making support, crisis assistance and education on issues caregivers face every day. The Call Center also provides referrals to local community programs and services. The Alzheimer's Disease Matching Grants to States Program provides funds to States for the development of innovative and cost effective programs that influence broader healthcare systems and provide community-based services for those with Alzheimer's and their caregivers. The program has a special emphasis on reaching hard-to-reach and underserved people such as minorities, low income persons, and those living in rural/frontier communities. 38 States, including Iowa, are currently participating in the program.

In addition, we urge you to increase funding for the Centers for Disease Control & Prevention (CDC) Brain Health Initiative to $3 million. Since fiscal year 2005, Congress has provided approximately $1.6 million annually to the CDC to develop and implement the first single-focused effort on brain health promotion. As a result of this initial support, the CDC and the Alzheimer's Association have begun collaborating on a multi-faceted approach to brain health that includes both programmatic and public health research components. This Initiative is currently focused on four primary activities: development of a Roadmap to Maintaining Cognitive Health, implementation of community demonstration programs, creation of communication linkages with the public, and elevation of brain health research. Increasing support for this Initiative to $3 million would allow for broader dissemination of the Roadmap to Maintaining Cognitive Health, provide funds to expand the community demonstration projects to other high risk, underserved populations, specifically the Hispanic/Latino population and support the development of a strategic initiative for early detection and secondary prevention of Alzheimer's disease, including consideration of appropriate screening/diagnostic tools, needed education strategies, and appropriate follow up to diagnosis.

We urge Congress to add the funding we need to break through the finish line ahead of the baby boomers who are nipping at our heels. The funding for Alzheimer research and care programs that we seek requires a modest investment in total Federal budget terms but it has the potential for enormous returns—in reduced health

and long-term care costs to Federal and State budgets and in improved quality of life for millions of American families.

Thank you again for the opportunity to submit this testimony for the record.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The 93,800 members of the American Academy of Family Physicians are grateful for this opportunity to submit for the record our recommendations for Federal fiscal year 2008 to the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education.

The American Academy of Family Physicians (AAFP) is one of the largest national medical organizations, representing family physicians, family medicine residents, and medical students nationwide. Founded in 1947, our mission has been to preserve and promote the science and art of family medicine and to ensure high-quality, cost-effective health care for patients of all ages. We believe that Federal spending policy can help to transform health care to achieve optimal health for everyone.

We recommend that, as an essential part of that policy, the fiscal year 2008 Appropriations bill to fund the Departments of Labor, Health and Human Services and Education should restore funding for health professions training programs, increase our investment in the Agency for Healthcare Research and Quality and continue support for rural health programs.

HEALTH RESOURCES & SERVICES ADMINISTRATION—HEALTH PROFESSIONS

For the last 40 years, the health professions training programs authorized under Title VII of the Public Health Services Act have evolved in order to meet our Nation's changing health care workforce needs.

Section 747 of Title VII, the Primary Care Medicine and Dentistry Cluster, is aimed at increasing the number of primary care physicians (family physicians, general internists and pediatricians) as well as the number of highly-skilled health care professionals to provide care to the underserved. Section 747 offers competitive grants for family medicine training programs in medical schools and in residency programs.

The value of these grants extends far beyond the medical schools that receive them. The United States lags behind other countries in its focus on primary care. However, the evidence shows that countries with primary care-based health systems have population health outcomes that are better than those of the United States at lower costs.[1] Health Professions Grants are one important tool to help refocus this Nation's health system on primary care.

Disease Prevention

First of all, Federal support of Title VII, section 747 for primary care training is critical to increase the number of family physicians whose specialty emphasizes a broad range of skills in caring for the whole patient regardless of age, gender or medical condition. Primary care provided by family physicians looks to a patient's total health needs and is strongly oriented toward preventing illness and injury.

Chronic Care Management

Second, primary care is ideally suited to managing chronic disease. Regrettably, nearly one in five Americans lacks access to primary medical care for regular and on-going care. A recent study "found 56 million Americans of all income levels, race and ethnicity, and insurance status have inadequate access to a primary care physician due to shortages of these physicians in their communities."[2]

Lower Costs

Americans with a "medical home" to provide primary care for such basic needs as treating ear infections, controlling high blood pressure, or managing diabetes have better health outcomes at a lower cost of care.[3] Without adequate numbers and distribution of primary care physicians, we cannot provide the quality of preventive care designed to avoid costlier services in hospital emergency departments.

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[1] Starfield B, et al. The effects of specialist supply on populations' health: assessing the evidence. Health Affairs. 15 March 2005.

[2] National Association of Community Health Centers, The Robert Graham Center. Access Denied: A Look at America's Medically Disenfranchised. March 2007.

[3] Ibid.

Primary Care Physician Shortages

Support for family medicine training programs is needed to address insufficient access to primary care services which is caused by both an overall shortage and an uneven distribution of physicians. Family medicine is a critical part of the solution to providing high-quality, affordable and accessible health care to everyone.

On March 15, 2007, the annual National Resident Matching Program announced results showing the number of medical students choosing careers in family medicine remains stagnant, raising concerns the primary care physician workforce will not be adequate to meet the needs of an aging population with an increased prevalence of chronic disease.

The AAFP's 2006 Family Physician Workforce Reform report called for a workforce of 139,531 family physicians, or a ratio of 41.6 family physicians per 100,000 U.S. population by 2020. To meet that demand, our medical education system must produce 4,439 new family physicians annually.

In the 2007 National Resident Matching Program 2,313 applicants matched to family medicine residency positions compared with 2,318 in 2006. Also down was the total number and percentage of U.S. students who match to family medicine: 1,107 or 7.8 percent of participating U.S. graduates matched to family medicine this year, compared to 1,132 or 8.1 percent in 2006. This year, there were 106 fewer family medicine residency positions offered than in 2006.

Last fall, the AAFP Congress of Delegates, in recognition of the need for more family physicians to meet the escalating health care needs of the American people, called for preferential funding for section 747 as well as those training programs that produce physicians from underrepresented minorities, or those whose graduates practice in underserved communities or serve rural and inner-city populations.

In opposition to funding for Health Professions Grants, the administration cited an Office of Management and Budget 2002 Program Assessment Rating Tool (PART) assessment of Title VII that called the program ineffective. In fact, data show that medical schools and primary care residency programs funded by Title VII section 747 do disproportionately serve as the medical education pipeline that produces physicians who go on to work in Community Health Centers and participate in the National Health Service Corps to treat underserved populations.[4]

In order to achieve a valid OMB PART analysis, the Health Professions program must be given clear goals and objectives. The Advisory Committee on Training in Primary Care Medicine and Dentistry called for by the Health Professions Education Partnership Act of 1998 has proposed steps to clarify, in the authorizing law, the purpose and objectives of Title VII, section 747. AAFP is working with the authorizing committees to ensure that the reauthorization addresses these recommendations.

Although the Title VII programs intended to support the preparation of an effective, diverse primary care workforce have been repeatedly targeted for elimination in Presidential budget requests, the committee has provided appropriations for these important accounts. The final spending resolution for fiscal year 2007 provided $184.75 million, a 27.2 percent increase above the fiscal year 2006 level for all of Title VII. The Primary Medicine and Dentistry Cluster, section 747, received an increase of 19.6 percent from the fiscal year 2006 level to $48.85 million. However, this level falls far short of the appropriation of $92 million provided in fiscal year 2003.

The AAFP is committed to a high level of support for education in family medicine residency programs and family medicine departments and divisions in medical schools.

We hope that the committee will make an adequate investment in a well-prepared primary care workforce in order to provide improved health care at a reduced cost.

AAFP recommends an increase in the fiscal year 2008 appropriation bill for the Health Professions Training Programs authorized under Title VII of the Public Health Services Act. We respectfully suggest that the committee provide at least $300 million for Title VII, including $92 million for the section 747, the Primary Care Medicine and Dentistry Cluster, which will restore this vital program to its fiscal year 2003 level.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The mission of the Agency for Healthcare Research and Quality (AHRQ)—to improve the quality, safety, efficiency, and effectiveness of health care for all Americans—closely mirrors AAFP's own mission. AHRQ has a unique responsibility for

[4] University of California, San Francisco.

research to inform decision-making and improve clinical care. In addition to AHRQ's charge to evaluate health care practice cost-effectiveness, the agency is engaged in the effort to advance personalized health care with the Health Information Technology Initiative.

Health Information Technology

The initial work by AHRQ to facilitate the adoption of health information technology is important to improve patient safety by reducing medical errors and to avoid costly duplication of services. AAFP recognizes that health information technology, used effectively, can transform health care. It is vital that AHRQ, as the lead Federal agency, have the necessary resources to promote standards for portability and interoperability which ensure that health data is appropriately available and privacy protected.

Comparative Clinical Effectiveness Research

According to the Centers for Medicare and Medicaid Services' National Health Statistics Group, health care spending will double to $4.1 trillion and account for 20 percent of every dollar spent by 2016. Our Nation must invest in the study of health care practice in order to improve outcomes and minimize unnecessary costs. One important tool to accomplish this is AHRQ's analysis of clinical effectiveness and appropriateness of health services and treatments. This practical research will improve Federal programs such as Medicare, Medicaid and SCHIP as well as privately-financed health care.

AAFP recommends an increase in the fiscal year 2008 appropriation bill for the Agency for Healthcare Research and Quality (AHRQ). We respectfully suggest that the committee provide at least $350 million for AHRQ, an increase of $31 million above the fiscal year 2007 level.

RURAL HEALTH PROGRAMS

Family physicians provide the majority of care for America's underserved and rural populations.[5] Despite efforts to meet shortages in rural areas, there continues to be a shortage of physicians. Studies, whether they be based on the demand to hire physicians by hospitals and physician groups or based on the number of individuals per physician in a rural area, all indicate a need for additional physicians in rural areas. Continued funding for rural programs is vital to provide adequate health care services to America's rural citizens. We support the Federal Office of Rural Health Policy; Area Health Education Centers; the Community and Migrant Health Center Program; and the NHSC. State rural health offices, funded through the National Health Services Corps budget, help States implement these programs so that rural residents benefit as much as urban patients.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PEDIATRICS

This statement is endorsed by: Ambulatory Pediatric Association and Society for Adolescent Medicine.

There can be no denying that there have been numerous and significant successes in improving the health and well-being of America's children and adolescents, from even just decades ago. Infant and child mortality rates have been radically lowered. The number of 2-year-olds who have received the recommended series of immunizations is at an all-time high, while vaccine-preventable diseases such as measles, pertussis, and diphtheria have decreased by over 98 percent. Teen pregnancy rates have declined by 28 percent over the last decade. Still, despite these successes, far too many children and adolescents in America continue to suffer from disease, injury, abuse, racial and ethnic health disparities, or lack of access to quality care. In addition, more than 9 million children and adolescents through the age 18 remain uninsured. Clearly there remains much work to do.

As clinicians we not only diagnose and treat our patients, we must also promote strong preventive interventions to improve the overall health and well-being of all infants, children, adolescents and young adults. The AAP, SAM and APA have identified three key priorities within this committee's jurisdiction that are at the heart of improving the health and well-being of America's children and adolescents: access to health care, quality of health care, and immunizations. A chart at the end of this

[5] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Division of Data Services. National ambulatory medical care survey.

statement will offer funding recommendations for other programs of importance to the child and adolescent community.

ACCESS

We believe that all children, adolescents and young adults should have full access to comprehensive, age-appropriate, quality health care. From the ability to receive primary care from a pediatrician trained in the unique needs of children and adolescents, to timely access, to pediatric medical subspecialists and pediatric surgical specialists, America's children and adolescents deserve access to quality pediatric care in a medical home. Given the recent cuts to the Medicaid program and fiscal belt-tightening in the States, discretionary programs now more than ever provide a vital health care safety net for America's most vulnerable children and youth.

Maternal and Child Health Block Grant.—The Maternal and Child Health (MCH) Block Grant Program at the Health Resources and Services Administration (HRSA) is the only Federal program exclusively dedicated to improving the health of all mothers and children. Nationwide, the MCH Block Grant Program provides preventive and primary care services to over 32 million women, infants, children, adolescents and children with special health care needs. In addition, the MCH Block Grant Program supports community programs around the country in their efforts to reduce infant mortality, prevent injury and violence, expand access to oral health care, and address racial and ethnic health disparities. Moreover, the MCH Block Grant Program includes efforts dedicated to addressing interdisciplinary training, services and research for adolescents' physical and mental health care needs, and supports programs for vulnerable adolescent populations, including health care initiatives for incarcerated and minority adolescents, and violence and suicide prevention. It also plays an important role in the implementation of the State Children's Health Insurance Program (SCHIP). One of the many successful MCH Block Grant programs is the Healthy Tomorrows Partnership for Children Program, a public/private collaboration between the MCH Bureau and the American Academy of Pediatrics. Established in 1989, Healthy Tomorrows has supported over 150 family-centered, community-based initiatives in almost all States, including Ohio, Wisconsin, New York, California, Rhode Island, and Maryland. These initiatives have addressed issues such as access to oral and mental health care, obesity, injury prevention, and enhanced clinical services for chronic conditions such as asthma. To continue to foster these and other community-based solutions for local health problems, in fiscal year 2008 we strongly support an increase in funding for the MCH Block Grant Program to $750 million.

Family Planning Services.—The family planning program, Title X of the Public Health Services Act, ensures that all teens have confidential access to valuable family planning resources. For every dollar spent on family planning through Title X, $3 is saved in pregnancy-related and newborn care costs to Medicaid. Title X—which does not provide funding for abortion services—provides critically needed preventive care services like pap tests, breast exams, and STI tests to millions of adolescents and women. But over 9.5 million cases of sexually transmitted infection (STIs) (almost half the total number) are in 15–24 year olds, and over 30 percent of women will become pregnant at least once before age 20. Teen pregnancy rates continue to vary between racial and ethnic groups, and nearly half (48 percent) of all teens say that they want more information from—and increased access to—sexual health care services. Responsible sexual decision-making, beginning with abstinence, is the surest way to protect against sexually transmitted infections and pregnancy. However, for adolescent patients who are already sexually active, confidential contraceptive services, screening and prevention strategies should be available. We therefore support a funding level in fiscal year 2008 of $385 million for Title X of the Public Health Service Act.

Mental Health.—It is estimated that over 13 million children and adolescents have a mental health problem such as depression, ADHD, or an eating disorder, and for as many as 6 million this problem may be significant enough to impact school attendance, interrupt social interactions, and disrupt family life. Despite these statistics, the National Institute of Mental Health (NIMH) estimates that 75–80 percent of these children fail to receive mental health specialty services, due to stigma and the lack of affordability of care and availability of specialists. Grants through the Children's Mental Health Services program have been instrumental in achieving decreased utilization of inpatient services, improvement in school attendance and lower law enforcement contact for children and adolescents. We recommend that $112 million be allocated in fiscal year 2008 for the Mental Health Services for Children program to continue these improvements for children and adolescents with mental health problems.

Child Abuse and Neglect.—Recent research from the CDC's Adverse Childhood Experiences study and others demonstrates that childhood trauma may contribute significantly to the development of numerous adult health conditions, including alcoholism, drug abuse, heart disease and more. However, few Federal resources are dedicated to bringing the medical profession into full partnership with law enforcement, the judiciary, and social workers, in preventing, detecting, and treating child abuse and neglect. We urge the subcommittee to provide an increase of $10 million in fiscal year 2008 for the Center for Disease Control and Prevention's National Center for Injury Prevention and Control to establish a network of consortia to link and leverage health care professionals and resources to address—and ultimately prevent—child maltreatment. We also support the recommendation of the National Child Abuse Coalition to fund the Child Abuse Prevention and Treatment Act program at $200 million.

Health Professions Education and Training.—Critical to building a pediatric workforce to care for tomorrow's children and adolescents are the Training Grants in Primary Care Medicine and Dentistry, found in Title VII of the Public Health Service Act. These grants are the only Federal support targeted to the training of primary care professionals. They provide funding for innovative pediatric residency training, faculty development and post-doctoral programs throughout the country. For example, a pediatrician in New Jersey stated the following: "Reduction in Title VII funding would negatively impact all areas of our current activities, including recruitment of under-represented minority trainees and faculty, cultural competency initiatives, clinical experiences for aspiring health professionals and patient care for thousands of underserved urban infants, children and adolescents."

Through the continuing efforts of this subcommittee, Title VII has provided a vital source of funding for critically important programs that educate and train tomorrow's generalist pediatricians in a variety of settings to be culturally competent and to meet the special health care needs of their communities. We recommend fiscal year 2008 funding of at least $40 million for General Internal Medicine/General Pediatrics. We also join with the Health Professions and Nursing Education Coalition in supporting an appropriation of at least $550 million in total funding for Titles VII and VIII. We support the administration's increase in funding for Community Health Centers, a key component with Title VII to ensuring an adequate distribution of health care providers across the country; but we emphasize the need for continued support of the training and education opportunities through Title VII for health care professionals, including pediatricians, who provide care for our Nation's communities.

Independent Children's Teaching Hospitals.—Equally important to the future of pediatric education and research is the dilemma faced by independent children's teaching hospitals. In addition to providing critical care to the Nation's children, independent children's hospitals play a significant role in training tomorrow's pediatricians and pediatric subspecialists. Children's hospitals train 30 percent of all pediatricians, half of all pediatric subspecialists, and the majority of pediatric researchers. However, children's hospitals qualify for very limited Medicare support, the primary source of funding for graduate medical education in other inpatient environments. As a bipartisan Congress has recognized in the last several years, equitable funding for Children's Hospitals Graduate Medical Education (CHGME) is needed to continue the education and research programs in these child- and adolescent-centered settings. Since 2000, CHGME hospitals accounted for nearly 87 percent of the growth in pediatric subspecialty training programs and 68 percent of the growth in pediatric subspecialty fellows trained. We are extremely disappointed in the 63 percent reduction in funding proposed by the administration for the CHGME program, and join with the National Association of Children's Hospitals to restore funding to $330 million for the CHGME program in fiscal year 2007. The support for independent children's hospitals should not come, however, at the expense of valuable Title VII and VIII programs, including grant support for primary care training.

QUALITY

Access to health care is only the first step in protecting the health of all children and youth. We must ensure that the care provided is of the highest quality. Robust Federal support for the wide array of quality improvement initiatives, including research, is needed if this goal is to be achieved.

Emergency Services for Children.—One program that assists local communities in providing quality care to children in distress is the Emergency Medical Services for Children (EMSC) grant program. There are approximately 30 million child and adolescent visits to the Nation's emergency departments every year. Children under the

age of 3 years account for most of these visits. Up to 20 percent of children needing emergency care have underlying medical conditions such as asthma, diabetes, sickle-cell disease, low birth weight, and bronchopulmonary dysplasia. In 2006, the Institute of Medicine's report Emergency Care for Children: Growing Pains acknowledged the many achievements of the EMSC program in improving pediatric emergency care and recommended that it be funded at $37.5 million. In order to assist local communities in providing the best emergency care to children, we once again reject the administration's proposed elimination of the EMSC program and strongly urge that the EMSC program be maintained and adequately funded at $25 million in fiscal year 2008

Agency for Healthcare Research and Quality.—Quality of care rests on quality research—for new detection methods, new treatments, new technology and new applications of science. As the lead Federal agency on quality of care research, the Agency for Healthcare Research and Quality (AHRQ) provides the scientific basis to improve the quality of care, supports emerging critical issues in health care delivery and addresses the particular needs of priority populations, such as children. Substantial gaps still remain in what we know about health care needs for children and adolescents and how we can best address those needs. Children are often excluded from research that could address these issues. The AAP and endorsing organizations strongly support AHRQ's objective to encourage researchers to include children and adolescents as part of their research populations. We also support increasing AHRQ's efforts to build pediatric health services research capacity through career and faculty development awards and strong practice-based research networks. Additionally, AHRQ is focusing on initiatives in community and rural hospitals to reduce medical errors and to improve patient safety through innovative use of information technology—an initiative that we hope would include children's hospitals as well. Through its research and quality agenda, AHRQ continues to provide policymakers, health care professionals and patients with critical information needed to improve health care and health disparities. We join with the Friends of AHRQ to recommend funding of $350 million for AHRQ in fiscal year 2008.

National Institutes of Health.—Over the years, NIH has made dramatic strides that directly impact the quality of life for infants, children and adolescents through biomedical and behavioral research. For example, NIH research has led to successfully decreasing infant death rates by over 70 percent, increasing the survival rates from respiratory distress syndrome, and dramatically reducing the transmission of HIV from infected mother to fetus and infant from 25 percent to just 1.5 percent. NIH is engaged in a comprehensive research initiative to address and explain the reasons for a major public health dilemma—the increasing number of obese and overweight children and adults in this country. Today U.S. teenagers are more overweight than young people in many other developed countries. And the Newborn Screening Initiative is moving forward to improve availability, accessibility, and quality of genetic tests for rare conditions that can be uncovered in newborns. The pediatric community applauds the prior commitment of Congress to maintain adequate funding for the NIH. We remain concerned, however, that the cumulative effect of several years of flat funding will stall or even set back the gains that were made under the years of the NIH's budget doubling. We urge you to begin to restore the funding lost over these last years. We support the recommendation of the Ad Hoc Group for Medical Research for a funding level in fiscal year 2008 of $30.8 billion an increase of 6.7 percent over the fiscal year 2007 joint resolution for the NIH In addition, to ensure ongoing and adequate child and adolescent focused research, such as the National Children's Study (NCS) led by the National Institute for Child Health and Human Development (NICHD), we join with the Friends of NICHD Coalition in requesting $1,337.8 billion in fiscal year 2008. Moreover we recommend that the NCS be adequately funded in fiscal year 2008 at $110.9 million to allow for the continued implementation of the NCS and bring us closer to the first results from this landmark study. We are greatly disappointed by the administration's failure to include the NCS in its budget proposal 2008. This large longitudinal study, authorized in the Children's Health Act of 2000, will provide critical research and information on major causes of childhood illnesses such as premature birth, asthma, obesity, preventable injury, autism, development delay, mental illness, and learning disorders.

We commend this committee's ongoing efforts to make pediatric research a priority at the highest level of the NIH. We urge continued Federal support of NIH efforts to increase pediatric biomedical and behavioral research, including such proven programs as targeted training and education opportunities and loan repayment. We recommend continued interest in and support for the Pediatric Research Initiative in the Office of the NIH Director and sufficient funding to continue the pediatric training grant and pediatric loan repayment programs both enacted in the

Children's Health Act of 2000. This would ensure that we have adequately trained pediatric researchers in multiple disciplines that will not come at the expense of other important programs.

Finally, as clinicians, we know first-hand the considerable benefits for children and society in securing properly studied and dosed medications. Proper pediatric safety and dosing information reduces medical errors and adverse events, ultimately improving children's health and reducing health care costs. But there is little market incentive for drug companies to study generic or off-patent drugs—older drugs that are widely used therapies for children. The Research Fund for the Study of Drugs, created as part of the Best Pharmaceuticals for Children Act of 2002, provides support for these critical pediatric testing needs, but unfortunately is currently funded at an amount sufficient to test only a fraction of the NIH and FDA-designated "priority" drugs. Therefore, we urge the subcommittee to provide the NIH with sufficient funding to fund the study of generic (off-patent) drugs for pediatric use.

IMMUNIZATION

Pediatricians, working alongside public health professionals and other partners, have brought the United States its highest immunization coverage levels in history—over 92 percent of children received all vaccinations by school age in 2004–2005. We attribute this, in part, to the Vaccines for Children (VFC) Program, and encourage Congress to maintain its commitment to ensuring the program's viability. The VFC program combines the efforts of public health and private pediatricians and other health care professionals to accomplish and sustain vaccine coverage goals for both today's and tomorrow's vaccines. It removes vaccine cost as a barrier to immunization for some and reinforces the concept of vaccine delivery in a "medical home." Additional section 317 funding is necessary to provide the pneumococcal conjugate vaccine (PCV–7), a vaccine that prevents an infection of the brain covering, blood infections and approximately 7 million ear infections a year, to those remaining States that currently do not provide it. Increased section 317 funding also is needed to purchase the influenza vaccine—now recommended for children between the ages of 6 months and 5 years of age. This age cohort is increasingly susceptible to serious infection and the risk of hospitalization. And an increase in funding is needed to purchase the recently recommended rotavirus vaccine, tetanus-diptheria-pertussis (Tdap) vaccine for adolescents and the meningococcal conjugate vaccine (MCV). Meningococcal disease is a serious illness, caused by bacteria, with 10–15 percent of cases fatal and another 10–15 percent of cases resulting in permanent hearing loss, mental retardation, or loss of limbs. And additional funding is important to provide the HPV vaccine recommended by the ACIP.

The public health infrastructure that now supports our national immunization efforts must not be jeopardized with insufficient funding. For example, adolescents continue to be adversely affected by vaccine-preventable diseases (e.g., chicken pox, hepatitis B, measles and rubella). Comprehensive adolescent immunization activities at the national, State, and local levels are needed to achieve national disease elimination goals. States and communities continue to be financially strapped and therefore, many continue to divert funds and health professionals from routine immunization clinics in order to accommodate anti-bioterrorism initiatives or now pandemic influenza. Moreover, continued investment in the CDC's immunization activities must be made to avoid the reoccurrence of childhood vaccine shortages by providing and adequately funding a national 6 month stockpile for all routine childhood vaccines—stockpiles of sufficient size to insure that significant and unexpected interruptions in manufacturing do not result in shortages for children.

While the ultimate goal of immunizations clearly is eradication of disease, the immediate goal must be prevention of disease in individuals or groups. To this end, we strongly believe that CDC's efforts must be sustained. In fiscal year 2008, we recommend an overall increase in funding to $802.4 million $257.5 million over the President's request to ensure that the CDC's National Immunization Program has the funding necessary to accommodate vaccine price increases, new disease preventable vaccines coming on the market, global immunization initiatives—including funds for polio eradication and the elimination of measles and rubella—and to continue to implement the recommendations developed by the IOM.

CONCLUSION

We appreciate the opportunity to provide our recommendations for the coming fiscal year. As this subcommittee is once again faced with difficult choices and multiple priorities we know that as in the past years, you will not forget America's children and adolescents.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

On behalf of the more than 60,000 clinically practicing physician assistants in the United States, the American Academy of Physician Assistants is pleased to submit comments on fiscal year 2008 appropriations for Physician Assistant (PA) educational programs that are authorized through Title VII of the Public Health Service Act.

A member of the Health Professions and Nursing Education Coalition (HPNEC), the Academy supports the HPNEC recommendation to provide at least $300 million for Title VII programs in fiscal year 2008, including a minimum of $7 million to support PA educational programs. This would fund the programs at the 2005 funding level, not accounting for inflation.

The Academy believes that the recommended restoration in funding for Title VII health professions programs is well justified. A review of PA graduates from 1990–2004 reveals that graduates from Title VII supported programs were 67 percent more likely to be from underrepresented minority backgrounds and 49 percent more likely to work in a Rural Health Clinic than graduates of programs that weren't supported by Title VII funding.

Title VII safety net programs are essential to the training of primary health care professionals and provide increased access to care by promoting health care delivery in medically underserved communities. Title VII funding for PA programs is especially important since it is the only Federal funding available to these programs, on a competitive application basis.

The Academy is extremely concerned with the administration's proposal to eliminate funding for most Title VII programs, including training programs in primary care medicine and dentistry. These programs are designed to help meet the health care delivery needs of the Nation's Health Professional Shortage Areas (HPSAs). By definition, the Nation's more than 5,500 HPSAs experience shortages in the primary care workforce that the market alone can't address. In addition, the Health Resources and Services Administration (HRSA) predicts that there will be a need for over 11,000 health care professionals to implement the President's Community Health Center (CHC) Initiative. The increased funding for these CHCs will provide medical care to approximately 6 million people in the United States. Title VII serves as crucial funding for the pipeline of health professionals that serve CHCs today.

We wish to thank the members of this subcommittee for your historical role in supporting funding for the health professions programs, and we hope that we can count on your support to restore funding to these important programs in fiscal year 2008 to the fiscal year 2005 funding level.

OVERVIEW OF PHYSICIAN ASSISTANT EDUCATION

The typical PA program consists of 26 months of instruction, and the typical student has a bachelor's degree and about 4 years of prior health care experience. The first phase of the program consists of more than 400 hours in classroom and laboratory instruction in the basic sciences, over 75 hours in pharmacology, approximately 175 hours in behavioral sciences, and almost 580 hours of clinical medicine.

The second year of PA education consists of clinical rotations, which typically includes more than 2,000 hours or 50–55 weeks of clinical education, divided between primary care medicine and various specialties. During clinical rotations, PA students work directly under the supervision of physician preceptors, participating in the full range of patient care activities, including patient assessment and diagnosis, development of treatment plans, patient education, and counseling. All PA educational programs are accredited by the Accreditation Review Commission on Education for the Physician Assistant.

After graduation from an accredited PA program, physician assistants must pass a national certifying examination jointly developed by the National Board of Medical Examiners and the independent National Commission on Certification of Physician Assistants. To maintain certification, PAs must log 100 continuing medical education credits every 2 years, and they must take a recertification exam every 6 years.

PHYSICIAN ASSISTANT PRACTICE

Physician assistants are licensed health care professionals educated to practice medicine as delegated by and with the supervision of a physician. In all States, physicians may delegate to PAs those medical duties that are within the physician's scope of practice and the PA's training and experience and are allowed by law. Physicians may also delegate prescriptive privileges to the PAs they supervise. PAs are located in almost all health care settings and medical and surgical specialties. Six-

teen percent of all PAs practice in non-metropolitan areas where they may be the only full-time providers of care (State laws stipulate the conditions for remote supervision by a physician). Approximately 48 percent of PAs work in urban and inner city areas. Approximately 38 percent of PAs are in primary care. In 2006, an estimated 231 million patient visits were made to PAs and approximately 286 million medications were prescribed or recommended by PAs.

CRITICAL ROLE OF TITLE VII PUBLIC HEALTH SERVICE ACT PROGRAMS

A growing number of Americans lack access to primary care either because they are uninsured, underinsured, or they live in a community with an inadequate supply or distribution of providers. The growth in the uninsured U.S. population increased from approximately 32 million in the early 1990s to almost 47 million today. The role of Title VII programs is to alleviate these problems by supporting educational programs that train more health professionals in fields experiencing shortages, improving the geographic distribution of health professionals, and increasing access to care in underserved communities.

Title VII programs are the only Federal educational programs that are designed to address the supply and distribution imbalances in the health professions. Since the establishment of Medicare, the costs of physician residencies, nurse training, and some allied health professions training have been paid through Graduate Medical Education (GME) funding. However, GME has never been available to support PA education. Furthermore, GME was not intended to generate a supply of providers who are willing to work in the Nation's medically underserved communities. That is the purpose of the Title VII Public Health Service Act programs.

In addition, as evidence indicates that race and ethnicity correlate to persistent health disparities among U.S. populations, it is essential to increase the diversity of health care professionals. Title VII programs seek to recruit students who are from underserved minority and disadvantaged populations. This is particularly important, as studies have found that those from disadvantaged regions of the country are three to five times more likely to return to underserved areas to provide care.

TITLE VII SUPPORT OF PA EDUCATIONAL PROGRAMS

Targeted Federal support for PA educational programs is authorized through section 747 of the Public Health Service Act. The program was reauthorized in the 105th Congress through the Health Professions Education Partnerships Act of 1998, Public Law 105–392, which streamlined and consolidated the Federal health professions education programs. Support for PA education is now considered within the broader context of training in primary care medicine and dentistry.

Public Law 105–392 reauthorized awards and grants to schools of medicine and osteopathic medicine, as well as colleges and universities, to plan, develop, and operate accredited programs for the education of physician assistants with priority given to training individuals from disadvantaged communities. The funds ensure that PA students from all backgrounds have continued access to an affordable education and encourage PAs, upon graduation, to practice in underserved communities. These goals are accomplished by funding PA educational programs that have a demonstrated track record of (1) placing PA students in health professional shortage areas; (2) exposing PA students to medically underserved communities during the clinical rotation portion of their training; and (3) recruiting and retaining students who are indigenous to communities with unmet health care needs.

The PA programs' success is linked to their ability to creatively use Title VII funds to enhance existing educational programs. For example, PA programs in Texas use Title VII funds to create new clinical rotation sites in rural and underserved areas, including new sites in border communities, and to establish non-clinical rural rotations to help students understand the challenges faced by rural communities. One Texas program uses Title VII funds for the development of Web based and distant learning technology, so students can remain at clinical practice sites. A PA program in New York, where over 90 percent of the students are ethnic minorities, uses Title VII funding to focus on primary care training for underserved urban populations by linking with community health centers, which expands the pool of qualified minority role models that engage in clinical teaching, mentoring, and preceptorship for PA students. Several other PA programs have been able to use Title VII grants to leverage additional resources to assist students with the added costs of housing and travel that occur during relocation to rural areas for clinical training.

Without Title VII funding, many of these special PA training initiatives would not be possible. Institutional budgets and student tuition fees simply do not provide sufficient funding to meet the special, unmet needs of medically underserved areas or

disadvantaged students. The need is very real, and Title VII is critical in meeting that need.

NEED FOR INCREASED TITLE VII SUPPORT FOR PA EDUCATIONAL PROGRAMS

Increased Title VII support for educating PAs to practice in underserved communities is particularly important given the market demand for physician assistants. Without Title VII funding to expose students to underserved sites during their training, PA students are far more likely to practice in the communities where they were raised or attended school. Title VII funding is a critical link in addressing the natural geographic maldistribution of health care providers by exposing students to underserved sites during their training, where they frequently choose to practice following graduation. Currently, 31 percent of PAs met their first clinical employer through their clinical rotations.

The supply of physician assistants is inadequate to meet the needs of society, and the demand for PAs is expected to increase. A 2006 article in the Journal of the American Medical Association (JAMA) concluded that the Federal Government should augment the use of physician assistants as physician substitutes, particularly in urban CHCs where the proportional use of physicians is higher. The article suggested that this could be accomplished by adequately funding Title VII programs. Additionally, the Bureau of Labor Statistics projects that the number of available PA jobs will increase 49 percent between 2004 and 2014. Title VII funding has provided a crucial pipeline of trained PAs to underserved areas.

Despite the increased demand for PAs, funding has not proportionately increased for Title VII programs that are designed to educate and place PAs in underserved communities. Nor has Title VII support for PA education kept pace with increases in the cost of educating PAs. A review of PA program budgets from 1984 through 2004 indicates an average annual increase of 7 percent, a total increase of 256 percent over the past 20 years, yet Federal support has decreased.

RECOMMENDATIONS ON FISCAL YEAR 2008 FUNDING

The American Academy of Physician Assistants urges members of the Appropriations Committee to consider the inter-dependency of all public health agencies and programs when determining funding for fiscal year 2008. For instance, while it is important to fund clinical research at the National Institutes of Health (NIH) and to have an infrastructure at the Centers for Disease Control and Prevention (CDC) that ensures a prompt response to an infectious disease outbreak or bioterrorist attack, the good work of both of these agencies will go unrealized if HRSA is inadequately funded. HRSA administers the "people" programs, such as Title VII, that bring the results of cutting edge research at NIH to patients through providers such as PAs who have been educated in Title VII-funded programs. Likewise, training is the key to emergency preparedness, and Title VII, section 747, is the ideal mechanism for educating primary care providers in public health competencies that ensures the CDC has an adequate supply of health care providers to report, track, and contain disease outbreaks.

The Academy respectfully requests that Title VII health professions programs receive $300 million in funding for fiscal year 2008, including a minimum of $7 million to support PA educational programs. Thank you for the opportunity to present the American Academy of Physician Assistants' views on fiscal year 2008 appropriations.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH

EXECUTIVE SUMMARY

The American Association for Cancer Research (AACR) would like to thank Members for their support of National Institutes of Health (NIH) and National Cancer Institute (NCI) research on the biology, treatment and prevention of the more than 200 diseases called cancer. The AACR, with more than 25,000 members worldwide, represents and supports scientists by publishing respected, peer-reviewed scientific journals, hosting international scientific conferences, and awarding millions of dollars in research grants. Together, we have made great strides in the war on cancer, but much remains to be done. One in four deaths in America this year will be caused by cancer. Cancer-related deaths will increase dramatically as the baby boom generation ages, and we must be prepared to prevent, treat, and manage the impending wave of new cancers.

Cancer is no longer a death sentence thanks to decades of research and development made possible by strong commitments from Congress and the American peo-

ple, but now that commitment is wavering. After expanding capacity during the NIH budget doubling, researchers at hospitals and universities across the country now face shrinking budgets. Promising young researchers, unable to secure grants, turn to other careers. This disruption of the research pipeline will slow the development of new treatments and set back America's biomedical leadership for decades to come.

We are at the vanguard of a revolution in healthcare, where personalized treatment will improve health, reduce harmful side effects, and lower costs. We have the opportunity to build upon our previous investments and accelerate the research process. Now is the time to face the Nation's growing healthcare needs, reaffirm our role as world leaders in science, and renew our commitment to the research and development that brings hope to millions of suffering Americans. The AACR urges the U.S. Senate to support the following appropriations funding levels for cancer research in fiscal year 2008:

—$30.8 billion for the National Institutes of Health, a 6.7 percent increase over fiscal year 2007.

—$5.8 billion for the National Cancer Institute (the NCI Professional Judgment budget level), or, at a minimum, $5.1 billion, a 6.7 percent increase over fiscal year 2007.

The American Association for Cancer Research (AACR) recognizes and expresses its thanks to the United States Congress for its longstanding support and commitment to funding cancer research. The completion of the 5-year doubling of the budget of the National Institutes of Health (NIH) in 2003 was a stunning accomplishment that is already showing impressive returns and benefits to patients with cancer. Recently, however, budgets for cancer research have declined; this commitment appears to be wavering. Budget doubling enabled a significant expansion of infrastructure and scientific opportunities. Budget cuts prevent us from capitalizing on them.

Unquestionably, the Nation's investment in cancer research is having a remarkable impact. Cancer deaths in the United States have declined for the second year in a row. Last year's decline was the first such decrease in the total number of annual cancer deaths since 1930 when record-keeping began. This progress occurred in spite of an aging population and the fact that more than three-quarters of all cancers are diagnosed in individuals aged 55 and older. Yet this good news will not continue without sustained and substantial Federal funding for critical cancer research priorities. The American Association for Cancer Research joins the broader biomedical research community in urging the United States Senate to support the following appropriations funding levels for cancer research in fiscal year 2008:

—$30.8 billion for the National Institutes of Health, a 6.7 percent increase over fiscal year 2007.

—$5.8 billion for the National Cancer Institute (the NCI Professional Judgment budget level), or, at a minimum, $5.1 billion, a 6.7 percent increase over fiscal year 2007.

AACR: FOSTERING A CENTURY OF RESEARCH PROGRESS

The American Association for Cancer Research has been moving cancer research forward since its founding 100 years ago in 1907. Celebrating its Centennial Year, the AACR and its more than 25,000 members worldwide strive tirelessly to carry out its important mission to prevent and cure cancer through research, education, and communication. It does so by:

—fostering research in cancer and related biomedical science;

—accelerating the dissemination of new research findings among scientists and others dedicated to the conquest of cancer;

—promoting science education and training; and

—advancing the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world.

FACING AN IMPENDING CANCER "TSUNAMI"

Over the past 100 years, enormous progress has been made toward the conquest of the Nation's second most lethal disease (after heart disease). Thanks to discoveries and developments in prevention, early detection, and more effective treatments, many of the more than 200 diseases called cancer have been cured or converted into manageable chronic conditions while preserving quality of life. The 5-year survival rate for all cancers has improved over the past 30 years to more than 65 percent. The completion of the doubling of the NIH budget in 2003 is bearing fruit as many new and promising discoveries are unearthed and their potential real-

ized. However, there is much left to be done, especially for the most lethal and rarer forms of the disease.

We recognize that the underlying causes of the disease and its incidence have not been significantly altered. The fact remains that men have a 1 in 2 lifetime risk of developing cancer, while women have a 1 in 3 lifetime risk. The leading cancer sites in men are the prostate, lung and bronchus, and colon and rectum. For women, the leading cancer sites are breast, lung and bronchus, and colon and rectum. And cancer still accounts for 1 in 4 deaths, with more than 564,830 people expected to die from their cancer in 2006. Age is a major risk factor—this Nation faces a virtual "cancer tsunami" as the baby boomer generation reaches age 65 in 2011. A renewed commitment to progress in cancer research through leadership and resources will be essential to dodge this cancer crisis.

FEDERAL INVESTMENT FOR LOCAL BENEFIT

Nearly half of the NCI budget is allocated to research project grants that are awarded to outside scientists who work at local hospitals and universities throughout the country. More than 5,400 research grants are funded at more than 150 cancer centers and specialized research facilities located in 49 States. Over half the States receive more than $15 million in grants and contracts to institutions located within their borders. Many AACR member scientists are engaged in this rewarding work. But too many of them have had their long-term research jeopardized by grant reductions caused by the flat and declining overall funding for the NCI since 2003. The AACR recommends, at a minimum, a 6.7 percent increase in funding for the National Cancer Institute to enable it to continue and expand its work on focused research questions.

UNDERSTANDING THE CAUSES AND MECHANISMS OF CANCER

Basic research into the causes and mechanisms of cancer is at the heart of what the NCI and many of AACR's member scientists do. Basic research is the engine that drives scientific progress. The outcomes from this fundamental basic research—including laboratory and animal research in addition to population studies and the deployment of state-of-the-art technologies—will inform and drive the cancer research enterprise in ways and directions that will lead to unparalleled progress in the search for cures.

ACCELERATING PROGRESS IN CANCER PREVENTION

Preventing cancer is far more cost-effective and desirable than treating it. The NCI uses multidisciplinary teams and a systems biology approach to identify early events and how to modify them. More than half of all cancers are related to modifiable behavioral factors, including tobacco use, diet, physical inactivity, sun exposure, and failure to get cancer screenings. The NCI supports research to understand how people perceive risk, make health-related decisions, and maintain healthy behavior. Prevention is the keystone to success in the battle against cancer.

DEVELOPING EFFECTIVE AND EFFICIENT TREATMENTS

The future of cancer care is all about developing individualized therapies tailored to the specific characteristics of a patient's cancer. Noteworthy recent advances in this area have included the development of oral versions of medicines that were formerly only available by injection, thus improving patients' quality of life; and the discovery of intraperitoneal (IP) chemotherapy—delivering drugs directly to the abdominal cavity—that can add more than a year to survival for some women with ovarian cancer.

OVERCOMING CANCER HEALTH DISPARITIES

Some minority and underserved population groups suffer disproportionately from cancer. Solving this issue will contribute significantly to reducing the cancer burden. Successful achievements in this important area include the development and dissemination of the patient navigator program that assists patients and caregivers to access and chart a course through the healthcare system, and the NCI Cancer Information Services Partnership Program that provides information and education about cancer in lay language to the medically underserved through community organizations.

AACR'S INITIATIVES AUGMENT SUPPORT FOR THE NCI

The NCI is not working alone or in isolation in any of these key areas. NCI research scientists reach out to other organizations to further their work. The AACR is engaged in scores of initiatives that strengthen, support, and facilitate the work of the NCI, including:

—sponsoring the largest meeting of cancer researchers in the world, with more than 17,000 scientists and 6,000 abstracts featuring the latest scientific advances;
—publishing more than 3,400 original research articles each year in five prestigious peer-reviewed scientific journals, including Cancer Research;
—sponsoring the annual International Conference on Frontiers of Cancer Prevention Research, the largest such prevention meeting of its kind in the world;
—raising and distributing more than $5 million in awards and research grants.

TRAINING AND CAREER DEVELOPMENT FOR THE NEXT GENERATION OF RESEARCHERS

Of critical importance to the viability of the long-term cancer research enterprise is supporting, fostering, and mentoring the next generation of investigators. The NCI devotes approximately 4 percent of its budget to multiple strategies to training and career development, including sponsored traineeships, a Medical Scientist Training Program, special set-aside grant programs and bridge grants for early career cancer investigators. Increased funding for these foundational opportunities is essential to retain the scientific workforce that is needed to continue the fight against cancer.

INCREASE RESEARCH FUNDING NOW

Remarkable progress is being made in cancer research, but much more remains to be done. Cancer costs the Nation more than $209 billion in direct medical costs and lost productivity due to illness and premature death. Respected University of Chicago economists Kevin Murphy and Robert Topel have estimated that even a modest 1 percent reduction in mortality from cancer would be worth nearly $500 billion in social value. Investments in cancer research have huge potential returns. Thanks to successful past investments, promising research opportunities abound and must not be lost. To maintain our research momentum, the American Association for Cancer Research (AACR) urges the United States Senate to support the following appropriations funding levels for cancer research in fiscal year 2008:

—$30.8 billion for the National Institutes of Health, a 6.7 percent increase over fiscal year 2007.
—$5.8 billion for the National Cancer Institute (the NCI Professional Judgment budget level), or, at a minimum, $5.1 billion, a 6.7 percent increase over fiscal year 2007.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING

The American Association of Colleges of Nursing (AACN) respectfully submits this statement highlighting funding priorities for nursing education and research programs in fiscal year 2008. AACN represents more than 600 schools of nursing at public and private universities and senior colleges with baccalaureate and graduate nursing programs that educate over 240,000 students and employ over 12,000 faculty members. These institutions are responsible for educating almost half of our Nation's registered nurses (RNs) and all of the nurse faculty and researchers. Nursing represents the largest health profession, with approximately 2.9 million dedicated, trusted professionals delivering primary, acute, and chronic care to millions of Americans.

NATIONWIDE NURSING SHORTAGE

For nearly a decade, our country's health care system has been negatively impacted by a shortage of RNs. In 2002, the Joint Commission on Accreditation of Healthcare Organizations noted that the nursing shortage contributed to nearly a quarter of all unexpected incidents that adversely affect hospitalized patients. A more recent comprehensive analysis published in the March 2006 issue of Nursing Economic$ found that the majority of nurses reported that the RN shortage is negatively impacting patient care and undermining the quality of care goals set by the Institute of Medicine and the National Quality Forum. Unfortunately, reports reveal that the nursing shortage is not expected to diminish in the foreseeable future. The Bureau of Labor Statistics projects that more than 1.2 million new and replacement

nurses will be needed by 2014. Government analysts further project that more than 703,000 new RN positions will be created through 2014, which will account for two-fifths of all new jobs in the health care sector.

A number of contributing factors add to the complexity and duration of the shortage. Within the next 20 years, there will be a wave of nurses retiring from the profession. According to the 2004 National Sample Survey of Registered Nurses released in February 2007 by the Federal Division of Nursing, the average age of the RN population in March 2004 was 46.8 years of age, up from 45.2 in 2000. With many nurses nearing the age of retirement, more nurses must enter the pipeline. However, the nursing profession is not growing to meet the demand of the shortage. While The National Sample Survey of Registered Nurses has indicated that the total RN population has increased at every 4-year interval since 1980, the growth from 2000 to 2004 was relatively low. The total RN population increased by only 7.9 percent in 2004. Earlier report intervals noted that the RN population grew by 14.2 percent between 1992 and 1996.

The approximately 1,500 schools of nursing nationwide have been working diligently to expand enrollments. AACN's 2006–2007 annual survey of 722 nursing schools with baccalaureate and graduate programs reveals that enrollments increased by 7.6 percent in entry-level baccalaureate nursing programs.

This makes the sixth consecutive year of enrollment increases that can be attributed to a combination of Federal support, private sector marketing efforts, public-private partnerships providing additional resources to expand capacity of nursing programs, and State legislation targeting funds towards nursing scholarships and loan repayment. While essential and important, these efforts have not fully met the increasing demand for RNs.

Health Resources and Services Administration (HRSA) officials stated in an April 2006 report that there must be a 90 percent increase in graduations from U.S. nursing programs in order to meet the demand for RN services. Yet, the inability of nursing schools to educate more RNs is the most urgent contributing factor that must be addressed in order to reverse the shortage and ensure that every patient receives the safest, highest quality health care. According to AACN's report on 2006–2007 Enrollment and Graduations in Baccalaureate and Graduate Programs in Nursing, U.S. nursing schools turned away 42,866 qualified applicants to baccalaureate and graduate programs due to an insufficient number of faculty, clinical sites, classroom space, clinical preceptors, and budget constraints. Almost three quarters of the nursing schools responding to the AACN survey pointed to faculty shortages as a reason for not accepting all qualified applicants into nursing programs. Federal support must continue to play an integral role in our Nation's efforts to address the nursing and nurse faculty shortage as well as the constraints encountered by nursing's educational system.

NURSING WORKFORCE DEVELOPMENT PROGRAMS: ADDRESSING THE SHORTAGE

Acknowledging the severity of the Nation's nursing shortage, Congress passed The Nurse Reinvestment Act of 2002. This legislation created new programs and expanded existing Nursing Workforce Development authorities. Administered by HRSA under Title VIII of the Public Health Service Act, these programs focus on the supply and distribution of RNs across the country. The programs support individual students in their nursing studies through scholarships and loan repayment programs. Title VIII programs stimulate innovation in nursing practice and bolster nursing education throughout the continuum, from entry-level preparation through graduate study. They are the largest source of Federal funding for nursing education assisting students, schools of nursing, and health systems in their efforts to educate, recruit, and retain RNs and nurse faculty. In fiscal year 2006, these programs helped to educate over 48,000 nursing students and nurses through individual and programmatic support.

However, funding for these authorities is insufficient to address the severity of the nursing and nurse faculty shortage. Currently, Nursing Workforce Development Programs receive $149.68 million, the same funding level as in fiscal year 2006. During the nursing shortage in 1974, Congress appropriated $153 million for nursing education programs. Translated into today's dollars, that appropriation would total $632 million, more than four times the current level. To fully meet the educational and practice demands of today's nursing shortage it would take billions of dollars.

AACN respectfully requests $200 million for Title VIII Nursing Workforce Development Programs in fiscal year 2008, an additional $50.32 million over the fiscal year 2007 level. New monies would expand nursing education, recruitment, and retention efforts to help resolve all aspects adding to the nursing shortage.

Nurse Faculty Shortage

AACN believes that the most effective strategy to resolve the nursing shortage is addressing the underlying nurse faculty shortage. The demand for nurse faculty far exceeds the rate at which nursing schools can educate them. HRSA reports that just 13 percent of the RN workforce holds either a master's or doctoral degree, the credentials required to teach. A Special Survey on Vacant Faculty Positions released by AACN in July 2006, reported a total of 637 faculty vacancies (8 percent vacancy rate) were identified at 329 nursing schools with baccalaureate and/or graduate programs across the country (almost two vacancies at each school of nursing). Most of the vacancies (53.7 percent) were faculty positions requiring a doctoral degree. Besides the vacancies, schools cited the need to create an additional 55 faculty positions to accommodate student demand. The ability to increase the pool of educators becomes increasingly difficult when 3,306 qualified applicants were turned away from master's programs and 299 qualified applicants were turned away from doctoral programs in 2006.

The inability of nursing schools to educate, recruit, and retain qualified teachers is fueling the nurse faculty shortage. Potential faculty members graduating from schools of nursing are slow to rise. In 2006, graduations from research-focused doctoral nursing programs were up by only 1.4 percent or six graduates from the 2005–2006 academic year. Complicating the problem further, those that are graduating from schools of nursing with a graduate degree are not choosing a career in education. An unpublished AACN study on employment plans found that almost a quarter of all graduates from doctoral nursing programs do not plan to work in academic settings. Higher compensation in clinical and private sector settings lures current and potential nurse educators away from the classroom.

Furthermore, the demand for nurse faculty will continue to grow in the very near future as schools of nursing will experience an increase in faculty retirement. According to an article published in the March/April 2002 issue of Nursing Outlook titled The Shortage of Doctorally Prepared Nursing Faculty: A Dire Situation, the average age of nurse faculty at retirement is 62.5 years. With the average age of doctorally-prepared faculty currently 53.5 years, a wave of retirements is expected within the next 10 years. Without sufficient nurse faculty, schools of nursing cannot expand enrollments, and the nursing shortage will continue to cripple our Nation's health care delivery system.

REVERSING THE NURSE FACULTY SHORTAGE AND NURSING EDUCATIONAL BARRIERS

The Nursing Workforce Development programs are essential in not only educating nurses, but more critically, in funding the education of additional nurse faculty. In fiscal year 2008, AACN recommends increasing funding for graduate education through the Advanced Education Nursing (AEN) Grants (Sec. 811) and bolstering funds for the Nurse Faculty Loan Program (Sec. 846A) as well as the Nurse Education, Practice, and Retention Grants (Sec. 831). These programs are essential in educating nurses, but more importantly in funding the education of nurse faculty, which allow schools of nursing to increase their student capacity.

Advanced Education Nursing Program (Sec. 811).—These grants support the majority of nursing schools preparing graduate-level nurses, many of whom become faculty. Receiving $57.06 million in fiscal year 2007, this grant program helps schools of nursing, academic health centers, and other nonprofit entities improve the education and practice of nurse practitioners, nurse-midwives, nurse anesthetists, nurse educators, nurse administrators, public health nurses, and clinical nurse specialists. Out of the 114 applications reviewed for program grants in fiscal year 2006, 45 new grants were awarded and 112 previously awarded grants were continued, totaling 157—the same number as in fiscal year 2004 and fiscal year 2005. In addition, 564 schools of nursing received traineeship grants, which in turn directly supported 9,000 individual student nurses. In fact, 2,105 nurses who received support from AEN grants in fiscal year 2006 are now practicing in underserved areas.

Nurse Faculty Loan Program (Sec. 846A).—Designed to increase the number of nurse faculty, schools of nursing receive grants to create a loan fund through the Nurse Faculty Loan Program. To be eligible for these loans, students must pursue full-time study for a master's or doctoral degree. In exchange for teaching at a school of nursing, loan recipients will have up to 85 percent of their educational loans cancelled over a 4-year period. In fiscal year 2006, 67 new grants and 26 continuing grants were awarded to schools of nursing. These grants are projected to assist 475 future nurse educators. Unfortunately, in fiscal year 2006 schools of nursing requested over three times the funds available to educate additional nurse faculty. In fiscal year 2007, $4.77 million was appropriated. If the current funding was doubled to almost $10 million, based on fiscal year 2006 projections, nursing schools

could educate over 900 future faculty members. Further, with an average faculty to student ratio of 1:10, those 900 faculty members could teach an additional 9,000 nurses each year.

Nurse Education, Practice, and Retention Grants (Sec. 831).—These grants help schools of nursing, academic health centers, nurse-managed health centers, State and local governments, and health care facilities strengthen programs that provide nursing education. In particular, the Education Grants expand enrollments in baccalaureate nursing programs. In addition, they develop internship and residency programs to enhance mentoring and specialty training as well as provide for new technology in education, including distance learning.

NATIONAL INSTITUTE OF NURSING RESEARCH

One of the 27 Institutes and Centers at the National Institutes of Health, the National Institute of Nursing Research (NINR) works to improve patient care and foster advances in nursing and other health professions' practice. The outcomes-based findings derived from NINR research are important to the future of the health care system and its ability to deliver safe, cost-effective, and high quality care. Through grants, research training, and interdisciplinary collaborations, NINR addresses care management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, enhancement of quality of life in those with chronic illness, and care for individuals at the end of life. To advance this research, AACN respectfully requests a funding level of $150 million in fiscal year 2008, an additional $12.66 million over the $137.34 million, NINR received in fiscal year 2007,

NINR Addresses the Shortage of Nurse Researchers and Faculty

NINR allocates 7 percent of its budget, a high proportion when compared to other NIH institutes, to research training to help develop the pool of nurse researchers. In fiscal year 2005, NINR training dollars supported 80 individual researchers and provided 155 institutional awards, which in turn supported a number of nurse researchers at each institution. Since nurse researchers often serve as faculty members for colleges of nursing, they are actively educating our next generation of RNs.

CONCLUSION

AACN acknowledges the fiscal challenges that the subcommittee and the entire Congress must work within. However, the nursing shortage can no longer be explained by the need to simply increase the number of nurses in the workforce. A demand for nurse educators weighs heavily on the ability to increase the pool of future nurses. This element of the shortage has created a negative chain reaction—without more nurse faculty, additional nurses cannot be educated, and without more nurses the shortage will continue. Ultimately, this chain reaction will continue to place the health care delivery system at risk. Title VIII programs can help to break this chain. These authorities provide a dedicated, long-term vision for supporting the education of the new nursing workforce. Yet, they must receive additional funding to be effective. AACN respectfully requests $200 million for Title VIII programs in fiscal year 2008. Additional funding for these programs will assist schools of nursing to expand their programs, educate more nurse faculty, increase the number of practicing RNs, and ultimately improve the patient care provided in our health care system. AACN also requests $150 million for NINR so that nurse researchers can continue their work to improve the nursing care provided to all patients.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF OSTEOPATHIC MEDICINE

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM), which represents the administrations, faculties, and students of all twenty-three colleges of osteopathic medicine in the United States, I am pleased to present our views on the fiscal year 2008 appropriations for Health Professions Education Programs under Title VII of the Public Health Service Act.

First, we want to express our profound concern at the devastating cuts sustained by the Title VII programs in appropriations for the last two fiscal years. The fiscal year 2006 Labor, Health and Human Services, Education and Related Agencies Appropriations bill cut Title VII programs from the fiscal year 2005 level by 51.5 percent. Unfortunately, the fiscal year 2007 funding level restored only a small fraction of these cuts.

Health Professions Education Programs under Title VII are essential components of America's health care safety net. An adequate, diverse, well-distributed and cul-

turally competent health workforce is indispensable to meeting our current and especially our future health service delivery needs. The Title VII programs have been especially valuable in our efforts to ensure continuation of this commitment. In Public Law 105–392, the Health Professions Education Partnership Act of 1998, forty-four different Federal health professions training programs were consolidated into seven clusters. These clusters provide support for training of primary care medicine and dental providers; the establishment and operation of interdisciplinary community-based training activities; health professions workforce analysis; public health workforce development; nursing education; and student financial assistance. These programs are designed to meet the health care delivery needs of over 2,800 Health Professions Shortage Areas in the country. Many rural and disadvantaged populations depend on the health professionals trained by these programs as their only source of health care. For example, without the practicing family physicians who are currently in place, an additional 1,332 of the United States' 1,082 urban and rural counties would qualify for designation as primary care Health Professions Shortage Areas.

Title VII programs have had a significant impact in reducing the Nation's Health Professions Shortage Areas. Indeed, a 1999 study estimated that if funding for Title VII program were doubled, the effect would be to eliminate the Nations' Health Professions Shortages Areas in as little as 6 years. (Politzer, RM, Hardwick, KC, Cultice, JM, Bazell, C. "Eliminating Primary Care Health Professions Shortage Areas: The Impact of Title VII Generalist Physician Education," The Journal of Rural Health, 1999: 15(1): 11–19).

A study by the Robert Graham Center showed that receipt of Title VII family medicine grants by medical schools produced more family physicians and more primary care doctors serving in rural areas and Health Professions Shortage Areas. Over 69 percent of Title VII funded internal medicine graduates practice primary care after graduation. This rate is nearly twice that of programs not receiving Title VII funding.

Among the programs within these clusters that have been especially important to enhancing osteopathic medical schools' ability to train the highest quality physicians are: General Internal Medicine Residencies; General Pediatric Residencies; Family Medicine Training; Preventive Medicine Residencies; Area Health Education Centers (AHECs); Health Education and Training Centers (HETCs); Health Careers Opportunity Programs (HCOP); Centers of Excellence (COE) programs; and Geriatric Training Authority.

Accordingly, Mr. Chairman and Members of the subcommittee, AACOM recommends that the fiscal year 2008 funding for Title VII Health Professions Education Programs and the equally important programs under Title VIII, Nursing Education be at least $550 million. This figure is consistent with the fiscal year 2008 level recommended by the Health Professions and Nursing Education Coalition (HPNEC) for Titles VII and VIII.

AACOM also strongly urges continuation of funding for the Council on Graduate Medical Education (COGME). Since its inception, COGME's diverse membership has given the health policy community an opportunity to discuss national workforce issues. The fifteen formal reports and multiple ancillary materials provided by COGME have offered important findings and observations in the rapidly changing health care environment and have argued for a system of graduate medical education that develops a physician workforce to meet the healthcare needs of the American people.

Some of the more significant recommendations include:

—Community-based education with an emphasis on primary care;
—Continued progress toward a more representative participation of minorities in medicine;
—The development and maintenance of a workforce planning infrastructure to improve the understanding, need and demand forces;
—The development of Federal-State partnerships to further workforce planning; and
—Encouragement and support for medical education and health care delivery programs that increase the flow of physicians to rural areas, with an emphasis on the smaller, more remote communities.

With a projected physician workforce shortage looming, the activities of COMGE have never been more important.

Mr. Chairman and members of the subcommittee, we appreciate the opportunity to submit this statement. If you have any questions or require additional information, please contact me at (301) 968–4141 or sshannon@aacom.org, or Michael J. Dyer, AACOM's Vice President for Government Relations at (301) 968–4152 or mdyer@aacom.org.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY

HHS SUPPORTED PROGRAMS AT COLLEGES AND SCHOOLS OF PHARMACY

AACP and its member colleges and schools of pharmacy appreciate the continued support of the House Appropriations Subcommittee on Labor, Health and Human Services, and Education. The 97 accredited colleges and schools of pharmacy are engaged in a wide-range of programs that are supported by grants and funding administered through the agencies of the Department of Health and Human Services (HHS). We also understand the difficult task you face annually in your deliberations to do the most good for the Nation and remain fiscally responsible to the same. AACP respectfully offers the following recommendations for your consideration as you undertake your deliberations.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AACP supports the Friends of AHRQ recommendation of $350 million for AHRQ programs in fiscal year 2008.

AACP also recommends that the committee direct AHRQ to reestablish the provider-based research network grant program.

The Institute of Medicine (IOM) published two reports in 2006 regarding the reduction of medication use errors and how we can improve medication safety http://www.nap.edu/catalog/11623.html#toc and http://www.nap.edu/catalog/11750.html#toc. Faculty at colleges and schools of pharmacy are actively engaged in teaching, research, and service to their communities that addresses nearly every one of these report recommendations. Our schools have significant community partnerships that can be furthered enhanced through congressional restoration of the provider-based research network program at AHRQ.

AACP members are active grantees in AHRQ Effective Health Care Program, providing advice on how pharmacy and pharmaceutical technology reduce medical errors and provide for greater patient safety.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The fiscal 2008 funding for the CDC should be increased to $6.44 billion to restore funding for the preventive health and health services block grants, to restore the health promotion line item to at least fiscal year 2005 levels, and to allow the CDC to continue to focus on keeping our Nation well and healthy. AACP also supports the Friends of the National Center for Health Statistics (NCHS) recommendation that fiscal year 2008 funding be $117 million.

The curriculum of the Nation's colleges and schools of pharmacy now includes significant focus on public health. Much of this focus is supported by research, information, and programs developed by the Centers for Disease Control and Prevention (CDC). For example, the public health elective offered by the University of Montana School of Pharmacy requires students to purchase the CDC's "Epidemiology and Prevention of Vaccine-Preventable Diseases."

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

AACP supports the Friends of HRSA recommendation of at least $7.65 billion for HRSA in fiscal year 2008.

Many research, education, and service activities at our Nation's colleges and schools are supported by HRSA. Over the last 6 years, HRSA and academic pharmacy have forged a much closer working relationship. This strengthened tie is increasing access to comprehensive pharmacy services, including better utilization of the 340B drug assistance program, for patients served by HRSA grantees and programs. Working more closely with academic pharmacy has also improved the care provided by HRSA supported providers as evidenced in the clinical pharmacy demonstration projects implemented in 18 community health centers across the country. The recognition of U.S colleges and schools of pharmacy as a resource to the public health safety-net providers can play a significant role in improving programs such as the Ryan White AIDS programs, including the AIDs Drug Assistance Programs, rural health and telemedicine programs, just as it has the community health centers program. We would encourage you to request that HRSA continue to utilize the academy as a resource for program improvement.

As mentioned above, AACP members are actively engaged with many HRSA programs or with HRSA grantees. The following are examples of that engagement.

COMMUNITY HEALTH CENTERS

AACP recommends that the subcommittee provide $100 million within the total funding appropriations to CHCs for the development of new comprehensive pharmacy programs. AACP further recommends that $50 million be made available within the total CHC appropriation for the creation of shared teaching positions between CHCs and colleges and schools of pharmacy to develop and support comprehensive pharmacy services programs. Another option for integrating comprehensive pharmacy services into CHC services would be to place the cost associated with this integration into the base budget of CHC grants.

Relationships between CHCs and academic pharmacists could decrease the gap between the "bench" and the "bedside" in medication management, resulting in more effective, cost-efficient medication therapy. CHCs and academic pharmacy institutions continue to forge an essential link towards improving the health care provided to patients. As the recognized key link in America's health safety net CHCs should be encouraged to improve or develop comprehensive pharmacy services within their institutions.

TITLE VII HEALTH PROFESSIONS EDUCATION PROGRAMS

AACP supports the Health Professions and Nursing Education coalition (HPNEC) recommendation of $300 million for Title VII programs in fiscal year 2008.

For nearly every health profession tracked by the U.S. Bureau of Labor Statistics, high demand will remain for the foreseeable future. Interprofessional education has the potential to help improve health care quality and create greater efficiencies by allowing health professionals to work productively together. NIH has also recognized the growing acceptance of interprofessional research through the "Road Map," including allowing multiple primary investigators. Colleges and schools of pharmacy are taking a leadership role in the creation of interprofessional approaches to health professions education. Faculty are working across disciplines to develop interprofessional programs and assess their effectiveness through: federally supported programs such as Area Health Education Centers across the country; organizations such as the Institute for Healthcare Improvement and the Association of Academic Health Center; and university level mandates such as that of the University of Minnesota. It is essential that Federal support for interprofessional education be maintained.

NATIONAL HEALTH SERVICES CORPS

AACP recommends that funding for these programs continue to increase, at least at a rate that takes into account inflation, and waiting lists.

As integral as the CHCs are, they require health professionals to provide the care. While the Title VII programs are essential in creating the education programs that create culturally competent health professionals able to provide team-based, patient-centered care, the NHSC is the program that gets those providers to the community in greatest need. Annual appropriations for the NHSC continue to increase in recognition of the role this program plays in helping to improve access to care in medically underserved and health professions shortage areas.

OFFICE OF RURAL HEALTH POLICY

AACP recommends that the subcommittee fully restore funding to Rural Health Care Programs. The ORHP supported Rural Health Research Centers grant program is the only source of rural-specific health services research supported by the HHS. Rural Health Research Centers collaborate with schools and colleges of pharmacy in rural health research and dissemination. A paper published by the Upper Midwest Rural Health Center (UMRHC) identified pharmacist staffing, finance, and access to technology as barriers to medication safety in rural hospitals. Through a nationwide survey, the UMRHC found a significant positive relationship between pharmacist staffing and the presence and quality of medication safety initiatives in rural hospitals. Better access to pharmacists in rural hospitals is necessary for reducing medication errors and implementing medication safety systems.

OFFICE OF TELEHEALTH ADVANCEMENT

AACP recommends that the subcommittee increase the fiscal year 2008 appropriation for telehealth to $7 million. AACP further recommends that the subcommittee direct the HRSA Office for the Advancement of Telehealth to include development of telepharmacy programs as an explicit grant funding option.

Colleges and schools of pharmacy, including North Dakota State University College of Pharmacy, Washington State University College of Pharmacy, and Texas

Tech University have developed successful telepharmacy programs that are assisting rural providers and their patients improve the management of their medications. The North Dakota Telepharmacy Program has restored, retained, or established pharmacy services to approximately 40,000 rural citizens in North Dakota and Minnesota. The project has not only increased access to medically underserved areas, but has also added approximately $12 million in economic development to the local rural economies. Duquesne University Mylan School of Pharmacy, located in Pittsburgh, Pennsylvania, has developed and implemented a telepharmacy program that is assisting hospice providers in rural southeastern Pennsylvania, Ohio, West Virginia.

NATIONAL INSTITUTES OF HEALTH

AACP, as a member of the Ad Hoc Group for Biomedical Research Funding recommends that fiscal year 2008 NIH funding be increased by 6.7 percent and this same increase be continued for the next 2 years.

AACP would also ask the Congress to commend the NIH for its development of the "PharmD Gateway to NIH" and support efforts for NIH to create opportunities for the development of new clinical pharmacy faculty research.

Our Nation benefits greatly from both intra and extramural NIH research. Our Nation's colleges and schools of pharmacy play an important part in that research agenda. Academic pharmacy supports the NIH Director's Road Map initiative and is especially pleased with recent decisions to allow multiple primary investigators on grants and the support of interdisciplinary research. According to 2006 NIH data, colleges and schools of pharmacy rank fourth after medicine, public health and biomedical engineering in total extramural grant funding. AACP is pleased to recognize the committee for its important role in doubling the NIH budget, however there is growing concern that without continued increases to the NIH budget that work will have been negated. In fiscal year 2006 biomedical research conducted by faculty at U.S. colleges and schools of pharmacy was supported by $239.7 million. Biomedical research is our Nation's best opportunity for finding cures for disease and reducing the economic burden of illness and chronic illness. The research of academic pharmacy faculty in discovery and application is essential at a time when we grow more dependent on medications to reduce the impact of chronic and acute illness and unexpected threats to our public health.

U.S. DEPARTMENT OF EDUCATION

AACP is pleased that the President continues to recognize the importance of higher education to America's global competitiveness. What is of growing concern is that the priorities of the administration frequently come at the expense of existing programs of importance to students attending colleges and schools of pharmacy and the other institutions of higher learning they attend in preparation. The ability of students to be fully prepared to begin pharmacy studies has been heightened through participation in college preparation courses for high school students, summer programs for graduated high school students, and students entering their professional education through programs such as GEAR UP and TRIO. We support the recommendation of the Student Aid Alliance that fiscal year 2008 program funding be $350 million and $1 billion respectively.

Academic pharmacy is a leader among the health professions education community in regard to the development of objective, measurable, terminal educational outcomes. Because of growing concern about the assessment of student learning and the value-added aspects of higher education, faculty at our Nation's colleges and schools of pharmacy are ideal resources to work beyond the politics of the Spellings Commission on Higher Education. Academic pharmacy is committed to improving and demonstrating the value of pharmacy education. This commitment led to the creation of AACP's Center for the Advancement of Pharmaceutical Education (CAPE). CAPE has established and recently redefined and expanded educational outcomes. The CAPE outcomes are intended to guide individual institutions in curriculum development. The Accrediting Council on Pharmaceutical Education (ACPE) has adapted these educational outcomes into its recently revised standards and guidelines.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR DENTAL RESEARCH (AADR) AND THE AMERICAN DENTAL EDUCATION ASSOCIATION (ADEA)

Discoveries stemming from dental research have reduced the burden of oral disease, have led to better oral health for tens of millions of Americans, and have un-

covered important associations between oral and systemic health. Now, dental researchers and educators are poised to make new breakthroughs that can result in dramatic progress in medicine and health, such as repairing natural form and function to faces destroyed by disease, accident, or war injuries; diagnosing systemic disease from saliva instead of blood samples; and deciphering the complex interactions and causes of oral health care disparities involving social, economic, cultural, environmental, racial/ethnic, and biological factors. Dental research in large part takes place in academic dental institutions where the future oral health workforce receives education and training and provides oral health care that improves the health of the public. Dental research and education are the underpinning of the profession; they enhance the quality of the Nation's oral and overall health. This testimony will cover the following programs and issues:

1. Oral Health Research—The National Institutes of Health (NIH) and the National Institute of Dental and Craniofacial Research (NIDCR)—
   a. Elimination of America's most prevalent infectious disease,
   b. Saliva as a diagnostic tool,
   c. Understanding factors that cause disparities in oral health,
   d. Emerging Possibilities from Dental Researchers,
2. Dental Education—Title VII General Dentistry and Pediatric Dentistry and Workforce Training Programs.
3. Access to Dental Care—
   a. State Children's Health Insurance Program (SCHIP),
   b. Dental Health Improvement Act,
   c. Centers for Disease Control and Prevention: Division of Oral Health,
   d. and Ryan White CARE Act: Dental Reimbursement and Community-based Partnerships Programs

INTRODUCTION

The American Association for Dental Research (AADR) represents the oral health research community within the United States, and the American Dental Education Association (ADEA) represents over 120 academic dental institutions as well as all of the educators, researchers, residents and students training at these institutions. Together our organizations represent over 21,000 members in academic dental and dental research institutions throughout the Nation. The joint mission of AADR and ADEA is to enhance the quality and scope of oral health, advance research and increase knowledge for the improvement of oral health, and increase opportunities for scientific innovation. Academic dental institutions play an essential role in conducting research and educating and training the future oral health workforce. Academic dental institutions provide dental care to underserved low-income populations, including individuals covered by Medicaid and the State Children's Health Insurance Program.

We thank the committee for this opportunity to submit testimony regarding the exciting advances in oral health sciences. There are extraordinary opportunities being created through oral health research and education. Herein we submit our fiscal year 2008 budget recommendations for the National Institute of Dental and Craniofacial Research (NIDCR), Title VII Health Professions Education and Training Programs administered by the Health Resources and Services Administration (HRSA), the Dental Health Improvement Act, the State Children's Health Insurance Program (SCHIP), the Centers for Disease Control and Prevention's Oral Health Programs, and the Ryan White CARE Act, HIV/AIDS Dental Reimbursement Program and the Community Based Dental Partnership Program.

ORAL HEALTH RESEARCH

Dental research is concerned with the prevention, causes, diagnosis, and treatment of diseases and disorders that affect the teeth, mouth, jaws, and related systemic diseases. Dental health is an important, vital part of health throughout life, and through dental research and education, we can enhance the quality and scope of oral health. Dental research has produced tremendous benefits for the health and well-being of our Nation and the world. Nonetheless, much remains to be done as identified in the Surgeon General's Report of 2000—Oral Health in America [1] and in the 2003—National Call to Action to Promote Oral Health.[2]

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[1] Oral Health in America: A Report of the Surgeon General, U.S. Department of Health and Human Services, 2000.

[2] National Call to Action to Promote Oral Health, U.S. Department of Health and Humans Services, 2003.

We applaud Congress for demonstrating its overwhelming bipartisan support for NIH by passing the NIH Reform Act of 2006. This reauthorization legislation is an affirmation of the importance of NIH and its vital role in advancing biomedical research to improve the health of the Nation. A renewed national commitment to research and fighting disease, through increased support for the NIH, will allow us to capitalize on new and unprecedented scientific opportunities in oral health research.

Eliminating American's most prevalent infectious disease

America's most prevalent infectious disease is dental decay (caries)! It is five times more common than asthma and seven times more common than hay fever in school children. Americans spend millions of dollars annually in dental caries treatments and tooth restoration. Over the past 50 years, discoveries stemming from dental research have reduced the burden of dental caries (tooth decay) for many Americans. Now, the burden of the disease, in terms of both extent and severity, has shifted dramatically to a subset of our population. About a quarter of the population now accounts for about 80 percent of the disease burden. Dental caries remains a significant problem for vulnerable populations of children and people who are economically disadvantaged, elderly, chronically ill, or institutionalized.

Dental caries is a chronic, infectious disease process that occurs when a relatively high proportion of bacteria within dental plaque begin to damage tooth structure. Most infectious diseases are treated through medications, not surgery. But, it has been difficult to treat caries this way because our existing diagnostic techniques lack the sensitivity to catch it early enough. New strategies for the prevention, diagnosis, cure and repair of dental caries are being studied and developed by scientists funded through the NIDCR. If caries can be diagnosed before irreversible loss of tooth structure occurs, it can be reversed using a variety of approaches that "remineralize" the tooth. In addition to improved diagnostics, some researchers are working to develop a vaccine to prevent tooth decay, while others use new methods to specifically target and kill the decay-causing bacteria.

Saliva as a Diagnostic Tool

The development of new diagnostic tests based on the analysis of biomarkers in saliva will allow clinicians to more reliably diagnose disease and monitor health conditions much earlier than is currently possible. Salivary diagnostics is already being used for rapid, non-invasive HIV screening, and saliva-based tests will soon be available for oral cancer screening. Oral cancers and cancer of the larynx are diagnosed in 41,000 individuals accounting for 12,500 deaths per year in the United States. The death rate associated with this cancer is especially high due to delayed diagnosis. Now, scientists funded by the NIDCR have taken a major step forward in using saliva to detect oral cancer. Elevated levels of distinct, cancer-associated molecules in saliva can be used to distinguish between healthy people and those with cancer. Soon, with further research, commercial diagnostic tests will be developed for oral squamous cell carcinoma with the 99+ percent accuracy expected for such tests.

Using saliva may also be possible for diagnosing and monitoring many other systemic health conditions as well as exposure to chemical and biological agents. Early diagnosis could potentially save thousands of lives.

Understanding Factors that Cause Disparities in Oral Health

Despite tremendous improvements in the Nation's oral health over the past decades, the benefits have not been equally shared by millions of low-income and underserved Americans. High-risk populations, including poor, inner-city, elderly, rural, and groups with special health-care needs, all suffer a disproportionate and debilitating amount of oral disease. Research is needed to identify the factors that determine disparities in oral health and disease. These factors may include proteomic, genetic, environmental, social, and behavioral aspects and how they influence oral health singly or in combination. Translational and clinical research is underway to analyze the prevalence, etiology, and impact of oral conditions on disadvantaged and underserved populations and on the systemic health of these populations. In addition, community- and practice-based disparities research, funded by the NIDCR and the Centers for Disease Control and Prevention's Oral Health Programs, can help to identify and reduce risks, enhance oral health-promoting behaviors, and help integrate research findings directly into oral health care practice.

Other Emerging Exciting Areas in Dental Research

Looking towards the future—imagine a time when you won't need x-rays to diagnose tooth decay; instead a molecular or electronic probe will do the job. Or imagine

teeth being restored to health, not with fillings, but with simple mineral rinses or bioengineering techniques. This is closer to reality than you might envision!

—*Tissue engineering*.—Tissue engineering holds great potential to repair the ravages of orofacial disease, trauma, war injuries, and birth defects, including the bioengineering of complete, fully functional replacement teeth.

—*Stem cells*.—Isolating stem cells from the ligament around third molars (wisdom teeth) and from human exfoliated deciduous teeth (baby teeth) holds the distinct possibility that one day—in the near future—we may be able to repair dental and craniofacial defects by growing new tissues.

—*System-oral health linkages*.—There is strong evidence of an association between gum (periodontal) disease and systemic events such as cardiovascular disease, diabetes, and adverse pregnancy outcomes. Continued oral health research will provide insight into the prevention and treatment of these and other systemic conditions with links to oral health.

—*Practice Based Research Networks*.—By connecting practitioners with experienced clinical investigators, Practice Based Research Networks (PBRNs) can enhance the utility of clinical research funded by NIDCR by developing data and new techniques that may be immediately relevant to practitioners and their patients.

DENTAL EDUCATION

Title VII Programs, Public Health Service Act

Title VII Education and Training Programs are critical. Support for these programs is essential to expanding existing or establishing new general dentistry and pediatric dentistry residency programs. Title VII general and pediatric dental residency training programs have shown to be effective in increasing access to care and enhancing dentists' expertise and clinical experiences to deliver a wide range of oral health services to a broad patient pool, including geriatric, pediatric, medically compromised patients, and special needs patients. Title VII support increases access to care for Medicaid and SCHIP populations. The value of these programs is underscored by reports of the Advisory Committee on Training in Primary Care Medicine and Dentistry and the Institute of Medicine. Without adequate funding for general dentistry and pediatric dentistry training programs it is anticipated that access to dental care for underserved populations will worsen.

AADR/ADEA also supports the funding requests advanced by National Council for Diversity in the Health Professions for the Health Resources and Services Administration's diversity programs, namely the Scholarship for Disadvantaged Students, Health Careers Opportunity Program, Centers of Excellence, and the Faculty Loan Repayment Program.

ACCESS TO DENTAL CARE

State Children's Health Insurance Program

Reauthorization of the State Children's Health Insurance Program (SCHIP) represents a singular opportunity to move closer to the widely-shared goal of ensuring that all of America's children have health care coverage. Congress has taken a significant step in that direction by signaling in the House and Senate budget resolutions a willingness to provide $50 billion in new funding for SCHIP reauthorization. Now, relying on the bipartisan support for SCHIP, Congress must work to ensure in a timely manner that SCHIP reauthorization legislation is fully funded and that it includes policies that will support States' efforts to cover more children.

Minority, low-income, and geographically isolated children suffer disproportionately from dental conditions. Dental care tops the list of parent reported unmet needs, with parent reports of unmet dental needs three times as often as medical care and four times that of vision care. For children with special needs, dental care is the most prevalent unmet health care need surpassing mental health, home health, hearing aids and all other services. Despite the magnitude of need, dental coverage has remained an optional benefit in SCHIP. All States have recognized that poor oral health affects children's general health and have opted to provide dental coverage. However, dental coverage is often the first benefit cut when States seek budgetary savings. SCHIP lacks a stable and consistent dental benefit that would provide a comprehensive approach to children's health while reducing costly treatments caused from advanced dental disease. Congress can help stabilize access to oral health care services to underserved children by improving funding for the SCHIP program. It is vital that Congress deliver on its pledge for children's health coverage of $50 billion in new funds for SCHIP and Medicaid as indicated in the congressional budget resolutions. This level of funding is the minimum amount needed to allow States to sustain their existing SCHIP programs, reach a significant

share of the uninsured children already eligible for SCHIP and Medicaid, and support ongoing State efforts to expand oral health care coverage.

Dental Health Improvement Act

The recent reports of tragic deaths of Deamonte Driver, a 12-year-old from Maryland, and Alexander Callender, a 6-year-old from Mississippi, as a result of unmet dental needs tragically illustrate that all children regardless of resources or economic status should have access to oral health care.

Congress provided first-time funding of $2 million in fiscal year 2006 for the Dental Health Improvement Act, a program established in 2001, to assist States in developing innovative dental workforce programs. The first grants were awarded to States last Fall and are being used for a variety of important initiatives including: increasing hours of operation at clinics caring for underserved populations, recruiting and retaining dentists to work in these clinics, prevention programs including water fluoridation, dental sealants, nutritional counseling, and augmenting the State dental offices to coordinate oral health and access issues.

Centers for Disease Control and Prevention (CDC) Division of Oral Health

The Centers for Disease Control and Prevention Oral Health Program expands the coverage of effective prevention programs by building basic capacity of State oral health programs to accurately assess the needs in their State, organize and evaluate prevention programs, develop coalitions, address oral health in State health plans, and effect allocation of resources to the programs. CDC's funding and technical assistance to States is essential to help oral health programs build capacity.

An additional $4 million over fiscal year 2007 funding of $11.6 million is necessary so additional States requesting support to improve their capacity to validate, build, and sustain effective preventive interventions to reduce health disparities among their citizens can be funded. Funding for current grantees expires at the end of fiscal year 2007. Twenty-four States have previously applied for these grants but due to limited funding only 12 States were awarded. Increasing CDC funding will help to ensure that all States that apply may be awarded an oral health grant.

Dental Reimbursement and Community-based Dental Partnership Program

Congress designated dental care as a "core medical service" when it reauthorized the Ryan White program in 2006. The Dental Reimbursement Program provides access to quality dental care to people living with HIV/AIDS while simultaneously providing educational and training opportunities to dental residents, dental students, and dental hygiene students who deliver the care. The Dental Reimbursement Program is a cost-effective Federal/institutional partnership that provides partial reimbursement to academic dental institutions for costs incurred in providing dental care to people living with HIV/AIDS. The Community-Based Dental Partnership Program fosters partnerships between dental schools and communities lacking academic dental institutions to ensure access to dental care for HIV/AIDS patients living in those areas.

AADR/ADEA FISCAL YEAR 2008 FUNDING RECOMMENDATIONS SUMMARY

To maintain support for the biomedical research at the NIH AADR/ADEA recommends $31.3 billion for the National Institutes of Health (NIH) including $425 million for the National Institute of Dental and Craniofacial Research (NIDCR).

Support the development of innovative dental workforce programs specific to States' needs and increase access to dental care for underserved populations. AADR/ADEA recommends $10 million for the Dental Health Improvement Act.

Help build basic capacity of State oral health programs. AADR/ADEA recommends $15.6 million for the CDC Dental Block Grants.

Support education and training of the dental workforce for the future. AADR/ADEA recommends $450.2 million for the full complement of Title VII health professions programs including:

—$89 million for the primary care medicine and dentistry cluster to assure:
  —$10 million for General and Pediatric Dental Residency Training.
—$118 million for the diversity and student assistance cluster:
  —$33.6 million for Centers of Excellence;
  —$35.6 million for Health Careers Opportunity Program;
  —$1.3 million for the Faculty Loan Repayment Program; and
  —$47.1 million for Scholarships for Disadvantaged Students.

Help provide access to oral health care services in SCHIP. AADR/ADEA recommends $50 billion in new funds for SCHIP and Medicaid.

Assist people with HIV/AIDS, whose immune systems are weakened, to have access to quality dental care. AADR/ADEA recommends $19 million for of the Ryan

White HIV/AIDS Treatment and Modernization Act, the Dental Reimbursement Program and the Community-based Dental Partnerships Program.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

The American Association for Geriatric Psychiatry (AAGP) appreciates this opportunity to present its recommendations on issues related to fiscal year 2008 appropriations for mental health research and services. AAGP is a professional membership organization dedicated to promoting the mental health and well being of older Americans and improving the care of those with late-life mental disorders. AAGP's membership consists of approximately 2,000 geriatric psychiatrists as well as other health professionals who focus on the mental health problems faced by senior citizens.

AAGP appreciates the work this subcommittee has done in recent years in support of funding for research and services in the area of mental health and aging through the National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration (SAMHSA). Although we generally agree with others in the mental health community about the importance of sustained and adequate Federal funding for mental health research and treatment, AAGP brings a unique perspective to these issues because of the elderly patient population served by our members.

DEMOGRAPHIC PROJECTIONS AND THE MENTAL DISORDERS OF AGING

With the baby boom generation nearing retirement, the number of older Americans with mental disorders is certain to increase in the future. By the year 2010, there will be approximately 40 million people in the United States over the age of 65. Over 20 percent of those people will experience mental health problems.

Current and projected economic costs of mental disorders alone are staggering. It is estimated that total costs associated with the care of patients with Alzheimer's disease is over $100 billion per year in the United States. Psychiatric symptoms (including depression, agitation, and psychotic symptoms) affect 30 to 40 percent of people with Alzheimer's and are associated with increased hospitalization, nursing home placement, and family burden. These psychiatric symptoms, associated with Alzheimer's disease, can increase the cost of treating these patients by more than 20 percent.

Depression is another example of a common problem among older persons. Of the approximately 32 million Americans who have attained age 65, about 5 million suffer from depression, resulting in increased disability, general health care utilization, and increased risk of suicide. Depression is associated with poorer health outcomes and higher health care costs. Co-morbid depression with other medical conditions affects a greater use and cost of medications as well as increased use of health services (e.g., medical outpatient visits, emergency visits, and hospitalizations). For example, individuals with depression are admitted to the emergency room for hypertension, arthritis, and ulcers at nearly twice the rate of those without depression. Those individuals with depression are more likely to be hospitalized for hypertension, arthritis, and ulcers than those without depression. Those with depression experience almost twice the number of medical visits for hypertension, arthritis and ulcers than those without depression. Finally, the cost of prescriptions and number of prescriptions for hypertension, arthritis, and ulcers were more than twice than those without depression.

Older adults have the highest rate of suicide compared to any other age group. Comprising only 13 percent of the U.S. population, individuals age 65 and older account for 19 percent of all suicides. The suicide rate for those 85 and older is twice the national average. More than half of older persons who commit suicide visited their primary care physician in the prior month—a truly stunning statistic.

THE CHALLENGE OF MEETING THE MENTAL HEALTH NEEDS OF THE AGING POPULATION—PROPOSAL FOR IOM STUDY ON MENTAL HEALTH WORKFORCE NEEDS OF OLDER AMERICANS

The Institute of Medicine (IOM) of the National Academy of Sciences is currently undertaking a study of the readiness of the Nation's healthcare workforce to meet the needs of its aging population. IOM has recommended in discussions with AAGP that, because this study will not delve deeply into the composition of the mental health workforce needed to meet future needs of the elderly, a complementary study be undertaken to consider specifically this vital area of concern. This complementary study will focus on the mental health professional workforce that will be needed to

meet the demands of the aging population in this country. IOM is extremely supportive of this proposed study and feel that it would complement their current study on broad health needs of older adults. IOM has advised AAGP that $1 million would be needed to undertake this complementary mental health study.

In discussions with AAGP, the senior staff of IOM suggested the following language for inclusion in the fiscal year 2008 Labor HHS Appropriations bill:

"The committee provides $1,000,000 for a study by the Institute of Medicine of the National Academy of Sciences to determine the multi-disciplinary mental health workforce needed to serve older adults. The initiation of this study should be not later than 60 days after the date of enactment of this act, whereby the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a thorough analysis of the forces that shape the mental health care workforce for older adults, including education, training, modes of practice, and reimbursement."

This proposal for funding for an IOM study on mental health workforce needs of older Americans is supported by the IOM, and AAGP strongly urges its inclusion in the fiscal year 2008 Labor HHS Appropriations bill.

NATIONAL INSTITUTE OF MENTAL HEALTH

In his fiscal year 2008 budget, the President again proposed decreased funding for the National Institutes of Health (NIH). This decline in funding would have a devastating impact on the ability of NIH to sustain the ongoing, multi-year research grants that have been initiated in recent years.

AAGP would like to call to the subcommittee's attention the fact that, even in the years in which funding was increased for NIH and NIMH, these increases did not always translate into comparable increases in funding that specifically address problems of older adults. Data supplied to AAGP by NIMH indicates that while extramural research grants by NIMH increased 59 percent during the 5-year period from fiscal year 1995 through fiscal year 2000 (from $485,140,000 in fiscal year 1995 to $771,765,000 in fiscal year 2000), NIMH grants for aging research increased at less than half that rate: only 27.2 percent during the same period (from $46,989,000 to $59,771,000).

Despite the fact that over the past 6 years Congress, through committee report language, has specifically urged NIMH to increase research grant funding devoted to older adults, this has not occurred. The critical disparity between Federally funded research on mental health and aging and the projected mental health needs of older adults is continuing. If the mental health research budget for older adults is not substantially increased immediately, progress to reduce mental illness among the growing elderly population will be severely compromised. While many different types of mental and behavioral disorders occur in late life, they are not an inevitable part of the aging process, and continued and expanded research holds the promise of improving the mental health and quality of life for older Americans.

CENTER FOR MENTAL HEALTH SERVICES

It is also critical that there be adequate funding for the mental health initiatives under the jurisdiction of the Center for Mental Health Services (CMHS) within SAMHSA. While research is of critical importance to a better future, the patients of today must also receive appropriate treatment for their mental health problems. SAMHSA provides funding to State and local mental health departments, which in turn provide community-based mental health services to Americans of all ages, without regard to the ability to pay. AAGP was pleased that the final budgets for the last 5 years have included $5 million for evidence-based mental health outreach and treatment to the elderly. AAGP worked with members of this subcommittee and its Senate counterpart on this initiative, which is a very important program for addressing the mental health needs of the Nation's senior citizens. However, AAGP is extremely alarmed to see that this program was eliminated in President Bush's fiscal year 2008 budget proposal. Restoring and increasing this mental health outreach and treatment program must be a top priority, as it is the only Federally funded services program dedicated specifically to the mental health care of older adults.

The greatest challenge for the future of mental health care for older Americans is to bridge the gap between scientific knowledge and clinical practice in the community, and to translate research into patient care. Adequate funding for this geriatric mental health services initiative is essential to disseminate and implement evidence-based practices in routine clinical settings across the States. Consequently, we would urge that the $5 million for mental health outreach and treatment for the

elderly included in the CMHS budget for fiscal year 2007 be increased to $20 million for fiscal year 2008. Of that $20 million appropriation, AAGP believes that $10 million should be allocated to a National Evidence-Based Practices Program, which will disseminate and implement evidence-based mental health practices for older persons in usual care settings in the community. This program will provide the foundation for a longer-term national effort that will have a direct effect on the well-being and mental health of older Americans.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Despite growing evidence of the need for more geriatric specialists to care for the Nation's elderly population, a critical shortage persists. AAGP appreciates the work of this subcommittee in providing for the restoration of funding for the geriatric health professions programs under Title VII of the Public Health Service Act, which was eliminated for fiscal year 2006. The restoration of this programs has prevented a devastating impact on physician workforce development over the next decade, with would have dangerous consequences for the growing population of older adults who will need access to appropriate specialized care. The administration has again proposed eliminating most Title VII programs, including geriatrics. We urge the subcommittee to fund them at the final fiscal year 2007 level. The geriatric health professions program supports three important initiatives. The Geriatric Faculty Fellowship trains faculty in geriatric medicine, dentistry, and psychiatry. The Geriatric Academic Career Award program encourages newly trained geriatric specialists to move into academic medicine. The Geriatric Education Center (GEC) program provides grants to support collaborative arrangements that provide training in the diagnosis, treatment, and prevention of disease.

CONCLUSION

Based on AAGP's assessment of the current need and future challenges of late life mental disorders, we submit the following fiscal year 2008 funding recommendations:

1. An Institute of Medicine study on the future mental health workforce needs for older adults should be funded at $1 million. This proposed report is fully supported by IOM.
2. The current rate of funding for aging grants at NIMH and CMHS is inadequate and should be increased to at least three times their current funding levels. In addition, the substantial projected increase in mental disorders in our aging population should be reflected in the budget process in terms of dollar amount of grants and absolute number of new grants.
3. To help the country's elderly access necessary mental health care, previous years' funding of $5 million for evidence-based mental health outreach and treatment for the elderly within CMHS must be increased to $20 million.
4. Funding for the geriatric health professions program under Title VII of the Public Health Service Act should be continued at fiscal year 2007 levels.

AAGP looks forward to working with the members of this subcommittee and others in Congress to establish geriatric mental health research and services as a priority at appropriate agencies within the Department of Health and Human Services.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

The American Association of Immunologists ("AAI"), a not-for-profit professional society representing more than 6,500 of the world's leading experts on the immune system, appreciates having this opportunity to submit testimony regarding fiscal year 2008 funding for the National Institutes of Health (NIH). The NIH budget is of great concern to our members—research scientists and physicians who work in academia, government, and industry—many of whom depend on NIH funding to support their work.[1] With approximately 83 percent of NIH's $28.9 billion budget awarded to more than 325,000 scientists throughout the United States and around the world, NIH's funding level drives not only the advancement of immuno-logical and biomedical research, but also the economic activity that fuels local and national economies.[2]

[1] The majority of AAI members are medical school and university professors and researchers who receive research grants from NIH, and in particular from the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and the National Institute on Aging (NIA).

[2] NIH funding "supports peer-reviewed . . . research at more than 3,000 universities, medical schools, hospitals, and research institutions throughout the 50 States and over-

WHY IMMUNOLOGY?

Basic research on the immune system provides a foundation for the discovery of ways to prevent, treat, and cure disease through the development of diagnostics, vaccines, and therapeutics.[3] Immunologists use animal models to test theories about immune system function and treatments;[4] if successful, treatments are then tested on human subjects through clinical trials before being approved for use by the Food and Drug Administration ("FDA") and made available to the general population.

Immunological research focuses on many of the diseases that most threaten life and health: infectious diseases like HIV/AIDS, influenza and avian flu, and malaria; and chronic diseases, like diabetes, cancer, and autoimmune diseases. In recent years, immunologists have also been studying the immune response to natural infectious organisms that may be modified for use as agents of bioterrorism, including plague, smallpox, and anthrax. As described below, this crucial work is already bearing fruit.

RECENT SCIENTIFIC DISCOVERIES: BLOCKBUSTERS AND HOPE

The past year has brought tremendous advances in vaccine development, with promising results in preliminary clinical trials of a vaccine for HIV/AIDS. The vaccine has been shown to be safe and to stimulate cellular immune responses against HIV in more than half of the subjects. Scientists have also discovered that the chickenpox vaccine can be given to adults in order to prevent the occurrence of painful shingles in later years. The hallmark of recent vaccine research was the final FDA approval of the first vaccine against cancer, a vaccine for HPV (Human Papillomavirus). HPV infects over 8 percent of women aged 15–50 and can cause cervical cancer; the new vaccine is efficacious both in preventing primary infection and importantly, in reducing the incidence of cervical cancer.

Immunologists have also made novel insights into understanding "innate" or "natural" immune responses (those that do not require immunization or prior exposure) and the role of soluble factors in inflammation; this has helped scientists discover what appears to have made the 1918 influenza strain so deadly. This discovery may lead to more effective life-saving treatments for influenza patients and will also have broader implications for diseases caused by pandemic influenza, other viruses and bacteria. This and other such advances depend on substantial, reliable, and sustained public investment in basic immunological research.

BUT THE NIH BUDGET HAS GONE DOWN, THREATENING ONGOING PROGRESS

AAI is very grateful to this subcommittee and the Congress for its successful bipartisan effort to double the NIH budget from fiscal year 1999 to fiscal year 2003. This unprecedented commitment by the Federal Government to biomedical research allowed scientists to grow the research enterprise and train new young investigators. Researchers had begun to capitalize on many important advances, leading to increased translational and clinical applications. Unfortunately, this momentum has already been hampered by sub-inflationary budget increases since fiscal year 2003.[5] As a result, although the NIH budget has slightly increased (from $27.067 billion in fiscal year 2003 to $28.931 billion in fiscal year 2007), NIH has already lost about

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seas . . . . Additionally, NIH supports 6,000 intramural scientists in its own laboratories." Fiscal Year 2008 Director's Budget Request Statement: Fiscal Year 2008 Budget Request, Witness appearing before the House Subcommittee on Labor-HHS-Education Appropriations, Elias A. Zerhouni, M.D., Director, National Institutes of Health (March 6, 2007).

[3] The immune system works by recognizing and attacking "foreign invaders" (i.e., bacteria and viruses) inside the body and by controlling the growth of tumor cells. A healthy immune system can protect its human or animal host from illness or disease either entirely—by attacking and destroying the virus, bacterium, or tumor cell—or partially, resulting in a less serious illness. It will also reject transplanted organs and bone marrow. The immune system can malfunction, allowing the body to attack itself instead of an invader (resulting in an "autoimmune" disease like Type 1 diabetes, multiple sclerosis, or rheumatoid arthritis).

[4] Without animal experimentation, immunologists and other researchers would have to use human subjects, an ethically unacceptable alternative. Despite the clear necessity for animal research, scientists continue to be threatened by people and organizations that oppose such research.

[5] NIH funding increases since the doubling period ended [fiscal year 2004 (3.03 percent), fiscal year 2005 (2.18 percent) and fiscal year 2006 (−.12 percent)] have all been below the "Biomedical Research and Development Price Index ("BRDPI"), a U.S. Department of Commerce annual estimate of the cost of inflation for biomedical research. U.S. Department of Health and Human Services memo dated February 5, 2007: "Biomedical Research and Development Price Index: Fiscal Year 2006 Update and Projections for Fiscal Year 2007–2012." http://officeofbudget.od.nih.gov/PDF/BRDPI__letter__25__07.pdf http://officeofbudget.od.nih.gov/BRDPI__2__5__07.pdf

8.5 percent in purchasing power since fiscal year 2003. This loss in purchasing power, which would grow to about 13.3 percent if the President's fiscal year 2008 budget were approved,[6] is already having a devastating effect:

1. Key NIH Institutes have already had to drop their RO1 paylines to 10–14 percent, significantly below the approximately 22 percent funded during the doubling. With funding so low, even outstanding grant applications are not being funded on their first submission, forcing even the most successful senior investigators to spend valuable time on revising and resubmitting their applications.

2. The President's budget would provide no inflationary increases for direct, recurring costs in non-competing Research Project Grants (RPGs), for the 3rd straight year.

3. Although the fiscal year 2007 Joint Funding Resolution provides $91 million to fund 1,500 first-time investigators, the President's fiscal year 2008 budget will either be unable to sustain that promising new effort, or will do so at the expense of funding established investigators.

4. The President's budget would not permit increases in already inadequate stipends and benefits for post-doctoral fellows, whose work is critical to today's established investigators and who will be the principal scientists of tomorrow.

The President's fiscal year 2008 budget would have rapid and long-term adverse repercussions on Americans' health and the national economy: in addition to their terrible human toll, disease and disability cost society trillions of dollars annually in medical care, lost wages and benefits, and lost productivity.[7] The President's budget would also jeopardize the future of the biomedical research enterprise: our brightest young people will be deterred from pursuing biomedical research careers if their chances of receiving an NIH grant, or of being able to sustain a career as an NIH-funded scientist, do not improve. If we are unable to attract and retain the best young minds, the United States will lose more of its senior scientists, as well as its preeminence in medical research, science, and technology, to nations (including India, Singapore, and China) that are already investing heavily in this essential economic sector.

AAI RECOMMENDS A 6.7 PERCENT BUDGET INCREASE FOR FISCAL YEAR 2008

AAI urges the subcommittee to increase the NIH budget by 6.7 percent ($1.9 billion) in fiscal year 2008, to $30.8 billion. This increase, which is only 3 percent above the projected rate of biomedical research inflation,[8] would begin to restore the loss in purchasing power that has occurred since the NIH budget doubling ended in fiscal year 2003. (Full restoration will require that NIH also receive 6.7 percent increases in fiscal year 2009 and fiscal year 2010.)

REAL AND IMMEDIATE THREATS: INFLUENZA AND BIOTERRORISM

Seasonal influenza leads to more than 200,000 hospitalizations and about 36,000 deaths nationwide in an average year. Moreover, an influenza pandemic as serious as the one that occurred in 1918 could result in the illness of almost 90 million Americans and the death of more than 2 million, at a projected cost of $683 billion.[9] And yet, while one potential pandemic influenza strain, H5N1 (avian influenza), has already killed more than 150 people around the world, the President's fiscal year 2008 NIH budget will permit NIAID to devote only $223.2 million to influenza ($11.5 million more than fiscal year 2007). This is an insufficient increase for the agency with primary responsibility for both the scientific research and clinical trials needed to develop vaccines, antiviral drugs, and diagnostic tools to combat both seasonal and pandemic influenza.[10]

AAI is also concerned that the President's fiscal year 2008 NIH budget leaves inadequate funding for biodefense research; the $1.7 billion allocated represents a net decrease of 0.4 percent (4.1 percent after accounting for projected inflation) from fis-

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[6] The President's fiscal year 2008 budget cuts the NIH budget by about $529 million.

[7] National health expenditures cost $3.28 trillion in 2006 and are projected to rise to $4.1 trillion in 2016. U.S. Department of Health and Human Services—Centers for Medicare and Medicaid Services National Health Expenditure Data http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf http://www.cms.hhs.gov/NationalHealthExpendData/downloads/highlights.pdf

[8] See Footnote 5, supra. The BRDPI for fiscal year 2008 is projected to be 3.7 percent.

[9] A report issued by Trust for America's Health ("Pandemic Flu and the Potential for U.S. Economic Recession") predicts that a severe pandemic flu outbreak could result in the second worst recession in the United States since World War II, resulting in a drop in the U.S. Gross Domestic Product of over 5.5 percent.

[10] The Department of Health and Human Services Pandemic Influenza Preparedness and Response Plan gives primary responsibility to NIH, and specifically to NIAID.

cal year 2007. Although the availability of non-recurring construction costs will allow NIAID to devote an additional $17 million to this research, this inadequate increase is restricting research into the human response to the many natural and man-made pathogens that could be used for nefarious purposes.

AAI strongly believes that the best preparation for a pandemic or bioterrorism is to focus on basic research: for a pandemic, the focus should be on seasonal flu, including building capacity, pursuing new production methods (cell based), and seeking optimized flu vaccines and delivery methods. For bioterrorism, the focus should be on identifying new pathogens, understanding the immune response, and developing tools (including new and more potent vaccines) to protect against the pathogen.[11]

The new "National Institutes of Health (NIH) Reform Act of 2006"

The NIH Reform Act of 2006 calls for the establishment of a Division of Portfolio Analysis and Strategic Initiatives to better analyze NIH's portfolio, provide leadership and coordination for trans-NIH research initiatives (including the NIH "Roadmap for Medical Research"), and fund new trans-NIH initiatives through a "Common Fund". Although AAI supports this effort to improve NIH analysis and management, AAI urges (1) that the funds allocated to the Common Fund not grow faster than the overall NIH budget, and (2) that all Common Fund awards/grants be awarded through a rigorous peer review process.

The NIH effort to require all grantees to give NIH author manuscripts

AAI strongly opposes any effort to require NIH grantees to submit to NIH manuscripts reporting research funded by NIH. Rather, AAI believes that NIH should partner with not-for-profit scientific publishers to provide public access to NIH-funded research results rather than to duplicate, at great cost to NIH and taxpayers, services which are already provided cost-effectively and well by the private sector. AAI urges the subcommittee to require NIH to work with the not-for-profit scientific publishing community to develop a plan to enhance public access that addresses publishers' concerns, including ensuring journals' continued ability to provide high quality, independent peer review of NIH-supported research.

Preserving high quality peer review and ensuring the independence of science

Millions of lives—as well as the prudent use of taxpayer dollars—depend on the independence of scientists and the willingness of government officials to accept the best, most independent scientific advice available. AAI urges this subcommittee to ensure that funds expended enhance the ability of scientists to provide independent scientific advice (particularly on government advisory panels) and to ensure the vigor of peer review, whether through the NIH peer review system or by supporting the vitality of independent scientific journals which provide independent, expert peer review of taxpayer funded research.

Ensuring NIH operations and oversight

AAI is concerned that the President's fiscal year 2008 budget proposal for Research, Management and Services (RM&S), which supports the management, monitoring, and oversight of all research activities (including NIH's peer review process), receives an increase of only $10 million (89 percent). AAI urges the subcommittee to explore whether this sub-inflationary increase will harm NIH's ability to supervise a portfolio of increasing size and complexity, and to ensure that NIH funds are well and properly spent.

CONCLUSION

AAI greatly appreciates this opportunity to submit testimony and thanks the members of the subcommittee for their strong support for biomedical research, the NIH, and the scientists who devote their lives to preventing, treating, and curing disease.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF MUSEUMS

Chairman Harkin, Senator Specter and distinguished members of the subcommittee, the American Association of Museums (AAM) appreciates the oppor-

[11] The President's fiscal year 2008 HHS budget requests only $211 million for the Biomedical Advanced Research and Development Agency ("BARDA"), a new agency established to foster the translation of NIH research into development of medical and bioterrorism countermeasures. AAI is concerned that if BARDA's budget is inadequate to support its work, NIH may be forced to assume either duties or costs for BARDA.

tunity to submit testimony on the fiscal year 2008 budget for the museum program at the Institute of Museum and Library Services (IMLS). This agency is the primary Federal entity devoted to assisting museums in fulfilling their role as centers for lifelong learning for all Americans. We respectfully request your approval of the administration's budget request of $39.897 million for grants to museums administered through the Office of Museum Services and the agency's overall budget request of $271.246 million, which reflects a strong endorsement of the vital public service role museums play in their communities.

The American Association of Museums has been bringing museums together since 1906, helping to develop standards and best practices, gathering and sharing knowledge, and providing advocacy on issues of concern to the entire museum community. AAM currently represents more than 15,000 individual museum professionals and volunteers, 3,000 institutions, and 300 corporate members.

Our Nation's museums are vital community assets. With more than 17,000 institutions collectively holding our Nation's cultural and natural heritage, they serve as a catalyst for our citizens to pursue a greater understanding of the world around them. Every day museums save the memories of our civilization and help create new memories for our visitors. We feed preschoolers' imaginations at children's museums; engage elementary school students in learning about art, history and science; provide teenagers and college students with opportunities to share new found knowledge as tour guides and floor staff; stimulate adult learning with lectures on wide array of topics; and offer grandparents a place to share memories and stories with their grandchildren.

Within your own State, you could easily name with pride the many museums in the communities you serve such as the Dubuque County Historical Society's Mississippi River Museum and Aquarium in Iowa or the Franklin Institute in Philadelphia. The vast majority of museums operate as private nonprofit organizations with nominal government funding unlike other community assets such as schools and libraries. According to our most recent financial survey, nonprofit museums receive approximately 16 percent of their budget from local, State, and the Federal Government. The bulk of their income is derived from private philanthropy in the form of donations, grants and corporate sponsorships and earned income from admission and gift shop sales.

It is critical, therefore, that the Federal Government continue to show leadership by supporting investments to advance America's museums in four important areas—caring for and conserving our collections, improving museum programs and operations, supporting museum professional's development, and conducting research and collecting data to help policymakers, museum trustees and leaders make smart decisions.

CARING FOR AND CONSERVING OUR COLLECTIONS

The Heritage Health Index, an example of IMLS-supported research, documented the condition of America's collections held in our Nation's museums, libraries, archives, historical societies and scientific research organizations. It is the first comprehensive survey ever conducted of the condition and preservation needs of our Nation's collections. Through the survey we learned that more than 630 million artifacts—works of art, historic objects, photographs, natural science specimens, books and periodicals—are at risk and require immediate attention and care.

As a result of this study, IMLS has made a commitment to increase public awareness and support for collections care. A national conservation summit will be held here in Washington this spring with future forums planned in four cities across the country to discuss this issue. We are excited at the prospect of increasing attention to this issue, as museums are responsible for the care of hundreds of millions of works of art, artifacts, and scientific specimens, which continue to grow in numbers.

Information related to collections stewardship continues to be the most frequently requested area where AAM members seek guidance on professional standards and best practices. Resources for collections care are often limited, especially in our small and mid-size institutions, due in part to the behind-the-scenes nature of the work. It is not well understood by the public and private funders. We are hopeful that a renewed commitment to and increased public awareness will bring new resources to museums to address the preservation and conservation needs that make public exhibitions possible.

IMLS assists museums with collections issues by providing consultation services through the Conservation and Museum Assessment Programs and financial assistance through the Conservation Project Support program to help ensure some basic safekeeping of museum collections. The demand for this support regularly exceeds the funds available. In fiscal year 2006, IMLS received 144 grant applications and

funded only 40 projects. Recipients matched the nearly $2.8 million IMLS awarded with an additional $4.6 million. The grants are helping these museums examine, document, treat, stabilize, and restore their collections. For example, IMLS supported a detailed conservation survey by the Putnam Museum of History and Natural Science in Davenport, Iowa of its approximately 800 lacquered and wood objects in their Japanese and Chinese collections.

IMPROVING MUSEUM PROGRAMS AND OPERATIONS

Since its inception, AAM has served as a forum for discussing, developing, disseminating, and measuring museum performance standards. In 1967, President Lyndon B. Johnson asked the U.S. Federal Council on the Arts and Humanities to conduct a study on the status of American museums and recommend ways to support and strengthen them. From this study, America's Museums: The Belmont Report, the AAM accreditation program was born. In 1971 AAM first recognized the achievement of 16 museums in meeting the highest standards of the profession. The Accreditation program continues to evolve. Over the past three decades, the program has been a critical tool in advancing the entire museum field, insured transparency and good governance to help museums operate in the best interest of the public.

As our partner in helping museums achieve excellence, IMLS has supported the Museum Assessment Program (MAP). MAP helps museums maintain and improve their operations. Museums participating in the program learn their strengths and weaknesses, receive guidance on how to improve their operations and set institutional priorities. The public benefits by having museums that are striving to improve their operations so they are in a better position to serve them through their public programs and fulfilling their collections stewardship responsibilities.

IMLS also supports museums in their efforts to continue to improve and expand their public service through the Museums for America program. In the program's first 3 years, fiscal year 2004-fiscal year 2006, more than 500 grants totaling $50.2 million have been awarded. The flexibility of the program has been invaluable to our museums. It allows them to apply for funds to address those high-priority activities that advance their institution's strategic plans. Grants have helped museums deal with a range of issues such as behind-the-scenes collections management projects and staff training, investments in digital technology to broaden public access, planning new public programs, and improving visitor experiences. In fiscal year 2006, the agency received 425 eligible grant applications and only 177 awards could be made.

Among those who were successful, the Children's Museum of Pittsburgh received support for improving its "Real Stuff" exhibits which are at the heart of the museum. The museum is seeking to make changes to areas which have low levels of visitor engagement. Modifications and new exhibits will be based on evaluations from its partnership with the University of Pittsburgh Center for Learning in Out-of-School Environments.

SUPPORTING MUSEUM PROFESSIONAL DEVELOPMENT

While museums have long supported the public pursuit of lifelong learning, the staff of museums must also continue to learn. Building the 21st century museum workforce is critical to ensure that museums have both intellectual leadership and financial stability to carry out their mission. The skills required of today's museum directors have changed. In the past, trustees sought individuals with a scholarly knowledge in the area of the museum's collection. Today museum boards are primarily looking for strategic thinkers, excellent communicators, and outstanding fundraisers who have energy, creativity, and an entrepreneurial focus. Museum operations have grown more complex and their leaders need much broader business skills.

Successful museum directors also need capable professionals who have the skills and knowledge to both move the institution forward and attend to the daily operations of running a museum. According to AAM's most recent financial survey, the median number of employees in a museum is 6 full-time and 4 part-time paid staff with 60 volunteers. This includes curators, educators, registrars, accountants, marketing and development professionals with some wearing more than one hat. Unlike our business counterparts, nonprofit museums are not investing time and money to develop and train their staff. Unfortunately, resources for training and career development are scarce. We see this as a looming problem as museums compete with other nonprofits to find and hire future leaders from a shrinking pool of qualified applicants.

In creating the 21st Century Museum Professionals program, IMLS is just beginning to help our field identify strategies for addressing these challenges. In the first year of the program, IMLS received 55 applications but only had the resources to award four grants. There is much work to be done. We urge you to provide the $2.14 million request by the agency and to consider increasing future investment in workforce development substantially.

CONDUCTING RESEARCH AND COLLECTING DATA

It is critical for IMLS to conduct research that assists museum professionals in making critical decisions about their daily operations, demonstrating their public value, ensuring their long-term viability and most effectively meet the needs of the diverse communities they serve. We need basic census data about museums, such as how many museums there are in the United States, how many people work in museums (both paid, professional staff and volunteers), and how many people visit museums annually. A commitment to regular data collection is critical to identifying trends that would inform decision-making by IMLS and the museum community.

For example the 2002 IMLS study, "True Needs, True Partners", about museums serving schools, documented not only the growth in the number of schools, students and teachers served, but also the changing nature of the services provided by museums. This research has helped museum professionals and their school partners understand the evolving nature of their work and documented the growing financial commitment museums have made to public education and how museums have expanded the learning experience for K–12 students.

A number of other topics should be the subject of future research, such as: measuring the social contributions of museums at the national level; studying the skills necessary to be a 21st century museum professional; supporting field research that collects core data, such as financial benchmarks and attendance figures; and examining areas of special interest to segments of the museum field. We need this information and data so that museum leaders and trustees, policy makers at all levels of government and private funders can make informed decisions about the future of our Nation's more than 17,000 museums.

CONCLUSION

We recognize that you face difficult choices in allocating resources. Our appeal is to ask you to consider what we lose if we do not continue to invest in our Nation's museums. The public places a great trust in our ability to preserve not only physical artifacts, but more importantly the stories and memories of our people and our Nation. We need museums where you can learn about the past and dream of the future, explore the smallest bugs to the vast expanses of our universe, and experience awe and wonder in the beauty of our world. We cannot do this alone. Working together we can and will continue to inspire future generations of citizens to become thoughtful leaders, creative entrepreneurs, scientists, artists and educators.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

The AANA is the professional association for more than 36,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. Today, CRNAs are directly involved in delivering 27 million anesthetics given to patients each year in the United States. CRNA services include administering the anesthetic, monitoring the patient's vital signs, staying with the patient throughout the surgery, as well as providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost 70 percent of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists and plastic surgeons.

Nurse anesthetists are experienced and highly trained anesthesia professionals whose record of patient safety in the field of anesthesia was bolstered by the Institute of Medicine report that found in 2000, that anesthesia is 50 times safer than 20 years previous. (Kohn L, Corrigan J, Donaldson M, ed. To Err is Human. Institute of Medicine, National Academy Press, Washington, DC, 2000.) Nurse anesthetists continue to set for themselves the most rigorous continuing education and re-certification requirements in the field of anesthesia. Relative anesthesia patient safety outcomes are comparable among nurse anesthetists and anesthesiologists,

with Pine having recently concluded, "the type of anesthesia provider does not affect inpatient surgical mortality." (Pine, Michael MD et al. Surgical mortality and type of anesthesia provider. Journal of American Association of Nurse Anesthetists. Vol. 71, No. 2, p. 109–116. April 2003.) Even more recently, obstetrical anesthesia, whether provided by Certified Registered Nurse Anesthetists (CRNAs) or anesthesiologists, is extremely safe, and there is no difference in safety between hospitals that use only CRNAs compared with those that use only anesthesiologists, according to the results of a new study published in the January/February issue of Nursing Research (Vol. 56, No. 1, pp. 9–17). In addition, a recent AANA workforce study's data showed that CRNAs and anesthesiologists are substitutes in the production of surgeries. Through continual improvements in research, education, and practice, nurse anesthetists are vigilant in their efforts to ensure patient safety.

CRNAs provide the lion's share of the anesthesia care required by our U.S. Armed Forces through active duty and the reserves, from here at home to the leading edge of the field of battle. In May 2003, at the beginning of "Operation Iraqi Freedom" 364 CRNAs were deployed to the Middle East to ensure military medical readiness capabilities. For decades, CRNAs have staffed ships, remote U.S. military bases, and forward surgical teams without physician anesthesiologist support.

IMPORTANCE OF TITLE VIII NURSE ANESTHESIA EDUCATION FUNDING

The nurse anesthesia profession's chief request of the subcommittee is for $4 million to be reserved for nurse anesthesia education and $76 million for advanced education nursing from the Title VIII program. This sustained funding is justified by two facts. First, there is a vacancy rate of nurse anesthetists in the United States impacting people's healthcare. Second, the Title VIII program, which has been strongly supported by members of this subcommittee in the past, is an effective means to help address the nurse anesthesia workforce demand. This demand for CRNAs is something that the nurse anesthesia profession addresses every day with success, and with the critical assistance of Federal funding through HHS' Title VIII appropriation.

The administration's 2008 budget eliminates funding for Advanced Education Nursing. We believe that nursing and nursing education workforce needs are such that this funding must not be eliminated, but preserved and increased for 2008 to meet patient care needs.

The increase in funding for advanced education nursing from $58 million to $76 million is necessary to meet the continuing demand for nursing faculty and other advanced education nursing services throughout the United States. Only a limited number of new programs and traineeships can be funded each year at the current funding levels. The program provides for competitive grants and contracts to meet the costs of projects that support the enhancement of advanced nursing education and practice and traineeships for individuals in advanced nursing education programs. This funding is critical to the efforts to meet the nursing workforce needs of Americans who need healthcare.

In 2003, the AANA conducted a nurse anesthesia workforce study that found a 12 percent vacancy rate in hospitals for CRNAs, and a lower vacancy rate in ambulatory surgical centers. The supply has increased in recent years, stimulated by increases in the number of CRNAs trained. However, there is a reasonable question of whether these increases are enough to offset the number of CRNAs intending to retire over the next few years. The retirement of baby boomers, both among patients and CRNAs alike, requires a continuous growth in the number of nurse anesthesia graduates to meet anticipated demand for anesthesia services.

The problem is not that our 105 accredited programs of nurse anesthesia are failing to attract qualified applicants. They have to turn them away by the hundreds, because the capacity of nurse anesthesia educational programs to educate qualified applicants is limited by the number of faculty, the number and characteristics of clinical practice educational sites, and other factors. A qualified applicant to a CRNA program is a bachelor's educated registered nurse who has spent at least 1 year serving in an acute care healthcare practice environment. Nurse anesthesia educational programs are located all across the country including the following:

State	No. of Accredited Nurse Anesthesia Programs
PA	12
FL	8
OH	5
TX	5

State	No. of Accredited Nurse Anesthesia Programs
IL	5
NY	4
CA	3
CT	3
MD	3
RI	2
WI	1

Recognizing the importance of nurse anesthetists to quality healthcare, the AANA has been working with the 105 accredited programs of nurse anesthesia to increase the number of qualified graduates. In addition, the AANA has worked with nursing and allied health deans to develop new CRNA programs.

The Council on Certification of Nurse Anesthetists (CCNA) reports that in 1999, our schools produced 948 new graduates. In 2005, that number had increased to 1,790, an 89 percent increase in just 5 years. This growth is expected to continue. The CCNA projects CRNA programs to produce over 2,000 graduates in 2007.

To truly meet the nurse anesthesia workforce challenge, the capacity and number of CRNA schools must continue to expand. With the help of competitively awarded grants supported by Title VIII funding, the nurse anesthesia profession is making significant progress, expanding both the number of clinical practice sites and the number of graduates.

The AANA is pleased to report that this progress is extremely cost-effective from the standpoint of Federal funding. Anesthesia can be provided by nurse anesthetists, physician anesthesiologists, or by CRNAs and anesthesiologists working together. As mentioned earlier, the study by Pine et al confirms, "the type of anesthesia provider does not affect inpatient surgical mortality." Yet, for what it costs to educate one anesthesiologist, several CRNAs may be educated to provide the same service with the same optimum level of safety. Nurse anesthesia education represents a significant educational cost/benefit for supporting CRNA educational programs with Federal dollars vs. supporting other models of anesthesia education.

To further demonstrate the effectiveness of the Title VIII investment in nurse anesthesia education, the AANA surveyed its CRNA program directors in 2003 to gauge the impact of the Title VIII funding. Of the eleven schools that had reported receiving competitive Title VIII Nurse Education and Practice Grants funding from 1998 to 2003, the programs indicated an average increase of at least 15 CRNAs graduated per year. They also reported on average more than doubling their number of graduates, who provide care to patients during and following their education. Moreover, they reported producing additional CRNAs that went to serve in rural or medically underserved areas. Under both of these circumstances, an increased number of student nurse anesthetists and CRNAs are providing healthcare to the people of medically underserved America.

We believe it is important for the subcommittee to allocate $4 million for nurse anesthesia education for several reasons. First, as this testimony has documented, the funding is cost-effective and well needed. Second, the Title VIII authorization previously providing such a reserve expired in September 2002. Third, this particular funding is important because nurse anesthesia for rural and medically underserved America is not affected by increases in the budget for the National Health Service Corps and community health centers, since those initiatives are for delivering primary and not surgical healthcare. Lastly, this funding meets an overall objective to increase access to quality healthcare in medically underserved America.

TITLE VIII FUNDING FOR STRENGTHENING THE NURSING WORKFORCE

The AANA joins a growing coalition of nursing organizations, including the Americans for Nursing Shortage Relief (ANSR) Alliance and representatives of the nursing community, and others in support of the subcommittee providing a total of $200 million in fiscal year 2008 for nursing shortage relief through Title VIII. This amount is approximately $51 million over the fiscal year 2007 level and $95 million above the President's fiscal year 2008 budget.

Every district in America is familiar with the importance of nursing. The AANA appreciates the support for nurse education funding in fiscal year 2007 and past fiscal years from this subcommittee and from the Congress.

The need for strengthening nurse educational funding to strengthen our healthcare is clear. According to the Office of the Actuary at the Centers for Medicare & Medicaid Services, America spent about $2 trillion on healthcare in the most

recent year for which the agency had records, the year 2005. About $342 billion of that was from Medicare outlays. Medicaid spending was $313 billion. The Congressional Budget Office States that Medicare directs about $8.7 billion of its outlays to Graduate Medical Education (GME), of which $2.3 billion was Direct GME. Approximately 99 percent of that educational funding helps to educate physicians and allied health professionals, and about 1 percent is allocated to help educate nurses.

In the interest of patients past and present, particularly those in rural and medically underserved parts of this country, we ask Congress to reject cuts from Federal investments in CRNA and nursing educational funding programs, and to provide these programs the sustained increases required to help ensure Americans get the healthcare that they need and deserve. Quality anesthesia care provided by CRNAs saves lives, promotes quality of life, and makes fiscal sense. This Federal support for nurse education will improve patient access to quality services and strengthen the Nation's healthcare delivery system.

Thank you.

PREPARED STATEMENT OF THE AMERICAN BRAIN COALITION

INTRODUCTION

The National Institutes of Health (NIH) is the world's leader in medical discoveries that improve people's health and save lives. NIH-funded scientists investigate ways to prevent, treat, and even cure the complex diseases of the brain. Because there is much work still to be done, the American Brain Coalition writes to ask for your support for biomedical research funding at NIH.

WHAT IS THE AMERICAN BRAIN COALITION?

The American Brain Coalition (ABC) is a nonprofit organization that seeks to reduce the burden of brain disorders and advance the understanding of the functions of the brain. The ABC, made up of nearly 50 member organizations, brings together afflicted patients, the families of those that suffer, the caregivers, and the professionals that research and treat diseases of the brain.

The brain is the center of human existence, and the most complex living structure known. As such, there are thousands of brain diseases from Rett Syndrome and autism to dystonia and Parkinson's disease. ABC, unlike any other organization, brings together people affected by all diseases of the brain.

The ABC is working toward the same level of public awareness and support for diseases of the brain that has been achieved by the American Heart Association and the American Cancer Society. Fifty million Americans—our relatives, friends, neighbors, and your constituents—are affected by diseases of the brain. Our goal is to be a united voice for these patients, and to work with Congress to alleviate the burden of brain disease. A large part of that goal involves support for NIH research.

THANK YOU FOR PAST SUPPORT

The American Brain Coalition would like to thank the members of this subcommittee for their past support, which resulted in the doubling of NIH budget between 1998 and 2003.

In addition, we are extremely grateful that the fiscal year 2007 Joint Resolution included an additional $620 million for NIH above the fiscal year 2006 funding level. This additional money will allow NIH to award an extra 500 research grants. It will also create a new program to support innovative, outside-the-box research, as well as to provide grants to first-time investigators.

The doubling of the NIH budget produced advances in the Nation's health. Since 2003, however, many policymakers have mistakenly come to think that NIH "has been taken care of." As a result, NIH has been relatively flat funded since that time.

Despite the doubling of the budget and the many advances in scientific knowledge, there is still much work to be done to uncover the mysteries of the brain. The recent start-stop funding approach has made efficient research planning extremely difficult, has disrupted steady progress, and must be reversed.

NIH-FUNDED RESEARCH SUCCESSES

Today, scientists have a greater understanding of how the brain functions due to NIH-funded research. The following are just a few areas where research efforts have improved the health of the American public:

—*Post Traumatic Stress Disorder (PTSD)*.—Experiencing or witnessing a crime, terrorist attack, being a victim of sexual abuse, or military combat can lead to

a form of stress that can last a life-time. Termed, PTSD, the condition afflicts 5.2 million Americans aged 18 to 54 each year. Its social and economic costs can be devastating. Almost half of the Vietnam veterans with PTSD have been arrested or jailed. With the ongoing wars in Iraq and Afghanistan, the incidence of PTSD is rising.

For years it was thought that those who survived or witnessed a trauma should be able to tough it out and move on. But NIH-funded studies helped reveal that PTSD is a serious brain disorder with biological underpinnings. For example, scientists determined that the part of the brain involved in learning, memory, and emotion appears to be smaller in people with PTSD and that levels of some brain chemicals are altered. These changes are believed to be caused by increased stress hormones from a traumatic event and by the constant reliving of the event.

New understanding of the disorder paved the way for use selective serotonin reuptake inhibitors in treating PTSD. Studies funded by NIH found that these drugs ease the symptoms of depression and anxiety and improve the memory of patients with PTSD, helping them better deal with traumatic memories. Talking with a counselor or therapist can also help PTSD victims to cope.

—*Multiple Sclerosis*.—Multiple sclerosis (MS) strikes people during the prime of their lives, right as they are settling into their careers and families. About 400,000 Americans have multiple sclerosis, and every week an estimated 200 more are diagnosed. Multiple sclerosis costs Americans $9.5 billion in medical care and lost productivity each year.

In multiple sclerosis, the immune system for unknown reasons mistakenly destroys the protective myelin covering around nerves. Without myelin, electrical signals are transmitted more slowly or not at all from the brain to the body, causing weakness, tremors, pain, and loss of feeling.

Fortunately, research funded by the NIH and others over the past two decades has led to many advances that allow physicians to diagnose MS earlier and better track its progress so that treatments can be more effective. Imaging techniques such as magnetic resonance imaging and magnetic resonance spectroscopy provide a window on the brain that allows physicians to better predict relapses and thus plan for patients' care.

In addition to steroids used in the past to reduce the duration and severity of attacks, there are now other drugs like interferon, glatiramer acetate, and mitoxantrone that can decrease disease severity. Studies have shown that these drugs can make relapses less frequent and severe and delay further damage from the disease.

—*Alcoholism*.—Excess consumption of alcohol can ruin a person's health, family life, and career. It also makes the world more dangerous for the rest of society. Many accidents, assaults, and robberies involve alcohol use by the offender. Society also pays a high financial price. Alcohol-related problems cost the country an estimated $185 billion per year.

Until recently, there were not many options to help keep problem drinkers off alcohol. Fortunately, the outlook is improving steadily with the development of new medications and therapies.

NIH-funded scientists discovered evidence that alcohol acts on several chemical systems in the brain to create its alluring effects. On the basis of these studies, the drug naltrexone—which targets one of these systems, called the opioid system—was approved as a treatment for alcoholism in the mid-1990s. Alcohol's effect on the opioid system is thought to produce the euphoric feelings that make a person want to drink again. Naltrexone can block this reaction and help cut cravings for alcohol in some alcoholic individuals.

Congressional investments in research have lead to significant improvements in patient care.

RESEARCH IMPROVES HEALTH AND FUELS THE ECONOMY

Diseases of the nervous system pose a significant public health and economic challenge, affecting nearly one in three Americans at some point in life. Improved health outcomes and positive economic data support the assertion that biomedical research is needed today to improve public health and save money tomorrow.

Research drives innovation and productivity, creates jobs, and fuels local and regional economies. In fiscal year 2003, the University of Wisconsin Madison brought over $228 million into the State from NIH-funded research.

Not only does research save lives and fuel today's economy, it is also a wise investment in the future. For example, 5 million Americans suffer from Alzheimer's disease today, and the cost of caring for these people is staggering. Medicare ex-

penditures are $91 billion each year, and the cost to American businesses exceeds $60 billion annually, including lost productivity of employees who are caregivers. As the baby boom generation ages and the cost of medical services increases, these figures will only grow. Treatments that could delay the onset and progression of the disease by 5 years could save $50 billion in healthcare costs each year. Research funded by the NIH is critical for the development of such treatments. The cost of investing in NIH today is minor compared to both current and future healthcare costs.

PRESIDENT'S BUDGET NEGATIVELY IMPACTS RESEARCH

Mr. Chairman, inflation has eaten into the NIH budget. The NIH now projects the Biomedical Research and Development Price Index (BRDPI) may increase by 3.7 percent for both fiscal year 2007 and fiscal year 2008; 3.6 percent for fiscal year 2009 and 2010; and 3.5 percent for fiscal year 2011 and fiscal year 2012.

Unfortunately, the President's fiscal year 2008 budget request for NIH did not factor in the increases in biomedical research inflation. In fact, his budget proposes to cut funding for the National Institutes of Health by more than a half billion dollars in fiscal year 2008.

FISCAL YEAR 2008 RECOMMENDATION

The American Brain Coalition supports a 6.7 percent increase in funding for the National Institutes of Health in fiscal year 2008. Additionally, ABC supports a 6.7 percent increase in funding in per year in fiscal years 2009 and 2010.

This sustained increase is necessary to make-up for lost purchasing power that has occurred in the past 3 years. In addition, it will help the NIH to achieve its broad research goals and provide hope for those people affected with neurological and psychiatric disorders.

Mr. Chairman, thank you for the opportunity to submit testimony before this subcommittee.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY

The American College of Cardiology (ACC) appreciates the opportunity to provide the subcommittee with recommendations for fiscal year 2008 funding for life-saving cardiovascular research and public education. The ACC is a 34,000 member nonprofit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy.

THE NEED FOR A FEDERAL INVESTMENT IN CARDIOVASCULAR DISEASE RESEARCH

Cardiovascular disease continues to be the leading cause of death for both women and men in the United States, killing more than 870,000 Americans each year. While the number of deaths due to cardiovascular disease is on the decline, more than one in three Americans lives with some form of heart disease. The economic impact of cardiovascular disease on the U.S. health care system continues to grow as the population ages and as the prevalence of it increases, costing the Nation an estimated $430 billion in 2007 alone due to medical expenses and lost productivity.[1]

The ACC is extremely concerned that the cuts proposed in the administration's fiscal year 2008 budget for many critical health agencies, particularly the National Institutes of Health (NIH), will negatively impact cardiovascular care. The doubling of the NIH budget from 1999 to 2003 resulted in a surge in demand for research grants. In recent years, the combination of inflation and stagnant Federal funding has threatened the laboratories and continuing research of established investigators and, by signaling a lack of Federal commitment to consistent funding, will discourage new investigators and new research initiatives.

The ACC encourages Congress to provide a strong Federal investment in research and public education that addresses cardiovascular disease. Federal research is providing for breakthrough advances that fundamentally change our understanding of the prevention and treatment of cardiovascular disease, leading to better outcomes, decreased costs, and increased quality of life for patients.

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[1] American Heart Association. Heart Disease and Stroke Statistics—2007 Update. Dallas, Texas: American Heart Association; 2007.

FUTURE CARDIOVASCULAR DISEASE RESEARCH NEEDS

As the health system continues its move toward using performance measurement to foster the delivery of the highest quality of care to patients, the need for meaningful clinical guidelines, from which performance measures are developed, becomes even more critical.

The performance measures that will be used to determine whether patients are receiving the most effective, efficient, and highest quality cardiovascular care are derived from clinical guidelines developed by the ACC and the American Heart Association (AHA). The ACC strives to produce the preeminent medical specialty practice guidelines, with more than 15 guidelines on a range of cardiovascular topics. They are developed through a rigorous, evidence-based methodology employing multiple layers of review and expert interpretation of the evidence on an ongoing, regular basis. Many clinical research questions remain unanswered or understudied, however. In fact, the percent of guideline recommendations that are based on expert opinion rather than clinical data vary by cardiovascular topic from only 20 percent for coronary bypass surgery to over 70 percent for valvular heart disease.

To this end, through its clinical policy development process, the ACC has identified knowledge gaps for cardiovascular disease. These unresolved issues, if addressed, have great potential to impact patient outcomes, costs, and the efficiency of care delivery. The ACC strongly supports and stands committed to assist the National Heart, Lung and Blood Institute (NHLBI) in fulfilling its strategic plan by helping to promote the development and speedy implementation of evidence-based clinical guidelines in a manner that impacts health outcomes. All medicine includes a degree of uncertainty about the ability of a particular procedure, device, or therapy to benefit a patient. Yet, an investment in answering the following scientific questions through the NIH, and in particular the NHLBI, as well as through the Agency for Healthcare Research and Quality (AHRQ), will help to better narrow the target population who can benefit from treatment and therefore increase the efficacy and efficiency of the care delivered.

1. What is the effect of common cardiovascular therapies on elderly populations whose metabolism and kidney function is lower and may not respond to medications in the same way as the younger patients typically included in clinical trials?
2. What is the effect of common cardiovascular therapies on patients with multiple other diseases/conditions?
3. What are the best approaches to increasing patient compliance with existing therapies?
4. What screening and risk models (existing or new) could further define who will benefit from various therapies?
5. What are the optimal management strategies for anticoagulation and antiplatelet agents in heart attack patients, patients with stents, and atrial fibrillation patients to maximize benefit and reduce bleeding risks?
6. What are the best approaches to managing complex but understudied cardiovascular topics such as congenital heart disease and valvular heart disease? Both congenital heart disease and valvular heart disease have become areas of higher research interest as techniques have developed to extend the lives of these patients.
7. What are the risks and benefits of common off-label uses of widely used therapies and procedures, such as drug eluting stents?
8. What are the best catheter-based techniques to increase treatment success and reduce complications for both coronary and cardiac rhythm procedures?

The list of topics above is not exhaustive but provides an overview of some of the general themes of the evidence gaps that exist across the ACC's current guidelines. In addition to specific clinical research topics, the ACC recommends funding to help address two structural issues that could help identify, prioritize, and interpret research findings over the long term:

1. The NHLBI should work with the clinical cardiology community to proactively design clinical trials to address unanswered clinical questions and identify methods that allow for greater comparability among studies. NHLBI should work with ACC and the AHA to develop an evidence model that would drive future research initiatives based on current evidence gaps in the guidelines; and
2. NIH should fund the development of a robust informatics infrastructure across Institutes to process research evidence. Studies should be designed such that their results could be "fed" into a computer model that would provide additional insights for developers of clinical recommendations.

COLLABORATING TO IMPROVE CARDIOVASCULAR CARE AND OUTCOMES

Facilitating the transfer of new knowledge to health care professionals, patients and the public is an important aspect of Federal research efforts. One example of

NHLBI's success in this area is the launch last year of the new Peripheral Arterial Disease (P.A.D.) national campaign to increase public and health care provider awareness of P.A.D. and its association with other cardiovascular diseases. As the leader in developing the P.A.D. Guidelines, the ACC is proud to collaborate with the NHLBI on the "Stay in Circulation: Take Steps to Learn about P.A.D." campaign. The ACC is promoting this important campaign through our membership and has formed a P.A.D. Guidelines Implementation Task Force that has developed tools—including wall charts, webcasts, and slide sets—to help physicians diagnose and treat the more than 8 million Americans affected by the disease.

NHLBI and AHRQ also have been important supporters of the "D2B: An Alliance for Quality" program. The D2B Alliance is a Guidelines Applied in Practice (GAP) program launched by the ACC to save time and save lives by reducing the door-to-balloon times in U.S. hospitals performing primary percutaneous coronary intervention (PCI) by providing hospitals with key evidence-based strategies and supporting tools needed to begin reducing their D2B times.

Through its Centers for Education and Research on Therapeutics (CERT), AHRQ has been crucial in helping fund research by ACC on its clinical policy development process. The CERT grant provided resources to help ACC better understand and adapt how its guidelines and performance measures are developed and disseminated. It also provided resources to support the development of a framework for ACC to address appropriateness of medical technology. This evaluation of ACC processes for the development of clinical policy has been an essential part of translating research from bench to bedside.

Recently, ACC leadership met with the NHLBI Director and senior staff to discuss opportunities to collaborate on current and future efforts. One initiative identified as a unique opportunity to make a positive impact on health care quality involves enhancing the NHLBI's Center for the Application of Research Discoveries (CARD) through the use of health information technology—namely by drawing on the ACC's substantial expertise, from the National Cardiovascular Data Registry, in developing and operating electronic data registries. Bringing the latest discoveries in cardiovascular care to the bedside is a critical mission of the NHLBI and is shared by the ACC. Sufficient funding from Congress can foster such efforts by the NHLBI and its partners to provide patients with effective cutting-edge care that also holds the promise of reducing health care costs.

ACC FUNDING RECOMMENDATIONS

As the subcommittee considers its appropriations for programs within the Department of Health and Human Services, the ACC urges support of the following fiscal year 2008 funding recommendations:

National Institutes of Health

The ACC, along with the broad medical community, supports an fiscal year 2008 NIH budget of $30.869 billion that would help get the NIH "back on track." Research conducted through the NIH has resulted in better diagnosis and treatment of cardiovascular disease, thereby improving the quality of life for those living with the disease and lowering the number of deaths attributable to it. Adequate funding through the NIH is necessary for basic, clinical, and translational research that facilitates the delivery of new discoveries to the bedside.

National Heart Lung and Blood Institute

The ACC recommends $3.1 billion for the NHLBI in fiscal year 2008 for continuing its critical research into the causes, treatment, and prevention of cardiovascular disease. Congress must maintain its investment in NHLBI to continue the great strides already being made in fighting cardiovascular disease. If accepted without an increase, the administration's budget request for NHLBI would critically impact the institute's ability to fund valuable initiatives and would further harm its ability to attract young investigators.

Agency for Healthcare Research and Quality

The ACC supports $350 million for the AHRQ. At a time when great focus is being put on comparative effectiveness research as a means to improve health quality, continuing and increasing the Federal investment in AHRQ health services research is critical.

Centers for Disease Control and Prevention's (CDC) Division for Heart Disease and Stroke Prevention

The ACC recommends $55 million for the CDC Division for Heart Disease and Stroke Prevention, whose public education efforts are making strides in the preven-

tion of and early intervention in treating cardiovascular disease—thereby potentially reducing future care costs significantly.

Health Resources and Services Administration (HRSA) Rural and Community Access to Emergency Defibrillation (AED) Program

The ACC supports $8.9 million in fiscal year 2008 for the HRSA Rural and Community AED program, an important initiative that saves lives by placing external defibrillators in public facilities.

The ACC urges Congress to provide a strong fiscal year 2008 investment in the cardiovascular research and education programs described above to continue fostering the great strides being made in the fight against all cardiovascular disease. If you have any questions, please contact Jennifer Brunelle at jbrunell@acc.org or (202) 375–6477.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

The American College of Obstetricians and Gynecologists (ACOG), representing 51,000 physicians and partners in women's health care, is pleased to offer this statement to the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education. We thank Chairman Harkin, ranking member Specter, and the entire subcommittee for their leadership to continually address maternal and child health care services.

The Nation has made important strides to improve women and children's health over the past several years, and ACOG is grateful to this committee for its commitment to ensure that vital research continues to eliminate disease and to ensure valuable new treatment discoveries are implemented. The NIH has examined and determined many disease pathways, while the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) have been successful in translating research findings into valuable public health policy solutions. This dedicated commitment to elevate, promote and implement medical research faces an uncertain future at a time when scientists are on the cusp of new cures.

We urge the committee to support a 6.7 percent increase for the National Institutes of Health (NIH), and a 6.7 percent increase for the National Institute of Child Health and Human Development (NICHD) in fiscal year 2008. We also continue to support efforts to secure adequate funds for important public health programs at HRSA ($7.5 billion) and the CDC ($10.7 billion including funding for the Agency for Toxic Substances and Disease Registry, and the Vaccines for Children Program).

NATIONAL INSTITUTES OF HEALTH—RESEARCH LEADING THE WAY

Ob-Gyn Research at the NICHD

The NICHD conducts research that holds great promise to improve maternal and fetal health and safety. With the support of Congress, the Institute has initiated research addressing the causes of cerebral palsy, gestational diabetes and pre-term birth. However, much more needs to be done to reduce the rates of maternal mortality and morbidity in the United States. More research is needed on such pregnancy-related issues as the impact of chronic conditions during pregnancy, racial and ethnic disparities in maternal mortality and morbidity, drug safety with respect to pregnancy, and preventing unintended pregnancies.

A commitment to research in women's health sheds light on a breadth of issues that save women's lives. Important research examining the following issues must continue:

Reducing High Risk Pregnancies

NICHD's Maternal Fetal Medicine Unit Network, working at 14 sites across the United States (University of Alabama, University of Texas-Houston, University of Texas-Southwestern, Wake Forest University, University of North Carolina, Brown University-Women and Infant's Hospital, Columbia University, Drexel University, University of Pittsburgh-Magee Women's Hospital, University of Utah, Northwestern University, Wayne State University, Case Western University, and Ohio State University), will help reduce the risks of cerebral palsy, caesarean deliveries, and gestational diabetes. This Network discovered that progesterone reduces preterm birth by one-third.

Reducing the Risk of Perinatal HIV Transmission

In the last 10 years, NICHD research has helped decrease the rate of perinatal HIV transmission from 27 percent to 1.2 percent. This advancement signals the near end to mother-to-child transmission of this deadly disease.

Reducing the Effects of Pelvic Floor Disorders

The Institute has made recent advancements in the area of pelvic floor disorders. The NICHD is investigating whether women that have undergone cesarean sections have fewer incidences of pelvic floor disorder than women who have delivered vaginally.

Reducing the Prevalence of Premature Births

NICHD is helping our Nation understand how adverse conditions and health disparities increase the risks of premature birth in high-risk racial groups.

Drug Safety During Pregnancy

The NICHD recently created the Obstetric and Pediatric Pharmacology Branch to measure drug metabolism during pregnancy.

Contraceptive Research

The United States has one of the highest unintended pregnancy rates of the industrialized nations. Of the approximately 6 million pregnancies each year, an estimated one half are unintended. It is critical that women have access to safe and effective contraceptives, to help them time and space their pregnancies. The NICHD conducts valuable research on both male and female contraceptives that can help reduce the number of unintended pregnancies and improve women's health.

The Challenge of the Future: Attracting New Researchers

Despite the NICHD's critical advancements, reduced funding has made it difficult for research to continue, largely due to the lack of new investigators. Congressional programs such as the loan repayment program, and the NIH Mentored Research Scientist Development Program for reproductive health, all attract new researchers, but low pay lines make it difficult for the NICHD to maintain them. We urge the committee to significantly increase funding for ob-gyn research at the NICHD to maintain a high level of research innovation and excellence, in turn reducing the incidence of maternal morbidity and mortality and discovering cures for other chronic conditions.

We encourage the committee, too, to realize and fund ob-gyn research possibilities in other Institutes within NIH. While pediatric and ob-gyn research are the two main areas of research in NICHD, ob-gyn research is very centralized in that Institute, with 56.7 percent of all NIH ob-gyn research funding occurring in NICHD in 2005. Pediatrics funding, on the other hand, is diversified throughout many Institutes. While 21.7 percent of pediatrics funding occurs in NICHD, 19 percent is in the National Heart, Lung and Blood Institute (NIHLB), 16 percent is in National Institute of Diabetes and Digestive and Kidney, (NIDDK), 13.5 percent in the National Institute of Aging (NIA), and 7 percent is in the National Cancer Institute (NCI). Altogether, pediatrics research at NIH totaled $520.7 million in 2005, compared with $156.8 million in ob-gyn research.

The future of women's health, including, reducing preterm labor, ensuring drug safety during pregnancy, and reducing the effects of pelvic floor disorders, depends on research conducted at the NIH. We encourage the committee to increase and expand ob-gyn research funding in NICHD and throughout the National Institutes of Health.

HRSA AND CDC: TURNING RESEARCH INTO PUBLIC HEALTH SOLUTIONS

It is critical that we rapidly transform women's health research findings into public health solutions. The Health Resources and Services Administration (HRSA) has created women and children's health outreach programs based on research conducted on prematurity, high risk pregnancies, gestational diabetes, and a variety of other health issues. The National Fetal Infant Mortality Review and the Provider's Partnership are two examples of the successful programs under the Healthy Start Initiative.

National Fetal Infant Mortality Review

The Fetal and Infant Mortality Review (FIMR) is a cooperative Federal agreement between ACOG and the Maternal Child Health Bureau at HRSA. FIMR uses the expertise of ob-gyns and local health departments to find solutions to problems related to infant mortality. In light of the recent increase in the infant mortality rate for 2002, the FIMR program is vital to develop community-specific, culturally appro-

priate interventions. Today 220+ local programs in 42 States are implementing FIMR and finding it is a powerful tool to bring communities together to address the underlying problems that negatively affect the infant mortality rate. We urge this committee to recognize the many positive contributions of the FIMR program and ensure it remains a fully funded program within HRSA.

Title X Family Planning Program

Since 1970, the Title X Family Planning program at HRSA has provided low income women with timely screenings, education, and contraception. Access to these services can be vital to preventing breast and cervical cancer, sexually transmitted infections (STIs), and unintended pregnancies.

Title X clinics serve more than 5 million low-income women at 4,500 clinics nationwide, helping women plan the number and timing of their pregnancies and stay healthy. Title X clinics are serving increasing numbers of patients without commensurate increases in funding. We urge you to increase funding for this vital program to $375 million for fiscal year 2008.

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) administered by the CDC is an indispensable health program in helping underserved women gain access to screening programs for early detection of breast and cervical cancers. The NBCCEDP has served over 2.5 million women and provided 5.8 million screening examinations. Early detection and treatment of breast and cervical cancers greatly increase a woman's odds of conquering these diseases. We strongly urge the committee to continue saving women's lives and to prevent cuts to this vital program.

National Center on Birth Defects and Developmental Disabilities (NCBDDD)

Birth defects affect about one in every 33 babies born in the United States each year. Babies born with birth defects have a greater chance of illness and long term disability than babies without birth defects. According to the CDC, a great opportunity for further improvement lies in prevention strategies that, if implemented prior to conception, would result in further improvement of pregnancy outcomes. A cooperative agreement between the NCBDDD and ACOG has resulted in increased provider knowledge of genetic screening and diagnostic tests, technical guidance on routine preconception care and prenatal genetic screening, and improved access to care for women with disabilities.

Again, we would like to thank the committee for its continued support of interagency cooperation to address the multiple factors that affect maternal and child health. We strongly urge this subcommittee to support increased ob-gyn research funding for the NICHD and throughout NIH, and renewed appropriations for the maternal child health programs at the CDC and HRSA. By continuing to translate research done at the NICHD into positive outreach programs such as the Title X program and the NBCCEDP, we can further improve our Nation's overall health.

PREPARED STATEMENT OF THE AMERICAN DIABETES ASSOCIATION

Thank you for the opportunity to submit testimony on the importance of Federal funding for diabetes programs at the Centers for Disease Control and Prevention (CDC) and diabetes research at the National Institutes of Health (NIH).

As the Nation's leading nonprofit health organization providing diabetes research, information and advocacy, the American Diabetes Association feels strongly that Federal funding for diabetes prevention and research efforts is critical not only for the 20.8 million Americans who currently have diabetes, but also for the 54 million who have a condition known as pre-diabetes.

Diabetes is a serious disease, and is a contributing cause of many of the chronic conditions on which the Federal Government spends the most health care dollars. In 2002, the direct and indirect costs spent solely on diabetes were $132 billion. In addition, diabetes is a significant cause of heart disease, stroke, and a leading cause of kidney disease, which combine to cost our Nation $356.7 billion a year. Diabetes is also the leading cause of adult-onset blindness and lower limb amputations.

Between 1990 and 2001 diabetes cases increased 60 percent and they have continued to increase by 8 percent a year. Every 21 seconds, another individual is diagnosed with diabetes. Diabetes is the single most prevalent chronic illness among children. Because of the systemic havoc that diabetes wreaks throughout the body, it is no surprise that the life expectancy of a person with the disease averages 10–15 years less than that of the general population.

As the statistics listed above illustrate, we are facing an epidemic of diabetes in this country, which if left unchecked could have significant health and economic implications for many future generations. Every 24 hours there are: 4,100 individuals diagnosed with diabetes, 230 amputations in people with diabetes, 120 people who enter end-stage kidney disease programs and 55 people who go blind.[1] According to the NIH, approximately 225,000 people died in 2002 from diabetes. Nearly a quarter of a million Americans! Please keep these numbers in mind as you look at the chart below. It tracks the Federal investment in fighting diabetes since fiscal year 2005—a period in which the prevalence of diabetes has grown by approximately 32 percent. In the case of the CDC budget for their Division of Diabetes Translation (DDT), funding has been relatively flat since fiscal year 2003. A change in formula makes it appear that there was a major decrease of 4 percent in fiscal year 2005, when in actuality there was a minor increase.

DDT at CDC	Funding Level	Difference from prior year	Percent increase	
			From prior year	In diabetes
Fiscal year:				
2005	$63.457	−2.59	−4.09	+8
2006	63.119	−9.34	−.54	+8
2007	62.806	−.31	−.50	+8
2008 administration	62.806	.....	.....	+8

DDK at NIH	Funding level	Difference from prior years	Percent increase	
			From prior year	In diabetes
Fiscal year:				
2005	$1,864	+43	+2.31	+8
2006	1,855	−9	−.49	+8
2007	1,854	−1	−.05	+8
2008 administration	1,858	+4	+.22	+8

Diabetes has become the greatest public health crisis of the 21st century. To stem the tide of this epidemic diabetes prevention and outreach efforts must expand, and at the same time scientists and researchers must continue their work towards finding a cure. Therefore, we are requesting:

—A $20.8 million increase for the CDC's Division of Diabetes Translation (DDT), only one dollar for each American suffering from diabetes. This program was left at flat funding in the recently-passed joint funding resolution, although it had been slated for an increase in both the House and Senate passed bills.

—An 8 percent increase over fiscal year 2007 funding at NIH's National Institute for Diabetes, Digestive and Kidney Diseases (NIDDK), the amount included in last year's NIH Reauthorization package. These funds would make up for previous cuts and allow for the ongoing cost of biomedical inflation, which continues to eat into the purchasing power of research funding.

DIABETES INTERVENTIONS AT THE CENTERS FOR DISEASE CONTROL & PREVENTION

The CDC's Division of Diabetes Translation is critical to our national efforts to prevent and manage diabetes because DDT literally translates research into real interventions at the community level. Currently, for every dollar that diabetes costs this country, the Federal Government invests less than one cent to help Americans prevent and manage this deadly disease. This dynamic must be changed. Our request of $20.8 million will allow these critical programs to expand to more adequately meet the growing demands of the diabetes epidemic.

In 2006, DDT provided support for more than 50 State, and territorial, based Diabetes Prevention and Control Programs (DPCPs) to increase outreach and education, and to reduce the complications associated with diabetes. However, due to funding constraints, DDT is able to provide full support to only 28 States. The remaining 22 States, 8 territories, and the District of Columbia are given no more than partial support. This level of funding, referred to as "capacity building," allows a State to do surveillance, but is not enough for the State to do much—or in some

[1] Frank Vinicor, Associate Director for Public Health Practice at the Centers for Disease Control, qtd. in N.R. Kleinfield, "Diabetes and Its Awful Toll Quietly Emerges as a Crisis," The New York Times, 9 January 2006.

cases, anything—in the way of intervention. Even more alarming, DDT's current funding level only allows for prevention activities in five States. While we know from clinical trials[2] that the onset of type 2 diabetes can be delayed or prevented in most cases, this dismal funding for primary prevention falls far short of the resources needed to address the 54 million Americans with pre-diabetes.

For those 28 States DDT was able to provide a higher level of support called basic implementation. At this level, States are able to devise and execute community based programs. Without adequately funded diabetes programs and projects in all parts of the country, it will be exceedingly difficult—if not impossible—to control the escalating costs associated with diabetes-associated complications and to stem the epidemic rise in diabetes rates. State DPCPs, when provided with enough funding, are proven to have been extremely successful in helping Americans prevent and manage their diabetes. In the Division of Diabetes Translation Program Review fiscal year 2004, the CDC stated, "The Basic Implementation DPCPs serve as the backbone for our growing primary prevention efforts. These State programs are the key elements to our success in meeting the challenges of controlling and preventing diabetes."

For example, the Pennsylvania DPCP provides funding to support two of the Commonwealth's eight community-based Diabetes Nurse Consultants which provide information and consultation services to patients and their families, health care providers, schools, nursing homes and countless others in all 67 counties. These programs have demonstrated success in promoting physical activity, weight and blood pressure control, and smoking cessation for those with diabetes. Americans in every State should have access to such quality programs. Unfortunately, States such as Iowa and Mississippi are currently funded at levels that don't allow for basic implementation. The Division's fiscal year 2007 budget of $63 million had no increase from fiscal year 2006 and the President has requested flat funding again for fiscal year 2008.

In addition to DPCP activities, the CDC's Division of Diabetes Translation conducts other activities to help people currently living with diabetes. To put research into action, CDC works with NIH to jointly sponsor the National Diabetes Education Program (NDEP), which seeks to improve the treatment and outcomes of people with diabetes, promote early detection, and prevent the onset of diabetes. The CDC is also currently working to develop a National Public Health Vision Loss Prevention Program that will investigate the economic burden and strengthen the surveillance and research of this all-to-common complication of diabetes. In addition, CDC funds work at the National Diabetes Laboratory to support scientific studies that will improve the lives of people with diabetes. In fiscal year 2005, the Division of Diabetes Translation alone published 53 manuscripts on the care, prevention, and science of diabetes, including 17 abstracts.

DIABETES RESEARCH AT THE NATIONAL INSTITUTES FOR HEALTH

While there is not yet a cure for diabetes, researchers at NIH are working on a variety of projects that represent hope for the millions of individuals with type 1 and type 2 diabetes. The list of advances in treatment and prevention is thankfully a long one, but it is important to understand what has been, and what can be, achieved for Americans with diabetes. For example, the Diabetes Control and Complications Trial (DCCT), a clinical trial of 1,441 people with type 1 diabetes, demonstrated that tight control of blood glucose through intensive insulin therapy could significantly reduce or delay many complications due to diabetes. This landmark finding spurred a shift in the daily management of type 1 diabetes and energized research in the field. Subsequent funding has allowed research to continue on topics like risk factors, genetics, and complications that provide new approaches to improve therapy of diabetes.

Obesity is a strong risk factor for type 2 diabetes, especially in minority populations. Recognizing the growing problem of obesity and its increasing prevalence among youth, the NIDDK is focusing on paths to prevention. One example of this focus is the HEALTHY study, which is led by the NIDDK and co-sponsored by the American Diabetes Association. This study is testing a middle school-based intervention to reduce students' risk factors for type 2 diabetes, such as obesity.

Additionally, based on NIH-funded research, scientists have made great progress in developing methods that slow the onset and progression of kidney disease in peo-

[2] The Diabetes Prevention Program (DPP) was a major clinical trial, or research study, aimed at discovering whether either diet and exercise or the oral diabetes drug metformin (Glucophage) could prevent or delay the onset of type 2 diabetes in people with impaired glucose tolerance.

ple with diabetes, such as employing drugs that are typically used to lower blood pressure. These antihypertensive drugs can slow the progression of kidney disease significantly. Two types of drugs, angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), have proven effective in slowing the progression of kidney disease.

A generation ago, 20 percent of individuals diagnosed with type 1 diabetes died within 20 years of diagnoses and 30 percent died within 25 years. Thanks to research at NIDDK, patients now use a variety of insulin formulations, including rapid-acting, intermediate acting, long-acting insulin, and even insulin pumps, to control their blood glucose with much better precision. When it comes to diabetes, real-life results from research do not merely represent potential advances; the advances are happening now and they are improving and saving lives.

The Association strongly encourages you to provide at least an 8 percent increase to the NIH to build upon and fulfill this promise of scientific research. Unfortunately, while the death rate due to diabetes has increased by 45 percent since 1987, diabetes research funding has not kept pace. Indeed, from 1987 to 2001, appropriated diabetes funding as a share of the overall NIH budget has dropped by more than 20 percent (from 3.9 percent to 2.9 percent). While Congress had initially begun to address this discrepancy, the fiscal year 2007 Joint Funding Resolution essentially maintained the cuts of recent years, although NIDDK did not have to contribute to the new Common Fund. Still, this does not account for even the cost of biomedical inflation. The Association believes that NIH research and CDC translational programs go hand in hand in the effort to combat the diabetes epidemic.

The Association, and the millions of individuals with diabetes it represents, firmly believes that we could rapidly move toward curing, preventing, and managing this disease by increasing funding for diabetes programs and research at both CDC and NIH. Your leadership is essential to accomplishing this goal. As you are considering fiscal year 2008 funding, we ask you to remember that chronic diseases, including diabetes, account for nearly 70 percent of all health care costs as well as 70 percent of American deaths annually. Unfortunately, less than $l.25 per person is directed toward public health interventions focused on preventing the debilitating effects associated with chronic diseases, demonstrating that Federal investment in chronic disease prevention remains grossly inadequate. We cannot ignore those Americans who are currently living with diabetes and other diseases.

In closing, the American Diabetes Association strongly urges the subcommittee and the Senate to provide a $20.8 million increase for the CDC's Division of Diabetes Translation. Providing this funding would be an important step towards empowering the effort fight diabetes at the community and national levels. Additionally, we urge the subcommittee to increase NIH funding by 8 percent, the level that was authorized in the bipartisan NIH Reauthorization legislation that passed both the House and Senate last year by overwhelming margins. These funding levels would allow for an increased commitment to diabetes research.

An important question has been raised, "Where will we be in 10 years?" For diabetes, the answer to that question is truly in your hands. The disease is growing at a rate of 8 percent annually, but the government has not increased the resources to prevent, treat or find a cure for diabetes in over 4 years. In 2002, the United States spent $132 billion in direct and indirect costs for diabetes. If these trends continue for the next 10 years, the costs—in human life and economics—will be truly unimaginable.

On behalf of the 20.8 million Americans with diabetes—a disease that crosses gender, race, ethnicity and political party; a disease that is among the most costly, debilitating, deadly and prevalent in our Nation; and a disease that is unnecessarily on the rise—I thank you for the opportunity to submit this testimony. The American Diabetes Association is prepared to answer any questions you might have on these important issues.

PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

Over the past 50 years, we have made enormous progress against heart disease, stroke and other forms of cardiovascular disease (CVD). According to the National Institutes of Health, 1.6 million lives have been saved since the 1960s that would have been lost to CVD. Americans can expect to live 4 years longer from a drop in heart disease deaths.

In spite of progress, we have not declared victory, and we may be losing ground. An estimated 80 million American adults suffer from CVD. Despite educational efforts, increased rates of diabetes, obesity and other risk factors may undo four dec-

ades of declining mortality. And, we are often not reaching those at most risk, like those with lower socioeconomic status.

The morbidity and mortality rates still startle. Nearly 2,400 Americans die from CVD each day—an average of one death every 36 seconds. Heart disease and stroke remain the No. 1 and No. 3 killers, respectively, for both men and women in the United States today and two of three men and one of two women will develop CVD during their lifetime.

To make matters worse, a perfect storm is taking shape fueled by demographics. As the baby boomers age, the number of Americans developing CVD will increase radically. CVD can strike at any age, but the odds increase with age. A report estimates that heart disease deaths will increase 130 percent from 2000 and 2050.

Beyond the toll in suffering and death, CVD comes with a steep price tag. It costs Americans an estimated $432 billion in medical expenses and lost productivity in 2007—more than any other disease. We will soon be facing a CVD crisis of staggering proportions and implications for health care costs and quality of care. We ignore it at our collective peril.

BUDGET RECOMMENDATIONS: INVESTING IN THE HEALTH OF OUR NATION

Although progress has been made in the prevention and treatment of CVD, there is still no cure and more Americans than ever are at risk. The most prudent way to address this looming crisis is to simultaneously invest in research, prevention and treatment. Regretfully, the funding levels proposed by the administration in its fiscal year 2008 budget undermine these efforts.

Now is not the time to reduce our investment in programs that prevent and treat America's leading and most costly killer. Solving a problem of this magnitude requires a major public investment. If we fail to take aggressive and deliberate action now—we will pay later in health care expenditures and lives. The American Heart Association's recommendations that follow address this problem in a comprehensive but fiscally responsible way.

Increase Funding for the National Institutes of Health (NIH)

NIH research has revolutionized patient care and holds the key to a cure for CVD. NIH research also fuels innovation that generates economic growth and preserves our Nation's role as the world leader in the pharmaceutical and biotechnology industries. The President's request is $511 million below fiscal year 2007 and the gap between the levels achieved during the doubling of the NIH budget and the request, when adjusted for biomedical research inflation, exceeds 13 percent.

AHA Recommendation.—AHA advocates for a fiscal year 2008 appropriation of $30.8 billion for NIH. It represents the first year of a 3-year campaign to get NIH funding "Back on Track." A 6.7 percent funding increase for each of the next 3 years would restore and protect the past investment made by the Congress in doubling the resources of the NIH.

Increase Funding for NIH Heart and Stroke Research: A Proven Investment

From 1994–2004, death rates from cardiovascular diseases, coronary heart disease and stroke have fallen respectively by 25 percent, 33 percent and 20 percent. Much of this progress can be attributed to NIH heart and stroke research which has improved health outcomes and in some cases, lowered health care costs. Examples of recent NIH research accomplishments include:

—*CVD Research a Good Value*.—NIH's cumulative investment in CVD research over the past 30 years has resulted in a 63 percent decrease in heart disease deaths at a projected value of $1.5 trillion per year from 1970 to 1990 due to increase in life expectancy.

—*Stroke Trials Benefit Economy*.—The original NIH tPA trial resulted in a 10-year net reduction in healthcare costs of $6.47 billion. The Stroke Prevention in Atrial Fibrillation Trial 1 resulted in a 10-year net benefit of $1.27 billion, with a savings of 35,000 quality-adjusted life years.

—*Stroke Rehabilitation*.—Constraint-Induced Movement Therapy, a rehabilitative method involving forced use of a paralyzed arm, can help stroke survivors regain arm function.

—*Late Angioplasty No Advantage*.—An international study found that stable heart attack survivors who received angioplasty and stenting three to 28 days after the attack did no better than patients receiving, primarily drug treatment. These findings could reduce unnecessary interventions and lower health care costs.

In spite of these and other successes, NIH heart and stroke research budget remains disproportionately under-funded compared to the disease burden. CVD meets NIH's priority setting criteria (public health needs, scientific quality of research, sci-

entific progress potential, portfolio diversification and adequate infrastructure support), yet only 7 percent of the NIH budget is invested in heart research and a mere 1 percent is devoted to stroke.

Cardiovascular Disease Research

Relative to the amount needed to keep pace with medical research inflation, proposed funding for cardiovascular research will decline by 15 percent since fiscal year 2003. These limited resources cannot adequately support and expand current activities or allow investments in promising initiatives to aggressively advance the fight against heart disease and stroke—the first and third causes of death among Americans. Additional funds could be used in the following areas:

—*Atherosclerosis Prevention Trial*.—Atherosclerosis is a main risk factor for heart disease and stroke. With increased funding, the National Heart, Lung, and Blood Institute (NHLBI) could initiate a clinical trial to determine if reducing low-density lipoprotein cholesterol, so-called "bad" cholesterol, to a level lower than currently recommended, reduces major CVD events in healthy patients at high risk of heart disease and or stroke.

—*Systolic Blood Pressure Intervention Trial*.—High blood pressure is a major risk factor for heart disease, heart failure and stroke. Additional funding would allow the NHLBI to conduct a multi-center clinical trial to determine whether reducing systolic blood pressure to a lower level than currently recommended could prevent heart attacks and strokes.

—*Preventing Weight Gain in Young Adults*.—With additional resources, NHLBI could support small-scale studies to develop and evaluate promising, innovative practical, cost-effective ways for young adults to reduce their risk for CVD by preventing weight gain.

Stroke Research

Stroke is the No. 3 killer of Americans and a major cause of permanent disability. In addition to the elderly, stroke also strikes newborns, children and young adults. An estimated 700,000 Americans will suffer a stroke this year, and nearly 150,000 will die. Many of America's 5.7 million stroke survivors face debilitating physical and mental impairment, emotional distress and huge medical costs; about 1 in 4 survivors are permanently disabled.

As a result of fiscal year 2001 congressional report language, the National Institute of Neurological Disorders and Stroke (NINDS) convened a Stroke Progress Review Group (PRG). Their report provided a long-range strategic plan for stroke research. The PRG was reconvened last year and took stock of interim progress and re-evaluated recommendations for future research. Since the issuance of the initial report, multiple scientific programs have been undertaken; but, more funding is needed to fully implement the strategic plan. The fiscal year 2008 request for NINDS stroke research falls 56 percent short of the strategic plan's target for that year. Additional funding could be used to conduct stroke research in the following areas:

—*Stroke Translational Research*.—Translational studies are vital to providing cutting-edge stroke treatment and prevention. Due to budget shortfalls, the NINDS has been forced to compress its Specialized Programs of Translational Research in Acute Stroke (SPOTRIAS) from the planned 10 extramural centers to the five currently funded. SPOTRIAS researchers facilitate translation of basic research into patient care and evaluate and treat victims rapidly after the onset of stroke symptoms.

—*Neurological Emergencies Treatment Trials Network*.—Limited resources will also force the NINDS to scale back its Neurological Emergencies Treatment Trials Network. This initiative is designed to develop a clinical research network of emergency medicine physicians, neurologists and neurosurgeons to develop through clinical trials more and improved treatments for acute neurological emergencies, such as stroke.

—*Stroke Education*.—In partnership with CDC, NINDS launched a grassroots program called "Know Stroke in the Community." It includes enlisting the aid of "Stroke Champions" who teach communities about signs and symptoms. The goal is to shift stroke treatment from supportive care to early brain-saving intervention. But, more funding is needed to teach the public and health providers.

AHA Recommendation.—AHA recommends an fiscal year 2008 appropriation of $2.2 billion for NIH heart research; $3.1 billion for the NHLBI; $362 million for NIH stroke research; and $1.6 billion for the NINDS. These figures represent a 6.7 percent increase over fiscal year 2007—commensurate with the Association's recommended funding increase for the NIH.

Increase Funding for the Centers for Disease Control and Prevention (CDC)

Basic research must be translated into easy-to-understand guidance so people can apply it in their daily lives. Prevention is the best way to protect Americans' health and ease the financial burden of disease. While literature indicates that increased and improved CVD interventions can be highly successful, investigators have also concluded that effective strategies for combating CVD are often not being implemented. A study suggests that not smoking, maintaining a healthy weight, and avoiding diabetes, high blood pressure and high cholesterol may add 10 years to life.

AHA commends Congress for supporting CDC's Division for Heart Disease and Stroke Prevention which funds 33 States to create or implement programs to prevent first and second instances of heart disease and stroke. These state-tailored programs aide collaboration among public and private sectors to help people lower blood pressure and cholesterol, learn signs and symptoms, call 9–1–1, improve emergency response and quality care, and end treatment disparities. Many of these programs have reduced risk, like high blood pressure.

In fiscal year 2007, only 14 States receive funding to implement these prevention programs. The remaining 19 receive funds for planning; which is now largely complete. Because cardiovascular disease is the No. 1 killer in every State, each State needs basic implementation money for this program; however, current funding levels are insufficient for its expansion.

AHA Recommendation.—For fiscal year 2008, AHA recommends an appropriation of $10.7 billion (including funding for ATSDR, and the current funding level for the Vaccines for Children Program) for CDC, with increases targeted for programs within the National Center for Chronic Disease Prevention and Health Promotion. Within that total, we recommend $64.3 million for the Division for Heart Disease and Stroke Prevention, allowing CDC to: (1) add up to 12 States to the program to conduct state-tailored plans; (2) elevate up to 6 States from planning to program implementation; (3) support the Paul Coverdell National Acute Stroke Registry; (4) start development of a state-based cardiac arrest registry; and (5) explore establishment of a National Heart Disease and Stroke Surveillance Unit to monitor data, identify grave gaps, and offer modifications to existing components to fill the gaps.

Restore Funding for Rural and Community Access to Emergency Devices (AED) Program

About 94 percent of cardiac arrest victims die outside of a hospital. Immediate CPR and early intervention using AEDs can more than double a victim's chance of survival. Small, easy-to-use AEDs can shock the heart back into normal rhythm. Placing AEDs in more public settings could save thousands of lives each year. Communities with comprehensive AED programs that include training of anticipated rescuers have achieved survival rates of 40 percent or higher.

The Rural and Community AED Program provides grants to States to train lay rescuers and first responders to use AEDs and buy and place them where sudden cardiac arrests are likely to occur. During the first year of the program, 6,400 AEDs were purchased and 38,800 individuals were trained. AEDs have been placed in schools, faith-based and recreation facilities, nursing homes, and other locations in communities across our Nation. In spite of this success, the Rural and Community AED Program is terminated in the President's fiscal year 2008 budget.

AHA Recommendation.—For fiscal year 2008, AHA recommends restoration of HRSA's Rural and Community AED Program to its fiscal year 2005 level of $8.927 million.

Increase funding for the Agency for Healthcare Research and Quality (AHRQ)

AHRQ is a key partner of the public and private health care sectors. AHRQ helps develop evidence-based information needed by consumers, providers, health plans and policymakers to improve health care decision making. Through its Effective Health Care Program, AHRQ supports research focusing on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices and health care services for conditions like ischemic heart disease, stroke, and high blood pressure. The research and comparative effectiveness reviews conducted and funded address issues raised in the Institute of Medicine's Crossing the Quality Chasm.

Their initiative on health information technology is key to our Nation's strategy to bring health care into the 21st century. It includes more than $166 million in grants. Through these and other projects, AHRQ and its partners help identify challenges to HIT adoption and use, solutions and best practices, and tools that help hospitals and clinicians incorporate HIT.

AHA Recommendation.—AHA joins with Friends of AHRQ in advocating for an appropriation of $350 million for AHRQ, restoring the agency to its fiscal year 2005

level to advance health care quality, cut medical errors and expand availability of health outcomes information.

Although heart disease, stroke and other cardiovascular diseases are largely preventable, they continue to exact a deadly and costly toll. And as baby boomers age, our Nation faces an expanding cardiovascular crisis that threatens to overwhelm us unless significant and meaningful steps are taken. But, adequate funding of research, treatment and prevention programs will save lives and reduce rising health care costs. We urge Congress to consider the Association's recommendations during its deliberations on the fiscal year 2008 budget.

PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

Summary of Requests.—Summarized below are the fiscal year 2008 recommendations for the Nation's 34 Tribal Colleges and Universities (TCUs), covering three areas within the Department of Education and one in the Department of Health and Human Services, Administration for Children and Families' Head Start Program.

DEPARTMENT OF EDUCATION PROGRAMS

A. Higher Education Act Programs

Strengthening Developing Institutions.—Section 316 of Title III Part A, specifically supports TCUs through two separate grant programs: (a) basic development grants, and (b) facilities/construction grants designed to address the critical facilities needs at TCUs. The TCUs urge the subcommittee to restore the funding cut proposed in the President's fiscal year 2008 Budget and increase funding to $32.0 million and that report language be restated clarifying that funds in excess of those needed to support continuation grants or new planning or implementation grants shall be used for facilities, renovation, and construction grants.

Pell Grants.—TCUs urge the subcommittee to fund the Pell Grants Program at the highest possible level.

B. Perkins Career and Technical Education Programs

The TCUs support $8.5 million for Sec. 117 of the Carl D. Perkins Career and Technical Education Improvement Act and request language reaffirming that this program remains specific to the two Tribally Controlled Postsecondary Vocational Institutions: United Tribes Technical College and Navajo Technical College. Additionally, TCUs strongly support the Native American Career and Technical Education Program (NACTEP) authorized under Sec. 116 of the act.

C. Relevant Title IX Elementary and Secondary Education Act (ESEA) Programs

Adult and Basic Education.—Although Federal funding for tribal adult education was eliminated in fiscal year 1996, TCUs continue to offer much needed adult education, GED, remediation and literacy services for American Indians, yet their efforts cannot meet the demand. The TCUs request that the subcommittee direct $5.0 million of the Adult Education State Grants appropriated funds to make awards to TCUs to support their adult and basic education programs.

American Indian Teacher and Administrator Corps.—The American Indian Teacher Corps and the American Indian Administrator Corps offer professional development grants designed to increase the number of American Indian teachers and administrators serving their reservation communities. The TCUs request that the subcommittee support these programs at $10.0 and $5.0 million, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES PROGRAM

D. Tribal Colleges and Universities Head Start Partnership Program (DHHS–ACF)

Tribal Colleges and Universities are ideal partners to help achieve the goals of Head Start in Indian Country. The TCUs are working to meet the mandate that Head Start teachers earn degrees in Early Childhood Development or a related discipline. The TCUs request that $5.0 million be designated for the TCU-Head Start partnership program, to ensure the continuation of current TCU programs and the funds necessary for additional TCU–Head Start partnership programs.

Mr. Chairman and members of the subcommittee, on behalf of this Nation's 34 Tribal Colleges and Universities (TCUs), which comprise the American Indian Higher Education Consortium (AIHEC), thank you for the opportunity to share our fiscal year 2008 funding recommendations for programs within the U.S. Department of Education and the U.S. Department of Health and Human Services—Head Start program.

I. BACKGROUND ON TRIBAL COLLEGES AND UNIVERSITIES:

The vast majority of tribal colleges is accredited by independent, regional accreditation agencies and like all institutions of higher education, must undergo stringent performance reviews on a periodic basis to retain their accreditation status. In addition to college level programming, TCUs provide much needed high school completion (GED), basic remediation, job training, college preparatory courses, and adult education. Tribal colleges fulfill additional roles within their respective reservation communities functioning as community centers, libraries, tribal archives, career and business centers, economic development centers, public meeting places, and child care centers. Each TCU is committed to improving the lives of its students through higher education and to moving American Indians toward self-sufficiency.

Tribal Colleges and Universities provide access to higher education for American Indians and others living in some of the Nation's most rural and economically depressed areas. The average family income for a student first entering a TCU is $14,000, which is 27 percent below the Federal poverty threshold for a family of four. In addition to serving their students, TCUs serve their communities through a variety of community outreach programs.

These institutions, chartered by their respective tribal governments, were established in response to the recognition by tribal leaders that local, culturally based institutions are best suited to help American Indians succeed in higher education. TCUs combine traditional teachings with conventional postsecondary curricula. They have developed innovative ways to address the needs of tribal populations and are overcoming long-standing barriers to success in higher education for American Indians. Since the first TCU was established on the Navajo Nation, these vital institutions have come to represent the most significant development in the history of American Indian higher education, providing access to and promoting achievement among students who may otherwise never have known postsecondary education success.

II. JUSTIFICATIONS

A. Higher Education Act

The Higher Education Act Amendments of 1998 created a separate section within Title III, Part A, specifically for the Nation's Tribal Colleges and Universities (Section 316). Programs under Titles III and V of the act support institutions that enroll large proportions of financially disadvantaged students and have low per-student expenditures. Although TCUs, which are truly developing institutions, are providing access to quality higher education opportunities to some of the most rural and impoverished areas of the country, the President's fiscal year 2008 budget proposes a 20 percent cut to the TCU Title III grants program. A clear goal of the Higher Education Act Title III programs is "to improve the academic quality, institutional management, and fiscal stability of eligible institutions, in order to increase their self-sufficiency and strengthen their capacity to make a substantial contribution to the higher education resources of the Nation." The TCU Title III program is specifically designed to address the critical, unmet needs of their American Indian students and communities, in order to effectively prepare them for the workforce of the 21st Century. The TCUs urge the subcommittee to reject the substantial cut proposed in the President's budget and fund Title III–A section 316 at $32.0 million in fiscal year 2008, an increase of $8.2 million over fiscal year 2007 and $13.5 million over the President's request to afford these developing institutions the resources necessary to address the needs of their historically underserved students and communities. Additionally, we request that report language be restated clarifying that funds in excess of those needed to support continuation grants or new planning or implementation grants shall be used for single year facilities, renovation, and construction grants to ensure TCUs will be able to operate in adequate and safe facilities.

The importance of Pell grants to TCUs students cannot be overstated. U.S. Department of Education figures show that the majority of TCU students receive Pell grants, primarily because student income levels are so low and our students have far less access to other sources of aid than students at State funded and other mainstream institutions. Within the tribal college system, Pell grants are doing exactly what they were intended to do—they are serving the needs of the lowest income students by helping them gain access to quality higher education, an essential step toward becoming active, productive members of the workforce. The TCUs urge the subcommittee to fund this critical grants program at the highest possible level.

B. Carl D. Perkins Career and Technical Education Act

Tribally-Controlled Postsecondary Vocational Institutions.—Section 117 of the Perkins Act provides basic operating funds for two of our member institutions: United

Tribes Technical College in Bismarck, North Dakota, and Navajo Technical College in Crownpoint, New Mexico. The TCUs urge the subcommittee to fund this program at $8.5 million.

Native American Career and Technical Education Program.—The Native American Career and Technical Education Program (NACTEP) under Sec. 116 of the act reserves 1.25 percent of appropriated funding to support Indian vocational programs. The TCUs strongly urge the subcommittee to continue to support NACTEP, which is vital to the survival of vocational education programs being offered at Tribal Colleges and Universities.

C. Greater Support of Indian Education Programs

American Indian Adult and Basic Education (Office of Vocational and Adult Education).—This program supports adult basic education programs for American Indians offered by TCUs, State and local education agencies, Indian tribes, institutions, and agencies. Despite a lack of funding, TCUs must find a way to continue to provide basic adult education classes for those American Indians that the present K–12 Indian education system has failed. Before many individuals can even begin the course work needed to learn a productive skill, they first must earn a GED or, in some cases, even learn to read. The number of students needing remedial educational programs before embarking on their degree programs is considerable at TCUs. There is a wide need for basic adult educational programs and TCUs need adequate funding to support these essential activities. Tribal colleges respectfully request that the subcommittee direct $5.0 million of the Adult Education State Grants appropriated funds to make awards to TCUs to help meet the ever increasing demand for basic adult education and remediation program services.

American Indian Teacher/Administrator Corps (Special Programs for Indian Children).—American Indians are severely under represented in the teaching and school administrator ranks nationally. These competitive programs are designed to produce new American Indian teachers and school administrators for schools serving American Indian students. These grants support recruitment, training, and in-service professional development programs for Indians to become effective teachers and school administrators and in doing so become excellent role models for Indian children. We believe that the TCUs are the ideal catalysts for these two initiatives because of their current work in this area and the existing articulation agreements they hold with 4-year degree awarding institutions. The TCUs request that the subcommittee support these two programs at $10.0 million and $5.0 million, respectively, to increase the number of qualified American Indian teachers and school administrators in Indian Country.

DEPARTMENT OF HEALTH AND HUMAN SERVICES/ADMINISTRATION FOR CHILDREN AND FAMILIES/HEAD START

Tribal Colleges and Universities (TCU) Head Start Partnership Program.—The TCU-Head Start Partnership has made a lasting investment in our Indian communities by creating and enhancing associate degree programs in Early Childhood Development and related fields. Graduates of these programs help meet the degree mandate for all Head Start program teachers. More importantly, this program has afforded American Indian children Head Start programs of the highest quality. A clear impediment to the ongoing success of this partnership program is the erratic availability of discretionary funds made available for the TCU-Head Start Partnership. In fiscal year 1999, the first year of the program, some colleges were awarded 3-year grants, others 5-year grants. In fiscal year 2002, no new grants were funded at all. In fiscal year 2003, funding for eight new TCU grants was made available, but in fiscal year 2004, only two new awards could be made because of the lack of adequate funds. The President's fiscal year 2008 budget includes a total request of $6,788,571,000 for Head Start Programs. The TCUs request that the subcommittee direct the Head Start Bureau to designate a minimum of $5.0 million of the $6.8 billion recommended for the TCU-Head Start Partnership program, to ensure that this critical program can continue and expand so that all TCUs have the opportunity to participate in the TCU-Head Start Partnership program.

III. CONCLUSION

Tribal Colleges and Universities provide access to higher education opportunities to many thousands of American Indians, and essential community services and programs to many more. The modest Federal investment in TCUs has already paid great dividends in terms of employment, education, and economic development, and continuation of this investment makes sound moral and fiscal sense. Tribal colleges

need your help if they are to sustain and grow their programs and achieve their missions to serve their students and communities.

Thank you again for this opportunity to present our funding recommendations. We respectfully ask the members of the subcommittee for their continued support of the Nation's Tribal Colleges and Universities and full consideration of our fiscal year 2008 appropriations needs and recommendations.

PREPARED STATEMENT OF THE AMERICAN LUNG ASSOCIATION

SUMMARY: FUNDING RECOMMENDATIONS

[In millions of dollars]

	Amount
National Institutes of Health	30,537
National Heart, Lung, and Blood Institute	3,114
National Cancer Institute	5,111
National Institute of Allergy and Infectious Disease	4,675
National Institute of Environmental Health Sciences	683
National Institute of Nursing Research	146
Fogarty International Center	70
Centers for Disease Control and Prevention	10,700
National Institute for Occupational Safety and Health	285
Office on Smoking and Health	145
Environmental Health: Asthma Activities	70
Tuberculosis Control Programs	252
Influenza Pandemic	2,652

The American Lung Association is pleased to present our recommendations to the Labor Health and Human Services and Education Appropriations Subcommittee. These programs will make a difference in the lives of millions of Americans who suffer from lung disease.

The American Lung Association is one of the oldest voluntary health organizations in the United States, with a National Office and local associations around the country. Founded in 1904 to fight tuberculosis, the American Lung Association today fights lung disease in all its forms.

THE TOLL OF LUNG DISEASE

Each year, close to 400,000 Americans die of lung disease. Lung disease is America's number three killer, responsible for one in every six deaths. More than 35 million Americans suffer from a chronic lung disease. Each year lung disease costs the economy an estimated $157.8 billion. Lung diseases include: asthma, chronic obstructive pulmonary disease, lung cancer, tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease and sarcoidosis.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Chronic Obstructive Pulmonary Disease, or COPD, is a growing health problem. Yet, it remains relatively unknown to most Americans and much of the research community. COPD refers to a group of largely preventable diseases, including emphysema and chronic bronchitis that generally gradually limit the flow of air in the body. COPD is the fourth leading cause of death in the United States and worldwide. In 2004, the annual cost to the Nation for COPD was $37.2 billion. This includes $20.9 billion in direct health care expenditures, $8.9 billion in indirect morbidity costs and $7.4 billion in indirect mortality costs. Medicare expenses for COPD beneficiaries were nearly 2.5 times that of the expenditures for all other patients.

It has been estimated that 11.4 million patients have been diagnosed with some form of COPD and as many as 24 million adults may suffer from its consequences. In 2004, 120,104 people in the United States died of COPD. Women have exceeded men in the number of deaths attributable to COPD since 2000. Over the past 30 years, the death rate due to COPD has doubled while the death rates for heart disease, cancer and stroke have decreased by over 50 percent.

Today, COPD is treatable but not curable. Fortunately, promising research is on the horizon for COPD patients. Research on the genetic susceptibility underlying COPD is making progress. Research is also showing promise for reversing the damage to lung tissue caused by COPD. Despite these promising research leads, the

American Lung Association believes that research resources committed to COPD are not commensurate with the impact COPD has on the United States and the world.

The American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to COPD research programs. We support increasing the National Heart, Lung and Blood Institute budget to $3,114 billion. The Lung Association supports the CDC in gathering more information about COPD as part of the National Health and Nutrition Examination Survey, the Behavioral Risk Factor Surveillance System and other health surveys. This information will help public health professionals and researchers understand the disease better and lead to possible control of the disease.

TOBACCO USE

Tobacco use is the leading preventable cause of death in the United States, killing more than 438,000 people every year. Smoking is responsible for one in five U.S. deaths. The direct health care and lost productivity costs of tobacco-caused disease and disability are also staggering, an estimated $167 billion each year.

The CDC's Office on Smoking and Health provides significant technical assistance to States to develop comprehensive and effective tobacco prevention programs, in addition to providing a small, yet essential, amount of Federal assistance directly to State tobacco control and prevention programs. Funds for tobacco prevention at CDC also are used to maintain comprehensive information on smoking and health and to support ongoing research on tobacco-related issues.

We believe Congress should fund the type of youth tobacco prevention programs that science tells us are essential to counter the impact of tobacco company marketing to our kids. The American Lung Association strongly supports a minimum level of $145 million in fiscal year 2008 funding for the Office on Smoking and Health.

ASTHMA

Asthma is a chronic lung disease in which the bronchial tubes become swollen and narrowed, preventing air from getting into or out of the lung. An estimated 32.6 million Americans have ever been diagnosed with asthma by a health professional. Approximately 22.2 million Americans currently have asthma, of which 12.2 million had an asthma attack in 2005. Asthma prevalence rates are almost 12 percent higher among African Americans than whites. Studies also suggest that Puerto Ricans have higher asthma prevalence rates and age-adjusted death rates than all other Hispanic subgroups.

Asthma is expensive. Asthma incurs an estimated annual economic cost of $16.1 billion to our Nation. Asthma is the third leading cause of hospitalization among children under the age of 15. It is also the number one cause of school absences attributed to chronic conditions. The Federal response to asthma has three components: research, programs and planning. We are making progress on all three fronts but more must be done:

Asthma Research

Researchers are developing better ways to treat and manage chronic asthma. The NHLBI has shown that using corticosteroids to treat children with mild to moderate asthma is safe and effective. Genetic research is also providing insights into asthma. Researchers in the NHLBI-supported Asthma Clinical Research Network have discovered that a genetic variation determines how well asthma patients will respond to the most common asthma medication, inhaled beta-agonists. This discovery will help physicians better target the drugs they proscribe.

Asthma Programs

Last year, Congress provided approximately $31.9 million for the CDC to conduct asthma programs. The American Lung Association recommends that CDC be provided $70 million in fiscal year 2008 to expand its asthma programs. This funding includes State asthma planning grants, which leverage small amounts of funding into more comprehensive State programs.

Asthma Surveillance

In addition to public education programs, the CDC has been piloting programs to determine how to establish a nationwide health-tracking system. Congress needs to increase funding to create a nationwide health-tracking system, based on the localized pilots that are underway now.

LUNG CANCER

An estimated 351,344 Americans are living with lung cancer. During 2007, an estimated 213,380 new cases of lung cancer will be diagnosed. Also, 160,390 Americans will die from lung cancer. Survival rates for lung cancer tend to be much lower than those of most other cancers. Men have higher rates of lung cancer than women. However, over the past 30 years, the lung cancer age-adjusted incidence rate has decreased 9 percent in males compared to an increase of 143 percent in females. Further, African Americans are more likely to develop and die from lung cancer than persons of any other racial group.

Given the magnitude of lung cancer and the enormity of the death toll, the American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to lung cancer research programs. We support increasing the National Cancer Institute budget to $5.111 billion.

INFLUENZA

Influenza is a highly contagious viral infection and one of the most severe illnesses of the winter season. It is responsible for an average of 200,000 hospitalizations and 36,000 deaths each year. Further, the emerging threat of a pandemic influenza is looming. Public health experts warn that over half a million Americans could die and over 2.3 million could be hospitalized if a moderately severe strain of a pandemic flu virus hits the United States. To prepare for a potential pandemic, the American Lung Association supports funding the Federal Pandemic Influenza Plan at the recommended level of $2.652 billion.

TUBERCULOSIS

Tuberculosis primarily affects the lungs but can also affect other parts of the body. There are an estimated 10 million to 15 million Americans who carry latent TB infection. Each has the potential to develop active TB in the future. About 10 percent of these individuals will develop active TB disease at some point in their lives. In 2005, there were 14,097 cases of active TB reported in the United States. While declining overall TB rates are good news, the emergence and spread of multidrug resistant TB pose a significant threat to the public health of our Nation. Continued support is needed if the United States is going to continue progress toward the elimination of TB. We request that Congress increase funding for tuberculosis programs to $252 million for fiscal year 2008.

The NIH also has a prominent role to play in the elimination of TB. Currently there is no highly effective vaccine to prevent TB transmission. However, the recent sequencing of the TB genome and other research advances has put the goal of an effective TB vaccine within reach. In addition, the American Lung Association encourages the subcommittee to fully fund the TB vaccine blueprint development effort at the NIAID.

Fogarty International Center TB Training Programs

The Fogarty International Center at NIH provides training grants to U.S. universities to teach AIDS treatment and research techniques to international physicians and researchers. Because of the link between AIDS and TB infection, FIC has created supplemental TB training grants for these institutions to train international health care professionals in the area of TB treatment and research. However, we believe TB training grants should not be offered exclusively to institutions that have received AIDS training grants. The TB grants program should be expanded and open to competition from all institutions. The American Lung Association recommends Congress provide $70 million for FIC to expand the TB training grant program from a supplemental grant to an open competition grant.

ENVIRONMENTAL HEALTH

The National Institute of Environmental Health Sciences funds vital research on the impact of environmental influence on disease. The American Lung Association supports increasing the appropriation from this subcommittee to $680 million.

RESEARCHING AND PREVENTING OCCUPATIONAL LUNG DISEASE

The American Lung Association recommends that the subcommittee provide $285 million for the National Institute for Occupational Safety and Health (NIOSH) at the CDC.

CONCLUSION

In conclusion, Mr. Chairman, lung disease is a continuing, growing problem in the United States. It is America's number three killer, responsible for one in seven deaths. The lung disease death rate continues to climb. Mr. Chairman, the level of support this committee approves for lung disease programs should reflect the urgency illustrated by these numbers.

PREPARED STATEMENT OF THE AMERICAN NATIONAL RED CROSS AND THE UNITED NATIONS FOUNDATION

Chairman Harkin, Senator Specter, and members of the subcommittee, the American Red Cross and the United Nations Foundation appreciate the opportunity to submit testimony in support of measles control activities of the U.S. Centers for Disease Control and Prevention (CDC). The American Red Cross and the United Nations Foundation recognize the leadership that Congress has shown in funding CDC for these essential activities.

In 2001, CDC—along with the American Red Cross, the United Nations Foundation, the World Health Organization, and UNICEF—became one of the spearheading partners of the Measles Initiative, a partnership committed to reducing measles deaths globally. When the Initiative began, the United Nations had set the goal of reducing measles deaths by 50 percent by 2005 compared with 1999 figures. Measles is one of the leading causes of vaccine-preventable death worldwide, and at its outset this partnership committed to meeting that global goal.

Thanks to your leadership in appropriating funds, the international effort to reduce measles deaths has made tremendous progress. In January 2007, in an article published in "The Lancet," WHO announced that this goal was not only reached, but surpassed: global measles deaths had dropped from 873,000 in 1999 to 345,000 in 2005, a reduction of 60 percent. In sub-Saharan Africa, the success was even greater during those years, with measles deaths dropping by 75 percent, from 506,000 to 126,000.

How was this remarkable international public health success achieved? Working closely with host governments, the Measles Initiative has been the main international supporter of mass measles immunization campaigns since 2001. The Initiative mobilized more than $300 million and provided technical support to host governments in 48 developing countries conducting these vaccination campaigns and improving routine vaccination services. As a result, almost 400 million children in Africa and Asia received measles immunizations, preventing an estimated 2.3 million child deaths.

Nearly all the measles vaccination campaigns have been able to reach more than 90 percent of their target populations. Countries recognize the opportunities that measles vaccination campaigns provide in accessing mothers and young children, and have begun increasingly "integrating" the campaigns with other life-saving health interventions. In addition to measles vaccine, Vitamin A (crucial for preventing blindness in under nourished children), de-worming medicine, and insecticide-treated bed nets (ITNs) for malaria prevention are distributed during vaccination campaigns. The scale of these distributions is immense. For example, more than 18 million ITNs were distributed in vaccination campaigns in the last few years saving more than 378,000 lives. Thus, these campaigns protect young children from both measles and malaria, which kills an African child every 30 seconds. The delivery of multiple child health interventions during a single campaign is far less expensive than delivering the interventions separately, and this strategy increases the potential positive impact on children's health from a single campaign.

Based on the success in reaching the 2005 measles mortality reduction goal, a bold new global goal has been set: to reduce measles deaths by 90 percent by 2010 compared with 2000 figures. In addition to sustaining the reduction of measles cases and deaths in sub-Saharan Africa, the Initiative will provide funds and technical support to South Asia, where countries with the largest measles burdens are now found. Countries such as Pakistan and India have not yet mounted national measles vaccination campaigns due to competing health priorities and the challenges and costs of vaccinating tens of millions of children. Achieving this new goal will require the continued and expanded support of CDC for the purchase of vaccine and the provision of technical expertise in Africa and Asia.

By controlling measles cases in other countries, U.S. children are also being protected from the disease. A major resurgence of measles occurred in the United States between 1989 and 1991, with more than 55,000 cases reported. This resurgence was particularly severe, accounting for more than 11,000 hospitalizations and 123 deaths. Since then, measles control measures in the United States have been

strengthened and endemic transmission of measles cases have been eliminated here since 2000. However, importations of measles cases into this country continue to occur each year.

ROLE OF CDC IN GLOBAL MEASLES MORTALITY REDUCTION

From fiscal year 2001–2007, Congress provided more than $250 million in funding to CDC for global measles control activities. These funds were used for the purchase of over 200 million doses of measles vaccine for use in large-scale measles vaccination campaigns in 42 countries in Africa and 6 countries in Asia, and for the provision of technical support to Ministries of Health in those countries. Specifically, this technical support includes:

—Planning, monitoring, and evaluating large-scale measles vaccination campaigns;
—Conducting epidemiological investigations and laboratory surveillance of measles outbreaks; and
—Conducting operations research to guide cost-effective and high quality measles control programs.

In addition, CDC epidemiologists and public health specialists have worked closely with WHO, UNICEF, the United Nations Foundation, and the American Red Cross to strengthen measles control programs at global and regional levels.

While it is not possible to precisely quantify the impact of CDC's financial and technical support to the Measles Initiative, there is no doubt that CDC's support—made possible by the funding appropriated by Congress—was essential in helping achieve the sharp reduction in measles deaths in just 6 years.

The American Red Cross and the United Nations Foundation would like to acknowledge the leadership and work provided by CDC and recognize that CDC brings much more to the table than just financial resources. The Measles Initiative is fortunate in having a partner that provides critical personnel and technical support for vaccination campaigns and in response to disease outbreaks. CDC personnel have routinely demonstrated their ability to work well with other organizations and provide solutions to complex problems that help critical work get done faster and more efficiently.

In fiscal year 2007, Congress has appropriated approximately $43 million to fund CDC for global measles control activities. The American Red Cross and the United Nations Foundation thank Congress for the financial support that has been provided to CDC in the past and this year. We respectfully request an additional $10 million increase in the fiscal year 2008 funding for CDC's measles control activities so that the gains made to date can continue and the 2010 goal of a 90 percent reduction in measles deaths can be achieved.

The additional funds we are seeking for CDC are critical for:

—Sustaining the great progress in measles mortality reduction in Africa by strengthening measles surveillance and strengthening the delivery of measles vaccine through routine immunization services to protect new birth cohorts;
—Conducting large-scale measles vaccination campaigns in South Asia, thus protecting million of children;
—Conducting nationwide measles vaccination campaigns in countries, such as the Philippines, lacking access to traditional and new funding sources.

Your commitment has brought us unprecedented victories in reducing measles mortality around the world. Measles can cause severe complications and death. Your continued support for this initiative helps prevent children from needlessly suffering from this debilitating disease in the United States and abroad.

Thank you for the opportunity to submit testimony.

PREPARED STATEMENT OF THE AMERICAN NEPHROLOGY NURSES' ASSOCIATION

INTRODUCTION

On behalf of the American Nephrology Nurses' Association (ANNA), I appreciate having the opportunity to submit written testimony to the Senate Labor, Health, and Human Services (LHHS) Subcommittee regarding funding for nursing and nephrology related programs in fiscal year 2008. ANNA is a professional nursing organization of more than 12,000 registered nurses practicing in nephrology, transplantation, and related therapies. Nephrology nurses use the nursing process to care for patients of all ages who are experiencing, or are at risk for, kidney disease.

ANNA understands that Congress has many concerns and limited resources, but believes kidney disease is a heavy burden on our society that must be addressed. The United States has the highest incidence rate of late stage kidney disease in the

world.[1] The direct economic cost for treating kidney failure is $20 billion a year in the United States and the number of people diagnosed with kidney failure has doubled each decade for the last 20 years. Because kidney disease imposes such a heavy burden in the United States, we must provide adequate funding for research and prevention programs.

KIDNEY DISEASE AND NEPHROLOGY NURSING

Chronic kidney disease (CKD) is the slow, progressive loss of kidney function as a result of abnormalities of the kidney. The National Kidney Foundation estimates that around 20 million Americans have CKD, and another 20 million are at risk. When CKD patients lose 85 percent of kidney function, it is known as end stage renal disease (ESRD).[2] When patients reach ESRD, they must receive replacement therapy either in the form of dialysis or kidney transplant in order to survive. While kidney transplant is a treatment option for many ESRD patients, unfortunately the need for donor organs exceeds the supply, resulting in long waiting times for those who do not have a living donor.

CKD is often undiagnosed until the signs and symptoms related to the loss of kidney function materialize. Risk factors for developing CKD include increasing age, family history and diabetes. The disease is more prevalent in men and people of African American, American Indian, Hispanic, Asian, or Pacific Islander descent.

Since treatment of kidney patients often spans the duration of their lifetime, nephrology nurses must be skilled in offering care for all stages of life and disease progression. Nephrology nurses work in dialysis clinics, hospitals, physician practices, transplant programs, and many other settings.

To ensure that patients receive the best quality care possible, ANNA supports Federal programs and research institutions that address the national nursing shortage and conduct biomedical research into kidney disease and related health problems. Therefore, ANNA respectfully requests the Senate LHHS Appropriations Subcommittee provide increased funding for the following programs:

NURSING WORKFORCE AND DEVELOPMENT PROGRAMS AT THE HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

ANNA supports efforts to resolve the national nursing shortage, including appropriate funding to address the shortage of qualified nursing teaching faculty. Nephrology nursing requires a high level of education and technical expertise, and ANNA is committed to assuring and protecting access to professional nursing care delivered by highly educated, well-trained, and experienced registered nurses for individuals with kidney disease or other disease processes that require replacement therapies.

According to the Department of Health and Human Services, the Nursing Workforce Development programs at HRSA have supported the recruitment, education, and retention of an estimated 36,750 nurses. A report issued by HRSA, Projected Supply, Demand, and Shortages of Registered Nurses: 2000–2020, predicts that the nursing shortage is expected to grow by 29 percent by 2020. The HRSA Nursing Workforce Development Programs provide the largest source of Federal funding to address the national nursing shortage, therefore:

ANNA strongly supports the national nursing community's request of $200 million in fiscal year 2008 funding for Nursing Workforce Development programs at HRSA.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

As the primary professional caretakers of patients with CKD and ESRD, ANNA members support legislative, regulatory, and programmatic efforts that promote prevention and management of chronic kidney disease, including early diagnosis, education and proactive creation of native fistulae for dialysis.

NIDDK supports and conducts research on many serious diseases, including chronic kidney disease and ESRD. Specifically, the National Kidney Disease Education Program (NKDEP) at NIDDK is focused on reducing the overall mortality and morbidity from kidney disease. The programs at NKDEP were created to increase awareness about the seriousness of kidney disease, and the importance of prevention, early diagnosis, and appropriate management of kidney disease.

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[1] Sources: National Kidney Disease Education Program, American Nephrology Nurses' Association.

[2] American Nephrology Nurses' Association. (2006). Chronic Kidney Disease Fact Sheet [Brochure]. ANNA Chronic Kidney Disease Special Interest Group: Author.

ANNA encourages Congress to support funding for research into and prevention of kidney disease by providing the maximum possible funding level for NIDDK in fiscal year 2008.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

ANNA understands that research is essential for the advancement of nursing science, and believes new concepts must be developed and tested to sustain the continued growth of the nephrology nursing profession. NINR works to create cost-effective and high-quality health care by testing new nursing science concepts and investigating how to best integrate them into daily practice. NINR has a broad mandate that includes seeking to prevent and delay disease and to ease the symptoms associated with both chronic and acute illnesses. NINR's recent areas of research focus include the following:

—End of life and palliative care in rural areas;
—Research in multi-cultural societies;
—Bio-behavioral methods to improve outcomes research; and
—Increasing health promotion through comprehensive studies.

ANNA respectfully requests $150 million in funding for NINR in fiscal year 2008 to continue their efforts to address issues related to nursing care for chronic and acute illnesses.

CONCLUSION

I appreciate the opportunity to share ANNA's fiscal year 2008 funding priorities for programs designed to address issues relating to kidney disease and provide for a sustainable nursing workforce. Providing $200 million in fiscal year 2008 funding to the HRSA Nursing Workforce Development programs, $150 million to NINR and the largest allocation possible for NIDDK will ensure we are providing adequate resources for this fight. ANNA thanks the Senate LHHS Appropriations Subcommittee for their consideration and is happy to serve as a resource regarding these programs or other kidney disease or nursing related issues.

PREPARED STATEMENT OF THE AMERICAN OPTOMETRIC ASSOCIATION

The American Optometric Association appreciates the opportunity to submit written testimony to the file of the hearing of the Labor, Health and Human Services, Education and Related Agencies Subcommittee of the Senate Appropriations Committee in support of increased funding the National Eye Institute (NEI), of the National Institutes of Health (NIH).

The American Optometric Association represents over 35,000 practicing Doctors of Optometry across the Nation. As a profession devoted to improving the vision care and health of the public, doctors of optometry examine eyes and the visual system, treat ocular diseases and disorders, and diagnose related systemic conditions.

Doctors of optometry (ODs) are the primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures, as well as identify related systemic conditions affecting the eye.

—ODs prescribe medications, low vision rehabilitation, vision therapy, spectacle lenses, contact lenses, and perform certain surgical procedures.
—Optometrists counsel their patients regarding surgical and non-surgical options that meet their visual needs related to their occupations, avocations, and lifestyle.
—An optometrist has completed pre-professional undergraduate education in a college or university and 4 years of professional education at a college of optometry, leading to the doctor of optometry (O.D.) degree. Some optometrists complete an optional residency in a specific area of practice.
—Optometrists are eye health care professionals state-licensed to diagnose and treat diseases and disorders of the eye and visual system.

The American Optometric Association (AOA) requests fiscal year 2008 National Institutes of Health (NIH) funding at $31 billion, or a 6.7 percent increase over fiscal year 2007, to balance the biomedical inflation rate of 3.7 percent and to maintain the momentum of discovery. Although AOA commends the leadership's actions in the 110th Congress to increase fiscal year 2007 NIH funding by $620 million, this was just an initial step in restoring the NIH's purchasing power, which had declined by more than 13 percent since fiscal year 2005. That power would be eroded even further under the administration's fiscal year 2008 budget proposal. Funding would also be eroded even further under the administration's fiscal year 2008 budget pro-

posal. AOA commends NIH Director, Dr. Elias Zerhouni, who has articulately described his agenda to foster collaborative, cost-effective research and to transform the health care research and delivery paradigm into one that is predictive, preemptive, preventive, and personalized. NIH is the world's premier institution and must be adequately funded so that its research can reduce health care costs, increase productivity, improve quality of life, and ensure our Nation's global competitiveness.

AOA requests that Congress make eye and vision health a top priority by funding the National Eye Institute (NEI) at $711 million in fiscal year 2008, or a 6.7 percent increase over fiscal year 2007. This level is necessary to fully advance the breakthroughs resulting from NEI's basic and clinical research that are resulting in treatments and therapies to prevent eye disease and restore vision. Vision impairment/eye disease is a major public health problem that is growing and that disproportionately affects the aged and minority populations, costing the United States at least $68 billion annually in direct and societal costs, let alone the indirect costs of reduced independence and decreased quality of life. Adequately funding the NEI is a cost-effective investment in our Nation's health, as it can delay, save, and prevent expenditures, especially to the Medicare and Medicaid programs.

FUNDING THE NEI AT $711 MILLION IN FISCAL YEAR 2008 WOULD ENABLE IT TO LEAD TRANS-INSTITUTE VISION RESEARCH THAT MEETS NIH'S GOAL OF PREEMPTIVE, PREDICTIVE, PREVENTIVE, AND PERSONALIZED HEALTH CARE

Funding NEI at $711 million in fiscal year 2008 represents the judgment of the AOA and its partners in the eye and vision research community as the level necessary to fully advance breakthroughs resulting from NEI's basic and clinical research that are resulting in treatments and therapies to prevent eye disease and restore vision.

—NEI research responds to the NIH's overall major health challenges, as set forth by NIH Director Dr. Zerhouni: an aging population; health disparities; the shift from acute to chronic diseases; and the co-morbid conditions associated with chronic diseases (e.g., diabetic retinopathy as a result of the epidemic of diabetes). In describing the predictive, preemptive, preventive, and personalized approach to health care research, Dr. Zerhouni has also frequently cited NEI-funded research as a tangible example of the value of our Nation's past and future investment in the NIH.

Although NEI's breakthroughs came directly from the past doubling of the NIH budget, their long-term potential to preempt, predict, prevent, and treat disease relies on adequately funding NEI's follow-up research. Unless its funding is increased, the NEI's ability to capitalize on the findings cited above will be seriously jeopardized, resulting in missed opportunities that include:

—Following up on the Age-related Macular Degeneration (AMD) gene discovery by developing diagnostics for early detection and developing promising therapies, as well as to further study the impact of the body's inflammatory response on other degenerative eye diseases.

—Fully investigating the impact of additional, cost-effective dietary supplements in the Age-Related Eye Disease Study (AREDS) study, singly and in combination, to determine if they can demonstrate enhanced protective effects against progression to advanced AMD.

In addition, NEI research into other significant eye disease programs, such as glaucoma and cataract, will be threatened, along with quality of life research programs into low vision and chronic dry eye. This comes at a time when the U.S. Census and NEI-funded epidemiological research (also threatened without adequate funding) both cite significant demographic trends that will increase the public health problem of vision impairment and eye disease.

VISION IMPAIRMENT/EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM THAT IS INCREASING HEALTH CARE COSTS, REDUCING PRODUCTIVITY AND DIMINISHING QUALITY OF LIFE

The 2000 U.S. Census reported that more than 119 million people in the United States were age 40 years or older, which is the population most at risk for age-related eye disease. The NEI estimates that, currently, more than 38 million Americans age 40 years and older experience blindness, low vision or an age-related eye disease such as AMD, glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million Americans by 2020. The economic and societal impact of eye disease is increasing not only due to the aging population, but to its disproportionate incidence in minority populations and as a co-morbid condition of other chronic, common disease, such as diabetes.

Although the NEI estimates that the current annual cost of vision impairment and eye disease to the United States is $68 billion, this number does not fully quantify the impact of direct health care costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. The continuum of vision loss presents a major public health problem and financial challenge to both the public and private sectors.

In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer. As a result, Federal funding for the NEI is a vital investment in the health, and vision health, of our Nation, especially our seniors, as the treatments and therapies emerging from research can preserve and restore vision. Adequately funding the NEI can delay, save, and prevent expenditures, especially those associated with the Medicare and Medicaid programs, and is, therefore, a cost-effective investment.

AOA urges fiscal year 2008 NIH and NEI funding at $31 billion and $711 million, respectively

Of course, vision impairment and eye disease are not limited to the middle-aged and the elderly. Public health experts recommend that children visit an eye care professional in the first year of life—one of the most critical stages of visual development—to identify the potential for eye and vision problems.

In fact, current research shows us that:

—One in 10 children is at risk from undiagnosed eye and vision problems, which, if undetected, could lead to permanent vision impairment, and in rare cases, life-threatening health risks.

—Only 14 percent of children from infancy to age 6 have had a comprehensive eye assessment from an eye care professional.

The NEI has funded several clinical trials in the area of children's vision. The VIP Study (Vision in Preschoolers) evaluated the best screening tests to identify preschool children in need of vision care for amblyopia ("lazy" eye), strabismus (crossed eyes) and significant refractive errors (e.g., nearsightedness or farsightedness). The CLEER Study (Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error) evaluated the role of ethnicity in children's vision conditions. The CITT Study (Convergence Insufficiency Treatment Trial) is studying the success rates of treatments for convergence insufficiency (eye turns in). The NEI budget should be sufficient to permit funding of grants at a high level in the areas of strabismus, amblyopia and refractive error. Since about 60 percent of Americans have refractive errors requiring eyeglasses or contact lenses, research in the cause and prevention of refractive error should continue.

The value of clinical trials to the public cannot be overestimated. NEI has a remarkable record of scientific breakthroughs attributed to clinical trial research, beginning with studies of diabetic retinopathy in the 1970s. NEI clinical trials involve collaboration with many institutions, health professionals and thousands of patients. Although significant progress has been made, further clinical trial research is needed to determine the causes of refractive error and amblyopia in children and subsequent prevention of visual impairment.

In an effort to encourage early detection and treatment, the American Optometric Association launched in 2005 a national public health initiative to provide no-cost vision assessments for infants. The program is called InfantSEE®, and it's achieving remarkable results for children and their families. Thanks to the more than 7,500 of my colleagues from across the country who have volunteered their time and expertise to make this optometry's most successful vision saving and lifesaving public health initiative, more than 80,000 babies have received a vision assessment at no cost from their local optometrist.

PREPARED STATEMENT OF THE AMERICAN PUBLIC HEALTH ASSOCIATION

The American Public Health Association (APHA) is the Nation's oldest, largest and most diverse organization of public health professionals in the world, dedicated to protecting all Americans and their communities from preventable, serious health threats and assuring community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States. We are pleased to submit our views on Federal funding for public health activities in fiscal year 2008.

RECOMMENDATIONS FOR FUNDING THE PUBLIC HEALTH SERVICE

APHA's budget recommendation for overall funding for the Public Health Service includes funding for the Centers for Disease Control and Prevention (CDC), the

Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health (NIH), as well as agencies outside the subcommittee's jurisdiction—the Food and Drug Administration (FDA) and the Indian Health Service (IHS).

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

APHA believes that Congress should support CDC as an agency—not just the individual programs that it funds. We support a funding level for CDC that enables it to carry out its mission to protect and promote good health and to assure that research findings are translated into effective State and local programs.

In the best professional judgment of APHA, in conjunction with the CDC Coalition—given the challenges and burdens of chronic disease, a potential influenza pandemic, terrorism, disaster preparedness, new and reemerging infectious diseases, increasing drug resistance to critically important antimicrobial drugs and our many unmet public health needs and missed prevention opportunities—we believe the agency will require funding of at least $10.7 billion including sufficient funding to prepare the Nation against a potential influenza pandemic, funding for the Agency for Toxic Substances and Disease Registry and to maintain the current funding level for the Vaccines for Children (VFC) program. This request does not include any additional funding that may be required to expand the mandatory VFC in fiscal year 2008.

APHA appreciates the subcommittee's work over the years, including your recognition of the need to fund chronic disease prevention, infectious disease prevention and treatment, programs to combat racial, ethnic and geographic disparities in health and health care and environmental health programs at CDC. Federal funding through CDC provides the foundation for our State and local public health departments, supporting a trained workforce, laboratory capacity and public health education communications systems.

CDC also serves as the command center for our Nation's public health defense system against emerging and reemerging infectious diseases. With the for an potential onset of an influenza pandemic, in addition to the many other natural and manmade threats, CDC is the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center.

CDC's budget has actually shrunk since 2005 in terms of real dollars—by almost 4 percent. If you add inflation, the cuts are even worse—and these are cuts to the core programs of the agency. The current administration request for fiscal year 2008 is inadequate, with a total cut to core budget categories from fiscal year 2005 to fiscal year 2008 of half a billion dollars. We are moving in the wrong direction, especially in these challenging times when public health is being asked to do more, not less. Funding public health outbreak by outbreak is not an effective way to ensure either preparedness or accountability. Until we are committed to a strong public health system, every crisis will force trade offs.

CDC serves as the lead agency for bioterrorism preparedness and must receive sustained support for its preparedness programs in order for our Nation to meet future challenges. APHA supports the proposed increase for anti-terrorism activities at CDC, including the increases for the Strategic National Stockpile. However, we strongly oppose the President's proposed $125 million cut to the State and local capacity grants. We ask the subcommittee to restore these cuts to ensure that our States and local communities can be prepared in the event of an act of terrorism.

Unfortunately, the President's budget proposes the elimination of some very important CDC programs, like the Preventive Health and Health Services (PHHS) Block Grant. Within an otherwise-categorical funding construct, the PHHS Block Grant is the only source of flexible dollars for States and localities to address their unique public health needs. The track record of positive public health outcomes from PHHS Block Grant programs is strong, yet so many requests go unfunded. We encourage the subcommittee to restore the cuts and fund the Prevention Block Grant at $131 million.

We must address the growing disparity in the health of racial and ethnic minorities. CDC's Racial and Ethnic Approaches to Community Health (REACH), helps States address these serious disparities in infant mortality, breast and cervical cancer, cardiovascular disease, diabetes, HIV/AIDS and immunizations. Please provide adequate funds for this program.

We encourage the subcommittee to provide adequate funding for CDC's Environmental Public Health Services Branch to revitalize environmental public health services at the national, State and local level. As with the public health workforce,

the environmental health workforce is declining. Furthermore, the agencies that carry out these services are fragmented and their resources are stretched. These services are the backbone of public health and are essential to protecting and ensuring the health and well being of the American public from threats associated with West Nile virus, terrorism, *E. coli* and lead in drinking water. We encourage the committee to provide at least $50 million for CDC's Environmental Health Tracking Network.

We also encourage the subcommittee to provide $50 million to CDC Environmental Health Activities to develop and enhance CDC's capacity to help the Nation prepare for and adapt to the potential health effects of global climate change. This new request for funding would help prepare State and local health department to prepare for the public health impacts of global climate change, allow CDC to fund academic and other institutions in their efforts to research the impacts of climate change on public health and to create a Center of Excellence at CDC to serve as a national resource for health professionals, government leaders and the public on climate change science.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

HRSA programs are designed to give all Americans access to the best available health care services. Through its programs in thousands of communities across the country, HRSA provides a health safety net for medically underserved individuals and families, including more than 45 million Americans who lack health insurance; 50 million Americans who live in neighborhoods where primary health care services are scarce; African American infants, whose infant mortality rate is more than double that of whites; and the estimated 1 to 1.2 million people living with HIV/AIDS. Programs to support the underserved place HRSA on the front lines in erasing our Nation's racial/ethnic and rural/urban disparities in health status. HRSA funding goes where needs exists, in communities all over America. In the best professional judgment of APHA, to respond to this challenge, the agency will require an overall funding level of at least $7.5 billion for fiscal year 2008.

APHA is gravely concerned about a number of programs that are slated for deep cuts or elimination under the administration's budget proposal. Building on the HRSA programs that were cut or eliminated in the fiscal years 2006 and 2007 appropriations bills, we strongly suggest that this trend is moving our Nation in the wrong direction. We urge the subcommittee to restore funding to HRSA programs that were cut last year, as well as ensure adequate funding for fiscal year 2008 by rejecting the proposed cuts contained in the President's budget.

We express our dismay at the eroding support from the administration for some of HRSA's programs. On top of the $250 million cut to the agency for fiscal year 2006, the President has proposed another $321 million overall cut from last year's appropriated level. Under the proposal, total cuts to HRSA since fiscal year 2005 would reach more than $570 million, a devastating 8 percent cut in 2 years, which has been even more severe for HRSA's core programs from which funding has been diverted to fund other administration priorities. We urge the subcommittee to restore the cuts delivered to these programs in fiscal years 2006 and 2007, and reject the President's proposed cuts for fiscal year 2008. We are again concerned that the HRSA health professions programs under Title VII and VIII of the Public Health Service Act have landed on the chopping block. Today our Nation faces a widening gap between challenges to improve the health of Americans and the capacity of the public health workforce to meet those challenges. These programs help meet the health care delivery needs of the areas in this country with severe health professions shortages, at times serving as the only source of health care in many rural and disadvantaged communities.

We believe the elimination of the Healthy Community Access Program, the Traumatic Brain Injury program, universal newborn hearing screening programs, and the Emergency Medical Services for Children Program, will further undermine the availability of basic health services for those most in need-especially children. The Healthy Community Access Program is an example of communities building partnerships among health care providers to deliver a broader range of health services to their neediest residents. Elimination of the universal newborn hearing screening programs in the administration's budget will leave hearing impairments in infants undetected, negatively impacting speech and language acquisition, academic achievement, and social and emotional development. The proposed elimination of EMSC jeopardizes improvements made to pediatric emergency care, disproportionately affecting children eligible for Medicaid and SCHIP, but not enrolled due to State enrollment limits and budgetary pressures, and therefore frequently use emergency health services.

The Maternal and Child Health Block Grant is also operating for a third year with less funds than in fiscal year 2005, yet with greater needs among pregnant women, infants, and children, particularly those with special health care needs.

We are pleased with the increases proposed by the President for programs under the Ryan White CARE Act, administered by HRSA's HIV/AIDS Bureau. The CARE Act programs are an important safety net, providing an estimated 571,000 people access to services and treatments each year. At a time when the number of new domestic HIV/AIDS cases is increasing, we support increased funding for these programs.

Through its many programs, HRSA helps countless individuals live healthier lives. APHA believes that with adequate resources, HRSA is well positioned to meet these challenges as it continues to provide needed health care to the Nation's most vulnerable citizens. Please restore funds to these important public health programs.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

We request a funding level of $350 million for the AHRQ for fiscal year 2008. This level of funding is needed for the agency to fully carry out its congressional mandate to improve health care quality, including eliminating racial and ethnic disparities in health, reducing medical errors, and improving access and quality of care for children and persons with disabilities. The cuts proposed in the administration budget will severely hamper these efforts.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

APHA supports a funding level of $3.532 billion for SAMHSA for fiscal year 2008. This funding level would provide support for substance abuse prevention and treatment programs, as well as continued efforts to address emerging substance abuse problems in adolescents, the nexus of substance abuse and mental health, and other serious threats to the mental health of Americans.

NATIONAL INSTITUTES OF HEALTH (NIH)

APHA supports a funding level of $30.869 billion for the NIH for fiscal year 2008. The translation of fundamental research conducted at NIH provides some of the basis for community based public health programs that help to prevent and treat disease.

In closing, we emphasize that the public health system requires financial investments at every stage. Successes in biomedical research must be translated into tangible prevention opportunities, screening programs, lifestyle and behavior changes, and other interventions that are effective and available for everyone. We ask you to think in a broad and balanced way, leveraging funding whenever possible to provide public health benefits as a matter of routine, rather than emergency.

We thank the subcommittee for the opportunity to present our views on the fiscal year 2008 appropriations for public health service programs.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF NEPHROLOGY

INTRODUCTION

The American Society of Nephrology (ASN) is pleased to submit this statement for the record to the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education.

The ASN is a professional society of more than 10,000 researchers, physicians, and practitioners committed to the treatment, prevention, and cure of kidney disease. Specifically, the ASN strives to enhance and assist the study and practice of nephrology, to provide a forum for the promulgation of research, and to meet the professional and continuing education needs of its members.

This ASN statement focuses on those issues and programs that most immediately fall under the committee's jurisdiction and assist our members to fulfill their missions. We want to express our strong support for advancing programs supported by the National Institutes of Health (NTH) and Agency for Healthcare Research and Quality (AHRQ). The ASN thanks the subcommittee for its commitment and steadfast support of these programs.

KIDNEY DISEASE: A GROWING PUBLIC HEALTH CONCERN

Kidney disease is the ninth leading cause of death in the United States. It is estimated that at least 15 million people have lost 50 percent of their kidney function. Another 20 million more Americans are at increased risk of developing kidney dis-

ease. The culmination of unimpeded progression is end stage renal disease (ESRD), a condition in which patients have permanent kidney failure, affects almost 400,000 Americans and directly causes 50,000 deaths annually. In the past 10 years, the number of patients in the United States with ESRD has almost doubled and it is expected to reach 700,000 by 2015, according to the United States Renal Data System (USRDS). ESRD disproportionately affects minorities. For example, although they constitute approximately 12 percent of the U.S. Population, African Americans comprise 32 percent of the prevalent ESRD population and are nearly four times more likely to develop kidney disease than Caucasians. Native Americans are twice as likely. The elderly are also disproportionately affected. One in four new ESRD patients was 75 or older in 2004. The two major therapies for ESRD are dialysis and kidney transplantation. The number of patients waiting for a kidney transplant increased from 9,452 in 1988 to 60,393 in 2004. Almost 50 percent of kidney transplants are received by people aged 45–64.

ECONOMIC COSTS

Although no dollar amount can be affixed to human suffering or the loss of human life, economic data can help to identify and quantify the current and projected future financial costs associated with ESRD. The 2000 report of the USRDS indicates that the total Medicare ESRD program cost will more than double, surpassing $28 billion, by 2010, as the prevalence of kidney failure is projected to double. Currently, the total Medicare cost for ESRD is nearly $20.1 billion. The annual average cost per ESRD patient is approximately $58,000. These escalating costs serve to magnify the need to investigate new, and better apply, recently proven strategies for preventing progressive kidney disease.

In short, we can treat and maintain patients who have lost their kidney function but the critical need is to prevent the loss of kidney function and its complications in the first place. Meeting this vital goal can only be accomplished through more concerted research and education.

MAJOR CAUSES OF END STAGE RENAL DISEASE

Diabetes, a disease that affects 18 million Americans, is the most common cause of ESRD in the United States, accounting for 44 percent of new cases in 2002. The time from the onset of diabetes-related kidney disease to kidney failure is 5–7 years. With current projections that the epidemic of obesity-related diabetes mellitus will continue to soar, a dramatic increase in kidney disease is anticipated in the next 10 years.

Hypertension, or high blood pressure, is the next leading cause of ESRD, accounting for 27 percent of ESRD patients. Higher rates of hypertension can be found among certain age and ethnic groups. For example, 35 percent of African Americans have hypertension. Among new patients whose kidney failure was caused by high blood pressure, more than half (51.2 percent) were African American. It is also a disease of the aged and accounts for 37 percent of new ESRD cases in those 65 years old and above.

Despite recent progress and discoveries regarding the major causes of ESRD, it is among many areas of disease research that remain under-investigated. Researchers agree that significant inroads in previously understudied sub-fields need to be made. Significant among them, more focus and direction need to be introduced into the general field of renal research and patient and physician education.

LACK OF PUBLIC AWARENESS

A major problem with kidney disease is that it is largely a "Silent Disease". In fact, of the 15 million Americans who have lost at least half of their kidney function, the vast majority have no knowledge of their condition. While people with chronic kidney disease may not show any symptoms, this does not mean that they are not going to have long-term damage to their kidney function, requiring dialysis or a transplant. These people may also be especially vulnerable to cardiovascular disease. If these 15 million people were identified early, there are new therapies, particularly special blood pressure drugs known as ACE inhibitors, which could be prescribed with potentially significant benefits. In addition, vigorous treatment of hypertension and other complications that cause illnesses and loss of productivity could be administered to the patients.

Given the cost to human life and to the Federal Government caused by the growing public health issues of CKD and ESRD, we urge this subcommittee to provide funding increases for kidney disease research.

KIDNEY DISEASE RESEARCH

National Institutes of Health (NIH)

The ASN applauds Congress and members of the subcommittee for leading the bipartisan effort to double our investment in promising biomedical research supported and conducted by the NIH. NIH has served as a vital component in improving the Nation's health through research, both on and off the NIH campus, and in the training of research investigators, including nephrology researchers. Strides in biomedical discovery have had an impact on the quality of life for people with kidney disease. If we are to sustain this momentum and translate the promise of biomedical research into the reality of better health, this Nation must maintain its commitment to medical research. Unfortunately, since the doubling ended in 2003, funding for NIH has failed to keep pace with biomedical inflation and as a result, the NIH has lost more than 13 percent of its purchasing power. We support the recommendation of the Ad-Hoc Group for Medical Research Funding to add 6.7 percent to the NIH budget for a total of $30.869 in fiscal year 2008.

National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK)

Many recent advances have been made in our understanding into the causes and progression of renal failure, such as: how diabetes and hypertension affect the kidney and the mechanisms responsible for acute renal failure. Despite these advances, the number of people with renal failure and the numbers who die of renal failure continue to increase each year. Most alarming is the significant increase in diabetes, the most common cause of chronic kidney failure, and its relationship to kidney disease. The ASN believes the rising incidence and prevalence of diabetes-related kidney disease warrants additional recourses to improve our understanding of the relationship between kidney disease and diabetes.

The NIDDK sponsors a number of activities that researchers hope will lead to improved detection, treatment and prevention of kidney disease and chronic kidney failure. To ensure ongoing kidney disease and kidney disease related research and important clinical trials infrastructure development we recommend a 6.7 percent increase for the NIDDK over fiscal year 2007 levels.

ASN RESEARCH GOALS & RECOMMENDATIONS FOR KIDNEY DISEASE

The ASN continues to evaluate its priorities for future kidney disease research. In the fall of 2004, the ASN conducted a series of research retreats to develop priorities to combat the growing prevalence of kidney disease in the United States. The ASN joined experts, both within and outside the renal community, and identified five areas requiring attention: acute renal failure, diabetic nephropathy, hypertension, transplantation, and kidney-associated cardiovascular disease.

The final research retreat report(s) highlighted priorities and contained three overriding recommendations. Theses include:

Development of Core Centers for kidney disease research

Expansion of the kidney research infrastructure in the United States can be achieved by vigorous funding of a program of kidney research core centers. Specifically, we propose that the number of kidney centers be increased with the goal of providing core facilities to support collaborative research on a local, regional and national level. It should be emphasized that such a program of competitively reviewed kidney core centers would facilitate investigator-initiated research in both laboratory and patient-oriented investigation. This approach is highly compatible with the collaborative research enterprise conceived in the NIH Road Map Initiative.

Support programs/research initiatives that impact the understanding of the relationship between renal and cardiovascular disease

It is now well recognized that chronic kidney dysfunction is an important risk factor for the development of cardiovascular disease. It is recommended that the NIDDK and NHLBI work cooperatively to support both basic and clinical science projects that will shed light on the pathogenesis of this relationship and to support the exploration of interventions that can decrease cardiovascular events in patients with CM). Thus, we specifically propose that NHLBI should support investigator-initiated research grants in areas of kidney research with a direct relationship to cardiovascular disease. Similarly, NHLBI should work collaboratively with NIDDK to support the proposed program of kidney core research centers.

Continued support and expansion of investigator initiated research projects

In each of the five subjects there are areas of fundamental investigation that require the support of investigator initiated projects, if ultimately progress is to be made in the understanding of the basic mechanisms that underlie the diseases proc-

esses. It is recommended that there should be an expansion of support for research in the areas that lend themselves to this mechanism of funding, by encouraging applications with appropriate program announcements and requests for proposals. In addition to vigorous support for RO1 grants, continued funding of Concept Development and R2 1/R33 grants is essential to support development of investigator-initiated clinical studies in these areas of high priority. Such funding is critical to accelerate the transfer of new knowledge from the bench to the bedside.

Agency for Health Care Research and Quality (AHRO)

Complementing the medical research conducted at NIH, the AHRQ sponsors health services research designed to improve the quality of health care, decrease health care costs, and provide access to essential health care services by translating research into measurable improvements in the health care system. The AHRQ supports emerging critical issues in health care delivery and addresses the particular needs of priority populations, such as people with chronic diseases. The ASN firmly believes in the value of AHRQ's research and quality agenda, which continues to provide health care providers, policymakers, and patients with critical information needed to improve health care and treatment of chronic conditions such as kidney disease. The ASN supports the Friends of AHRQ recommendation of $350 million for AHRO in fiscal year 2008.

CONCLUSION

Currently, there is no cure for kidney disease. The progression of chronic renal failure can be slowed, but never reversed. Meanwhile, millions of Americans face a gradual decline in their quality of life because of kidney disease. In many cases, abnormalities associated with early stage chronic renal failure remain undetected and are not diagnosed until the late stages. In sum, chronic renal failure requires our serious and immediate attention.

As practicing nephrologists, ASN members know firsthand the devastating effects of renal disease. ASN respectfully requests the subcommittees' continued support to enable the nephrology community to continue with its efforts to find better ways to treat and prevent kidney disease.

Thank you for your continued support for medical research and kidney disease research. To obtain further information about ASN, please go to http://www.asn-online.org or contact Paul Smedberg, ASN Director of Policy & Public Affairs at 202–416–0646.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS

The American Society for Pharmacology and Experimental Therapeutics (ASPET) is pleased to submit written testimony in support of the National Institutes of Health fiscal year 2008 budget. ASPET is a 4,500 member scientific society whose members conduct basic and clinical pharmacological research within the academic, industrial and government sectors. Our members discover and develop new medicines and therapeutic agents that fight existing and emerging diseases as well as increasing our knowledge regarding how these therapeutics work.

ASPET members are grateful for the U.S. Congress' historic support of the NIH. However, appropriations in recent years have failed to adequately fund the NIH to meet the scientific opportunities and challenges to our public health. For the fourth year in a row, the NIH research portfolio will not keep pace with the Biomedical Research and Development Price Index. After a 5 year bipartisan plan to double the NIH budget that ended in 2003, the budget in now going backwards. The administration's recommended fiscal year 2008 budget, if enacted would mean that the NIH's ability to conduct biomedical research would be cut by more than 13 percent in inflation adjusted dollars since fiscal year 2003.

To prevent this erosion and sustain the biomedical research enterprise, ASPET recommends that the NIH receive $30.8 billion in fiscal year 2008. This would represent an increase of 6.7 percent ($1.9 billion) over the fiscal year 2007 Joint Funding Resolution passed by Congress. ASPET joins other biomedical research organizations and professional societies, including the Ad Hoc Group for Medical Research, the Federation of American Societies for Experimental biology (FASEB), and Research!America, in advocating for a 6.7 percent increase in each of the next 3 years to help regain the momentum of discovery and pre-eminent research, and to help increase NIH's purchasing power and recover the losses caused by biomedical research inflation.

NIH IMPROVES HUMAN HEALTH AND IS AN ECONOMIC ENGINE

Recent budget levels for the NIH constitute a retraction in the budget, sending the wrong signal to the best and brightest of American students who will not be able to or have chosen not to pursue a career in biomedical research. A diminished NIH research enterprise will mean a continued reduction in research grants and the resulting phasing-out of research programs and declining morale, an increasing loss of scientific opportunities such as the discovery of new therapeutic targets to develop, fewer discoveries that produce spin-off companies that employ individuals in districts around the country. In contrast, the requested funding level would provide the institutes with an opportunity to raise or at least maintain their paylines, fund more high quality and innovative research, and provide an incentive for young scientists to continue their research careers.

Many important drugs have been developed as a direct result of the basic knowledge gained from federally funded research, such as new therapies for breast cancer, the prevention of kidney transplant rejection, improved treatments for glaucoma, new drugs for depression, and the cholesterol lowering drugs known as statins that prevent 125,000 deaths from heart attack each year. AIDS related deaths have fallen by 73 percent since 1995 and the 5-year survival rate for childhood cancers rose to almost 80 percent in 2000 from under 60 percent in the 1970s. And for the first time in 70 years, the number of deaths from cancer has fallen. The link between basic research, drug discovery and clinical applications was vividly illustrated when three pharmacologists were awarded the 1998 Nobel Prize in Physiology or Medicine for their research on nitric oxide. More recently, NIH funded research for the 2005 Nobel Prize winners in chemistry. These scientists developed metal-containing molecules that are now being used by the pharmaceutical industry to aid in the drug discovery process. Historically, our past investment in basic biological research has led to innovative medicines that have virtually eliminated diphtheria, whooping cough, measles and polio in the United States 8 out of 10 children now survive leukemia. Death rates from heart disease and stroke have been reduced by half in the past 30 years. Molecularly targeted drugs such as Gleevec™ to treat adult leukemia do not harm normal tissue and dramatically improve survival rates. NIH research has developed a class of drugs that slow the progression of symptoms of Alzheimer's disease. The robust past investment in the NIH has provided major gains in our knowledge of the human genome, resulting in the promise of pharmacogenetics and a reduction in adverse drug reactions that currently represent a major, worldwide health concern. But unless more robust funding is restored, such scientific opportunities from the human genome investment and others will be delayed, lost, or forfeited to biomedical research opportunities in other countries.

The human cost of not adequately investing in the NIH impact us all. The total economic cost to our Nation is also staggering: cancer, $190 billion; obesity, $99 billion; heart disease, $255 billion; diabetes, $131 billion; and arthritis, $125 billion.

Scientific inquiry leads to better medicine but there remain challenges and opportunities that need to be addressed, including:

—The need to increase support for training and research in integrative/whole organ science to see how drugs act not just at the molecular level—but also in whole animals, including human beings.

—The need to meet public health concerns over growing consumer use of botanical therapies and dietary supplements. These products have unsubstantiated scientific efficacy and may adversely impact the treatment of chronic diseases, create dangerous interactions with prescription drugs, and may cause serious side effects including death among some users.

SUPPORT FOR INTEGRATIVE ORGAN SYSTEM SCIENCE

ASPET supports efforts to increase funding for training and research in integrative organ system science (IOSS). IOSS is the study of responses in organs and organisms, including intact animals. Identification of isolated cellular and molecular components of drugs *in vitro* are important for identifying mechanisms of actions but are inadequate in determining all the complex interactions that happen *in vivo* in the actual organs of species. Because of the great advances in cellular and molecular biology over the past two decades, there has been much less emphasis in whole organ biology such that academic infrastructure in this area has eroded and there remain few faculty and institutions that can provide the appropriate scientific training in this important area of research. Too few individuals have opportunities to be trained beyond cellular and molecular techniques. As a consequence, the pool of talent with expertise in whole organs has greatly diminished and the biotechnology and pharmaceutical industry are having great difficulty finding well-trained whole organ scientists to fill critical positions in their drug discovery departments. As a

result of this training and research deficit, a more thorough and comprehensive examination of new therapeutic approaches may be compromised before clinical trials begin.

The lack of training and research opportunities to develop scientists well rounded in cellular, molecular and in vivo whole organ biology impacts progress in medicine and the training of future physicians. Development of preventive approaches and effective therapeutic strategies for many disorders with devastating health consequences and increasing incidence in an aging population will require intensive study at all levels from molecular to whole organ. For instance, obesity is not just a metabolic disorder. Obesity impacts many organ functions, including the heart, circulatory system, and brain. Similarly, clinical depression should not be viewed as just a neurological disorder because depression affects multiple organs in a variety of ways. And the discovery of new drugs to treat neurodegenerative diseases such as Alzheimer's and Parkinson's will ultimately need to look at complex whole animal systems. For these reasons, scientists must be trained to look broadly at complex medical problems afflicting humans. Medical progress in the post-genomic era needs scientists or teams of scientists who can integrate the results of studies in gene function at the molecular, cellular, organ system, whole animal and behavioral levels to fully understand the actions of current drugs and to facilitate the development of safe new drugs and treatment strategies.

To reverse the decline and adequately support training and research in integrative organ systems, integrative biology, program project grants, and pre and post-doctoral training programs should be implemented that support integrative training and research activities. Multi-disciplinary institutional and individual training and research grants on whole systems and integrative biology should be funded to investigate disease processes. ASPET is pleased that the National Institute of General Medical Sciences has recognized this training and research deficit and has funded four summer workshops to train students in integrative whole organ sciences. ASPET encourages other institutes to explore available mechanisms to begin developing a pool of talented scientists with the appropriate skills in integrative, whole organ systems biology. While many industrial concerns provide limited support for training and research at the post-doctoral level, their efforts remain necessarily focused on drug discovery and development. It is the role of the NIH and academic institutions to provide adequate training opportunities to develop the next generation of integrative scientists.

Support for training and research in integrative whole organ sciences has been affirmed in the fiscal year 2002 U.S. Senate Labor/Health and Human Services & Related Agencies Appropriations Report (107–84). The Senate report supports ASPET recommendation that "Increased support for research and training in whole systems pharmacology, physiology, toxicology, and other integrative biological systems that help to define the effects of therapy on disease and the overall function of the human body." These principles and recommendations are also affirmed in the FASEB Annual Consensus Conference Report on Federal Funding for Biomedical and Related Life Sciences Research for Fiscal Year 2002.

SUPPORT FOR RESEARCH ON BOTANICALS AND HERBAL THERAPIES TO MEET PUBLIC HEALTH NEEDS

ASPET has for years supported peer-reviewed pharmacological examination of the mechanisms of actions of medicinal plants and is pleased that the NIH's National Center for Complementary and Alternative Medicine (NCCAM) continues rigorous investigations into the basic biology of various botanical agents. ASPET continues to recommend increased support to study the interaction of botanical remedies and dietary supplements with prescription medications. This support is critical to the promotion and funding of the highest quality research in botanical medicine, will help meet urgent needs of this neglected area of biological research, and will address a growing public health problem. Support for highly innovative research on botanicals should be encouraged among all institutes and centers.

The increased use of botanical and dietary supplements by consumers to treat various ailments and diseases is a major public health concern. One national survey reported that in 1997 an estimated 15 million adults (18.4 percent of all prescription users) took herbal remedies concurrently with prescription medicines. Between 1990 and 1997, the use of herbal products grew by 380 percent. Although there is little solid scientific evidence to support the therapeutic efficacy of many botanical and dietary supplement products, the industry records over $19 billion in annual sales. Botanical products were once regulated as drugs and the FDA had authority to prevent the sale of unproven herbal ingredients. However, legislative reforms in 1994 eliminated the FDA's authority to test or approve herbal products prior to mar-

keting. Thus, at a time when many more consumers are using more herbal products, there is little research on either their clinical efficacy or basic mechanisms of action. The growing use of herbal products by consumers, their interactions with prescription drugs—and mechanisms of such interactions—represent a serious and growing public health problem that demands scientific attention and redress by regulatory and legislative action.

Through the NIH, research into the safety and efficacy of botanical products can be conducted in a rigorous and high quality manner. Sound pharmacological studies will help determine the value of botanical preparations and the potential for their interactions with prescription drugs as well as chronic disease processes. This research will allow the FDA to review the available pharmacology and review valid evidence-based reviews to form a valid scientific foundation for regulating these products.

CONCLUSION

The biomedical research enterprise is facing a critical moment as funding stagnates. Reversing this trend and helping to sustain the extraordinary scientific progress that has been made at the NIH and at the academic institutions funded by the NIH over the past years is a major challenge facing this subcommittee. A 6.7 percent increase for the NIH in fiscal year 2008 will allow the NIH to make greater strides to prevent, diagnose and treat disease, improving the health of our Nation. A 6.7 percent increase in the fiscal year 2008 NIH budget will begin to restore NIH's role as a national treasure that attracts and retains the best and brightest scientists to biomedical research.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE

OVERVIEW

The American Society of Tropical Medicine and Hygiene appreciates the opportunity to submit written testimony to the House Labor, Health and Human, Services, and Education Appropriations Subcommittee. With more than 3,300 members, ASTMH is the world's largest professional membership organization dedicated to the prevention and control of tropical diseases. We represent, educate, and support tropical medicine scientists, physicians, clinicians, researchers, epidemiologists, and other health professionals from this field.

We respectfully request that the subcommittee provide the following allocations in the fiscal year 2008 Labor, Health and Human, Services, and Education Appropriations bill to support a comprehensive effort to eradicate malaria:

—$18 million to the Centers for Disease and Control and Prevention (CDC) for malaria research, control, and program evaluation efforts with a $6 million set-aside for program monitoring and evaluation;

—$30.8 billion to National Institutes of Health (NIH);

—$4.7 billion to the National Institute of Allergy and Infectious Diseases (NIAID); and

—$70.8 million to the Fogarty International Center (FIC).

We very much appreciate the subcommittee's consideration our views, and we stand ready to work with the subcommittee members and staff on these and other important global health matters.

ASTMH

ASTMH plays an integral and unique role in the advancement of the field of tropical medicine. Its mission is to promote world health by preventing and controlling tropical diseases through research and education. As such, the Society is the principal membership organization representing, educating, and supporting tropical medicine scientists, physicians, researchers, and other health professionals dedicated to the prevention and control of tropical diseases. Our members reside in 46 States and the District of Columbia and work in a myriad of public, private, and non-profit environments, including academia, the U.S. military, public institutions, Federal agencies, private practice, and industry.

ASTMH aims to advance policies and programs that prevent and control those tropical diseases which particularly impact the global poor.

TROPICAL MEDICINE AND TROPICAL DISEASES

The term "tropical medicine" refers to the wide-ranging clinical work, research, and educational efforts of clinicians, scientists, and public health officials with a focus on the diagnosis, mitigation, prevention, and treatment of diseases prevalent in the areas of the world with a tropical climate. Most tropical diseases are located in either sub-Saharan Africa, parts of Asia (including the Indian subcontinent), or Central and South America. Many of the world's developing nations are located in these areas; thus tropical medicine tends to focus on diseases that impact the world's most impoverished individuals.

The field of tropical medicine encompasses clinical work treating tropical diseases, work in public health and public policy to prevent and control tropical diseases, basic and applied research related to tropical diseases, and education of health professionals and the public regarding tropical diseases.

Tropical diseases are illnesses that are caused by pathogens that are prevalent in areas of the world with a tropical climate. These diseases are caused by viruses, bacteria, and parasites which are spread through various mechanisms, including airborne routes, sexual contact, contaminated water and food, or an intermediary or "vector"—frequently an insect (e.g. a mosquito)—that transmits a disease between humans in the process of feeding.

MALARIA

Malaria is a global emergency affecting mostly poor women and children; it is an acute and sometimes fatal disease caused by the single-celled Plasmodium parasite that is transmitted to humans by the female *Anopheles* mosquito.

Malaria is highly treatable and preventable. The tragedy is that despite this, malaria is one of the leading causes of death and disease worldwide. According to the CDC, as many as 2.7 million individuals die from malaria each year, with 75 percent of those deaths occurring in African children. In 2002, malaria was the fourth leading cause of death in children in developing countries, causing 10.7 percent of all such deaths. Malaria-related illness and mortality extract a significant human toll as well as cost Africa's economy $12 billion per year perpetuating a cycle of poverty and illness. Nearly 40 percent of the world's population lives in an area that is at high risk for the transmission of malaria.

Fortunately, malaria can be both prevented and treated using four types of relatively low-cost interventions: (1) the indoor residual spraying of insecticide on the walls of homes; (2) long-lasting insecticide-treated nets; (3) Artemisinin-based combination therapies; and (4) intermittent preventive therapy for pregnant women. However, limited resources preclude the provision of these interventions and treatments to all individuals and communities in need.

REQUESTED MALARIA-RELATED ACTIVITIES AND FUNDING LEVELS

CDC Malaria Efforts

ASTMH calls upon Congress to fund a comprehensive approach to malaria control, including public health infrastructure improvements, increased availability of existing anti-malarial drugs, development of new anti-malarial drugs and better diagnostics, and research to identify an effective malaria vaccine. Much of this important work currently is underway; however, additional funds and a sustaining commitment from the Federal Government are necessary to make progress in malaria prevention, treatment, and control.

The CDC conducts research to address pertinent questions regarding issues related to malaria as well as engages in prevention and control efforts, especially as a lead collaborator on the President's Malaria Initiative. To maximize CDC's efforts and expertise, we request $18 million for the CDC for malaria research, control, and program evaluation efforts with a $6 million set-aside for program monitoring and evaluation. The CDC maintains several domestic activities, international activities, and research activities, including:

—Surveillance of malaria
—Investigations of locally transmitted malaria
—Advice and consultations such as a toll-free information service
—Diagnostic assistance to State health departments on malaria diagnosis
—Research to improve understanding of malaria
—International Activities including the President's Malaria Initiative (PMI), the Amazon Malaria Initiative (AMI), the West Africa Network against Malaria during Pregnancy

CDC collaborations support treatment and prevention policy change based on scientific findings; formulation of international recommendations through membership

on World Health Organization (WHO) technical committees; and work with Ministries of Health and other local partners in malaria-endemic countries and regions to develop, implement, and evaluate malaria programs. In addition, CDC has provided direct staff support to WHO; UNICEF; the Global Fund to Fight AIDS, Tuberculosis, and Malaria; and the World Bank—all stakeholders in the Roll Back Malaria (RBM) Partnership.

NIH Malaria Efforts

As the Nation's and world's premier biomedical research agency, the NIH and its Institutes and Centers play an essential role in the development of new anti-malarial drugs, better diagnostics, and an effective malaria vaccine. NIH estimates that its fiscal year 2007 spending on malaria research will total $101 million while malaria vaccine efforts will receive $45 million. ASTMH urges that NIH malaria research portfolio and budget be increased by at least 6.7 percent in fiscal year 2008. To support a comprehensive effort to eradicate malaria, ASTMH respectfully requests the following funding:

—$30.8 billion to NIH;
—$4.7 billion NIAID; and
—$70.8 million to the Fogarty International Center to support training in biomedical research on behalf of the developing nations of the world.

National Institute of Allergy and Infectious Diseases (NIAID)

NIH estimates that in fiscal year 2007 it will spend approximately $101 million for malaria research and $45 million for research related specifically to creating a malaria vaccine. NIAID, the lead institute for this research, has developed an Implementation Plan for Global Research on Malaria, which is focused on five research areas: vaccine development, drug development, diagnostics, vector control, and infrastructure and research capability strengthening.

—*Vaccine Development*.—No malaria vaccine currently exists. NIAID introduced a research agenda for malaria vaccine development in 1997, the aim of which is to support discovery and characterization of new vaccine candidates, production of pilot lots, and clinical evaluation of promising candidate vaccines.
—*Drug Development*.—Drug-resistant malaria increasingly is being reported around the world. NIAID is involved in improving the monitoring of drug resistance and developing new drugs.
—*Diagnostics*.—Improved diagnostic tools are essential in making early diagnosis and providing rapid treatment.
—*Vector Control*.—NIAID is working to create next-generation, environmentally-friendly insecticides for public health use.
—*Strengthening Infrastructure and Research Capability*.—NIAID is working with partners to strengthen research capabilities of scientists in their own countries.

ASTMH encourages the subcommittee to increase funding for NIAID to ensure that we do not lose ground in the fight against malaria.

Fogarty International Center (FIC)

The FIC addresses global health challenges and supports the NIH mission through myriad activities, including: collaborative research and capacity building projects relevant to low- and middle-income nations; institutional training grants designed to enhance research capacity in the developing world; the Forum for International Health, through which NIH staff share ideas and information on relevant programs and develop input from an international perspective on cross-cutting NIH initiatives; the Multilateral Initiative on Malaria, which fosters international collaboration and co-operation in scientific research against malaria; and the Disease Control Priorities Project, which is a partnership to develop recommendations on effective health care interventions for resource-poor settings. ASTMH urges the subcommittee to allocate additional resources to the FIC in fiscal year 2008 to increase these efforts, particularly as they apply to abatement and treatment of malaria.

CONCLUSION

Thank you for your attention to these important global health matters. We know that you face many challenges in choosing funding priorities and we hope that you will provide the requested fiscal year 2008 resources to those agencies programs identified above. ASTMH appreciates the opportunity to share its views, and we thank you for your consideration of our requests.

PREPARED STATEMENT OF THE AMERICAN THORACIC SOCIETY

SUMMARY.—FUNDING RECOMMENDATIONS

[In millions of dollars]

	Amount
National Institutes of Health	30,537
National Heart, Lung and Blood Institute	3,114
National Institute of Allergy and Infectious Disease	4,675
National Institute of Environmental Health Sciences	683
Fogarty International Center	70
National Institute of Nursing Research	146
Centers for Disease Control and Prevention	10,700
National Institute for Occupational Safety and Health	253
Environmental Health: Asthma Activities	70
Tuberculosis Control Programs	252.4

The American Thoracic Society (ATS) is pleased to submit our recommendations for programs in the Labor Health and Human Services and Education Appropriations Subcommittee purview.

The American Thoracic Society, founded in 1905, is an independently incorporated, international education and scientific society that focuses on respiratory and critical care medicine. For 100 years, the ATS has continued to play a leadership role in scientific and clinical expertise in diagnosis, treatment, cure and prevention of respiratory diseases. With approximately 18,000 members who help prevent and fight respiratory disease around the globe, through research, education, patient care and advocacy, the Society's long-range goal is to decrease morbidity and mortality from respiratory disorders and life-threatening acute illnesses.

LUNG DISEASE IN AMERICA

Lung disease is a serious health problem in the United States. Each year, close to 400,000 Americans die of lung disease. Lung disease is responsible for one in every seven deaths, making it America's number three cause of death. More than 35 million Americans suffer from a chronic lung disease. In 2005, lung diseases cost the U.S. economy an estimated $157.8 billion in direct and indirect costs.

Lung diseases represent a spectrum of chronic and acute conditions that interfere with the lung's ability to extract oxygen from the atmosphere, protect against environmental or biological challenges and regulate a number of metabolic processes. Lung diseases include chronic obstructive pulmonary disease, lung cancer, tuberculosis, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease, sarcoidosis, asthma and severe acute respiratory syndrome (SARS).

The ATS is pleased that the subcommittee provided increases in the National Institutes of Health (NIH) budget last fiscal year. However, we are extremely concerned that the President's fiscal year 2008 budget proposes a 1.7 percent cut for NIH and significant cuts for the Centers for Disease Control and Prevention (CDC). We ask that this subcommittee recommend a 6.7 percent increase for NIH so that the NIH can respond to biomedical research opportunities and public health needs. In order to stem the devastating effects of lung disease, research funding must continue to grow to sustain the medical breakthroughs made in recent years. We also ask that the CDC budget be adjusted to reflect increased needs in chronic disease prevention, infectious disease control, including strengthened TB control to prevent the spread of extensively drug-resistant (XDR)-TB, and occupational safety and health research and training. There are three lung diseases that illustrate the need for further investment in research and public health programs: Chronic Obstructive Pulmonary Disease, pediatric lung disease, asthma and tuberculosis.

COPD

Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in the United States and the third leading cause of death worldwide. Yet, COPD remains relatively unknown to most Americans. COPD is the term used to describe the airflow obstruction associated mainly with emphysema and chronic bronchitis and is a growing health problem.

While the exact prevalence of COPD is not well defined, it affects tens of millions of Americans and can be an extremely debilitating condition. It is estimated that 11.2 million patients have COPD while an additional 12 million Americans are unaware that they have this life threatening disease.

According to the National Heart, Lung and Blood Institute (NHLBI), COPD cost the U.S. economy an estimated $37 billion per year. We recommend the subcommittee encourage NHLBI to devote additional resources to finding improved treatments and a cure for COPD.

Medical treatments exist to relieve symptoms and slow the progression of the disease. Today, COPD is treatable but not curable. Fortunately, promising research is on the horizon for COPD patients. Despite these leads, the ATS feels that research resources committed to COPD are not commensurate with the impact the disease has on the United States and that more needs to be done to make Americans aware of COPD, its causes and symptoms. The ATS commends the NHLBI for its leadership on educating the public about COPD through the National COPD Education and Prevention Program. As this initiative continues, we encourage the NHLBI to maintain its partnership with the patient and physician community.

While additional resources are needed at NIH to conduct COPD research, CDC has a role to play as well. The ATS encourages the CDC to add COPD-based questions to future CDC health surveys, including the National Health and Nutrition Evaluation Survey (NHANES), the National Health Information Survey (NHIS) and the Behavioral Risk Factor Surveillance Survey (BRFSS). By collecting information on the prevalence of COPD, researchers and public health professionals will be better able to understand and control the disease.

PEDIATRIC LUNG DISEASE

Lung disease affects people of all ages. The ATS is pleased to report that infant death rates for various lung diseases have declined for the past 10 years. However, of the seven leading causes of infant mortality, four are lung diseases or have a lung disease component. In 2003, lung diseases accounted for 18 percent of all deaths under 1 year of age. It is also widely believed that many of the precursors of adult respiratory disease start in childhood. The ATS encourages the NHLBI to continue with its research efforts to study lung development and pediatric lung diseases.

The pediatric origins of chronic lung disease extend back to early childhood factors. For example, many children with respiratory illness are growing into adults with COPD. In addition, it is estimated that close to 20.5 million people suffer from asthma, including an estimated 6.2 million children. While some children appear to outgrow their asthma when they reach adulthood, 75 percent will require life-long treatment and monitoring of their condition. Asthma is the third leading cause of hospitalization among children under the age of 15 and is the leading cause of chronic illness among children.

ASTHMA

The ATS believes that the NIH and the CDC must play a leadership role in assisting individuals with asthma. National statistical estimates show that asthma is a growing problem in the United States. Approximately 22.2 million Americans currently have asthma, of which 12.2 million had an asthma attack in 2005. African Americans have the highest asthma prevalence of any racial/ethnic group. The age-adjusted death rate for asthma in the African-American population is three times the rate in whites.

ASTHMA SURVEILLANCE

There is a need for more data on regional and local asthma prevalence. In order to develop a targeted public health strategy to respond intelligently to asthma, we need locality-specific data. CDC should take the lead in collecting and analyzing this data and Congress should provide increased funding to build this these tracking systems.

In fiscal year 2007, Congress provided approximately $31.9 million for CDC's National Asthma Control Program. The goals of this program are to reduce the number of deaths, hospitalizations, emergency department visits, school or work days missed, and limitations on activity due to asthma. We recommend that CDC be provided with $70 million in fiscal year 2008 to expand the program and establish grants to community organizations for screening, treatment, education and prevention of childhood asthma.

SLEEP

Sleep is an essential element of life, but we are only now beginning to understand its impact on human health. Several research studies demonstrate that sleep illnesses and sleep disordered breathing affect over 50 million Americans. The public health impact of sleep illnesses and sleep disordered breathing is still being deter-

mined, but is known to include traffic accidents, lost work and school productivity, cardiovascular disease, obesity, mental health disorders, and other sleep-related comorbidities. We cannot appropriately address these problems if we do not consider how chronic sleep loss contributes to them. Despite the increased need for study in this area, research on sleep and sleep-related disorders has been underfunded. The ATS recommends increased funding to support activities related to sleep and sleep disorders at the CDC, including for the National Sleep Awareness Roundtable (NSART), and research on sleep disorders at the Nation Center for Sleep Disordered Research (NCSDR) at the NHLBI.

TUBERCULOSIS

Tuberculosis (TB) is a global public health crisis that remains a concern for the United States. Tuberculosis is an airborne infection caused by a bacterium, Mycobacterium tuberculosis. Tuberculosis primarily affects the lungs but can also affect other parts of the body, such as the brain, kidneys or spine. The statistics for TB are alarming. Globally, one-third of the world's population is infected with the TB germ, 8.8 million active cases develop each year and 1.6 million people die of tuberculosis annually. It is estimated that 9–14 million Americans have latent tuberculosis. Tuberculosis is the leading cause of death for people with HIV/AIDS.

According to the CDC, although the overall rate of new TB cases is declining in the United States, the annual rate of decrease in TB cases has slowed significantly, from about 7.3 percent (1993 to 2000) to 3.8 percent currently (2000–2006). This rate represents one of the smallest declines since 1992, when over $1 billion was spent in New York City alone to regain control of TB. The ATS is concerned that TB rates in African Americans remain high and that TB rates in foreign-born Americans are growing.

The emergence of extensively drug-resistant XDR–TB has created a global health emergency. Because it is resistant to most of the drugs used to treat TB, XDR–TB is virtually untreatable and has an extremely high fatality rate. In one of the latest outbreaks in South Africa from late 2005 until early 2006, XDR–TB killed 52 out of 53 infected patients. According to data released by the CDC in March, between 1993 and 2006, there were 49 reported XDR–TB cases in the United States. Because of the ease with which TB can spread, XDR TB will continue to pose a serious risk to the United States as long as it exists anywhere else in the world.

While we urge immediate action in response to the XDR–TB emergency, we also recognize the best way to prevent the future development of other resistant strains of tuberculosis is through supporting effective tuberculosis control programs in the United States and throughout the globe. We ask the subcommittee to take the first steps to eliminating TB in the United States and prevent further outbreaks of drug resistant forms of TB. The ATS, in collaboration with the National Coalition for Elimination of Tuberculosis, recommends an increase of $120 million in fiscal year 2008 for CDC's National Program for the Elimination of Tuberculosis.

The NIH also has a prominent role to play in the elimination of tuberculosis. Currently there is no highly effective vaccine to prevent TB transmission. However, the recent sequencing of the TB genome and other research advances have put the goal of an effective TB vaccine within reach. The National Institute of Allergy and Infectious Disease has developed a Blueprint for Tuberculosis Vaccine Development. We encourage the subcommittee to fully fund the TB vaccine blueprint. We also encourage the NIH to continue efforts to develop drugs to combat multi-drug resistant tuberculosis a serious emerging public health threat.

Fogarty International Center TB Training Programs

The Fogarty International Center (FIC) at NIH provides training grants to U.S. universities to teach AIDS treatment and research techniques to international physicians and researchers. Because of the link between AIDS and TB infection, FIC has created supplemental TB training grants for these institutions to train international health care professionals in the area of TB treatment and research. These training grants should be expanded and offered to all institutions. The ATS recommends Congress provide $70 million for FIC to expand the TB training grant program from a supplemental grant to an open competition grant.

RESEARCHING AND PREVENTING OCCUPATIONAL LUNG DISEASE

The National Institute of Occupational Safety and Health (NIOSH) is the sole Federal agency responsible for conducting research and making recommendations for the prevention of work-related diseases and injury. In addition to conducting research, NIOSH investigates potentially hazardous working conditions, makes recommendations and disseminates information on preventing workplace disease, in-

jury, and disability; and provides training to occupational safety and health professionals. The ATS recommends that Congress provide $253 million for NIOSH to expand or establish the following activities: the National Occupational Research Agenda (NORA); tracking systems for identifying and responding to hazardous exposures and risks in the workplace; emergency preparedness and response activities; and training medical professionals in the diagnosis and treatment of occupational illness and injury.

CONCLUSION

Lung disease is a growing problem in the United States. It is this country's third leading cause of death. The lung disease death rate continues to climb. Overall, lung disease and breathing problems constitute the number one killer of babies under the age of 1 year. Worldwide, tuberculosis is one of the leading infectious disease killers. The level of support this subcommittee approves for lung disease programs should reflect the urgency illustrated by these numbers. The ATS appreciates the opportunity to submit this statement to the subcommittee.

PREPARED STATEMENT OF AMERICANS FOR THE ARTS

Americans for the Arts and the Los Angeles County Arts Commission respectfully request the subcommittee to adopt an appropriation of $53 million for the Arts in Education programs of the U.S. Department of Education. We also ask that it require the U.S. Department of Education to conduct much-needed research on the status of arts education, including the Fast Response Statistical Survey (FRSS) and the National Assessment of Educational Progress (NAEP).

Before considering funding levels, members of the subcommittee need to be aware of a simple but breathtaking fact: Students with an education rich in the arts have better grade point averages in core academic subjects, score better on standardized tests, and have lower drop-out rates than students without arts education. This fact is demonstrated by an increasing amount of compelling research. It is not seriously contested. Further, research confirms that these results occur across the socio-economic range.

Artists believe that the arts are important for their own sake. Educators know they are rigorous and standards-based, and they are essential for supporting the learning styles of all students while providing them with the unique opportunity to develop problem solving skills, to develop critical thinking skills and to foster their creativity. In essence, the arts help students develop skills that are needed for the 21st century workforce. In fact, CEOs have stated that the MFA (Masters in Fine Arts) is the new MBA and seek employees that have had a solid arts education. You can agree or disagree with us, of course. But you can't ignore the research, which shows that the arts help kids do better in school And for that reason, we believe that the Federal Government has an essential role in ensuring that all children have access to excellent arts education.

For several decades, the U.S. Department of Education's Arts in Education programs have provided funding for the national programs of the John F. Kennedy Center for the Performing Arts and VSA arts (formerly Very Special Arts). Since 2001 they have also run two important competitive grant programs:

—The Model Development and Dissemination program identifies, develops, documents, and disseminates models of excellence in arts education that impact schools and communities nationwide. These projects strengthen student learning through standards-based arts education and integration of arts instruction into other subject areas.

—The Professional Development grants program supports projects that serve as national models for effective professional development that improve instruction for arts specialists and classroom teachers. State and local education agencies can adapt these models to provide rigorous arts instruction for all students.

A recent Model Development grant was given to the Los Angeles Unified School District, in partnership with Inner-City Arts, a non-profit organization providing arts learning services to students in the district, and the University of California, Los Angeles (UCLA) Graduate School of Education and Information Sciences. The three-year Arts in the Middle (AIM) Project will expand and rigorously evaluate an innovative, cohesive model for delivery of arts-based instruction to remedial grade six English learners. The Project's strategy will extend community resources to under-resourced urban middle schools in order to improve academic performance among English learners by integrating standards-based arts education within the core Language Arts curricula of grade six students. The Project's target population is remedial grade six students who are at extreme high risk of academic failure due

to low levels of English Language Development. Assuming it is successful, the goal is to replicate it within other Los Angeles schools. This project directly supports the school district's 10-year plan for arts education.

With increased funding, the Arts in Education programs will be able to support additional such models that improve arts learning in high-poverty schools, and findings from the model projects may be more widely disseminated.

With regard to another aspect of our request: despite research showing the positive effects of arts education, there is a serious lack of empirical data on how much arts education is being delivered in our Nation's schools. We do not have comprehensive, reliable information about student access to arts instruction or student performance in the arts. The last Fast Response Survey report was for the 1999–2000 school year, and the next round is long overdue.

Congress has repeatedly urged the Department of Education to implement the Fast Response Survey in the arts to no avail. In public statements, U.S. Secretary of Education Margaret Spellings has said, "Art, dance, music, and theater are as much a part of education as reading, math, and science." And yet, the Department has told Congress that among the "many tough choices" made in the area of research, the arts survey did not rate as a priority.

The Senate included report language in the fiscal year 2007 appropriations bill that explicitly directed the Department of Education to conduct the FRSS, and it also provided funding for that purpose. As you know, however, the bill did not become law, and therefore the Department of Education has been able to delay implementing the FRSS for yet another year. We thank this subcommittee for taking this step last year and urge you to adopt similar language in your fiscal year 2008 bill.

Good data does exist in some localities, but only data that is national in scope will allow Congress to make national policy. We would like to tell you about data was gathered and used to affect policy in Los Angeles County. The task was an essential step in helping the County and community stakeholders such as school districts, arts organizations, elected officials, business leaders, foundations, and corporations strategically organize their efforts to restore K–12 arts education. We hope the story of how the information was collected, and the way it was used, will convince you of the need to compel the Department of Education to collect national data.

In 2000, the Arts Commission commissioned the Arts in Focus survey, which detailed the status of arts education for 1.7 million students in 82 school districts. These students represent 27 percent of all public school students in the State, and 3.4 percent of all public school students in the country. With 80 of the 82 superintendents in the County participating, it was found that:

—54 percent of school leaders reported no adopted arts policy and 37 percent reported no defined sequential arts education in any discipline, at any school level.

—64 percent reported no district level arts coordinator, and the current average ratio of credentialed arts teachers to students was 1:1,200.

—Nearly 50 percent reported "lack of instructional time in students' schedules" as their most significant challenge.

—Many districts would not have arts programs without the support of parents and partnerships with non-profit arts organizations. Seventy-eight percent of districts allocated less than 2 percent of their budget to arts education and 82.3 percent used partnerships with non-profit organizations to provide arts education.

One hundred percent of superintendents who were interviewed stated that they believe in the importance of the arts. However, what the data revealed was the lack of an infrastructure to support arts education and, given the three decades without sequential arts education, limited capacity of school districts to incorporate it back into the school day.

In response to the findings of Arts in Focus, Los Angeles County (the Arts Commission in partnership with the Los Angeles County Office of Education) embarked on a year-long, community-based planning process. In 2002, the County Board of Supervisors, the County Board of Education and the County Arts Commission unanimously adopted Arts for All: Los Angeles County Regional Blueprint for Arts Education, which presents a series of policy changes, educational initiatives, and establishment of a new infrastructure to ensure all 1.7 million students receive a high-quality K–12 arts education.

The first goal of the Blueprint is to help school districts create a sustainable infrastructure for arts education by conducting a needs assessment and utilizing district data to develop and adopt an arts education policy and long-range budgeted plan with benchmarks. To date, 20 school districts are at various stages of receiving technical assistance from a coach to strategically, and thoughtfully, identify and imple-

ment key budgeted priorities for arts education in the areas of standards-based curriculum, instruction and methodology, assessment, professional development, program administration and personnel, partnerships and collaborations, funding, resources and facilities, and evaluation.

As a key strategy in the Blueprint, the County created the Arts Education Performance Indicators report, or AEPI, to collect pertinent school district data to track the status of an arts education infrastructure based on five critical factors: an arts education policy adopted by the school board; an arts education plan adopted by the school board; a district level arts coordinator; an arts education budget of at least 5 percent of the district's total budget; and a student to credentialed arts teacher ratio of no higher than 400:1. With these pieces in place, school districts can deliver sustainable arts education.

The AEPI is released every other year. It is interesting to note that for the 2005 report, those districts making the greatest progress in achieving the five critical success factors received technical assistance while those showing little to no improvement did not. AEPI is an invaluable tool in providing a county-wide picture of the status of an arts education infrastructure, target technical assistance to help school districts plan, keep arts education visible and at the forefront of policy discussions, provide a mechanism for school districts to self-evaluate and reflect on their progress in providing equal access to a quality arts education and to compare themselves to other districts, and encourage County-wide dialogue on arts education among diverse stakeholders in the community—from elected officials, to educators, to parents and students.

Access to up-to-date, accurate data is imperative to drive strategic planning and policy change. In addition, Arts for All illustrates the importance of providing customized assistance to help school districts effectively plan for the implementation of arts education based on identified needs and priorities. Without this help, we have found that it is difficult for school districts to use available funds effectively—including, for example, Federal Title I funds.

You may be aware that the fiscal year 2006–2007 budget for the State of California includes $500 million in one-time funding for arts education and physical education equipment, supplies and professional development and $105 million in ongoing funding especially for arts education personnel, supplies, materials, and professional development. As it turns out, the districts that have received technical assistance and that have established policies and plans are able to effectively and strategically utilize this funding. Seventeen County school districts have expressed an interest in receiving arts education planning assistance through Arts for All in light of the new State money. With these additional school districts, 37 districts in Los Angeles County will be planning for and implementing standards-based arts education—close to 50 percent of County school districts—with more school districts joining Arts for All each year.

Each level of government has its part to play, in concert with stakeholders at each level. We have described the massive commitment of Los Angeles County government to providing excellent arts education, and we have touched on the increased recognition by the State of California of its responsibility to help. The Federal Government needs to step up as well. It has a unique role in collecting and publishing data, and an essential role in supporting, researching and disseminating locally developed projects. Both of these roles are the focus of this testimony.

We would also like to ask you to encourage local districts to use Federal education funds, such as Title I, to institute data collection and technical assistance programs similar to what was done in Los Angeles County. They should also use Federal funds to hire local district-wide arts education coordinators.

Finally, we would like to mention that the NAEP—the national arts "report card"—is scheduled to be administered in 2008, and must stay on track. It is designed to measure students' knowledge and skills in dance, music, theatre, and visual arts, and it provides critical information about the arts skills and knowledge of our Nation's students. The last arts NAEP was performed in 1997. Like the FRSS, the next round is long overdue.

Thank you very much for the opportunity to submit this testimony.

PREPARED STATEMENT OF THE AMERICANS FOR NURSING SHORTAGE RELIEF (ANSR) ALLIANCE

The undersigned organizations of the ANSR Alliance greatly appreciate the opportunity to submit written testimony regarding fiscal year 2008 appropriations for Title VIII—Nursing Workforce Development Programs. The ANSR Alliance is comprised of 52 national nursing organizations that united in 2001 to identify and pro-

mote creative strategies for addressing the nursing and nurse faculty shortages, including passage of the Nurse Reinvestment Act of 2002.

The ANSR Alliance stands ready to work with lawmakers to advance programs and policy that will sustain and strengthen our Nation's nursing workforce. To ensure that our Nation has a sufficient and adequately prepared nursing workforce to provide quality care to all well into the 21st century, ANSR urges Congress to:

—Appropriate at least $200 million in funding for Nursing Workforce Development Programs under Title VIII of the Public Health Service Act at the Health Resources and Services Administration (HRSA) in fiscal year 2008.

—Restore the Advanced Education Nursing program (Sec. 811) and fund it at a level on par with the proposed fiscal year 2008 increase for the other Title VIII programs.

NURSING SHORTAGE

Nurses play a critical role in our Nation's health care system. An estimated 2.9 million licensed registered and advanced practice registered nurses (RNs and APRNs) represent the largest professional occupation of all health care workers providing patient care in virtually all locations in which health care is delivered. The diversity of practice settings and differing scopes of practice makes the nursing shortage an even more complex challenge. Some facts to consider:

—The nursing workforce is aging. In 1980, 26 percent of RNs were under the age of 30. Today, approximately 8 percent of RNs are under the age of 30 with the average nurse being 46.8 years of age;

—Approximately half of the RN workforce is expected to reach retirement age within the next 10 to 15 years. The average age of new RN graduates is almost 30 years old;

—A December 2005 Bureau of Labor Statistics report projected that registered nursing would create the second largest number of new jobs among all occupations within 9 years. In addition, employment of RNs is expected to grow much faster than average for all occupations through 2014. It is anticipated that approximately 703,000 additional jobs, for a total of 3,096,000, will be available for RNs by that date;

—The national nursing shortage also is affecting our Nation's 7.6 million veterans who receive care through the 1,300 Department of Veterans Affairs (VA) health care facilities. The VA, the largest sole employer of RNs in the United States, has a 10 percent RN vacancy rate;

—The nurse faculty vacancies in the United States continued to grow even as the numbers of full- and part-time educators increased during the 2005–2006 academic year. According to the National League for Nursing's 2006 Nurse Faculty Census, the estimated number of budgeted, unfilled, full-time positions in 2006 was 1,390. This number represents a 7.9 percent vacancy rate in baccalaureate and higher degree programs, which is an increase of 32 percent since 2002; and a 5.6 percent vacancy rate in associate degree programs, which translates to a 10 percent rise in the same period.

NURSING SUPPLY IMPACTS AMERICA'S EMERGENCY PREPAREDNESS

The National Center for Health Workforce Analysis at the Bureau of Health Professions in HRSA reports that the nursing shortage makes it challenging for the health care sector to meet current service needs. Nursing shortfalls exacerbating capacity insufficiencies throughout the health care system have ripple effects, for example, seen in the problems encountered by most communities' day-to-day emergency care services. Facing a pandemic flu or other natural or man-made disaster of significant proportions makes the nursing shortage an even greater national concern, as well as an essential part of national preparedness and response planning

Nurses play a critical role as front-line, first-responders. When word of the devastation caused by Hurricanes Katrina and Rita reached nurses across the country, they immediately volunteered in American Red Cross shelters, medical clinics, and hospitals throughout that widespread region. Nurses and advanced practice registered nurses (e.g., nurse midwives, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists) are particularly critical national resources in an emergency, able to provide clinical nursing care as well as primary care. During Katrina and Rita, nurse midwives delivered babies in airplane hangars, and nurses trained in geriatric care assisted in caring for those traumatized by their evacuation from the comforts of their homes, assisted living facilities or nursing homes. Nurse practitioners diligently staffed temporary and permanent health care clinics to provide needed primary care to hurricane victims. Many nurses con-

tributed not just through their clinical expertise, but also by offering psychological support as they listened to survivors recount their stories of pain and tragedy.

These stories seem particularly relevant in demonstrating the essential assistance nurses provide during tragedies, and reinforce the need to ensure an adequate supply of all types of nurses. Unless steps are taken now, the Nation's ability to respond to disasters will be further hindered by the growing nursing shortage. An investment in the nursing workforce is a reasonable and cost-effective investment toward rebuilding the public health infrastructure and increasing our Nation's health care readiness and emergency response capabilities.

DESPERATE NEED FOR NURSE FACULTY

After years of declining interest, the nursing profession is seeing a resurgence of interest in the profession. Many people in America have come to find nursing an attractive career because of job openings, salary levels, and the opportunity to help others. However, the common theme among prospective nursing students is that due to a lack of enrollment openings, owing to faculty shortages, they can face waiting periods of up to 3 years before matriculating. When all nursing programs are considered, the number of qualified applications turned away during the 2004–2005 academic year was estimated to be nearly 147,000 by the National League for Nursing. Without sufficient support for current nurse faculty and adequate incentives to encourage more nurses to become faculty, nursing schools will fail to have the teaching infrastructure necessary to educate and train the next generation of nurses that the Nation so desperately need.

The current and deepening nurse faculty shortfall is the critical reason that the Advanced Education Nursing line item in the Title VIII programs must be fully funded. This program supported 11,949 graduate nursing students in fiscal year 2005. The students that are supported by this funding are the pool of future faculty for the nursing profession. Whether supporting students in clinical education or as faculty in schools of nursing, it is essential that advanced education nursing funding be restored.

FUNDING REALITY

Enacted in 2002, the Nurse Reinvestment Act (Public Law 107–205) addressed new and expanded initiatives, including loan forgiveness, scholarships, career ladder opportunities, and public service announcements to advance nursing as a career. Despite the enactment of this critical measure, HRSA fails to have the resources necessary to meet the current and growing demands for our Nation's nursing workforce. For example:

—*Fiscal Year 2005 Nursing Education Loan Repayment Program*.—Of the 4,465 applicants, 803 awards were made (599 initial 2-year awards and 204 amendment awards) with 18 percent of applicants receiving awards.

—*Fiscal Year 2006 Nursing Education Loan Repayment Program*.—Of the 4,222 applicants, 615 awards were made (373 initial 2-year awards and 242 amendment awards). This translates to 14.6 percent of applicants receiving awards.

—*Fiscal Year 2005 Nursing Scholarship Program*.—This program received 3,482 applicants and was able to provide 212 awards or 6.1 percent of the applicants received scholarships.

—*Fiscal Year 2006 Nursing Scholarship Program*.—3,320 applicants were received and 218 awards made or 6.6 percent of the applicants received scholarships.

The ANSR Alliance requests that the subcommittee provide a minimum of $200 million in fiscal year 2008 to fund the Title VIII—Nursing Workforce Development Programs. We also urge the restoration of the Advanced Education Nursing program (sec. 811) funded at a level on par with the proposed fiscal year 2008 increase for the other Title VIII programs.

This funding can be used to restore the Advanced Education Nursing program and fund a higher rate of Nurse Education Loan Repayment and Nursing Scholarship applications, as well as implement other essential endeavors to sustain and boost our Nation's nursing workforce. We thank you for consideration of our request.

SUMMARY

Programmatic area	Final fiscal year 2007	President's budget fiscal year 2008	ANSR Alliance request
Title VIII—Nursing Workforce Development Programs at HRSA	$149,679,000	$105,263,000	$200,000,000

ANSR ALLIANCE ORGANIZATIONS

Academy of Medical-Surgical Nurses; American Academy of Ambulatory Care Nursing; American Academy of Nurse Practitioners; American Association of Critical-Care Nurses; American Association of Nurse Anesthetists; American Association of Nurse Assessment Coordinators; American Association of Occupational Health Nurses; American College of Nurse Practitioners; American Organization of Nurse Executives; American Radiological Nurses Association; American Society for Pain Management Nursing; American Society of PeriAnesthesia Nurses; American Society of Plastic Surgical Nurses; Association of periOperative Registered Nurses; Association of Rehabilitation Nurses; Asociation of State and Territorial Directors of Nursing; Association of Women's Health, Obstetric and Neonatal Nurses; Emergency Nurses Association; Infusion Nurses Society; National Association of Clinical Nurse Specialists; National Association of Neonatal Nurses; National Association of Nurse Practitioners in Women's Health; National Association of Orthopaedic Nurses; National Association of Pediatric Nurse Practitioners; National Conference of Gerontological Nurse Practitioners; National Council of State Boards of Nursing, Inc.; National Gerontological Nursing Association; National League for Nursing; National Nursing Centers Consortium; National Nursing Staff Development Organization; National Organization for Associate Degree Nursing; National Organization of Nurse Practitioner Faculties; National Student Nurses' Association, Inc.; Society for Vascular Nursing; Society of Pediatric Nurses; Society of Trauma Nurses; and Society of Urologic Nurses and Associates.

PREPARED STATEMENT OF THE ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES AND THE MEDICAL LIBRARY ASSOCIATION

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2008

(1) A 6.7 percent increase for the NationaL Library of Medicine at the National Institutes of Health and support for the National Library of Medicine's Urgent Facility construction needs.

(2) Continued support for the Medical Library community's role in the National Library of Medicine's Outreach, Telemedicine, Disaster Preparedness and Health Information Technology Initiatives.

Mr. Chairman, thank you for the opportunity to testify today on behalf of the Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL) regarding the fiscal year 2008 budget for the National Library of Medicine (NLM). I am Marianne Comegys, Director of the Louisiana State University (LSU) Health Sciences Center Library in Shreveport, Louisiana.

MLA is a nonprofit, educational organization with more than 4,500 health sciences information professional members worldwide. Founded in 1898, MLA provides lifelong educational opportunities, supports a knowledgebase of health information research and works with a global network of partners to promote the importance of quality information for improved health to the healthcare community and the public.

AAHSL is comprised of the directors of the libraries of 142 accredited American and Canadian medical schools belonging to the Association of American Medical Colleges (AAMC). AAHSL's goals are to promote excellence in academic health sciences libraries and to ensure that the next generation of health professionals is trained in information-seeking skills that enhance the quality of healthcare delivery.

Together, MLA and AAHSL address health information issues and legislative matters of importance through a joint task force.

With respect to NLM's budget for the upcoming year, I would like to touch briefly on five issues: (1) the growing demand for NLM's basic services, (2) NLM's outreach and education services, (3) NLM's role in emergency preparedness and response, (4) NLM's health information technology initiatives and (5) NLM's facility needs.

THE GROWING DEMAND FOR THE NLM'S BASIC SERVICES

Mr. Chairman, it is a tribute to NLM that the demand for its services and expertise continues to grow. As the world's foremost digital library and knowledge repository in the health sciences, NLM provides the critical infrastructure in the form of data repositories and integrated services such as GenBank and PubMed that are helping to revolutionize medicine and advance science to the next important era—individualized medicine based on an individual's unique genetic differences.

As the world's largest and most comprehensive medical library, services based on NLM's traditional and electronic collections continue to steadily increase each year.

These collections stand at more than 8.5 million items—books, journals, technical reports, manuscripts, microfilms, photographs, and images. By selecting, organizing and ensuring permanent access to health science information in all formats, NLM is ensuring the availability of this information for future generations, making it accessible to all Americans, irrespective of geography or ability to pay, and ensuring that each citizen can make the best, most informed decisions about their healthcare.

Mr. Chairman, simply stated NLM is a national treasure and support for its programs and services could not be more important at the present time. I can tell you that without NLM our Nation's medical libraries would be unable to provide the quality information services that our Nation's health professionals, educators, researchers and patients have all come to expect.

Recognizing the invaluable role that NLM plays in our healthcare delivery system, MLA and AAHSL join with the Ad Hoc Group for Medical Research in asking for a 6.7 percent increase for NLM, and the NIH overall, in fiscal year 2008.

OUTREACH AND EDUCATION

NLM's outreach programs are of particular interest to both MLA and AAHSL. These activities are designed to educate medical librarians, health professionals and the general public about NLM's services.

NLM has taken a leadership role in promoting educational outreach aimed at public libraries, secondary schools, senior centers and other consumer-based settings. Furthermore, NLM's emphasis on outreach to underserved populations assists the effort to reduce health disparities among large sections of the American public.

We applaud the success of NLM's outreach initiatives, particularly those initiatives that reach out to medical libraries and health consumers. We ask the committee to encourage NLM to continue to coordinate its outreach activities with the medical library community in fiscal year 2008.

Partners in Information Access

NLM's "Partners in Information Access" program is designed to improve the access of local public health officials to information needed to prevent, identify and respond to public health threats. With nearly 6,000 members in communities across the country, the National Network of Libraries of Medicine (NNLM) is well-positioned to ensure that every public health worker has electronic health information services that can protect the public's health. My own facility, the LSU Health Sciences Center in Shreveport, Louisiana, participates in this program. Through it, we are able to train public health workers on how to access health information online.

PubMed/Medline

NLM's PubMed/Medline is the Nation's premier online bibliographic database. PubMed/Medline makes accessing important medical information easier and quicker, which in turn lowers healthcare costs while improving care. For more than 10 years, PubMed/Medline has afforded anyone with access to the Internet the opportunity to tap into the vast resources of NLM.

The NIH Public Access policy makes use of NLM's PubMed Central electronic archive of full-text journal articles and manuscripts. This policy supports NLM's mission to archive and enhance access to healthcare information. We are concerned however that the current rate of participation in the voluntary policy is low. Even with an increasing number of journals depositing their complete contents in PubMed Central less than 15 percent of NIH-funded articles are available to the public there.

We concur with the NLM Board of Regents that the NIH Public Access policy cannot achieve its stated goals unless the deposit of manuscripts becomes mandatory. An informal survey conducted by AAHSL of faculty and research administrators at 19 universities illustrated that NIH-funded researchers are aware of the NIH Public Access policy. This finding has been confirmed by NIH focus groups. Hence, lack of awareness does not appear to be the primary reason for the low submission rate; rather lack of incentive is impeding the success of this policy.

In September, NLM, NIH and the Friends of NIH, launched NIH MedlinePlus Magazine. This new publication will be distributed in doctors' waiting rooms, and will provide the public with access to high quality, easily understood health information.

NLM also continues to work with medical librarians and health professionals to encourage doctors to provide MedlinePlus "information prescriptions" to their patients. This initiative has been expanded to encourage genetics counselors to prescribe the use of NLM's Genetics Home Reference website. "Go Local" is another new exciting feature of MedlinePlus that enables local and State agencies and oth-

ers to participate by creating sites that link the MedlinePlus information seeker to local pharmacies, doctors and other health and social services. This service further enhances the value of NLM and MedlinePlus, not just for medical librarians and health professionals, but also for health consumers. It also provides a platform for enhancing public access to the information needed to prepare for and respond to disasters and emergencies.

Clinical Trials

NLM's clinical trials database was launched in February 2000 and lists more than 38,000 United States and international trials for a wide range of diseases. The clinical trials database is a free and invaluable resource to patients and families who are interested in participating in cutting-edge treatments for serious illnesses. MLA and AAHSL thank NLM for its leadership in creating ClinicalTrials.gov and looks forward to assisting NLM in advancing this important initiative.

We are aware of current proposals to mandate the submission of clinical trial results to this or a related database. We strongly endorse the notion of improving public access to information about the results of clinical trials, but are concerned about the possibility of results being posted without having been subject to some form of external review. If such information is to be used by patients and their physicians to make informed decisions, the information must be trustworthy and should be held to the same standard as other publicly available information made available on the NLM web sites.

EMERGENCY PREPAREDNESS AND RESPONSE

MLA and AAHSL support the recommendation of the NLM Board of Regents Long Range Plan for 2006–2016 that NLM establish a Disaster Information Management Research Center to expand NLM's capacity to support disaster response and management initiatives. Following Hurricane Katrina, NLM provided health professionals and the public with access to needed health and environmental information by: (1) quickly compiling Web pages on toxic chemicals and environmental concerns, (2) rapidly providing funds, computers and communication services to assist librarians in the field who were restoring health information services to displaced clinicians and patients, and (3) rerouting interlibrary loan requests from the afflicted regions through the NNLM.

HEALTH INFORMATION TECHNOLOGY AND BIOINFORMATICS

Mr. Chairman, NLM has played a pivotal role in creating and nurturing the field of medical informatics, most notably through the creation of GenBank and a wide array of related scientific data and analysis tools which provide critical infrastructure for the Nation's researchers. This critical infrastructure will be key to advances in medicine in the future.

For nearly 35 years, NLM has supported informatics research and training and the application of advanced computing and informatics to biomedical research and healthcare delivery including a variety of telemedicine projects. Many of today's informatics leaders are graduates of NLM-funded informatics research programs at universities across the country, and many of the country's exemplary electronic health record systems benefited from NLM grant support.

A leader in supporting, licensing, developing and disseminating standard clinical terminologies for free United States-wide use (e.g., SNOWMED), NLM works closely with the Office of the National Coordinator for Health Information Technology (ONCHIT) to promote the adoption of interoperable electronic records.

MLA and AAHSL encourage Congress to continue their strong support of NLM's medical informatics and genomic science initiatives, at a point when the linking of clinical and genetic data holds increasing promise for enhancing the diagnosis and treatment of disease. MLA and AAHSL also support Health Information Technology initiatives at

ONCHIT and the Agency for Healthcare Research and Quality (AHRQ) that build upon initiatives housed at NLM.

NLM'S FACILITIES NEEDS

Mr. Chairman, over the past two decades NLM has assumed many new responsibilities, particularly in the areas of biotechnology, health services research, high performance computing and consumer health. As a result, NLM has had tremendous growth in its basic functions related to the acquisition, organization and preservation of an ever-expanding collection of biomedical literature an expanded staff. NLM now houses 1,100 staff in a facility built to accommodate only 650. This increase in the volume of biomedical information and in the number of personnel has

led to a serious space shortage. Digital archiving—once thought to be a solution to the problem of housing physical collections—has only added to the challenge, as materials must often be stored in multiple formats and as new digital resources consume increasing amounts of storage space. As a result, the space needed for computing facilities has also grown, further squeezing out staff. In order for NLM to continue its mission as the world's premier biomedical library, a new facility is urgently needed. The NLM Board of Regents has assigned the highest priority to supporting the acquisition of a new facility. Further, Senate Report 108–345 that accompanied the fiscal year 2005 appropriations bill acknowledged that the design for the new research facility at NLM had been completed and the committee urged the NIH to assign a high priority to this construction project so that NLM's information-handling capabilities are not jeopardized.

We encourage the subcommittee to provide the resources necessary to construct a new facility.

Mr. Chairman, thank you again for the opportunity to present the views of the medical library community.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN CANCER INSTITUTES

The Association of American Cancer Institutes (AACI), representing 89 of the Nation's premier academic and free-standing cancer centers, appreciates the opportunity to submit this statement for consideration as the Labor, Health and Human Services Appropriations Subcommittee plans the fiscal year 2008 appropriations for the National Institutes of Health (NIH) and the National Cancer Institute (NCI).

CANCER BURDEN

In 2007, there will be approximately 1.44 million new cases of cancer in the United States.[1] Today, lifetime cancer risk in the United States is one in two for men and one in three for women.[2] This number will continue to climb as the population ages, with an estimated 18.2 million cancer survivors (those undergoing treatment, as well as those who have completed treatment) alive in 2020. By comparison, 11.7 million survivors were living in the United States in 2005.[3]

RESEARCH IN JEOPARDY

A recent analysis published in the Journal of Oncology Practice suggested that the increase in the number of cancer patients and survivors over the next decade will be coupled with a shortage of clinical oncologists.[3] And there is another shortage that is all too real now, the implications of which will be felt for generations to come if our government's policymakers do not address the problem immediately. Because of continuing decreases to the budgets of the NIH and NCI (in actual dollars and as a result of biomedical inflation), grants to support cancer researchers as they discover new treatments for cancer and strategies to prevent and detect the disease continue to be cut. Without these grants, fewer and fewer cancer researchers will be able to maintain their commitment to science—a dearth of cancer researchers is on the horizon.

CANCER RESEARCH: BENEFITING ALL AMERICANS

The cancer research enterprise in the United States is second-to-none. Cancer research, conducted in academic laboratories across the country saves money by reducing healthcare costs associated with the disease, enhances the United States' global competitiveness, and has a positive economic impact on localities that house a major research center. While these aspects of cancer research are important, what cannot be overstated is the impact cancer research has had on individuals' lives—lives that have been lengthened and even saved by virtue of discoveries made in cancer research laboratories across the United States.

Our Nation's cancer researchers are making advances against this disease—for the second year in a row, statistics show that the number of people dying of cancer has declined.[2] And for the first time ever, coming generations may be able to prevent some cancers from occurring at all. For instance, with the recent FDA approval of the HPV (human papillomavirus) vaccine Gardasil, young women will be protected against the virus that causes up to 70 percent of cervical cancer cases world-

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[1] Cancer Statistics, 2007. CA: Cancer Journal for Clinicians 2007; 57: 43–66.

[2] The Nations' Investment in Cancer Research; A Plan and Budget Proposal for Fiscal Year 2008, National Cancer Institute, 2007.

[3] Future Supply and Demand for Oncologists, Journal of Oncology Practice 2007; 3(2): 79–86.

wide.[4] In 2007 11,150 women will develop cervical cancer and 3,670 will die as a result of the disease.[5] Gardasil is expected to significantly reduce the number of cases of cervical cancer as young women begin receiving the vaccine. Also, the HPV infection may play some role in the development of other diseases such as head and neck cancer, suggesting that the vaccine may have wider applicability in the future.

Recent headlines have linked dropping breast cancer rates with a decrease in the use of hormone replacement therapy among millions of older women. An NCI-funded study conducted at The University of Texas M.D. Anderson Cancer Center explored factors that may be involved in the 7 percent age-adjusted decline—or 14,000 fewer cases—in breast cancer incidence between 2002 and 2003.[6] The researchers, led by Dr. Donald Berry, concluded that "only the potential impact of hormone replacement therapy was strong enough to explain the effect."[2] Without a strong research infrastructure to examine this relationship, health professionals might still routinely prescribe menopausal hormones without knowing that the hormones may increase their patients' risk of developing breast cancer.

This and other success stories are positive news in the war on cancer, but are only one small part of the battle. Research advances that have led to increased cancer survivorship, prevention efforts, and enhanced treatment and understanding of the disease are at stake with research funding becoming more and more limited. Now is the time to provide funding to NIH and NCI to fully capitalize on the accelerated pace of research that was fostered by the doubling of the NIH budget from 1998 through 2003, not to risk losing out on lifesaving opportunities by cutting funding to the Nation's biomedical infrastructure.

EFFECTS OF THE "UNDOUBLING" OF THE NIH BUDGET

During the period from 1998 through 2003 the budget of the NIH was doubled. This doubling provided resources that allowed a greater number of promising young investigators to enter the field of cancer research, and also supported research into the ideas of established investigators. In 2007, however, funding for NIH is in the process of being "undoubled" through actual budget cuts and because of the effects of biomedical inflation. This year, NIH's budget is approximately $28.9 billion—an impressive sum to be sure. However, if NIH's 2003 budget (the last year of the doubling period) had been increased each year only to account for biomedical inflation, its 2007 budget would be $31.6 billion.

While the doubling of the NIH budget was an ambitious undertaking, the effort has ultimately resulted in inconsistent funding for the institutes that make up the NIH. The budget of the NCI alone has lost approximately 12 percent of its purchasing power due to the effects of biomedical inflation.[7] The Biomedical Research and Development Price Index (BRDPI) is calculated each year to determine how NIH expenditures must increase to compensate for inflation. In 2005 BRDPI was estimated at 3.9 percent, meaning that each research dollar lost 3.9 percent of its value for the year.[8] The NIH budget also decreased 0.5 percent from 2005 to 2006, which caused a net loss of 4.4 percent purchasing power for 2006. NCI Director Dr. John E. Niederhuber estimates that because of actual cuts in funding and the effects of BRDPI, in fiscal year 2006 NCI was unable to fund 180 grants that would otherwise have been deemed worthy of funding.[7] These projects would have built upon progress made during the doubling period—progress that will now be unrealized.

In 2007, NCI's Clinical Trials Cooperative Group Program will have to cut as much as 60 percent of its members' new clinical trials. This will result in an 11 percent decrease in the number of patients accrued into clinical trials, or approximately 3,000 eligible patients who will be unable to enroll in a cooperative group trial.[7] These trials would answer questions that help lead to more effective therapies and other interventions for cancer, as well as methods for screening and prevention. Not only will these patients be unable to benefit from the cutting-edge treatments available only through clinical trials, patients for generations to come will not benefit from the results of this research.

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[4] Taking Pride in an Important Achievement, The NCI Cancer Bulletin, 2006; 3(24): 1–2.

[5] American Cancer Society. Cancer Facts & Figures 2007, 2007, 20–21.

[6] Decline in Breast Cancer Cases Likely Linked to Reduced Use of Hormone Replacement. M.D. Anderson Cancer Center News Release, December 14, 2006.

[7] Cancer Research Budget Cuts Cause "Missed Opportunities," NCI Director Tells Advisors, The Cancer Letter; 33(9), 5–8.

[8] Biomedical Research and Development Price Index (BRDPI), BRDPI Table of Annual Values Index. Office of Budget, National Institutes of Health, 2007. http://officeofbudget.od.nih.gov/ui/GDP__FromGenBudget.htm

Additionally, NCI's Specialized Programs of Research Excellence (SPOREs) program that promotes interdisciplinary research to move basic research findings from the laboratory to clinical settings was cut by 8 percent, or $8 million, in fiscal year 2006, with more cuts expected this year. NCI's Tobacco Control Research Branch has been cut by $6.5 million between fiscal year 2004 and fiscal year 2007 and its Cancer Survivorship Program by $1 million. Patient accrual for clinical trials at NCI's Center for Cancer Research (CCR) was at 4,210 in fiscal year 2004, but in fiscal year 2006 that number was down to 3,795.[7]

THE NATION'S CANCER CENTERS

The nexus of cancer research in the United States is the Nation's network of cancer centers, both with and without NCI designation, that are represented by AACI. These cancer centers are highly integrated, multidisciplinary hubs of scientific excellence and exceptional patient care. They are uniquely patient oriented, research intensive, translationally adept, and clinically superb. In 2005, these academic based institutions received 86 percent of the grant dollars available for 2005, or 59 percent of NCI's budget as a whole. Because these centers are networked nationally, opportunities for collaborations are many—assuring wise and non-duplicative investment of scarce Federal dollars.

In addition to conducting basic, clinical, and population research, the cancer centers are largely responsible for training the cancer workforce that will practice in the United States in the years to come. Much of this training is dependent on Federal dollars, via training grants and other funding from NCI. Decreasing Federal support will significantly undermine the centers' ability to continue to train the next generation of cancer specialists—both researchers and providers of cancer care.

Success stories at the cancer centers are common—but are in danger of becoming less so as research dollars are lost. For instance, a patient at a major academic cancer center had been told he had 6 months to live after being diagnosed with an aggressive form of brain cancer. But through an innovative clinical trial at the center, this patient was tumor-free 6 years later.[9] Without the Federal funding that supported his treatment, he may not have been so fortunate.

FINANCIAL IMPACT ON CANCER CENTERS

The cancer center network in the United States forms the country's cancer research infrastructure. As the nationwide hubs of cancer-related scientific inquiry, the negative impact of reduced Federal funding for cancer research on these centers is enormous. The rapid pace of cancer research at AACI centers requires that investigators and clinicians from diverse disciplines work together to share information, expertise and resources. These interactions yield many insights into the cancer problem. Reduced, or—even worse—no support for even one member of this multidisciplinary team affects the collective progress and productivity of the entire program.

Furthermore, the grants that comprise the core funding for the NCI-designated cancer centers have been flat for the past 3 years.[7] This core funding helps support academic and research institutions to sustain coordinated interdisciplinary programs in cancer research. With no annual adjustment for inflation, the actual purchasing power over the course of a typical multi-year grant has decreased, essentially resulting in a cut to funding. Stagnant funding prevents expansion at existing centers, but also—and perhaps more importantly—prevents new centers from achieving NCI designation. While most major metropolitan areas in the United States have easy access to an NCI-designated cancer center, several States and many underserved areas do not.

SOCIAL VALUE

Though cancer statistics can seem daunting, even small steps forward will have tremendous results. Dr. Kevin M. Murphy, the George J. Stigler Distinguished Service Professor of Economics at the University of Chicago Graduate School of Business, estimates that even a 1 percent reduction in cancer deaths would result in almost $500 billion in social value to the United States. Social value is calculated in terms of improved health and longevity. Curing the disease would be worth as much as $50 trillion in social value.[10]

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[9] Road to Nowhere, Frontiers Magazine, Winter 2006.

[10] AACR Meeting: Increase Research Funding that Cuts U.S. Cancer Mortality by 1 percent Could Provide Payback of Nearly $500 Billion, Oncology Times, May 10, 2006.

CONCLUSION

These are very exciting times in science and, particularly, in cancer research. Recent discoveries in the molecular biology of cancer have led to important advances and new approaches to the prevention and treatment of the disease. Drug discovery often is now based on the understanding of molecular targets unique to cancer cells compared with normal cells. Because of the Nation's investment in this research, we are learning how to target and treat cancer specifically, while sparing healthy tissues, and we are helping survivors lead more vibrant lives. Reduced or flat funding will have a grave impact on progress in targeted therapies and other promising research endeavors that could lead to increased cancer survivorship.

Simply put, cancer research is a marathon, not a sprint. While the period of NIH doubling briefly helped speed the pace of cancer research, the potential legacy of this doubling will be squandered if the NCI and NIH budgets are not funded—at a minimum—to account for the effects of biomedical inflation. AACI and its members urge Congress to support an NIH budget increase for fiscal year 2008 of at least 6.7 percent to make up for recent annual inflationary shortfalls. AACI and its members also urge Congress to appropriate $5.1 billion for NCI's fiscal year 2008 budget, which reflects a 6.7 percent increase over fiscal year 2007, consistent with our overall NIH request.

We must, as a Nation, commit to fully funding the budget of the NCI and the NIH. Our generation has been fortunate—a diagnosis of cancer is no longer the certain death sentence it was for our parents and grandparents. We owe the same to our children and grandchildren, and we urge your support to increase this critical funding.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN PUBLISHERS

I am pleased to submit the following statement for the record on behalf of the Professional and Scholarly Publishing Division of the Association of American Publishers (PSP/AAP) in conjunction with the subcommittee's hearing on the fiscal year 2008 Budget for the National Institutes of Health (NIH). The AAP represents commercial and non-profit entities who publish scientific, technical and medical journals. Scholarly publishers are committed to working with NIH to successfully implement NIH's Public Access Policy and ensure that articles based on NIH-funded research are deposited with NIH. Publishers believe that such a proactive public-private partnership between NIH and journal publishers is critical to the success of the NIH policy. As a result of the voluntary efforts by publishers, the number of articles deposited with NIH has increased significantly.

The number of articles deposited with NIH has increased well beyond the low figures referenced by NIH. The voluntary effort initiated by publishers to deposit manuscripts on behalf of authors has resulted in an increase in deposits from 4 percent to over 20 percent. This significant increase is just the beginning. We will be able to do more as additional publishers join this effort. However, we need NIH's help to make that happen. To date, NIH has been slow to work with publishers to resolve key implementation issues necessary to bring on additional publishers.

We strongly oppose any move to a mandatory policy and feel that NIH should instead engage publishers more broadly so we may achieve our mutual objectives. This is important to attain the maximum article deposition rate without adversely affecting the valuable peer review process or the stability of important scientific journals and their publishers. Considering the immense stakes, it is prudent to work through the outstanding issues under the voluntary policy in a way that optimizes participation by all players to ensure the greatest benefit to the public interest and scientific progress.

We are confident that through a cooperative approach involving the publishing community, deposition rates for manuscripts reporting on NIH-funded research can reach optimum levels within a period of month, not years. We encourage Congress to direct NIH to work together with publishers to improve the implementation of the voluntary Public Access Policy and further increase deposit rates. We stand ready to work with NIH to achieve this important goal.

Publishers remain committed to working with NIH to ensure the successful implementation of the current voluntary program, while protecting the peer review process that helps ensure the quality and integrity of scientific and medical research. On behalf of the AAP, I appreciate this opportunity to submit this statement and look forward to enhanced collaboration with NIH.

PREPARED STATEMENT OF THE ASSOCIATION FOR CLINICAL RESEARCH TRAINING

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

A 6.7 percent increase for the National Institutes of Health, including the National Center for Research Resources.

$462 million for the Clinical and Translational Science Awards.

$350 million for the agency for Healthcare Research and Quality.

$750 million for a Center for Comparative Effectiveness at the agency for Healthcare Research and Quality. Of this $750 million, a substantial portion should be for research training.

The Association for Clinical Research Training (ACRT) is committed to improving the Nation's health by increasing the amount and quality of clinical research through the expansion and improvement of clinical research training. This training is funded by both the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ).

NATIONAL INSTITUTES OF HEALTH

The NIH's Clinical and Translational Science Awards (CTSAs) aim to meet one of the profound challenges of 21st Century medicine, namely that the ever increasing complexities involved in conducting clinical research are making it more difficult to translate new knowledge from the bench to the bedside. As Dr. Elias Zerhouni, the Director of the NIH, wrote in the October 13, 2005 edition of the New England Journal of Medicine, "it is the responsibility of those of us involved in today's biomedical research enterprise to translate the remarkable scientific innovations we are witnessing into health gains for the Nation."

The CTSAs assist institutions in creating a home for clinical and translational science that has the resources necessary to train and advance a cadre of investigators. The CTSAs transform basic research into clinical practice, advance information technology, integrate research networks and improve workforce training.

The ACRT supports the fiscal year 2008 President's budget request of $462 million for the CTSAs, and joins the Ad Hoc Group for Medical Research in asking for a 6.7 percent increase in fiscal year 2008 for the NCRR and the NIH overall.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ is the lead Federal agency charged with supporting research to improve healthcare quality, reduce costs, advance patient safety, decrease medical errors, eliminate disparities and broaden access to essential services. AHRQ supports health services research that will improve the quality of healthcare and improve evidence-based decision making. The agency also transforms research into in practice in order to facilitate wider access to effective healthcare services.

By providing funds to train clinical researchers, AHRQ ensures that there continues to be researchers who are able to provide the Nation with high quality, unbiased information about healthcare. Once consumers have this information, they will then be able to make effective, evidence based healthcare choices. A Center for Comparative Effectiveness would help to leverage AHRQ's expertise in providing this information to consumers. But in order to continue AHRQ's mission of training clinical researchers, there must be ample funding for training the investigators who will move this center forward.

The ACRT joins the Friends of AHRQ in requesting $350 million for AHRQ in fiscal year 2008. The ACRT also joints the Society of General Internal Medicine (SGIM) and other organizations in advocating for a Center for Comparative Effectiveness at AHRQ. This center should have an initial investment of $750 million, including a substantial portion for research training.

PREPARED STATEMENT OF THE ASSOCIATION OF MATERNAL AND CHILD HEALTH PROGRAMS

Mr. Chairman and members of the subcommittee, I am pleased to submit testimony on behalf of the Association of Maternal and Child Health Programs (AMCHP) regarding the critical need for increased funding of the Maternal and Child Health Services Block Grant, Title V of the Social Security Act. The Maternal and Child Health Services Block Grant is the only Federal program devoted to improving the health of all women, children and families. The program provides funding to State maternal and child health programs, which serve 33 million women and children in the United States.

When our children are healthy, they are more likely to succeed. Maternal and child health (MCH) programs help promote our children's success by identifying emerging and urgent health needs, while continuing to assure services like prenatal care, universal newborn screening, immunizations and access to health services. In fact, 80 percent of all American children access or connect with one or more programs funded by the Title V MCH Block Grant, making this program a vital resource for families—especially those with special health care needs.

INCREASE THE BLOCK GRANT TO $750 MILLION

The MCH Block Grant "Works."—The Office of Management and Budget reported that the block grant-funded programs helped to decrease the infant mortality rate, prevent disabling conditions, increase the number of children immunized, increase access to care for uninsured mothers and children, and improve the overall health of all mothers and children. Funding for the program has decreased since fiscal year 2002, yet participation has increased. These funding shortages have threatened the MCH programs' ability to continue achieving successful outcomes. As health care costs rise and the number of under- or un-insured women and children continue to grow, block grant programs will face a critical erosion of their successes. This erosion will impact the health and well-being of hundreds of thousands of women and children.

The Need for Programs for Families and Children With Special Health Care Needs Continues to Grow.—As States face economic hardships and limit their enrollment and benefit packages in Medicaid and State Children's Health Insurance Programs (SCHIP), more women and children seek and receive services through MCH programs. This is especially true for children with special health care needs who require services that are not covered in most health insurance plans. Block grant funds also are used to reduce infant mortality, provide mental health care, improve oral health, provide care coordination to children with special health care needs and reduce racial disparities in health care.

The Block Grant Funds Improvements to Vital Health Care Systems.—State MCH programs establish health care standards that promote preventive health care; provide outreach and health care education to assure that children receive services through insurance programs; and, measure the impact of health care practices. The block grant allows States to fund efforts to increase the quality health care, collect data and conduct analyses. MCH programs identify factors associated with infant mortality, inadequate immunizations, and late prenatal care so that strategies can be developed to address these needs. Every funding cut means the provision of fewer direct services and limits the development of health care system improvements.

MATERNAL AND CHILD BLOCK GRANT-FUNDED PROGRAMS HAVE FAR–REACHING IMPACT AND USE MONIES EFFICIENTLY AND EFFECTIVELY

Working with Efficiency and Agility, Spending Limited Resources Wisely

The care coordination of MCH programs ensures that all mothers and children, insured, under- and un-insured, utilize available health care coverage to receive all possible benefits. All payment sources (private insurance, State or federally funded health care) are integrated to deliver quality care.

Dollars invested in MCH programs yield a high return on investment.

The State of Iowa was awarded an Early Hearing Detection and Intervention grant through 2008 to focus on reducing the number of infants who are "lost" in the system, delaying the provision of early intervention services. The States' Child Health Specialty Clinics use the funds to screen all newborns and enroll eligible children into early intervention programs.

The Pennsylvania Department of Health currently funds the Pennsylvania Shaken Baby Syndrome Prevention and Awareness Program in the amount of approximately $100,000 annually. This program seeks to increase awareness of new parents on the dangers of shaking a baby. Medical care over the lifetime of a single child that suffers from Shaken Baby Syndrome can easily surpass the million dollar mark.

In Florida, for every dollar spent on newborn screening, $17 are saved. Newborn screening detects diseases and disorders that, without intervention, are debilitating, costly and potentially deadly.

Focusing on Those with the Greatest Need

Nationally, the incidence of low birth weight babies and infant mortality for African Americans is twice the rate for whites. MCH programs share strategies and tactics to reduce these racial and ethnic disparities.

Nevada contracts with local agencies to serve uninsured pregnant women with prenatal care including screening and referral for depression during and post-pregnancy.

Many young people are at risk for serious chronic diseases and premature death. Among 5- to 24-year-olds, nearly 75 percent of deaths are behavior-related, as are many illness and social problems, such as substance abuse. State MCH programs work to build the capacity of adolescent health coordinators and child health professionals at the State level to address adolescent health and make it a priority.

State technical assistance programs funded by the Title V MCH Block Grant help prevent HIV transmission from mothers to babies, help women quit smoking during pregnancy and promote safe motherhood.

A recent survey of State MCH program adolescent health coordinators identified teen pregnancy prevention as the number one priority related to adolescent health. State MCH programs work to raise the visibility of teen pregnancy prevention efforts to increase State capacity to address teen pregnancy and develop sustained and effective prevention efforts.

Serving America's Families

MCH State programs serve more than 33 million people, striving to improve the health of all women, infants, children and adolescents including those with special health care needs by delivering critical screening services, and supporting preventive, primary and specialty care.

Montana's MCH funding was the financial basis for public health services, especially in many small counties until recent bioterrorism funding. Federal and State MCH funding enables local public health to leverage small amounts of match funding at the county level.

Eighty percent of America's children utilize one or more maternal and child health program.

California's MCH program is collaborating with the Children's Hospital of Los Angeles and State Epilepsy Foundation on a HRSA grant called Improving Access to Care for Children and Youth with Epilepsy. The overall goal is to improve access to health and other services and supports related to epilepsy by facilitating the development of state-wide community-based interagency models of comprehensive, family-centered and culturally effective statewide standards of care. The program collaborates with Family Voices and the Children's Regional Integrated Service Systems which comprises 14 MCH county programs to implement integrated community systems of care for children and youth with special health care needs.

More families are turning to MCH services. Over the last 5 years, the number of individuals served increased by 18 percent.

The number of families served through Regional Genetics Clinics in Washington State grew from 2,736 families to 4,406 families in 5 years.

Touching the Lives of Women and Children from Every Walk of Life

MCH clients are as diverse as the country itself. MCH programs serve families in urban, suburban, rural, and frontier settings.

Many MCH clients are "special populations," those that face severe health problems and access issues to needed health care. They include children with complex health care needs, the under- and uninsured, American Indian and Alaska Natives, migrant and seasonal workers, immigrants, and racial and ethnic minorities.

Pennsylvania's MCH program has partnered with the Pennsylvania Chapter of the American Academy of Pediatrics on the Educating Practices in Community Integrated Care (EPIC–IC) Medical Home Training Program. Between Oct. 2006 to Feb. 2007, the EPIC IC program has prevented over 200 hospitalizations and almost 700 emergency doctor visits from. Future cost benefit modeling with parent and insurance data can translate this savings into real time dollars. In addition, care coordination and the EPIC IC program has favorably impacted the quality of life of both parents and children and youth with special health care needs by preventing almost 400 missed school days and over 250 parental work days missed.

MATERNAL AND CHILD HEALTH PROGRAMS WORK HAND IN HAND WITH MEDICAID AND SCHIP. THE HEALTH AND CONTINUITY OF OUR PROGRAMS ARE VITAL TO THEIR CONTINUED EFFECTIVENESS

AMCHP represents the State public health leaders and others working to assure that all women, children and families receive quality health care. MCH programs provide services and supports that augment Medicaid and SCHIP coverage and ensure eligible women and children access to needed services. MCH programs work

with other programs such as WIC, community health providers, Head Start and schools to make referrals to Medicaid and SCHIP programs. They also train public health workers who inform families about the availability of Medicaid and SCHIP and how to apply. These programs participate in the development of Medicaid and SCHIP policies and practice standards that help providers work with special populations, such as children and youth with special health care needs.

Changes to Medicaid and SCHIP often have a great effect on MCH programs and the people they serve. As some States restrict eligibility for Medicaid and SCHIP, people in need look to MCH-funded services to meet their health care needs. This puts an increased demand on MCH programs to offer more services without additional funding. With the increasing cost of health care and tighter State budgets, States are examining ways to offer health care services with decreasing resources. It is more important than ever to maintain the necessary services for pregnant women, children and adolescents by using the expertise, creativity and resources of Medicaid, SCHIP and Title V in joint program planning and development.

CONCLUSION

After its creation, the Title V Maternal and Child Health Block Grant grew from a $2.7 million program in fiscal year 1936 to a $731 million program in fiscal year 2002 to address the developing needs of America's women and children. However, since then, as maternal and child health related needs have increased, the Block Grant funding has decreased. Title V remains vital as a source of flexible funding that allows States to meet the needs of their most vulnerable populations through effective, efficient and integrated programs. Increased funding is crucial to sustain and expand these efforts to assure quality health care for families and children with special health care needs.

Please provide $750 million for the Block Grant in fiscal year 2008. Thank you for this opportunity to provide testimony.

PREPARED STATEMENT OF THE ASSOCIATION OF MINORITY HEALTH PROFESSIONS SCHOOLS

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

$300 million for the Title VII Health Professions Training Programs, including:
—$33.6 million for the minority centers of excellence.
—$35.6 million for the health careers opportunity program.

$250 million for the National Institutes of Health's National Center on Minority Health and Health Disparities.

Support for the National Center for Research Resources Extramural Facilities Construction program.
—$6.7 percent increase for Research Centers for Minority Institutions.
—$119 million for extramural facilities construction.

$65 million for the Department of Health and Human Services' Office of Minority Health.

$65 million for the Department of Education's Strengthening Historically Black Graduate Institutions program.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Barbara Hayes, president of the Association of Minority Health Professions Schools (AMHPS) and the dean of the school of pharmacy at Texas Southern University. AMHPS, established in 1976, is a consortium of our Nation's 12 historically black medical, dental, pharmacy, and veterinary schools. The members are two dental schools at Howard University and Meharry Medical College; four schools of medicine at The Charles Drew University, Howard University, Meharry Medical College, and Morehouse School of Medicine; five schools of pharmacy at Florida A&M University, Hampton University, Howard University, Texas Southern University, and Xavier University; and one school of veterinary medicine at Tuskegee University. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

Mr. Chairman, time and time again, you have encouraged your colleagues and the rest of us to take a look at our Nation and evaluate our needs over the next 10 years. I want to say that minority health professional institutions and the Title VII Health Professionals Training programs address a critical national need. Persistent and sever staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, our Nation's health professions workforce

does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. Mr. Chairman, I would like to share with you how your committee can help AMHPS continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Institutions that cultivate minority health professionals, like the AMHPS members, have been particularly hard-hit as a result of the cuts to the Title VII Health Profession Training programs in fiscal year 2006 and fiscal year 2007 Funding Resolution passed earlier this Congress. Given their historic mission to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The cuts to the Title VII Health Professions Training programs amount to a loss of core funding at these institutions and have been financially devastating.

In fiscal year 2008, funding for the Title VII Health Professions Training programs must be restored to the fiscal year 2005 level of $300 million, with two programs—the Minority Centers of Excellence (COEs) and Health Careers Opportunity Program (HCOPs)—in particular need of a funding restoration. In addition, the National Institutes of Health (NIH)'s National Center on Minority Health and Health Disparities (NCMHD), as well as the Department of Health and Human Services (HHS)'s Office of Minority Health (OMH), are both in need of a funding increase.

Minority Centers of Excellence

COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions (the Medical and Dental Institutions at Meharry Medical College; The College of Pharmacy at Xavier University; and the School of Veterinary Medicine at Tuskegee University) to the training of minorities in the health professions. Congress later went on to authorize the establishment of "Hispanic", "Native American" and "Other" Historically black COEs.

Presently the statute is configured in such a way that the "original four" institutions compete for the first $12 million in funding, "Hispanic and Native American" institutions compete for the next $12 million, and "Other" institutions can compete for grants when the overall funding is above $24 million. For funding above $30 million all eligible institutions can compete for funding.

However, as a consequence of limited funding for COEs in fiscal year 2006 and fiscal year 2007, "Hispanic and Native American" and "Other" COEs have lost their support. Out of 34 total COEs in fiscal year 2005, only 4 now remain due to the

cuts in funding. Many AMHPS institutions lost its COE funding as well, which was a devastating blow to our institutions.

For fiscal year 2008, I recommend a funding level of $33.6 million for COEs.

Health Careers Opportunity Program (HCOP)

HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional.

Collectively, the absence of HCOPs will substantially erode the number of minority students who enter the health professions. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. If HCOPs continue to lose Federal support, then these numbers will drastically decrease. It is estimated that the number of minority students admitted to health professional schools will drop by 25–50 percent without HCOPs. A reduction of just 25 percent in the number of minority students admitted to medical school will produce approximately 600 fewer minority medical students nationwide.

As a result of cuts in the fiscal year 2006 and fiscal year 2007 Labor-HHS Appropriations process, only 4 out of 74 total HCOPs currently receive Federal funding.

For fiscal year 2008, I recommend a funding level of $35.6 million for HCOPs.

NATIONAL INSTITUTES OF HEALTH (NIH): EXTRAMURAL FACILITIES CONSTRUCTION

Mr. Chairman, if we are to take full advantage of the recent funding increases for biomedical research that Congress has provided to NIH over the past decade, it is critical that our Nation's research infrastructure remain strong. The current authorization level for the Extramural Facility Construction program at the National Center for Research Resources is $250 million. The law also includes a 25 percent set-aside for "Institutions of Emerging Excellence" (many of which are minority institutions) for funding up to $50 million. Finally, the law allows the NCRR Director to waive the matching requirement for institutions participating in the program. We strongly support all of these provisions of the authorizing legislation because they are necessary for our minority health professions training schools.

Unfortunately, funding for NCRR's Extramural Facility Construction program was completely eliminated in the fiscal year 2006 Labor-HHS bill, and no funding was restored in the funding resolution for fiscal year 2007. In fiscal year 2008, please restore funding for this program to its fiscal year 2004 level of $119 million, or at a minimum, provide funding equal to the fiscal year 2005 appropriation of $40 million.

RESEARCH CENTERS IN MINORITY INSTITUTIONS

The Research Centers at Minority Institutions program (RCMI) at the National Center for Research Resources has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2008.

STRENGTHENING HISTORICALLY BLACK GRADUATE INSTITUTIONS—DEPARTMENT OF EDUCATION

The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, section 326) is extremely important to AMHPS. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2008, an appropriation of $65 million (an increase of $7 million over fiscal year 2007) is suggested to continue the vital support that this program provides to historically black graduate institutions.

National Center on Minority Health and Health Disparities

The National Center on Minority Health and Health Disparities (NCMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NCMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued

development of faculty, labs, and other learning resources. The NCMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NCMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the Minority Centers of Excellence program.

For fiscal year 2008, I recommend a funding level of $250 million for the NCMHD.

Department of Health and Human Services' Office of Minority Health

Specific programs at OMH include:

(1) Assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals,

(2) Assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers,

(3) Supporting conferences for high school and undergraduate students to interest them in health careers, and

(4) Supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

The OMH has the potential to play a critical role in addressing health disparities. Unfortunately, the OMH does not yet have the authority or resources necessary to support activities that will truly make a difference in closing the health gap between minority and majority populations.

For fiscal year 2008, I recommend a funding level of $65 million for the OMH.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, AMHPS's member institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. The Association seeks to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity everyday.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

PREPARED STATEMENT OF THE ASSOCIATION FOR PSYCHOLOGICAL SCIENCE

SUMMARY OF RECOMMENDATIONS

As a member of the Ad Hoc Group for Medical Research Funding, APS recommends $30.8 billion for NIH in fiscal year 2008, a 6.7 percent increase.

APS requests committee support for establishing behavioral and social science research and training as a core priority at NIH in order to: better meet the Nation's health needs, many of which are behavioral in nature; realize the exciting scientific opportunities in behavioral and social science research, and; accommodate the changing nature of science, in which new fields and new frontiers of inquiry are rapidly emerging.

Given the critical role of basic behavioral science research and training in addressing many of the Nation's most pressing public health needs, we ask the committee to (1) require NIMH to coordinate its efforts with other Institutes to ensure that these and related areas are adequately supported at NIH; and (2) request a report from NIH outlining a structure for basic behavioral science within NIGMS.

APS encourages the committee to review behavioral science activities at a number of individual institutes. Examples are provided in this testimony to illustrate the exciting and important behavioral and social science work being supported at NIH.

Mr. Chairman, members of the committee: As our organization's name indicates, APS is dedicated to all areas of scientific psychology, in research, application, teaching, and the improvement of human welfare. Our 18,000 members are scientists and educators at the Nation's universities and colleges, conducting NIH-supported basic and applied, theoretical and clinical research. They look at such things as: the connections between emotion, stress, and biology and the impact of stress on health; they look at how children grow, learn, and develop; they use brain imaging to explore thinking and memory and other aspects of cognition; they develop ways to manage debilitating chronic conditions such as diabetes and arthritis as well as depression and other mental disorders; and they address the behavioral aspects of smoking and drug and alcohol abuse. Still others look at how genes and the environment influence behavioral traits such as aggression and anxiety; the development of a normative model of vision to understand how it is used in behavior; and the study of the behavioral and neural mechanisms of sound localization.

As a member of the Ad Hoc Group for Medical Research Funding, APS recommends $30.8 billion for NIH in fiscal year 2008, an increase of 6.7 percent over the fiscal year 2007 Joint Funding Resolution level. This increase would halt the erosion of the Nation's public health research enterprise, and help restore momentum to our efforts to improve the health and quality of life of all Americans.

Within the NIH budget, APS is particularly focused on behavioral and social science research and the central role of behavior in health. The remainder of this testimony concerns the status of those areas of research at NIH.

BASIC AND APPLIED PSYCHOLOGICAL RESEARCH RELATED TO HEALTH

Behavior is an indelible part of health. Many leading health conditions—heart disease; stroke; lung disease and certain cancers; obesity; AIDS, suicide; teen pregnancy, drug abuse and addiction, depression and other mental illnesses; neurological disorders; alcoholism; violence; injuries and accidents—originate in behavior and can be prevented or controlled through behavior. As just one example, stress is something we all feel in our daily lives, and we now have a growing body of research that illustrates the direct link between stress and health: chronic stress accelerates not only the size but also the strength of cancer tumors; mounting evidence indicates that chronic stressors weaken the immune system to the point where the heart is damaged, paving the way for cardiac disease; children who are genetically vulnerable to anxiety and who are raised by stressed parents are more likely to experience more anxiety and stress later in life; animal research has shown that stress interferes with working memory; and stressful interactions may contribute to systemic inflammation in older adults which in turn may maintain negative emotion and pain over time.

None of the conditions or diseases described above can be fully understood without an awareness of the behavioral and psychological factors involved in causing, treating and preventing them. Just as there exists a layered understanding, from basic to applied, of how molecules affect brain cancer, there is a similar spectrum for behavioral research. For example, before you address how to change attitudes and behaviors around AIDS, you need to know how attitudes develop and change in the first place. Or, to design targeted therapies for bipolar disorder, you need to know how to understand how circadian rhythms work as disruptions in sleeping patterns have been shown to worsen symptoms in bipolar patients.

Despite the clear central role of behavior in health, behavioral research has not received the recognition or support needed to reverse the effects of behavior-based health problems in this Nation. APS asks that you continue to help make behavioral research more of a priority at NIH, both by providing maximum funding for those institutes where behavioral science is a core activity, by encouraging NIH to advance a model of health that includes behavior in its scientific priorities, and by encouraging stable support for basic behavioral science research at NIH.

BASIC BEHAVIORAL SCIENCE RESEARCH NEEDS A STABLE INFRASTRUCTURE

Broadly defined, behavioral research explores and explains the psychological, physiological, and environmental mechanisms involved in functions such as memory, learning, emotion, language, perception, personality, motivation, social attachments, and attitudes. Within this, basic behavioral research aims to understand the fundamental nature of these processes in their own right, which provides the foundation for applied behavioral research that connects this knowledge to real-world concerns such as disease, health, and life stages. We are sorry to have to tell you that basic behavioral research is not faring well at NIH, a circumstance that jeopardizes the success of the entire behavioral research enterprise. Let us describe the current situation:

Traditionally, the National Institute of Mental Health (NIMH) has been the home for far more basic behavioral science than any other institute. Many basic behavioral and social questions were being supported by NIMH, even if their answers could also be applied to other institutes. Recently, NIMH has begun to aggressively reduce its support for many areas of the most basic behavioral research, in favor of translational and clinical research. This means that previously funded areas now are not being supported.

NIMH's abrupt decision to narrow its portfolio came without adequate planning and is happening at the expense of critical basic behavioral research. We favor a broader spectrum of support for basic behavioral science across NIH as appropriate and necessary for a vital research enterprise. But until other Institutes have the capacity to support more basic behavioral science research connected to their missions, programs of research in fundamental behavioral phenomena such as cognition, emotion, psychopathology, perception, and development, will continue to lan-

guish. The existing conditions for basic behavioral science research undermine the scientific community's efforts to address many of the Nation's most pressing public health needs. We ask the committee to require NIMH to coordinate its efforts with other Institutes to ensure that these areas are adequately supported at NIH.

NIGMS SHOULD SUPPORT BASIC BEHAVIORAL SCIENCE RESEARCH

The situation at NIMH underscores the need for a dependable "home" for basic behavioral science research and training at NIH. In fact, that is the recommendation of the NIH Director's own Working Group on Research Opportunities in the Basic Behavioral and Social Sciences, which also recommended the National Institute of General Medical Sciences (NIGMS), known as NIH's "basic research institute." Congress has given NIGMS a statutory mandate [TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 11, Sec. 285k] to support basic behavioral research and training, but that mandate has not been fulfilled.

As early as fiscal year 2000, this committee, along with your colleagues in the House, has repeatedly issued report language urging NIGMS to fund basic behavioral research and training, saying, for example: "There is a range of basic behavioral research and training that the institute could support, such as the fundamental relationships between the brain and behavior, basic cognitive processes such as motivation, learning, and information processing, and the connections between mental processes and health. The committee encourages NIGMS to support basic behavioral research and training and to consult with the behavioral science research community and other Institutes to identify priority research and training areas." [House Fiscal Year 2000 Appropriations Report 106–370]

As a result of meetings between NIH Deputy Director Raynard Kington and Representatives Kennedy and Baird, the NIH Director commissioned a panel of outside experts in 2004 to study the matter. This Working Group, which was convened under the auspices of the NIH Director's Advisory Council, spent a year assessing the state of basic behavioral research throughout NIH. In its final report to NIH, the Working Group formally recommended the establishment of a secure and stable home for basic behavioral science research and training at NIH. In particular, it suggested that an Institute such as NIGMS should be that home, as this committee, the Institute of Medicine, and the National Academy of Sciences have recommended. NIH has deflected this request, made by multiple entities, time and time again. In view of the fact that 8 of the 10 leading causes of death have a significant behavioral component and that basic research is the underpinning of advances in applied behavioral research, the continued lack of focus of scientific leadership at NIH for this important field of science is counter to the interests of the Nation's health needs.

Basic behavioral research in the cognitive, psychological, and social processes underlying substance abuse and addiction (significance for NIDA, NIAAA, NCI and NHLBI), obesity (significance for NIDDK, NHLBI, and NICHD) and the connections between the brain and behavior (significance for NIMH, NINDS, and NHGRI) just to name a few, all are within the NIGMS mission. Greater involvement between the behavioral science community and NIGMS is an alliance that can reap enormous benefits for NIGMS, for behavioral science, for medical science, and for the public welfare. It is our feeling that the time is ripe for NIGMS to provide a supportive home for the kinds of basic behavioral science research that will be critical to fulfilling the NIGMS mission in the coming years. Given the statutory mandate, the recommendations of a recent Director's advisory council's task force, the strong congressional interest, the recommendations of the National Academy of Sciences and the Institute of Medicine, the scientific imperative, and most important, the health needs of the Nation, APS asks the committee to request the Office of the Director to submit to the committee a report indicating the structure for scientific leadership for this important field within the appropriate grant making institute, by November 16, 2007.

BEHAVIORAL SCIENCE AT KEY INSTITUTES

In the remainder of this testimony, we highlight examples of cutting-edge behavioral science research being supported by individual institutes.

National Institute of Mental Health (NIMH).—In addition to our earlier discussion of NIMH, we would like to give special recognition to the Institute's support of the emerging field of Social Neuroscience, which investigates the interaction of biological mechanisms and social processes and behavior. We commend NIMH for making this a priority. Elucidating the complex interplay between brain and social behavior will help us better understand and treat mental disorders such as autism and schiz-

ophrenia, and will lead to cognitive therapies for treating the emotion dysregulation associated with post-traumatic stress, depression, and cardiovascular disease.

National Institute on Drug Abuse (NIDA).—By supporting a comprehensive research portfolio that stretches across basic neuroscience, behavior, and genetics, NIDA is leading the Nation to a better understanding and treatment of drug abuse. Risky Decision-Making and HIV/AIDS–NIDA-funded research is examining every aspect of the transmission of HIV/AIDS through drug abuse and addiction, including risk-taking behaviors associated with both injection and non-injection drug abuse, how drugs of abuse alter brain function and impair decision making, and HIV prevention and treatment strategies for diverse groups. The goal is to achieve a broad understanding of the multiple ways that drug abuse and addiction affect HIV/AIDS and how research can inform public health policy. APS asks this committee to support this and other critical behavioral science research at NIDA, and to increase NIDA's budget in proportion to the overall increase at NIH in order to reduce the health, social and economic burden resulting from drug abuse and addiction in this Nation.

It's not possible to highlight all of the worthy behavioral science research programs at NIH. In addition to those reviewed in this statement, many other institutes play a key role in NIH behavioral science research enterprise. These include the National Institute on Alcohol Abuse and Alcoholism, the National Cancer Institute, the National Institute for Child Health and Human Development, the National Institute on Aging, the National Heart, Lung, and Blood Institute, and the National Institute of Diabetes and Digestive and Kidney Diseases. Behavioral science is a central part of the mission of these institutes, and their behavioral science programs deserve the committee's strongest possible support.

This concludes our testimony. Again, thank you for the opportunity to discuss NIH appropriations for fiscal year 2008 and specifically, the importance of behavioral science research in addressing the Nation's public health concerns. We would be pleased to answer any questions.

PREPARED STATEMENT OF THE ASSOCIATION FOR RESEARCH IN VISION AND OPHTHALMOLOGY (ARVO)

EXECUTIVE SUMMARY

ARVO requests fiscal year 2008 NIH funding at $31 billion, or a 6.7 percent increase over fiscal year 2007, to balance the biomedical inflation rate of 3.7 percent and to maintain the momentum of discovery. Although ARVO commends the leadership's actions in the 110th Congress to increase fiscal year 2007 NIH funding by $620 million, this was just an initial step in restoring the NIH's purchasing power, which has declined by more than 13 percent since the budget doubling ended in fiscal year 2003. That power would be eroded even further under the President's proposed fiscal year 2008 budget. ARVO commends NIH Director Dr. Zerhouni, who has articulately described his agenda to foster collaborative, cost-effective research and to transform the healthcare research and delivery paradigm into one that is predictive, preemptive, preventive, and personalized. NIH is the world's premier institution and must be adequately funded so that its research can reduce healthcare costs, increase productivity, improve quality of life, and ensure our Nation's global competitiveness.

ARVO requests that Congress make vision health a top priority by funding the NEI at $711 million in fiscal year 2008, or a 6.7 percent increase over fiscal year 2007. This level is necessary to fully advance the breakthroughs resulting from NEI's basic and clinical research that are resulting in treatments and therapies to prevent eye disease and restore vision. Vision impairment/eye disease is a major public health problem that is growing and which disproportionately affects aging and minority populations, costing the United States $68 billion annually in direct/societal costs, reduced independence, and quality of life. NEI funding is a cost-effective investment in our Nation's health, as it can delay and prevent expenditures, especially to the Medicare and Medicaid programs.

Adequate NEI funding is also essential to a strong and vibrant research community, which risks losing established investigators. The flat funding in recent years may cause young investigators to pursue other careers and thus fail to keep the research pipeline strong. ARVO is especially concerned about the impact on clinician scientists who have been so instrumental to the NEI's successful track record of the translations of basic research into clinical applications that directly benefit the American people.

ABOUT ARVO

ARVO is the world's largest association of physicians and scientists who study diseases and disorders affecting vision and the eye. ARVO has more than 11,700 members from the United States and 70 countries, and some 80 percent of U.S. members have grants from the National Eye Institute. It is in that regard that ARVO submits these comments in support of increased fiscal year 2008 NIH and NEI funding.

FUNDING THE NEI AT $711 MILLION IN FISCAL YEAR 2008 ENABLES IT TO LEAD TRANS-INSTITUTE VISION RESEARCH THAT MEETS NIH'S GOAL OF PREEMPTIVE, PREDICTIVE, PREVENTIVE, AND PERSONALIZED HEALTHCARE

Funding NEI at $711 million in fiscal year 2008 represents the eye and vision research community's judgment as that necessary to fully advance breakthroughs resulting from NEI's basic and clinical research that are resulting in treatments and therapies to prevent eye disease and restore vision.

NEI research responds to the NIH's overall major health challenges, as set forth by Dr. Zerhouni: an aging population; health disparities; the shift from acute to chronic diseases; and the co-morbid conditions associated with chronic diseases (e.g., diabetic retinopathy). In describing the predictive, preemptive, preventive, and personalized approach to healthcare research, Dr. Zerhouni has frequently cited NEI-funded research as tangible examples of the value of our Nation's past and future investment in the NIH. These include:

—Dr. Zerhouni has cited as a breakthrough the collaborative Human Genome Project/NEI-funded discovery of gene variants strongly associated with an individual's risk of developing age-related macular degeneration (AMD), the leading cause of blindness (affecting more than 10 million Americans) which increasingly robs seniors of their independence and quality of life. These variants, which are responsible for about 60 percent of the cases of AMD, are associated with the body's inflammatory response and may relate to other inflammation-associated diseases, such as Alzheimer's and Parkinson's disease. As NEI Director Dr. Paul Sieving has stated, "One of the important stories during the next decade will be how Alzheimer's disease and macular degeneration fit together."

—Dr. Zerhouni has cited the NEI-funded Age-Related Eye Disease Study (AREDS) as a cost-effective preventive measure. In 2006, NEI began the second phase of the AREDS study, which will follow up on initial study findings that high levels of dietary zinc and antioxidant vitamins (Vitamins C, E and beta-carotene) are effective in reducing vision loss in people at high risk for developing advanced AMD—by a magnitude of 25 percent.

—NEI has funded research, along with the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI), into factors that promote new blood vessel growth (such as Vascular Endothelial Growth Factor, or VEGF). This has resulted in anti-VEGF factors that have been translated into the first generation of ophthalmic drugs approved by the Food and Drug Administration (FDA) to inhibit abnormal blood vessel growth in "wet" AMD, thereby stabilizing vision loss. Current research is focused on using treatments singly and in combination to improve vision or prevent further vision loss due to AMD. As part of its Diabetic Retinopathy Clinical Research Network, NEI is also evaluating these drugs for treatment of macular edema associated with diabetic retinopathy.

Although these breakthroughs came directly from the past doubling of the NIH budget, their long-term potential to preempt, predict, prevent, and treat disease relies on adequately funding NEI's follow-up research. Unless its funding is increased, the NEI's ability to capitalize on the findings cited above will be seriously jeopardized, resulting in "missed opportunities" that could include:

—Following up on the AMD gene discovery by developing diagnostics for early detection and promising therapies, as well as to further study the impact of the body's inflammatory response on other degenerative eye diseases.

—Fully investigating the impact of additional, cost-effective dietary supplements in the AREDS study, singly and in combination, to determine if they can demonstrate enhanced protective effects against progression to advanced AMD.

—Following up with further clinical trials on patients with the "wet" form of AMD, as well as patients with diabetic retinopathy, using the new anti-angiogenic ophthalmic drugs singly and in combination to halt disease progression and potentially restore vision.

In addition, NEI research into other significant eye disease programs, such as glaucoma and cataract, will be threatened, along with quality of life research programs into low vision and chronic dry eye. This comes at a time when the U.S. Census and NEI-funded epidemiological research (also threatened without adequate

funding) both cite significant demographic trends that will increase the public health problem of vision impairment and eye disease.

Adequate NEI funding is also essential to a strong and vibrant research community, which risks losing established investigators. The flat funding in recent years may cause young investigators to pursue other careers and thus fail to keep the research pipeline strong. ARVO is especially concerned about the impact on clinician scientists who have been so instrumental to the NEI's successful track record of the translations of basic research into clinical applications that directly benefit the American people.

VISION IMPAIRMENT/EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM THAT IS INCREASING HEALTHCARE COSTS, REDUCING PRODUCTIVITY, AND DIMINISHING QUALITY OF LIFE

The 2000 U.S. Census reported that more than 119 million people in the United States were age 40 or older, which is the population most at risk for an age-related eye disease. The NEI estimates that, currently, more than 38 million Americans age 40 and older experience blindness, low vision or an age-related eye disease such as AMD, glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million Americans by year 2020. The economic and societal impact of eye disease is increasing not only due to the aging population, but to its disproportionate incidence in minority populations and as a co-morbid condition of other chronic disease, such as diabetes.

Although the NEI estimates that the current annual cost of vision impairment and eye disease to the United States is $68 billion, this number does not fully quantify the impact of direct healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. The continuum of vision loss presents a major public health problem and financial challenge to both the public and private sectors.

In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer. As a result, Federal funding for the NEI is a vital investment in the health, and vision health, of our Nation, especially our seniors, as the treatments and therapies emerging from research can preserve and restore vision. Adequately funding the NEI can delay and prevent expenditures, especially those associated with the Medicare and Medicaid programs, and is, therefore, a cost-effective investment.

ARVO urges fiscal year 2008 NIH and NEI funding at $31 billion and $711 million, respectively.

PREPARED STATEMENT OF THE ASSOCIATION OF WOMEN'S HEALTH, OBSTETRIC AND NEONATAL NURSES

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) appreciates the opportunity to provide comments on the fiscal year 2008 appropriations for nursing education, research, and workforce development programs as well as programs designed to improve maternal and child health. AWHONN is a membership organization of 22,000 nurses, and our mission is to promote the health and well-being of all women and newborns. AWHONN members are registered nurses, nurse practitioners, certified nurse-midwives, and clinical nurse specialists who work in hospitals and health systems, physicians' practices, universities, and community clinics throughout the United States.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

AWHONN recommends $1 million in fiscal year 2008 funding to convene a Surgeon General's conference on preterm birth

Premature birth is the leading cause of neonatal death. Each year, an estimated 1 in 8 births is premature. A 2006 report by the Institute of Medicine found that the annual economic burden associated with preterm birth is at least $26.2 billion. This translates to $51,600 per preterm infant. The PREEMIE Act (Public Law 109–450) authorized funding to convene a Surgeon General's conference to establish a public-private research and education agenda to accelerate the development of new strategies for preventing preterm birth. This Surgeon General's conference is a critical step in reducing this growing challenge.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

AWHONN recommends a minimum of $7.5 billion in funding for HRSA

AWHONN is deeply concerned by the President's budget request, which eliminates 12 programs and cuts over $200 million from the Federal funds HRSA received in 2007. Through its many programs and new initiatives, HRSA provides for the Nation's most vulnerable citizens. Rapid advances in research and technology promise unparalleled change in the Nation's health care delivery system. In order to take reasonable advantage of these opportunities, HRSA will require an overall funding level of at least $7.5 billion for fiscal year 2008.

TITLE VIII—NURSING WORKFORCE DEVELOPMENT PROGRAMS UNDER HRSA

AWHONN recommends a minimum of $200 million in funding for Title VIII

Nursing workforce development programs authorized under Title VIII of the Public Health Service Act, are an essential component of the American health care safety net. Title VIII programs are the only comprehensive Federal programs that provide annual funds for nursing education. These funds help nursing schools and students prepare to meet changing patient needs and provide clinical education to promote practice in medically underserved communities and Health Professional Shortage Areas.

The President's budget recommends a 30 percent reduction in funding at $105 million for fiscal year 2008, despite the worsening nursing shortage. AWHONN believes a minimum of $200 million is needed to adequately fund in funding for Title VIII Nursing Workforce Development. In addition, AWHONN supports funding the Advanced Education Nursing Training Program (sec. 811) at an increased level on par with other Title VIII programs in fiscal year 2008.

In 2002, Congress enacted the Nurse Reinvestment Act, which provides funding for programs such as the Nurse Education Loan Repayment Program (NELRP), internships and residencies, retention programs, and faculty loans designed to encourage students to consider nursing, retain nurses, and increase nurse educators. These new programs received an initial appropriation of $20 million in fiscal year 2003, in addition to $93 million provided for existing Title VIII programming. Inadequate funding stunted the potential of loan and scholarship programs and limited the support to nursing students. For example, NELRP is a competitive program that repays 60 percent of the qualifying loan balance of registered nurses selected for funding in exchange for 2 years of service at a critical shortage facility. In fiscal year 2005, the NELRP received 4,465 applications and dispersed 803 awards; an 18 percent award rate. In fiscal year 2006, NELRP assessed 4,222 applications and gave 615 awards; only a 14 percent award rate. The award trend is going in the wrong direction.

Increased Funding for Title VIII Will Make a Positive Impact on the Nursing Shortage.—Recent data from the Bureau of Health Professions, Division of Nursing's The Registered Nurse Population: National Sample Survey of Registered Nurses, Preliminary Findings—March 2007, confirm that of the approximately 2.9 million registered nurses in the Nation only 83 percent of these nurses work full-time or part-time in nursing. A dominant factor in this shortage is the impending retirement of up to 40 percent of the workforce by 2010. The average age of a nurse according to a 2004 sample survey is 46.8 compared to 45.2 in the 2000 survey. This anticipated wave of retirement will occur as the needs of the aging baby boomer population will markedly increase demand for health care services and registered nurses. Also, the 2007 U.S. Bureau of Labor and Statistics report projected that registered nurses will have the largest 10-year job growth; about 1 million new job openings by 2010.

The shortage of registered nurses and its effect on staffing levels, patient safety, and quality care demands attention and a significant increase in funding to bolster and improve these programs. Nursing is the largest health profession, yet only .2 percent of Federal health funding is devoted to nursing education. A significant increase in funding for these programs can help lay the groundwork for expanding the nursing workforce, through education, clinical training and retention programs.

Increased Funding for Title VIII Will Help Fill the Nursing Faculty Gap.—AWHONN supports efforts to recruit new faculty and increase nursing faculty available to teach in nursing schools. Currently, according to the National League for Nursing, there are fewer than 17,000 full-time faculty members. The estimated number of nurse faculty required to meet current demand is estimated to be 40,000 nurse educators. The Advanced Nurse Education funding in fiscal year 2005 produced 11,949 graduate nursing students, who are the primary pool for future faculty.

Nursing faculty continues to decrease in number as nursing school applications have surged more than 59 percent over the past decade. In a NLN survey of the 2004–2005 academic year, nursing programs at all degree levels turned away an estimated 147,000 qualified applications because of the lack of faculty. This number represents a 17.6 percent increase from last year's figures. Without sufficient support for current nursing faculty and adequate incentives to attract future faculty, nursing schools will fail to have the teaching infrastructure necessary to educate and train our next generation of nurses.

While the capacity to implement faculty development is currently available through section 811 and section 831, adequate funding and direction is needed to ensure that these programs are fully operational. Options to provide support for full-time doctoral study are essential to rapidly prepare future nurse educators. AWHONN recommends that a portion of the funds be allocated for faculty development and mentoring.

Funding Advanced Practice Nurses Provides Needed Faculty and Primary Care Providers.—Advanced Practice nurses such as nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives are essential to eliminating the nursing shortage. As in other professions, the advanced degree has become a necessary achievement for career advancement. Registered nurses who pursue MSN and PhD degrees often go on to become faculty and essential health care providers. The nursing shortage encompasses both advanced practice and basic nursing; each must receive additional funding but not at the expense of one another. In addition, advanced practice nurses are critical and sometimes the only available primary care providers, and often serve in inner city, rural and frontier health care settings.

The entire nursing workforce needs strengthening. As a result, it will take long-term planning and innovative initiatives at the local, State and Federal levels to ensure an adequate supply of a qualified nurse workforce for the Nation. Federal investment in nursing education and retention programs is critical for meeting the health care needs of our Nation.

TITLE V—MATERNAL AND CHILD HEALTH BUREAU (MCHB) UNDER HRSA

AWHONN recommends $731 million in funding for MCHB

The Maternal and Child Health Bureau incorporates valuable programs like the Traumatic Brain Injury program, Universal Newborn Hearing Screening, Emergency Medical Services for Children, and Healthy Start, which were zeroed out, and the Maternal and Child Health Block Grant (MCH) that saw no funding growth from the previous year. These programs provide comprehensive, preventive care for mothers and young children, and an array of coordinated services for children with special needs. In fact, MCH serves over 80 percent of all infants, half of all pregnant women and 20 percent of all children in the United States.

NATIONAL INSTITUTES OF HEALTH (NIH)

AWHONN recommends a 6.7 percent increase in appropriation funding for NIH

Multiple institutes housed under the National Institutes of Health (NIH) serve valuable roles in helping promote the importance of nursing in the health care industry along with the health and well-being of women and newborns. AWHONN calls on Congress to implement a 6.7 percent increase in funding for NIH in each of the next 3 years. This funding will allow scientists, including nurse scientists, to continue making life-saving research breakthroughs and discoveries. This funding also is the estimated amount needed to sustain the current model of NIH research funding.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR) UNDER NIH

AWHONN recommends $150 million in funding for NINR

The National Institute of Nursing Research (NINR) engages in significant research affecting areas such as health disparities among ethnic groups, training opportunities for management of patient care and recovery, and telehealth interventions in rural/underserved populations. This research allows nurses to refine their practice and provide quality patient care. For example, NINR research is invaluable in contributing to improved health outcomes for women. Recent public awareness campaigns target differences in the manifestation of cardiovascular disease between men and women. The differing symptoms are the source of many missed diagnostic opportunities among women suffering from the disease, which is the primary killer of American women. Because of the emphasis on biomedical research in this country, there are few sources of funds for high-quality behavioral research for nursing

other than NINR. It is critical that we increase funding in this area in an effort to optimize patient outcomes and decrease the need for extended hospitalization. While the President's budget recommended a decrease at $138 million, AWHONN requests $150 million for fiscal year 2008, consistent with the overall increase for all National Institutes of Health.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD) UNDER NIH

AWHONN recommends $1.34 billion in funding for NICHD

The National Institute of Child Health and Human Development (NICHD) seeks to ensure that every baby is born healthy, that women suffer no adverse consequences from pregnancy, and that all children have the opportunity for a healthy and productive life unhampered by disease or disability. For example, with increased funding, NICHD could expand its use of the NICHD Maternal-Fetal Medicine Network to study ways to reduce the incidence of low birth weight. Prematurity/low birth weight is the second leading cause of infant mortality and the leading cause of death among African American infants. AWHONN is directly involved in programs to improve the health of women and newborns and looks to NICHD to provide national initiatives that assist with the care of pregnant women and babies. AWHONN suggests a 6.7 percent increase in NICHD funding to $1.34 billion.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS) UNDER NIH

AWHONN recommends $673 million for NIEHS

Research conducted by NIEHS plays a critical role in what we know about the relationship between environmental exposures and the onset of diseases. Through their research, we know that Parkinson's disease, breast cancer, birth defects, miscarriage, delayed or diminished cognitive function, infertility, asthma and many other diseases have confirmed environmental triggers. Our expanded knowledge, allows policymakers and the public to make important decisions about how to reduce toxin exposure, the risk of disease and other negative health outcomes. As the prevalence of infertility and related reproductive challenges continues to increase according to the CDC, the investment in improving our understanding of environmental impacts should be increased to $673 million.

INDIAN HEALTH SERVICE (IHS) UNDER THE DEPARTMENT OF HEALTH AND HUMANS SERVICES (HHS)

AWHONN recommends $3.5 billion in funding for IHS

The Indian Health Service (IHS) is the principal Federal health care provider and health advocate for the American Indian and Alaska Native populations. The President's budget recognizes this importance by requesting a 6.9 percent increase of $211 million to the IHS budget, bringing the fiscal year 2008 total to $3.27 billion. While AWHONN applauds this increase, we recommend that a total of $3.5 billion is needed for IHS to fully achieve its legitimate goals. A recent study of Federal health care spending per capita found that the United States spends $5,065 per year for the general population, $3,803 per year for a Federal prisoner, and only $1,914 for a Native American. Where health needs continue at unprecedented levels ad the average age of nurses (48) is higher than for the general public. The nursing shortage has disproportionately affected Indian Health Services. Further, the average reported vacancy rate for RNs in 2006 was 18 percent. IHS administers three severely under-funded interrelated scholarship programs designed to meet the health professional staffing needs of IHS and other health programs serving Indian people. Targeted resources need to be invested in the IHS health professions programs to recruit and retain registered nurses.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) UNDER HHS

AWHONN recommends $52 million for Safe Motherhood/Infant Health to fund activities authorized by the PREEMIE Act

This would include epidemiological studies on preterm birth, including the relationship between prematurity, birth defects and developmental disabilities.

AWHONN thanks you for your consideration and greatly appreciates this opportunity to submit testimony on these critical funding areas.

PREPARED STATEMENT OF THE AUTISM SOCIETY OF AMERICA

My name is Ruth Elaine Hane. I live in Minneapolis, Minnesota, where I facilitate a social group, the Aspie Get-Together, for adults with Aspergers and autism. It is a privilege to testifying on behalf of my self and other adults on the spectrum of autism. I appreciate sharing my story with strong advocates for autism, Senators Harkin, Specter and Durbin. Thank you, for all you do, to improve the lives of those affected by autism.

Several others have given testimony to this subcommittee, emphasizing the needs of children with autism who are waiting for essential services, and I do not deny that this is a critical issue, but, there are others who are also waiting, adults who have aged out of the system after 21, and are now left without support. A portion of these adults benefited from the various programs for early intervention in the past two decades, but are lacking employment and life skills to live independently. Many are sitting at home in front of their parent's computer or television screen without the quality of life they were promised.

I was born with autism, sometimes referred to as a "Rubella baby," since my mother had a severe case of Rubella Measles during her pregnancy with me. A delivery using forceps injured and distorted my head. I screamed for continuously, could not swallow or tolerate touch. My mother was advised by her doctor, not to become attached to her baby girl, because there was little hope of my survival, and, even if I did, I would never be normal. But, I did live, because of a community of neighbors who problem solved, volunteered, and taught my mother how to care for me. The bases of their practical advice came from sheep ranching, and the methods they used to nurture baby lambs who were born with neurological problems like mine . . . to wrap me tightly in a warm blanket, place me in a box set on the slightly warmed oven door and to drip goat's milk into my mouth. Since the sound of ticking clock calmed me, it was placed near the box. I was not to be clothed, or disturbed for 3 hours at a time. Over time, I began to grow, however I did not acclimate to touch, or learn to coo, or respond to others.

I identified with cats and not people, and did not talk until I was 4 years old. The small town where we lived accepted me as an "unusual" child who was stubborn, independent, and overly active, skipping, twirling, and singing to herself. Autism was not well-known by the doctors at that time. My grandmother, who was a school teacher, stepped in to give me love, taught me manners and structured learning. I graduated with honors from college, married and had two children, who are now grown. My second husband and I are grandparents. Presently, I volunteer in the community and serve as First vice Chair on the national board, of the Autism Society of America. I consult with sensitive people, many of whom are on the spectrum of autism.

My message is that most adults with autism are greatly underserved. Autism is sometimes called hidden, because many people like me look normal. Some, have learned to accommodate, to pretend to be normal, but, others have odd social communication and behaviors especially when there are stressful situations, such as loud noise, flashing emergency lights, florescent lighting, confusing verbal directions and poor signs in public places. Since our brains are unable to processes the incoming information in a timely way, we are put a risk socially, sometimes hurt, bullied, raped or even killed. Depression is common with little hope of living a productive independent life, even though many are educated, with college degrees, and some with graduate and doctoral degrees.

After I was diagnosed, as an adult, with High Functioning autism, I became active in the local Autism Society of America, Minnesota State Chapter. In 1999, several young adults on the spectrum asked if I would organize and facilitate a group for people diagnosed with Aspergers and autism. They wanted a place to socialize and meet friends. I formed the Aspic Get-Together.

The Aspic Get-Together is an all voluntary group of mostly young adults, run and governed by the participants. Since most of our members are unemployed or under employed, the nominal membership dues are often waived. We are limited in the activities that we can do because of this lack of funding. However it is a demonstration of how people who are often marginalized and at times, ostracized, because of a difference in social skills, can become, productive members of a group, and, of society at large if given structure, guidance and the opportunity to be themselves.

Those with autism, who are living with their parents, are under a cloud of uncertainty with parents who are aging, anguishing about the future of their dependent adult with autism. With our population shifting toward a nuclear family unit, we can no longer depend on the extended family to fill in this gap. We need appropriations to fund services to change this grave situation in America. With applied research, job and life skills training, community building and mentors, who could pro-

vide several hours of weekly planning and guidance, so that the underserved people with autism could work, lead productive lives and contribute to society in unique and beneficial ways. In addition, there are those who are profoundly affected by autism, who need 24 hours a day of assistance and supervision. The best and most successful programs today, are based on empowering the individual to make personal choices, allowing for, as much independence as is possible. Without exception, these providers are under funded.

Although those of us with autism diagnoses are directly affected by choices others make about and for us, our voice is seldom heard.

I dream of a society that embraces difference of all kinds, including autism, and a society that listens to those with autism—who can speak.

Please remember to include us so that there is . . . Nothing about us . . . without us.

Thank you.

PREPARED STATEMENT OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION COALITION

The CDC Coalition is a nonpartisan coalition of more than 100 groups committed to strengthening our Nation's prevention programs. Our mission is to ensure that health promotion and disease prevention are given top priority in Federal funding, to support a funding level for the Centers for Disease Control and Prevention (CDC) that enables it to carry out its prevention mission, and to assure an adequate translation of new research into effective State and local programs. Coalition member groups represent millions of public health workers, researchers, educators, and citizens served by CDC programs.

The CDC Coalition believes that Congress should support CDC as an agency—not just the individual programs that it funds. In the best judgment of the CDC Coalition—given the challenges and burdens of chronic disease, a potential influenza pandemic, terrorism, disaster preparedness, new and reemerging infectious diseases, increasing drug resistance to critically important antimicrobial drugs and our many unmet public health needs and missed prevention opportunities—we believe the agency will require funding of at least $10.7 billion including sufficient funding to prepare the Nation against a potential influenza pandemic, funding for the Agency for Toxic Substances and Disease Registry and to maintain the current funding level for the Vaccines for Children (VFC) program. This request does not include any additional funding that may be required to expand the mandatory VFC in fiscal year 2008.

The CDC Coalition appreciates the subcommittee's work over the years, including your recognition of the need to fund chronic disease prevention, infectious disease prevention and treatment, and environmental health programs at CDC. Federal funding through CDC provides the foundation for our State and local public health departments, supporting a trained workforce, laboratory capacity and public health education communications systems.

CDC also serves as the command center for our Nation's public health defense system against emerging and reemerging infectious diseases. With the potential onset of a worldwide influenza pandemic, in addition to the many other natural and man-made threats that exist in the modern world, the CDC has become the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center. States and communities rely on CDC for accurate information and direction in a crisis or outbreak.

CDC's budget has actually shrunk since 2005 in terms of real dollars—by almost 4 percent. If you add inflation, the cuts are even worse—and these are cuts to the core programs of the agency. The current administration request for fiscal year 2008 is inadequate, with a total cut to core budget categories from fiscal year 2005 to fiscal year 2008 of half a billion dollars. We are moving in the wrong direction, especially in these challenging times when public health is being asked to do more, not less. It simply does not make any sense to cut the budget for CDC core public health programs at a time when the threats to public health are so great. Funding public health outbreak by outbreak is not an effective way to ensure either preparedness or accountability. Until we are committed to a strong public health system, every crisis will force trade offs.

CDC serves as the lead agency for bioterrorism preparedness and must receive sustained support for its preparedness programs in order for our Nation to meet future challenges. In the best judgment of CDC Coalition members, given the challenges of terrorism and disaster preparedness, and our many unmet public health needs and missed prevention opportunities, we support the proposed increase for

anti-terrorism activities at CDC, including the increases for the Strategic National Stockpile. However, we strongly oppose the President's proposed $125 million cut to the State and local capacity grants. We ask the subcommittee to restore these cuts to ensure that our States and local communities can be prepared in the event of an act of terrorism or other public health threat.

Public health programs delivered at the State and local level should be flexible to respond to State and local needs. Within an otherwise-categorical funding construct, the Preventive Health and Health Services (PHHS) Block Grant is the only source of flexible dollars for States and localities to address their unique public health needs. The track record of positive public health outcomes from PHHS Block Grant programs is strong, yet so many requests go unfunded. However, the President's budget once again proposes the elimination of the PHHS Block Grant. We greatly appreciate the work of the subcommittee to at least partially restore the fiscal year 2007 elimination of the Block Grant. Nevertheless, the cut to the Block Grant in fiscal year 2006 reduces the States' ability to tailor Federal public health dollars to their specific needs.

ADDRESSING URGENT REALITIES

Heart disease remains the Nation's No. 1 killer. In 2004, more than 650,000 people died from heart disease, accounting for 27 percent of all U.S. deaths. In 1998, the U.S. Congress provided funding for CDC to initiate a national, state-based Heart Disease and Stroke Prevention Program with funding for eight States. Now, 32 States and the District of Columbia are funded, 19 as capacity building and 14 as basic implementation. We must expand these efforts to continue the gains we have made in combating heart disease and stroke.

The CDC funds proven programs addressing cancer prevention, early detection, and care. In 2006, about 1.4 million new cases of cancer will be diagnosed, and about 564,830 Americans—more than 1,500 people a day—are expected to die of the disease. The financial cost of cancer is also significant. According to the National Institutes of Health, in 2005, the overall cost for cancer in the United States was nearly $210 billion: $74 billion for direct medical costs, $17.5 billion for lost worker productivity due to illness, and $118.4 billion for lost worker productivity due to premature death.

Among the ways the CDC is fighting cancer, is through funding the National Breast and Cervical Cancer Early Detection Program that helps low-income, uninsured and medically underserved women gain access to lifesaving breast and cervical cancer screenings and provides a gateway to treatment upon diagnosis. CDC also funds programs to raise awareness about colorectal, prostate, lung, ovarian and skin cancers, and the National Program of Cancer Registries, a critical registry for tracking cancer trends in all 50 States.

Although more than 20 million Americans have diabetes, 6.2 million cases are undiagnosed. From 1980–2002, the number of people with diabetes in the United States more than doubled, from 5.8 million to 13.3 million. Unfortunately funding for diabetes, along with many other core CDC programs, has either been cut or flat funded for the past several years. Without additional funds, most States will not be able to create programs based on these new data. States also will continue to need CDC funding for diabetes control programs that seek to reduce the complications associated with diabetes.

Over the last 25 years, obesity rates have doubled among adults and children, and tripled in teens. Obesity, diet and inactivity are cross-cutting risk factors that contribute significantly to heart disease, cancer, stroke and diabetes. The CDC funds programs to encourage the consumption of fruits and vegetables, to get sufficient exercise, and to develop other habits of healthy nutrition and activity. In order to fully support these activities, we urge the subcommittee to provide at least $43 million for the Steps to a Healthier U.S. program and $65 million for CDC's Division of Nutrition and Physical Activity.

Childhood immunizations provide one of the best returns on investment of any public health program. Despite the incredible success of the program, it faces serious financial challenges. In the past 10 years, the number of recommended childhood vaccines has jumped from 10 to 16. Even more striking, the cost of fully vaccinating an adolescent female has increased from $285 to over $1,200 in past 8 years alone. Despite these challenges funding for vaccine purchases under section 317 has remained stagnant. The consequence of this disconnect, is that while 747,000 children and adolescents could potentially receive their full series of vaccinations with 317 funds in 1999, that number has plummeted by over 70 percent to just 218,000 in 2007.

More than 400,000 people die prematurely every year due to tobacco use. CDC's tobacco control efforts seek to prevent tobacco addition in the first place, as well as help those who want to quit. We must continue to support these vital programs and reduce tobacco use in the United States.

Almost 80 percent of young people do not eat the recommended number of servings of fruits and vegetables, while nearly 30 percent of young people are overweight or at risk of becoming overweight. And every year, almost 800,000 adolescents become pregnant and about 3 million become infected with a sexually transmitted disease. School health programs are one of the most efficient means of correcting these problems, shaping our Nation's future health, education, and social well-being.

Much of CDC's work in chronic disease prevention and health promotion is guided by its prevention research activities. Healthy Passages is a longitudinal study that is following a cohort of children will have to be discontinued without $6 million in additional appropriations. If allowed to continue, the study would follow children from birth through adulthood in order to discover critical links between risks and protective factors and health outcomes.

CDC provides national leadership in helping control the HIV epidemic by working with community, State, national, and international partners in surveillance, research, prevention and evaluation activities. CDC estimates that up to 1,185,000 Americans are living with HIV, one-quarter of who are unaware of their infection. Prevention of HIV transmission is our best defense against the AIDS epidemic that has already killed over 500,000 U.S. citizens and is devastating the populations of nations around the globe, and CDC's HIV prevention efforts must be expanded.

The United States has the highest sexually transmitted diseases (STD) rates in the industrialized world. More than 18 million people contract STDs each year. Untreated STDs contribute to infant mortality, infertility, and cervical cancer. State and local STD control programs depend heavily on CDC funding for their operational support.

CDC conducts several surveys that help track health risks and provide information for priority setting at the State and local levels. The Behavioral Risk Factor Surveillance System, Youth Risk Behavior Survey, Youth Tobacco Survey, and National Health and Nutrition Examination Survey (NHANES) are important national sources of objective health data. NHANES is a unique collaboration between CDC, the National Institutes of Health (NIH), and others to obtain data for biomedical research, public health, tracking of health indicators, and policy development. Ensuring adequate funding for this survey is essential for determining rates of major diseases and health conditions and developing public health policies and prevention interventions.

We must address the growing disparity in the health of racial and ethnic minorities. CDC's Racial and Ethnic Approaches to Community Health (REACH), helps States address these serious disparities in infant mortality, breast and cervical cancer, cardiovascular disease, diabetes, HIV/AIDS and immunizations. We encourage the subcommittee to provide adequate funds for CDC's REACH program.

CDC oversees immunization programs for children, adolescents and adults, and is a global partner in the ongoing effort to eradicate polio worldwide. The value of adult immunization programs to improve length and quality of life, and to save health care costs, is realized through a number of CDC programs, but there is much work to be done and a need for sound funding to achieve our goals. Influenza vaccination levels remain low for adults. Levels are substantially lower for pneumococcal vaccination and significant racial and ethnic disparities in vaccination levels persist among the elderly.

Injuries are the leading cause of death in the United States for people ages 1–34. Of all injuries, those to the brain are most likely to result in death or permanent disability. Traumatic brain injury (TBI) is widely recognized as the signature wound of the Iraq war with estimates of the numbers of injured service members as high as 150,000. Each year, however, more than 50,000 civilians die and 90,000 civilians are left with a long-term disability as a result of TBI. The Traumatic Brain Injury Act is the Nation's only law that specifically responds to this growing public health crisis. The Institute of Medicine found that this law has been effective in addressing a wide variety of gaps in service system development.

Injury at work remains a leading cause of death and disability among U.S. workers. During the period from 1980 through 1995, at least 93,338 workers in the United States died as a result of injuries suffered on the job, for an average of about 16 deaths per day. The injury prevention and workforce protection initiatives of NIOSH need continued support.

Created by the Children's Health Act of 2000 (Public Law 106–310), the National Center on Birth Defects and Developmental Disabilities (NCBDDD) at CDC con-

ducts programs to protect and improve the health of children and adults by preventing birth defects and developmental disabilities; promoting optimal child development and health and wellness among children and adults with disabilities. We must ensure adequate funding for this important Center.

We also encourage the subcommittee to provide adequate funding for CDC's Environmental Public Health Services Branch to revitalize environmental public health services at the national, State and local. These services are essential to protecting and ensuring the health and well being of the American public from threats associated with West Nile virus, terrorism, *E. coli* and lead in drinking water. We encourage the committee to provide at least $50 million for CDC's Environmental Health Tracking Network and to provide $50 million in new funding to CDC Environmental Health Activities to develop and enhance CDC's capacity to help the Nation prepare for and adapt to the potential health effects of global climate change. This new request for funding would help prepare State and local health department to prepare for the public health impacts of global climate change, allow CDC to fund academic and other institutions in their efforts to research the impacts of climate change on public health and to create a Center of Excellence at CDC to serve as a national resource for health professionals, government leaders and the public on climate change science.

We appreciate the subcommittee's hard work in advocating for CDC programs in a climate of competing priorities. We encourage you to consider our request for $10.7 billion, plus sufficient funding to prepare for a possible influenza pandemic, for CDC in fiscal year 2008.

MEMBERS OF THE CDC COALITION

Advocates for Youth; AIDS Action; AIDS Alliance for Children, Youth and Families; AIDS Foundation Chicago; Alliance to End Childhood Lead Poisoning; American Academy of Ophthalmology; American Academy of Pediatrics; American Association for Health Education; American Association of Orthopedic Surgeons; American Cancer Society; American College of Obstetricians and Gynecologists; American College of Preventive Medicine; American College of Rheumatology; American Dietetic Association; American Foundation for AIDS Research; American Heart Association; American Indian Higher Education Consortium; American Lung Association; American Medical Women's Association; American Optometric Association; American Podiatric Medical Association; American Psychological Association; American Psychological Society; American Public Health Association; American Red Cross; American School Health Association; American Society for Clinical Pathology; American Society for Gastrointestinal Endoscopy; American Society for Microbiology; American Society for Reproductive Health; American Thoracic Society; American Urological Association c/o MARC Assoc.; Arthritis Foundation; Assn. for Professionals in Infection Control & Epidemiology; Association of American Medical Colleges; Association of Maternal & Child Health Programs; Association of Minority Health Professions Schools; Association of Public Health Laboratories; Association of Reproductive Health Professionals; Association of Schools of Public Health; Association of State and Territorial Health Officials; Association of Teachers of Preventive Medicine; Barbara Levine & Associates; Brain Injury Association; Bread for the World Institute; Campaign for Tobacco-Free Kids; CDC Foundation; Center for Science in the Public Interest; Coalition for Health Funding; Coalition for Health Services Research; Commissioned Officers Association of the U.S. Public Health Service; Consortium for Citizens with Disabilities; Consortium of Social Science Associations; Council of Professional Association on Federal Statistics; Council of State and Territorial Epidemiologist; Crohn's and Colitis Foundation of America; Environmental Defense; ESA, Inc.; Every Child By Two; GLMA; Health and Medicine Counsel of Washington; Hepatitis Foundation International; Immune Deficiency Foundation; Infectious Diseases Society of America; Latino Council on Alcohol & Tobacco; Legal Action Center; March of Dimes; NASEMSD; National Alliance of State and Territorial AIDS Directors; National Association of Children's Hospitals; National Association of County and City Health Officials; National Association of Councils on Developmental Disabilities; National Association of Local Boards of Health; National Association of School Nurses; National Black Nurses Association; National Coalition for the Homeless; National Coalition of STD Directors; National Council of La Raza; National Episcopal AIDS Coalition; National Family Planning and Reproductive Health Association; National Health Care for the Homeless Council; National Hemophilia Foundation c/o MARC Assoc.; National Medical Association; National Osteoporosis Foundation; National Partnership for Immunization; National Rural Health Association; National Safe Kids Campaign; National Association for Public Health Statistics & Information Systems & Information Systems; Partner-

ship for Prevention; Planned Parenthood Federation of America; Powers, Pyles, Sutter and Verville; Research!America; Society for Maternal Fetal-Medicine c/o CRD Associates; Society for Public Health Education; Society of General Internal Medicine (SGIM); Spina Bifida Association of America; The Alan Guttmacher Institute; Trust for America's Health; U.S. Conference of Mayors; United Cerebral Palsy; YMCA of the USA; and YWCA of the USA/Office of Women's Health Initiative.

PREPARED STATEMENT OF THE CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

$300 million for the Health Resources and Services Administration Title VII Health Professisons Training programs, including:

—$33.6 million for the Minority Centers of Excellence, and

—$35.6 million for the Health Careers Opportunity program.

Provide a 6.7 percent increase for fiscal year 2008 to the National Institutes of Health (NIH), specifically:

—A proportional increast to the National Cancer Institute (NCI),

—$250 million for the National Center on Minority Health and Health Disparities (NCMHD),

—Support the National Center for research resources:

  —Proportional increase for Research Centers for Minority Institutions and Institutional Development Award (IDeA) program institutions, and

  —$119 million for extramural facilities construction.

Continue to urge NCI to support the Establishment of a Collaborative Minority Health Comprehensive Research Center at a Historically Minority Institution in collaboration with the existing NCI cancer centers. continue to urge NCRR and NCMHD to collaborate on the Establishment of a Minority Health Comprehensive Research Center.

$65 million for the Department of Health and Human Services' Office of Minority Health, and

—Urge support for the Health Professions Leadership Development and Support program at the Charles Drew University.

$65 million for the Department of Education's Strengthening Historically Black Graduate Institutions program.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present you with testimony. The Charles Drew University is distinctive in being the only dually designated Historically Black Graduate Institution and Hispanic Serving Institution in the Nation. We would like to thank you and your predecessors,

Mr. Chairman, for the support that this subcommittee has given to the National Institutes of Health (NIH) and its various institutes and centers over the years, NIH has been and continues to be invaluable to our university and especially our community.

The Charles Drew University is located in the Watts-Willowbrook area of South Los Angeles. Its mission is to prepare predominantly minority doctors and other health professionals to care for underserved communities with compassion and excellence through education, clinical care, outreach, pipeline programs and advanced research that makes a rapid difference in clinical practice. In our over 35 years of enrolling students, the university has become a significant source of Latino and African American doctors and health professionals. We have made a measurable contribution to improving health care in this Nation by graduating over 400 physicians, 2,000 physician assistants, 2,500 physician specialists, and numerous other health professionals—almost all from diverse communities. Even more importantly, our graduates go on to serve underserved communities and 10 years later, over 70 percent of them are still working with people who are in most need and who have the poorest access to decent health care.

The Charles Drew University has established a national reputation for translational research that addresses the health disparities and social issues that strike hardest and deepest among urban and minority populations. As you can see, we are a unique institution, and we serve a very important constituency, which regrettably, represents a growing segment of the overall U.S. population.

Currently, The Charles Drew University is experiencing a period of positive, dynamic growth. Though our former affiliate hospital, Martin Luther King-Harbor, is experiencing difficulties, our institution is transforming and continues to make an expanding contribution to the health work force, by graduating the highest caliber

of health professionals—particularly, significant number of Latinos and African Americans, who are highly sought after for employment and further training positions. Many serve in our community where recent circumstances and public health budget cuts have reduced the number of beds and physicians back to the low level that existed in 1965, when the voiceless community of South Los Angeles was forced to rebel in order to get the health and social resources it deserves.

Our university continues to flourish and garner respect and support from our colleagues, community partners and those we serve. After 30 years, in partnership with the University of California, we are establishing our own 4-year medical school and a new School of Nursing to prepare nurses as well as nursing faculty—particularly from minority populations. The Charles Drew University remains a beacon of hope for our students and our community as we have been since we began when we rose out of the ashes of the 1965 Watts civil unrest.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Title VII Health Professions Training Programs

The health professions training programs administered by the Health Resources and Services Administration (HRSA) are the only Federal initiatives designed to address the longstanding under representation of minorities in health careers. HRSA's own report, "The Rationale for Diversity in the Health Professions: A Review of the Evidence," found that minority health professionals disproportionately serve minority and other medically underserved populations, minority populations tend to receive better care from practitioners of their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health professions institutions, they are significantly more likely to: (1) serve in medically underserved areas, (2) provide care for minorities, and (3) treat low-income patients.

HRSA's Minority Centers of Excellence (COE) and Health Careers Opportunity Program (HCOP) support health professions institutions with a historic mission and commitment to increasing the number of minorities in the health professions.

Mr. Chairman, in fiscal year 2006 these programs were cut by over 50 percent. Unfortunately, those cuts were sustained in the funding resolution passed earlier in this Congress. Looking ahead a decade, as you have encouraged your colleagues and us to do, the cuts of recent years to these programs will seriously hamper our ability to provide the desperately needed healthcare advances for our citizens. Those cuts will widen the health disparities gap that is already far too wide, and they will exacerbate the already present national physician shortage, particularly in urban areas.

Minority Centers of Excellence

The purpose of the Minority Centers of Excellence (COE) program is to assist schools, like Charles Drew University, that train minority health professionals, by supporting programs of excellence. The COE program focuses on improving student recruitment and performance; improving curricula and cultural competence of graduates; facilitating faculty and student research on minority health issues; and training students to provide health services to minority individuals by providing clinical teaching at community-based health facilities. For fiscal year 2008, the funding level for Minority Centers of Excellence should be $33.6 million (an increase of $21.8 million over fiscal year 2007).

Health Careers Opportunity Program

Grants made to health professions schools and educational entities under Health Careers Opportunity Program (HCOP) enhance the ability of individuals from disadvantaged backgrounds to improve their competitiveness to enter and graduate from health professions schools. HCOP funds activities that are designed to develop a more competitive applicant pool through partnerships with institutions of higher education, school districts, and other community based entities. HCOP also provides for mentoring, counseling, primary care exposure activities, and information regarding careers in a primary care discipline. Sources of financial aid are provided to students as well as assistance in entering into health professions schools. For fiscal year 2008, the HCOP funding level of $35.6 million is suggested (an increase of $31.6 million).

NATIONAL INSTITUTES OF HEALTH'S CONTRIBUTION TO FIGHTING HEALTH DISPARITIES

Racial and ethnic disparities in health outcomes for a multitude of major diseases in minority and underserved communities continue to plague a Nation that was built on the premise of equality. As articulated in the Institute of Medicine report entitled "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care," this problem is not getting better on its own. For example, African American males develop cancer 15 percent more frequently than their white counterparts. While African American women are not as likely as white women to develop breast cancer, they are much more likely to die from breast cancer once it is detected. In fact, according to the American Cancer Society, those who are poor, lack health insurance, or otherwise have inadequate access to high-quality cancer care, typically experience high cancer incidence and mortality rates. Similarly to African American populations, Latino communities uffer much higher incidences of heart disease, diabetes, obesity and some cancers than white populations. These devastating statistics beg for more research dollars and better access to quality clinical resources to address the deep-seated problems.

In response to these and similar findings in our own community and across the Nation, The Charles Drew University has been working to build a new Life Sciences Research Facility on its campus. The Center will specialize in providing not only cutting-edge research but associated medical treatments for the community that focus on prevention and the development of new strategies in the fight against cancer. These strategies will be disseminated locally and nationally to communities at risk, as well as to others engaged in comprehensive cancer prevention programs everywhere.

Mr. Chairman, as I mentioned earlier, the support that the subcommittee has given to the National Institutes of Health (NIH) and its various institutes and centers has been and continues to be critical to the effectiveness of our university and our community. The dream of a state-of-the-art research facility to aid in the fight against cancer and other diseases in our underserved community would be infeasible in our disadvantaged location without the resources of NIH.

To help establish the Life Sciences Research Building and expand our innovative translational research activities that focus on improving the health of underserved communities, The Charles Drew University is requesting increased congressional support for the National Center for Research Resources (NCRR), the National Center for Minority Health and Health Disparities (NCMHD), the National Cancer Institute (NCI), Health Resources and Services Administration (HRSA) and the Department of Health and Human Services' Office of Minority Health.

National Center for Minority Health and Health Disparities

The National Center on Minority Health and Health Disparities (NCMHD) is charged with addressing the longstanding health status gap between under-represented minority and non minority populations. The NCMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, telemedicine technology and other learning resources. The NCMHD also supports biomedical research focused on eliminating health disparities and developed a comprehensive plan for research on minority health at NIH. Furthermore, the NCMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the COE program and HCOP.

For fiscal year 2008, $250 million is recommended for NCMHD to support these critical activities.

Research Centers At Minority Institutions

The Research Centers at Minority Institutions program (RCMI) at the National Center for Research Resources (NCRR) has a long and distinguished record of helping institutions like The Charles Drew University develop the research infrastructure necessary to be leaders in the area of translational research focused on reducing health disparities research. Although NIH has received some budget increases over the last 5 years, funding for the RCMI program has not increased by the same rate. The new Clinical and Translational Research Applications (CTSA) essentially preclude smaller institutions such as RCMI and IDeA schools to compete and link to the CTSA roadmap. We request an additional $40 million to support a CTSA-like roadmap mechanism for RCMI and IDeA schools, and $9.5 million to support the RCMI Translational Research Network, and alsosmall grant mechanisms to fund pilot studies linked to the NIH Roadmap, the newly developed Global Alliance for HIV/AIDS, and community centers of health research and education excellence. This is a total of an additional $49.5 million in fiscal year 2008.

Extramural Facilities Construction

Mr. Chairman, one issue that sets The Charles Drew University and many minority-dedicated institutions apart from the major universities of this country is the facilities where research takes place. The need for research infrastructure at our Nation's minority serving institutions must also remain strong to maximize efforts to reduce health disparities. The current authorization level for the Extramural Facility Construction program at the National Center for Research Resources (NCRR) is $250 million. The law also includes a 25 percent set-aside for "Institutions of Emerging Excellence" (many of which are minority institutions) for funding up to $50 million. Also, the law allows the NCRR director to waive the matching requirement for institutions participating in the program. We strongly support all of these provisions of the authorizing legislation in order to ensure the continued growth of relevant research from our minority health professions training schools.

Unfortunately, funding for NCRR's Extramural Facility Construction program was completely eliminated in the fiscal year 2006 Labor-HHS bill, and funding was not restored in the fiscal year 2007 funding resolution. In fiscal year 2008, we respectfully request the restoration of funding for this program to the fiscal year 2004 level of $119 million.

DEPARTMENT OF HEALTH AND HUMAN SERVICES' OFFICE OF MINORITY HEALTH

Specific programs at OMH include:

Assisting medically underserved communities,

Supporting conferences for high school and undergraduate students to interest them in health careers, and

Supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

OMH has the potential to play a critical role in addressing health disparities. Unfortunately, OMH does not yet have the authority or resources necessary to support activities that will truly make a difference in closing the health gap between minority and majority populations.

One recent OMH pilot project is the Health Professions Leadership Development and Support Program, which is designed to enhance faculty recruitment and retention support for academicians providing for the supervision, instruction, and guidance of resident physicians-in-training in underserved communities. This is a critical program for improving the minority pipeline filling a gap outlined in the report by a committee chaired by former Secretary of the Department of Health and Human Services (HHS),

Dr. Louis Sullivan titled "Missing Persons: Minorities in the Health Professions September 20, 2004." This report highlights the critical role played by institutions such as The Charles Drew University as a major training site for minority health care professions and biomedical scientists.

For fiscal year 2008, I recommend a funding level of $65 million for OMH to support these critical activities.

STRENGTHENING HISTORICALLY BLACK GRADUATE INSTITUTIONS—DEPARTMENT OF EDUCATION

The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, section 326) is extremely important to MMC and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2008, an appropriation of $65 million (an increase of $7 million over fiscal year 2007) is suggested to continue the vital support that this program provides to historically black graduate institutions.

CONCLUSION

Despite all the knowledge that exists about racial/ethnic, socio-cultural and gender-based disparities in health outcomes, the gap continues to widen. Not only are minority and underserved communities burdened by higher disease rates, they are less likely to have access to quality care upon diagnosis. As you are aware, in many minority and underserved communities preventative care and research are inaccessible either due to distance or lack of facilities and expertise. As noted earlier, in just one underserved area, South Los Angeles, the number and distribution of beds, doctors, nurses and other health professionals are as parlous as they were at the time of the Watts Rebellion, after which the McCone Commission attributed the so-named "Los Angeles Riots" to poor services—particularly access to affordable, qual-

ity healthcare. The Charles Drew University has proven that it can produce excellent health professionals who "get" the mission—years after graduation they remain committed to serving people in the most need. But, the university needs investment and committed increased support from Federal, State, and local governments and is actively seeking foundation, philanthropic and corporate support.

Even though institutions like The Charles Drew University are ideally situated (by location, population, community linkages and mission) to study conditions in which health disparities have been well documented, research is limited by the paucity of appropriate research facilities. With your help, the Life Sciences Research Facility will translate insight gained through research into greater understanding of disparities and improved clinical outcomes. Additionally, programs like Title VII Health Professions Training programs will help strengthen and staff facilities like our Life Sciences Research Facility.

We look forward to working with you to lessen the huge negative impact of health disparities on our Nation's increasingly diverse populations, the economy and the whole American community.

Mr. Chairman, thank you again for the opportunity to present testimony on behalf of The Charles Drew University. It is indeed an honor.

PREPARED STATEMENT OF THE COALITION FOR THE ADVANCEMENT OF HEALTH THROUGH BEHAVIORAL AND SOCIAL SCIENCE RESEARCH

Mr. Chairman and members of the subcommittee, the Coalition for the Advancement of Health Through Behavioral and Social Science Research (CAHT–BSSR) appreciates and welcomes the opportunity to comment on the fiscal year 2008 appropriations for the National Institutes of Health (NIH). CAHT–BSSR includes 16 professional organizations, scientific societies, coalitions, and research institutions concerned with the promotion of and funding for research in the social and behavioral sciences. Collectively, we represent more than 120 professional associations, scientific societies, universities, and research institutions.

The behavioral and social sciences regularly make important contributions to the well-being of this Nation. Due in large part to the behavioral and social science research sponsored by the NIH, we are now aware of the enormous contribution behavior makes to our health. At a time when genetic control over diseases is tantalizingly close but not yet possible, knowledge of the behavioral influences on health is a crucial component in the Nation's battles against the leading causes of morbidity and mortality: obesity, heart disease, cancer, AIDS, diabetes, age-related illnesses, accidents, substance abuse, and mental illness. As a result of the strong congressional commitment to the NIH in years past, our knowledge of the social and behavioral factors surrounding chronic disease health outcomes is steadily increasing. The NIH's behavioral and social science portfolio has emphasized the development of effective and sustainable interventions and prevention programs targeting those very illnesses that are the greatest threats to our health, but the work is just beginning.

To ensure that progress is sustained, the Coalition joins the Ad Hoc Group for Medical Research in supporting a fiscal year 2008 appropriation of $30.8 billion for the NIH, a 6.7 percent increase over fiscal year 2007. This level of funding will provide adequate resources to sustain the momentum of the recently completed campaign to double the Nation's investment in the promising research supported and conducted by the NIH. Unfortunately, the President's request does not allow us to fully reap the research opportunities that the doubling campaign have made available.

Nearly 125 million Americans are living with one or more chronic conditions, like heart disease, cancer, diabetes, kidney disease, arthritis, asthma, mental illness and Alzheimer's disease. The Centers for Medicare and Medicaid Services (CMS) recently reported that health care spending in the United States rose to $1.6 trillion in 2002, up from $1.4 trillion in 2001 and $1.3 trillion in 2000. Health expenditures per person averaged $5,440 in 2002, up from $5,021 in 2001 and $4,670 in 2000. Today, it is even more. Significant factors driving this increase are the aging of the U.S. population, and the rapid rise in chronic diseases, many caused or exacerbated by behavioral factors: for example, obesity, caused by sedentary behavior and poor diet; addictions and resulting health problems caused by tobacco and other drug use.

Behavioral and social sciences research supported by NIH is increasing our knowledge about the factors that underlie positive and harmful behaviors, and the context in which those behaviors occur. NIH supports behavioral and social science research throughout most of its 27 institutes and centers. Numerous reports by the National Academy of Sciences (e.g. The Aging Mind, New Horizons in Health: An Integrative

Approach, and Health and Behavior) have presented cutting edge research agendas and made eloquent cases for the applicability of the social and behavioral scientific disciplines to the myriad, complex problems of prevention, treatment and cure of diseases as well as the enhancement of quality of life.

CAHT–BSSR supports an appropriation of $27.8 million for NIH Office of Behavioral and Social Sciences Research, an increase of 6.7 percent, commensurate with an overall increase of 6.7 percent for the NIH. OBSSR's purpose is to serve a convening and coordinating role among the institutes and centers at NIH. The Office was authorized by Congress in the NIH Revitalization Act of 1993 and established in 1995.

As highlighted by NIH Director Elias Zerhouni on the occasion of OBSSR's 10th anniversary in June 2006, "the OBSSR has been a tremendous asset to NIH throughout its first 10 years . . . we are faced with an enormous and evolving national burden of disease and disability, much of which has roots in personal behavior or socioeconomic influences. The need for behavioral and social research and intervention has never been greater, and its impact has never been clearer. We need but look at recent decreases in rates of cancer, largely due to dramatic decreases in tobacco use. We can point to a remarkable demonstration of the pronounced benefits of diet and exercise—more effective than drug therapy—in preventing the onset of type 2 diabetes among high-risk individuals. These are but two among many shining examples of the widespread benefits to public health realized through our investment in basic and applied behavioral and social science research, so critical to our understanding of health and disease.

OBSSR focuses on cross-cutting behavioral and social research issues (e.g. "Long-term Maintenance of Behavior Change") using its modest budget to seed cross-institute research initiatives. OBSSR has spurred cutting edge research in areas such as measures of community health, socioeconomic status, and new methodology development. The Office has been able to leverage substantive funding initiatives with a small budget.

In fiscal year 2008, OBSSR plans to work with the 27 NIH Institutes and Centers (ICs) to initiate two new programs. The first program is in the area of health disparities. The Behavioral and Social Science Contributions to Understanding and Reducing Health Disparities will be designed to support trans-disciplinary research involving teams of behavioral, social, and biomedical scientists, on prevention, policy, and health care. The research program will emphasize both basic research on the behavioral, social, and biomedical pathways, giving rise to disparities in health and applied research on the development, testing, and delivery of interventions to reduce disparities in the areas of policy, prevention, and health care.

The second initiative planned by OBSSR is in the area of Genes, Behavior and the Social Environment. OBSSR plans to work across the institutes and centers to consider the recommendations from the Institute of Medicine's report, Genes, Behavior, and the Social Environment, Moving Beyond the Nature/Nurture Debate, commissioned by OBSSR, along with the National Institute of General Medical Sciences (NIGMS) and the National Human Genome Research Institute (NHGRI). The report identifies gaps in knowledge and barriers that hamper the integration of social, behavioral, and genetic research.

The IOM panel recognized "that understanding the association between health and interactions among social, behavioral, and genetic factors require research that embraces the systems view and includes an examination of the interactive pathways through which these fields operate to affect health." Such research requires the participation of scientific investigators from a variety of fields and a shift in focus from efforts that are dominated by single disciplines to research that involves collaborative participation of scientists from various expertise at all stages of the research process. Below are the IOM's 14 recommendations.

1. *Conduct Trans-disciplinary, Collaborative Research*.—The NIH should develop Requests for Applications (RFAs) to study the impact on health of interactions among social, behavioral, and genetic factors and their interactive pathways (i.e., physiological).

2. *Measure Key Variables Over the Life Course and Within the Context of Culture*.—NIH should develop RFAs for studies of interactions that incorporate measurement, over the life course and within the context of culture, of key variables in the important domains of social, behavioral, and genetic factors.

3. *Develop and Implement New Modeling Strategies to Build More Comprehensive, Predictive Models of Etiologically Heterogeneous Disease*.—NIH should emphasize research aimed at developing and implementing such models (e.g., pattern recognition, multivariate statistics, and systems-oriented approaches) for incorporating social, behavioral, and genetic factors, and their interactive pathways in testable models within populations, clinical settings, or animal studies.

4. *Investigate Biological Signatures*.—Researchers should use genomic, transcriptomic, proteomic, metabonomic, and other high dimensional molecular approaches to discover new constellations of genetic factors, biomarkers, and mediating systems through which interactions with social environment and behavior influence health.

5. *Conduct Research in Diverse Groups and Settings*.—NIH should encourage research on the impact of interactions among social, behavioral, and genetic factors and their interactive pathways on health that emphasizes diversity in groups and settings. NIH should also support efforts to ensure that the findings of such research is validated by replication in independent studies, translated to patient-oriented research, conducted and applied in the context of public health, and used to design preventive and therapeutic approaches.

6. *Use Animal Models to Study Gene-Social Environment Interaction*.—NIH should develop RFAs that use carefully selected animal models for research on the impact on the impact of interactions among social, behavioral, and genetic factors and their interactive pathways.

7. *Advance the Science of Study of Interactions*.—Researchers should base testing for interaction on a conceptual framework rather than simply the testing of a statistical model, and they must specify the scale (e.g., additive or multiplicative) used to evaluate whether or not interactions are present. NIH should develop RFAs for research on developing study designs that are efficient at testing interactions, including variation in interactions over time and development.

8. *Expand and Enhance Training for Trans-disciplinary Researchers*.—NIH should use existing and modified training tools both to reach the next generation of researchers and to enhance the training of current researchers. Approaches include individual fellowships and senior fellowships, trans-disciplinary institutional grants, and short courses.

9. *Enhance Existing and Develop New Datasets*.—NIH should support datasets that can be used by investigators to address complex levels of social, behavioral, and genetic variables and their interactive pathways. This should include enhancement of existing datasets that already provide many, but not all of the needed measures and the encouragement of their use. NIH should also develop new datasets that address specific topics that have high potential for showing genetic contribution, social variability, and behavioral contributions—topics such as obesity, diabetes, and smoking.

10. *Create Incentives to Foster Trans-disciplinary Research*.—NIH and universities should explore ways to create incentives for the kinds of team science needed to support trans-disciplinary research.

11. *Communicate with Policymakers and the Public*.—Researchers should (1) be mindful of public and policymakers' concerns; (2) develop mechanisms to involve and inform these constituencies; (3) avoid overstating their scientific findings; and (4) give careful consideration to the appropriate level of community involvement and the level of community oversight needed for such studies.

12. *Expand the Research Focus*.—NIH should develop RFAs for research that elucidates how best to encourage people to engage in health—promoting behaviors that are informed by a greater understanding of these interactions; how best to effectively communicate research results to the public and other stakeholders; and how best to inform research participants about the nature of the investigation (gene-environment interactions) and the uses of data following the study.

13. *Establish Data-Sharing Policies That Ensure Privacy*.—Institutional Review Boards and investigators should establish policies regarding the collection, sharing, and use of data that include information about: (1) whether and to what extent data will be shared; (2) the level of security to be provided by all members of the research team as well as the research and administrative process; (3) the use of state-of-the-art security data in ways that are consistent with those agreed to by the research participants.

14. *Improve Informed Consent Process*.—Researchers should ensure that informed consent includes the following: (1) descriptions of the individual and social risks and benefits of the research; (2) the identification of which individual results participants will and will not receive; (3) the definition of the procedural protections that will be provided, including access policies and scientific oversight; and (4) specific security, privacy, and confidentiality protections to protect the data and samples of research participants.

Implementing the IOM's recommendations would go a long ways towards helping to realize the ultimate goal of personalized health care, one of Secretary Michael Leavitt's priorities. Personalization needs to reflect genes, behaviors, and environments. Assessing behavior is critical to helping individuals see how they can improve their health. It is also critical to helping health care see where it needs to

put resources for behavior change. As noted by Dr. Zerhouni, "Right now, everyone is focused on finding the magic answer. But health care is different from region to region across the country." Full personalization needs to consider the environmental, community, and neighborhood circumstances that govern how individuals' genes and behavior will influence their health. For personalized health to be realized, we need a sophisticated understanding of the interplay between genetics and the environment, broadly defined.

CAHT–BSSR would be pleased to provide any additional information on these issues. We have attached a list of coalition member societies to the end of the testimony. We thank the subcommittee for its generous support of the National Institutes of Health and for the opportunity to present our views.

CAHT–BSSR MEMBERS

American Educational Research Association; American Psychological Association; American Sociological Association; Association of Population Centers; Center for the Advancement of Health; Consortium of Social Science Associations; Gerontological Society of America; Institute for the Advancement of Social Work Research; National Association of Social Workers; National Council on Family Relations; National Mental Health Association; Population Association of America; Sex Information and Education Council of the United States; Society for Public Health Information; Society for Research in Child Development; and The Alan Guttmacher Institute.

PREPARED STATEMENT OF THE COALITION FOR AMERICAN TRAUMA CARE

The Coalition for American Trauma Care is pleased to provide its recommendations for fiscal year 2008 appropriations for public health programs that support trauma care, trauma care research, and injury prevention.

The Coalition for American Trauma Care is a nonprofit association of national health and professional organizations that seeks to improve care for the seriously injured patient through improved delivery of trauma care services, research and rehabilitation activities. The Coalition also supports efforts to prevent injury from occurring.

Injury is one of the most important public health problems facing the United States today. It is the leading cause of death for Americans from age 1 through age 34. More than 145,000 people die each year from injury, 88,000 from unintentional injury such as car crashes, fires, and falls, and 56,000 from violence-related causes. Over 85 children and young adults die from injuries in the United States every day translating into 30,000 deaths annually. Injury is also the most frequent cause of disability. Millions of Americans are non-fatally injured each year leaving many temporarily disabled and some permanently disabled with severe head, spinal cord, and extremity injuries. Because injury so often strikes the young, injury is also the leading cause of years of lost work productivity and, at an estimated $224 billion in lifetime costs each year, trauma is our Nation's most costly disease.

Trauma Care Systems.—The Coalition is extremely disappointed that Congress failed to appropriate any funding for the Health Resources and Services administration's Trauma-EMS program in fiscal year 2007 and urges the subcommittee to provide $12 million in funding for fiscal year 2008. Congress is in the process of reauthorizing the program (H.R. 727; S. 657) at a level of $12 million for fiscal year 2008. In recent days both the House Energy and Commerce Committee and the Senate Health, Education, Labor and Pensions Committees approved their respective bills unanimously. The Trauma-EMS program, administered by HRSA for 5 years, from fiscal year 2001–2005, provided critical national leadership which leveraged additional scarce State dollars to strengthen trauma systems so that seriously injured individuals, wherever they live, receive prompt emergency transport to the nearest appropriate trauma center within the "golden hour." Receiving appropriate, quality trauma care within 1 hour of injury saves lives and provides the best chance for a good recovery. Achieving this result takes coordination, commitment of staff, development and implementation of standards of care, a process for designating trauma centers, and evaluation.

No other program in the Federal Government addresses this critical aspect of the Nation's emergency response infrastructure. According to the Trauma-EMS Systems Program Assessment Rating Tool (PART) released by the OMB, "the Trauma Care program has demonstrated success in assisting States in adopting statewide standardized triage protocols and designating trauma centers. Studies indicate with some consistency that improving organized systems of trauma care, specifically States designating trauma centers and adopting standardized triage protocols, leads to measurable decreases in mortality due to trauma."

Despite this progress, only 8 States have fully developed trauma systems; 12 States do not even have the authority to designate trauma centers. In a recent Harris Poll, large majorities of the American public said they valued trauma centers and systems as highly as having a police or fire department in their community. We therefore request that you reinstate funding for this vital, life saving program.

National Center for Injury Prevention and Control.—The Coalition supports $168 million in funding in fiscal year 2008 for the National Center for Injury Prevention and Control which is currently funded at $138 million. The Coalition is exceedingly pleased with the support CDC has provided for the National Evaluation of the Effect of Trauma Center Care on Mortality. The results of this study, published in the January 26, 2006 New England Journal of Medicine, were that care at a trauma center lowers by 25 percent the risk of death for injured patients compared to treatment received at non-trauma centers. The NCIPC supports a range of injury prevention activities and through evaluation has proven their effectiveness in many areas. Just two examples of these: reduction of the more than 20,000 head injuries that occur every year by encouraging the use of bicycle helmets and reduction of burn-related injuries through smoke detector implementation programs.

Traumatic Brain Injury (TBI).—Traumatic brain injury is a leading cause of trauma-related disability. Brain injury is a silent epidemic that compounds every year, but about which still little is known. The Coalition is opposed to the proposed elimination of this important program in the President's fiscal year 2008 budget request and urges you to provide a total of $30 million for the Traumatic Brain Injury (TBI) Act, as follows: $9 million for CDC to strengthen State and local data collection activities, improve linkage of persons with TBI to services, increase public education and awareness, and conduct public health research related to TBI. Within the $30 million, the Coalition also supports $15 million for the HRSA TBI State Grant Program to ensure that every State, territory and American Indian Consortia can coordinate and maximize resources to serve their TBI population and provide training and technical assistance to grantees. Also within the $30 million total, $6 million is needed for the HRSA Protection and Advocacy Program for population-based allotments to all States to ensure adequate and appropriate assistance to individuals with brain injury in exercisng their rights and accessing public service systems.

Children's EMS.—The Coalition is opposed to the proposed elimination of this program in the President's fiscal year 2008 budget request and urges you to provide $25 million in fiscal year 2008. While this amount represents a 25 percent increase for this program, it has been flat-funded for 6 years causing an erosion in available resources due to inflation. Children currently account for up to 30 percent of all emergency department visits and 10 percent of ambulance runs annually, but many facilities lack the specialized equipment needed to care for them. Moreover, many emergency personnel do not have the necessary education or training to provide optimal care to children. In order to assist local communities in providing the best emergency care to children the Children's EMS program needs to continue and continue at a level that allows resources to keep pace with inflation.

Preventive Health/Health Services Block Grant (PHHS).—The Coalition is deeply disappointed that Congress cut funding in fiscal year 2006 for this program by $32 million, or 24 percent, and that the President has proposed to eliminate funding in fiscal year 2008. The Coalition urges you to restore funding to the fiscal year 2005 of $131 million when the subcommittee marks up its fiscal year 2008 bill. The PHHS Block Grant provides flexible funding to States to allow them to address specific health problems identified under the Healthy People 2010 assessment process. The funding allows States to take innovative approaches to address significant health issues and complements, not duplicates, some of CDC's other program activities. In addition, the PHHS Block Grant is the largest single source of Federal funding for support of basic State Emergency Medical Services' (EMS) infrastructure—the first line of defense against death and disability resulting from severe injury.

Rural EMS Training and Equipment Program.—The Coalition urges you to provide $900,000 in funding for the Rural EMS Training and Equipment Program. This program was eliminated in fiscal year 2006 and needs not only restoration, but expansion in fiscal year 2008. Rural areas are in critical need of emergency medical services training and equipment. Recent national events have continued to draw attention to the need for communities to have strong emergency medical systems in place. Unfortunately, while the need for effective emergency medical care may have increased, the number of individuals able to provide these services has declined. This is a particular problem in rural areas where the majority of EMS personnel are unpaid volunteers. As rural economies continue to suffer, it has become progressively more difficult for rural EMS providers to recruit and retain these personnel. As a consequence, emergency medical squads are becoming smaller. The rural EMS training and equipment program awards competitive grants to State EMS Offices,

State Offices of Rural Health, local government, and State or local ambulance providers to improve emergency medical services in rural areas.

The funds can be used to:

—Recruit emergency and volunteer medical service personnel;

—Train emergency medical service personnel in emergency response, injury prevention, safety awareness, and other topics relevant to the delivery of emergency medical services;

—Fund specific training to meet Federal or State certification requirements;

—Develop new ways to educate emergency health care providers through the use of technology enhance educational methods (such as distance learning);

—Acquire emergency medical services equipment including cardiac defibrillators;

—Acquire personal protective equipment for emergency medical services personnel; and

—Educate the public concerning cardiopulmonary resuscitation, first aid, injury prevention, safety awareness, illness prevention, and other related emergency preparedness topics.

The Coalition for American Trauma Care is both deeply disappointed and alarmed by the President's fiscal year 2008 budget which proposes elimination of all funding for four programs specifically designed to build infrastructure to ensure that trauma and emergency medical services are available and appropriate to need: HRSA's Trauma-EMS systems program; HRSA's Traumatic Brain Injury program; HRSA's Children's EMS program and CDC's Preventive Health and Health Services Block Grant. If these cuts are enacted, the results would be devastating for emergency care in the United States for everyone and particularly for children and those who have suffered head injury. The burden of injury in America has been well documented by numerous IOM reports and injury facts speak for themselves: injury is the leading cause of death and disability for children and adults up to age 44. While much more can and needs to be done to prevent injury from occurring at all, we will never be able to eliminate it entirely. Cutting these programs will not lessen the injury burden in America; on the contrary, it will significantly increase the burden of death, disability and direct and indirect health care costs. We need to increase our investment in these program areas, not reduce our commitment.

The Coalition greatly appreciates the support the subcommittee has provided to trauma related programs in the past and looks forward to working with the subcommittee in the coming weeks and months.

PREPARED STATEMENT OF THE COALITION OF EPSCOR/IDEA STATES

Thank you for the opportunity to submit this testimony in support of fiscal year 2008 funding for the National Institutes of Health's Institutional Development Award or "IDeA" Program. The IDeA program is funded by NIH's National Center for Research Resources (NCRR), and was authorized by the 1993 NIH Revitalization Act (Public Law 103–43).

My name is Dr. Peter Alfonso and I am the Vice Provost for Research, Graduate Studies and Outreach and Dean of the Graduate School at the University of Rhode Island. I submit this testimony on behalf of the Coalition of EPSCoR/IDeA States.[1] EPSCoR is the "Experimental Program to Stimulate Competitive Research," and IDeA, as previously stated, is the NIH's Institutional Development Award program.

IDeA is an important program because it increases our Nation's biomedical research capability by improving research in States that have historically been less successful in obtaining biomedical research funds. Twenty-three States and Puerto Rico are eligible.

IDeA funds only merit-based, peer-reviewed research that meets NIH research objectives.

As previously mentioned, IDeA was authorized by the 1993 NIH Revitalization Act (Public Law 103–43), but the program was funded at very low levels during its early years. However, between fiscal year 2000 and fiscal year 2003, IDeA grew rapidly, due in large part to the thoughtful actions of this subcommittee. This funding permitted the initiation of two new program elements:

The first was COBRE or "Centers of Biomedical Research Excellence;" which are research clusters targeting specific biomedical research problems. The COBRE pro-

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[1] Alabama, *Alaska, Arkansas, Delaware, Hawaii, Idaho, Kansas, Kentucky, Louisiana, Maine, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, Puerto Rico, Rhode Island, South Carolina, South Dakota, Vermont,* Virgin Islands, *West Virginia,* and *Wyoming*. (States in italic letters are eligible for the IDeA program. All of the States listed above are also eligible for the EPSCoR program.)

gram is designed to increase the pool of well-trained investigators in the IDeA States by expanding research facilities, equipping laboratories with the latest research equipment, providing mentoring for promising candidates, and developing research faculty through support of a multi-disciplinary center, led by an established, senior investigator with expertise in the research focus area of the center.

The second was BRIN or "Biomedical Research Infrastructure Networks;" which targeted key areas such as bioinformatics and genomics and facilitated the development of cooperative networks between research-intensive and primarily undergraduate colleges. The BRIN grants underwent competitive renewals in 2004 under the new name of IDeA Networks of Biomedical Research Excellence (INBRE). The INBRE program prepares students for graduate and professional schools as well as careers in the biomedical sciences, supports research and mentoring of young investigators, and enhances research infrastructure at participating institutions.

Although IDeA is relatively new, there is already objective evidence of its success. In fiscal year 1999, the year before COBRE grants were initiated, IDeA States received a total of $595 million from NIH. In fiscal year 2005, NIH funding for the IDeA States had increased to $1.556 billion, representing an increase of 162 percent in 6 years. It is important to note, however, that in the following year as the IDeA budget started to decrease, NIH funding for the IDeA States fell to $1.458 billion, the same level as in fiscal year 2003.

I would like to describe a few examples of how both COBRE and INBRE (formerly BRIN) grants have changed the biomedical research landscape of Rhode Island. The first COBRE award in Rhode Island was made to Brown University in 2000. Prior to this award the biomedical research infrastructure of the University was severely lacking and the interactions between researchers at Brown and at other institutions within the State were minimal at best.

The COBRE award allowed the PI to fund five promising junior investigators, all of whom won subsequent major NIH grants by the end of the award period. State-of-the-art core facilities in microscopy, genomics, and transgenics were established and staffed with Ph.D. level directors. Seminar series and workshops were initiated with COBRE funding, and served as the basis for developing collaborative ties with researchers throughout the State. COBRE funding also was directly translated into the establishment of a "Center for Genomics and Proteomics" at Brown that included the purchase and renovation of significant new research space in an old industrial section of the city. This area of the city has now been filled with new businesses and is prospering.

The 2000 COBRE award was renewed for another 5 years and the focus is now on signaling and cancer, with the long term goal of establishing a cancer center. Since the first COBRE award to Brown University in 2000, three other COBREs have been awarded to three separate institutions: Rhode Island Hospital, Roger Williams Hospital, and Women and Infants Hospital. In all three cases, the awarded funds have directly led to the establishment of critical Core Facilities that provide new faculty with valuable access to state-of-the-art instrumentation that they would not be able to acquire through standard grant award mechanisms For all of these reasons, COBRE is a critical mechanism of support for States with limited budgets for research support.

The 3-year BRIN grant, awarded to Rhode Island in 2001 and competitively renewed as INBRE for 5 years in 2004, provided another mechanism for addressing both the lack of critical mass of biomedical researchers at the University of Rhode Island and other primarily undergraduate institutions in the States, and the lack of high-end state-of-the-art equipment for biomedical research at these institutions. Lack of critical mass and the necessary infrastructure to support biomedical research meant that existing researchers were unable to perform cutting edge research and effectively compete for research dollars from Federal agencies such as the National Institutes of Health. Meager startup funds available for hiring new faculty hampered efforts to recruit quality research-oriented faculty. There were limited opportunities for student training in faculty laboratories, and finally, there was a lack of the type of interinstitutional cooperation needed to create a network of biomedical researchers.

Through funding received as a result of the BRIN/INBRE awards, more than $2 million in biomedical research equipment for genomics, proteomics and drug development studies has been purchased and housed in a renovated laboratory. This equipment is accessible to all researchers from the participating institutions: University of Rhode Island; Rhode Island College; Providence College; Roger Williams University; Salve Regina University; and Brown University Through BRIN/INBRE funding, the Center for Molecular Toxicology at the University of Rhode Island was established. The Center has allowed us to leverage the creation of new faculty positions at all participating institutions in the related thematic areas of toxicology, cell

biology and environmental health, and helped provide competitive new faculty start-up packages. New faculty research, coupled with regularly scheduled seminars and workshops, is generating increased student interest in research and also greater training opportunities for students in faculty laboratories. Greater student training in turn translates into workforce development in the biomedical and biotechnological fields.

The Rhode Island BRIN/INBRE awards have led to the creation of an effective state-wide collaborative network of biomedical researchers, which is essential for implementing an environment that will foster collaborative research. Finally, and most importantly, this funding has helped biomedical researchers in our State to achieve greater success in competing for Federal research dollars. This is the ultimate goal of the IDeA program.

Despite these successes, our task is far from complete. Funding disparities between the States remain and may have a detrimental impact on our national self-interest. And that is why the IDeA program is so important. It is helping to ensure that all regions of the country participate in biomedical research. Citizens from all States should have the opportunity to benefit from the latest innovations in health care, which are most readily available in centers of biomedical research excellence.

For this reason, I am deeply concerned by the fiscal year 2008 Budget Request for the IDeA program. The fiscal year 2008 Budget Request for the IDeA program is $210,963,000, which is a $9,023,000 decrease from the fiscal year 2006 level of funding for the program. This is the second year in a row that the IDeA program has been cut in the President's Budget. The fiscal year 2007 budget request was the first time since 1993 that the budget request for IDeA was below the previous year's appropriated level for the program.

I applaud the efforts your subcommittee has made over the years to provide increased funding for IDeA, and hope that you will continue to invest in this program, which is so important to almost half of our States. The cut proposed in the fiscal year 2008 budget request will have a crippling effect on the biomedical research centers, researchers and students in IDeA States. The IDeA program is important to so many in our States, but especially to the junior investigators who are starting to become competitive for NIH funding. I think we send these young investigators the wrong message by cutting or even possibly eliminating funding for their research projects after encouraging them to pursue a career in biomedical research.

For this reason, the Coalition of EPSCoR/IDeA States believe the program should be funded at $250 million in fiscal year 2008. This level of funding would restore and continue funding for COBRE and INBRE, provide funding for information technoIogy (IT) infrastructure upgrades through IDeANet, and also, some funding would be used for a co-funding program, which would allow researchers and institutions to merge with the overall national biomedical research community.

By any reasonable standard, an already proven "IDeA" for increasing biomedical research capacity in a cohort of States which comprise one-sixth of our population and yet still receive barely one-twentieth of the NIH budget, deserves increased support. I am sensitive to the tough budget environment that NIH has faced over the past 4 years. Yet, when I consider that in 2005, the top 7 States that were recipients of NIH funding received over a $1 billion each, California alone received over $3 billion, $250 million for 23 States and Puerto Rico seems more than reasonable. Every region of the country has talent and expertise to contribute to our Nation's biomedical research efforts—and every region of the country must participate if we are to increase our Nation's biomedical research capacity substantially. On behalf of the Coalition of EPSCoR/IDeA States, I thank the subcommittee for the opportunity to submit this testimony.

PREPARED STATEMENT OF THE COALITION FOR HEALTH FUNDING

The Coalition for Health Funding is pleased to provide the subcommittee with its testimony recommending fiscal year 2008 funding levels for the agencies and programs of the U.S. Public Health Service. Since 1970, the Coalition's member organizations, representing 40 million health care professionals, researchers, patients and families, have been advocating for sufficient resources for PHS agencies and programs to meet the changing health challenges confronting the American people. One of the important principles that unites the Coalition's members is that the health needs of the Nation's population must be addressed by strong, sustained support for a continuum of activities that includes biomedical, behavioral and health services research; community-based disease prevention and health promotion; health care services for vulnerable and medically underserved populations; ensuring a safe and

effective food and drug supply; and education of a health professions workforce in adequate numbers to address the breadth of need.

The Coalition for Health Funding believes the Bush administration, and Congress, have undermined progress that has been made and also missed an important opportunity to improve the health of all Americans by reducing rather than investing more resources in the agencies and programs of the U.S. Public Health Service. Federal spending for public health has always been low compared to other health spending, amounting to 3 percent of total health care spending according to the Centers for Medicare and Medicaid, and yet an investment in public health has the potential to slow unsustainable growth in mandatory costs, reduce lost productivity at work, school and home, and strengthen every citizen's contribution for a healthy, economically strong America.

Instead of investing in these proven approaches, in recent years we have seen serious erosion of resources. Last year, through the strong efforts of a few House and Senate Members of Congress working with the advocacy community, the bleeding was staunched somewhat through the addition of $7 billion in funding for the agencies and programs under the jurisdiction of the Labor-HHS-Education Appropriations Subcommittees. However, as the table below shows, health agencies did not benefit across the board, with CDC, HRSA and SAMHSA funded in the final fiscal year 2007 Joint Resolution below fiscal year 2005 by a total of $837 million. In addition, all of the health agencies still face shortfalls when compared with fiscal year 2005 when inflation is accounted for. The President's fiscal year 2008 budget request cuts even more deeply—another $1.1 billion below fiscal year 2007 and a full $1.6 billion below fiscal year 2005.

The Coalition for Health Funding urges the subcommittee to reject the President's proposal to reduce the Nation's investment in public health and instead join over 400 health organizations that, in letter dated February 26, urged Congress to make an investment in public health of $4 billion over fiscal year 2007 levels. As that letter states:

"The investment in disease prevention and health promotion for all Americans needs to grow, as our Nation struggles with escalating health care costs, growing numbers of uninsured, and the prospect of declining health measured by overall morbidity and mortality. Over the past 4 years we have seen a decrease in that investment. The President's budget for fiscal year 2008 continues to seriously underfund and undermine an important part of the solution: public health activities and programs.

While the final fiscal year 2007 funding resolution provided needed increases to selected programs, most public health programs were held at fiscal year 2006 funding levels. The undersigned organizations urge you to increase funding for public health through the Function 550/discretionary budget allocation in fiscal year 2008 by an amount that will restore funding cuts to public health programs enacted in fiscal year 2006, and restore lost purchasing power. It is estimated that an additional $4 billion, 7.8 percent, will be needed in fiscal year 2008 to meet that goal and reverse the erosion of support for the continuum of biomedical, behavioral and health services research, community-based disease prevention and health promotion, basic and targeted services for the medically uninsured and those with disabilities, health professions education, and robust regulation of the Nation's food and drug supply."

The following is a partial list of the Coalition's fiscal year 2008 recommendations for specific U.S. Public Health Service agencies. The Coalition developed these recommendations working with eight other health coalitions with a more targeted focus on one agency.

NATIONAL INSTITUTES OF HEALTH (NIH)

The Coalition supports $30.869 billion in fiscal year 2008 for the National Institutes of Health, a 6.7 percent increase over the fiscal year 2007 funding level. This recommendation begins a 3 year process for restoring NIH's purchasing power following 4 years of flat funding at the end of the doubling in fiscal year 2003. The President's fiscal year 2008 budget request, by contrast, cuts NIH $310 million below fiscal year 2007. Enactment of the administration's proposal would mean about a 13 percent cut in inflation-adjusted dollars in the biomedical research capacity of our Nation. The result is NIH is funding fewer research projects, slowing our progress against disease and disability and discouraging talented young people from pursuing careers in medical research. Scientific discoveries are the result of a series of incremental steps that pave the way for future breakthroughs. This process needs sustained support.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The Coalition for Health Funding recommends a level of $7.7 billion for CDC's core programs in fiscal year 2008. This amount is $1.6 billion more than the fiscal year 2007 funding level and $1.8 billion more than the President's request for fiscal year 2008. This amount reflects CDC's professional judgment for core CDC programs that address prevention of chronic diseases, infectious diseases including adult and child immunization, and support for basic public health infrastructure. CDC is the Nation's primary investment in disease prevention and health promotion. Since fiscal year 2005, the agency's core programs have lost $500 million in funding. It is astounding this decline has been allowed to occur when the Nation faces the challenge of galloping obesity and its ensuing costly chronic disease; new and emerging infectious diseases like West Nile virus and those caused by antimicrobial resistant bacteria; vaccine-preventable diseases that occur every day; still growing numbers of Americans with HIV, with an estimated 250,000 who do not know they are infected; and a public health infrastructure that still needs shoring up after decades of neglect and that is facing massive loss of its trained workforce. One example that summarizes the shocking condition of core CDC programs is the National Center for Health Statistics (NCHS). Due to a shortfall of a mere $3 million in fiscal year 2007, NCHS does not have the funding it needs to collect vital birth and death statistics from States for the last 3 months of this calendar year. If this is not addressed, the United States will be the first industrialized Nation in the world unable to collect this information, and as Rep. Rosa DeLauro, a member of the House Labor-HHS–Education Subcommittee on Appropriations commented, ". . . [this will] compromise our ability not only to target our own public health interventions and evaluate our health standing on the international stage, but also monitor causes of death, including infectious diseases like influenza. As you know, death records are the first line of defense in our preparedness system, serving as the warning bell for a pandemic outbreak."

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

The Coalition for Health Funding recommends an overall funding level of $7.5 billion for HRSA in fiscal year 2008. This amount is $617 million, or 8.9 percent, more than the fiscal year 2007 funding level, and is $1.7 billion more than the President's request. This is the amount that the Coalition believes is needed to provide adequate resources for the important programs that HRSA administers.

The Coalition is extremely concerned about recent deep cuts in funding to HRSA, the Federal agency whose central stated mission is to achieve 100 percent access to health care services with zero disparities. This is simply not achievable with a cut of over 6 percent in fiscal year 2006 and a proposed additional cut of 8.5 percent in the President's fiscal year 2008 budget. Chief among the cuts enacted in fiscal year 2006, and proposed for complete elimination in the President's budget request, are the Title VII Health Professions education programs. In addition, the President's fiscal year 2008 budget cuts the Title VIII nursing education programs by $44 million, or nearly 30 percent. The Title VII and the Title VIII nursing education programs are the only Federal programs designed to train providers in multidisciplinary settings to meet the needs of special and underserved populations, as well as increase the minority representation in the health care workforce. Cuts imposed in fiscal year 2006 of 51.5 percent, including elimination of 7 Title VII programs, will only exacerbate racial and geographic disparities. Graduates of these programs are 3–10 times more likely to practice in underserved areas and are 2–5 times more likely to be minorities. The Coalition urges the subcommittee to restore funding levels for Title VII to the fiscal year 2005 level, and not only reject proposed cuts for Title VIII, but increase funding for this program addressing well-documented nursing shortages.

The Coalition also rejects the proposed 63 percent cut in Children's Hospitals Graduate Medical Education. Children's hospitals do not have access to Medicare funds to help train physicians that care for sick children.

The Coalition deplores the elimination of several other HRSA programs in fiscal year 2006 including the Trauma-EMS Systems program, which supports States in the development of systems to ensure severely injured individuals receive quality trauma care in a timeframe that ensures optimal outcomes, and the Healthy Community Access program and State planning grants designed to close gaps in access to health care for uninsured individuals. Proposed elimination in the President's fiscal year 2008 budget of the Children's EMS program, the Traumatic Brain Injury program, the Universal Newborn Screening program, the Rural and Community Access to Emergency Devices program to train lay rescuers and first responders to us Automated External Defibrillators, and a 90 percent cut for the Office of Rural

Health Policy diminish both targeted prevention activities and health care access. Further, a cut of $31 million in fiscal year 2006 to the Maternal and Child Health program, followed by a hard freeze in fiscal year 2007 and a proposed freeze in the President's fiscal year 2008 budget request, has reduced services across the Nation to the more than 26 million pregnant women, infants and special needs children served by the MCH Block Grant. MCH programs increase immunizations, newborn screening, reduce infant mortality and developmentally handicapping conditions, prevent childhood accidents and injuries, and reduce adolescent pregnancy.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

The Coalition for Health Funding recommends an overall funding level of $3.532 billion for SAMHSA in fiscal year 2008. This amount is $207 million, or 6.2 percent, more than the fiscal year 2007 funding level, and $364 million more than the President's budget request, which includes a $157 million cut for SAMHSA programs.

Despite the recent release of the Federal "Action Agenda" to ensure that people with mental illness have every opportunity for recovery, the President's fiscal year 2008 budget proposes to cut mental health services by $77 million, or 8.7 percent, following a cut in fiscal year 2006 of $17 million. This means that the charge from the President's New Freedom Commission on Mental Health for transforming the mental health system cannot occur if SAMHSA funding continually erodes. The need to make mental health a national priority is nowhere better illustrated than in the shocking rates of suicide and suicide attempts in the United States despite the Commission's finding that suicides are "a largely preventable public health problem." According to CDC, the suicide rate among U.S. residents younger than age 20 increased by 18 percent from 2003–2004, the only cause of death for teens that increased. Up to 35,000 children displaced by Hurricane Katrina in 2005 are having emotional, behavioral or school problems with a fourfold increase in those diagnosed with clinical depression or anxiety and a doubling of behavioral, or conduct problems after the hurricane. A proposed fiscal year 2008 mental health budget that is less than it was in fiscal year 2003 does not allow SAMHSA to meet existing needs, let alone respond to the consequences following a disaster.

The Coalition is disappointed that the President's fiscal year 2008 budget proposes cuts in funding for substance abuse programs by $84 million and recommends a $100 million increase for the Substance Abuse Treatment and Prevention Block Grant and a $15 million increase for discretionary treatment programs and a $17 million increase for discretionary prevention programs. Substance abuse is a significant and very costly national problem involving an estimated 21.6 million Americans—over 9 percent of the population—and needs investment in both treatment and prevention. Currently only 18 percent of all Americans over the age of 12 who need treatment receive it. Emerging trends also need specific attention: returning veterans with mental health and substance abuse problems that are not eligible for VA services, or will not use them due to stigma; and growing methamphetamine addiction. Clearly, a stronger investment for this problem, which is estimated to cost the Nation $346 billion, is needed.

The Coalition appreciates this opportunity to provide its fiscal year 2008 recommendations and looks forward to working with the subcommittee in the coming weeks and months.

PREPARED STATEMENT OF THE COALITION FOR INTERNATIONAL EDUCATION

Mr. Chairman and members of the subcommittee: We are pleased to have the opportunity to present the views of the Coalition for International Education on fiscal year 2008 funding for the Higher Education Act, Title VI and the Mutual Educational and Cultural Exchange Act, section 102(b)(6), commonly known as Fulbright-Hays. The Coalition for International Education is an ad hoc group of over 30 national higher education organizations with interest in the Department of Education's international and foreign language education programs. Together the Coalition represents the Nation's 3,300 colleges and universities, and organizations encompassing various academic disciplines, as well as the international exchange and foreign language communities. The urgency about United States shortfalls in international expertise against a backdrop of enormous global challenges is so strong within the higher education community that it draws our different perspectives into a single consensus position.

We express our deep appreciation for the subcommittee's long-time support for these programs. We believe that global challenges to our Nation and its leadership continue to underscore the importance of training specialists in foreign languages, cultures and international business who can offer their skills to the government, the

private sector, educational institutions and the media, and who can communicate across cultures on our behalf.

PROGRAM OVERVIEW AND FUNDING HISTORY

In 1958 at the height of the cold war, Congress created these programs out of a sense of crisis about United States ignorance of other countries and cultures. They have served as the lynchpin for producing international specialists for nearly five decades. Expanding over time to meet new global challenges, fourteen Title VI/Fulbright-Hays programs support activities to improve our educational capabilities, from K–12 through the graduate levels and advanced research, with emphasis on the less commonly-taught languages and areas of the world. Title VI largely supports the domestic side of training and research, while Fulbright-Hays supports the overseas component. The programs leverage a large amount of additional non-Federal resources and are relied upon by other Federal and non-Federal programs. Outside resources are essential incentives to develop and sustain these interdisciplinary programs, underwrite high cost programs in the less commonly-taught languages and areas, and provide extensive outreach and collaboration among educational institutions, government agencies, and corporations.

Developing the international expertise the Nation will need in the 21st Century requires educational reform and sustained financing. International expertise cannot be produced quickly. Just as the Federal Government maintains military reserves to be called upon when needed, it should invest steadily in an educational infrastructure that trains sufficient numbers and diversity of American students. Unfortunately, historical under-funding of Title VI and Fulbright-Hays combined with expanding needs and rising costs have contributed to the Nation's shortfall in specialists today. A March 2007 report by the National Research Council concludes: "Title VI/FH funding, including staff resources, has not kept pace with the expansion in the mission of the programs." Funding for key Title VI/Fulbright-Hays programs is more than 30 percent below the high point in fiscal year 1967. For example, only 1,561 or 33 percent fewer Foreign Language and Area Studies fellowships were awarded in fiscal year 2007 compared to 2,344 in fiscal year 1967. Four years of level funding combined with across-the-board cuts since fiscal year 2003 eroded by 10 percent in real terms the fiscal year 2002–2003 funding increases. Our statement today speaks to the urgent need to resume the infusion of new funds into Title VI/Fulbright-Hays, to ensure that this expertise is readily available when needed.

WHY INVESTING IN TITLE VI/FULBRIGHT-HAYS IS IMPORTANT

Our national security, stability and economic vitality depend, in part, on American experts who have sophisticated language skills and cultural knowledge about the various areas of the world.

Government Needs.—The quantity, level of expertise, and availability of U.S. personnel with high-level expertise in foreign languages, cultures, political, economic and social systems throughout the world do not match our national strategic needs at home or abroad.

—"All of our efforts in Iraq, military and civilian, are handicapped by Americans' lack of language and cultural understanding. Our embassy of 1,000 has 33 Arabic speakers, just six of whom are at the level of fluency. In a conflict that demands effective and efficient communication with Iraqis, we are often at a disadvantage. There are still far too few Arab language—proficient military and civilian officers in Iraq, to the detriment of the U.S. mission." *The Iraq Study Group: The Way Forward—A New Approach, December 2006.*

—"We have begun the process to imbed language and regional expertise as a core military skill. The need for language and regional expertise has long been a core requirement for Special Forces Command, but as the type of conflicts and wars in which we engage change, and irregular operations and counterinsurgency and stability operations increase, language and regional expertise and cultural awareness become key skills needed by every Soldier, Marine, Sailor, and Airman for this century's global and ever-changing mission." *David S.C. Chu, Under Secretary of Defense for Personnel and Readiness, before the Senate Armed Services Personnel Subcommittee, March 2006.*

—"It is a mark of how far the FBI still has to go to remake itself into a first-rate counter-terrorism force that 5 years after Sept. 11, 2001, it has only 33 special agents, with one more on the way, who speak Arabic. Most of them don't speak it very well. Only six have a rating of "advanced professional" in the language one twentieth of 1 percent of the bureau's 12,000 agents." *Washington Post Editorial, October 2006.*

Workforce Needs.—National security is increasingly linked to commerce, and U.S. business is widely engaged around the world with joint ventures, partnerships, and economic linkages that require its employees to have international expertise both at home and abroad.

—"Most of the growth potential for U.S. businesses lies in overseas markets. Already, one in five U.S. manufacturing jobs is tied to exports. In 2004, 58 percent of growth in the earnings of U.S. businesses came from overseas. Foreign consumers, the majority of whom primarily speak languages other than English, represent significant business opportunities for American producers, as the United States is home to less than 5 percent of the world's population." *Education for Global Leadership, Committee for Economic Development, 2006.*

—"A study on the internationalization of American business education found that knowledge of other cultures, cross-cultural communications skills, experience in international business, and fluency in a foreign language ranked among the top skills sought by corporations (especially small and mid-size) involved in global business. Despite new efforts to internationalize business education in the last decade, U.S. business schools still fall short of fulfilling the need of businesses for personnel who can think and act in a global context." *U.S. Business Needs for Employees with International Expertise, Ben L. Kedia and Shirley Daniel, January 2003.*

—The war on terrorism threatens U.S. economic prosperity—and economic stability worldwide—in ways that are not yet entirely understood. Businesses are re-evaluating the risks they face for their employees, their products and services, and their investments in domestic and global markets. The Title VI Centers for International Business Education and Research are mobilizing the intellectual resources of U.S. universities to focus on homeland security and risks in global markets for American business. *See: Homeland Security & U.S. International Competitiveness, CIBERWeb.msu.edu.*

Improving our Image Abroad.—More Americans with understanding of other cultures and proficiency in foreign languages helps to improve the Nation's tarnished image abroad.

—Undersecretary of State for Public Diplomacy and Public Affairs Karen Hughes in an interview with Parade magazine places some of the responsibility for America's image abroad on the United States. The article states: "She talks about how—before 9/11—people abroad perceived the United States as being uninterested in the rest of the world. Our military, cultural and economic power 'buy resentment around the world,' she says. 'It will take all of us to address that. Any American who travels abroad is an ambassador for our country, and I hope you'll demonstrate the respect America has for different countries and cultures.' She'd like more U.S. students to study abroad and more Americans to learn a foreign language." *Interview with Karen Hughes in PARADE MAGAZINE: "Can the U.S. Rebuild Its Image?" January 28, 2007.*

Language and Area Training.—Title VI/Fulbright-Hays programs expand foreign language and area studies enrollments, train K–16 foreign language teachers, and build the training infrastructure in the less commonly-taught languages and areas most needed by the national security agencies, such as Chinese, Russian, Arabic, Korean, Hindi, Urdu, among many others.

—Title VI institutions account for 3 percent of all colleges and universities that offer language instruction, but 21 percent of undergraduate enrollment and 56 percent of graduate enrollment in the less commonly taught languages. For the rare languages, Title VI institutions account for 49 percent of undergraduate and 78 percent of graduate enrollments.

—Title VI institutions provide instruction in roughly over 130 languages and in 19 world areas, and have the capacity to teach over 200 languages. Because of the high cost per student, many of these languages would not be taught on a regular basis at all but for Title VI and Fulbright-Hays support.

—The decline in foreign language enrollments in higher education from 16 percent of total student enrollments in 1960 to just 8.7 percent today must be reversed to meet the increasing demand for globally competent personnel, and to address national needs.

—Only 5 percent of all higher education students taking foreign languages study non-European languages spoken by roughly 85 percent of the world's population.

—U.S. educational institutions from K–16 face a shortage of teachers with global competence, especially foreign language teachers of the less commonly taught languages. Faculty in professional disciplines require greater international expertise.

PRESIDENT'S FISCAL YEAR 2008 REQUEST AND THE COALITION'S RESPONSE

The President's fiscal year 2008 budget recommends $105.75 million for Title VI and Fulbright-Hays. This represents the same level as fiscal year 2006 for these programs. As part of the National Strategic Language Initiative (NSLI), a $1 million E-learning clearinghouse for critical need languages is proposed at the expense of existing Title VI programs that also serve foreign language needs. The Coalition proposes $132.6 million for fiscal year 2008. We support the creation of the E-learning clearinghouse only if new funds are made available and a broader spectrum of less commonly taught languages than the administration is recommending is included.

WHAT ADDITIONAL FUNDING OF $26.9 MILLION OVER THE REQUEST WOULD ACCOMPLISH

Strengthen foreign language, area and international business education and research: $114 million for Title VI, Parts A&B—a $22.5 million increase.

—*Fund an Additional 350 Academic Year and 200 Summer Title VI Foreign Language (FLAS) Fellowships—35 Percent More Than the Request*.—This would restore the number of foreign language academic year fellowships to about 85 percent of the number funded in fiscal year 1967, and 100 percent of the number of summer fellowships funded in that year. Cuts or level funding since fiscal year 2003 have resulted in a cumulative loss of over 340 academic year fellowships in the last 4 years. ($10.75 million)

—*Increase the Center Grants for the National Resource Centers (NRC), Language Resource Centers (LRCs), and Centers for International Business Education and Research (CIBERs) to Their Fiscal Year 2003 Levels Adjusted for Inflation*.—Cuts, inflation, and an increase in the number of centers in last year's competition have caused a 15–20 percent reduction (adjusted for inflation) in the average grant for these vital centers. This would restore center awards that have eroded over the last 4 years to about 100 percent of their fiscal year 2003 levels in real terms. The additional funding will: (1) accelerate efforts to begin training a new generation of international/language specialists and faculty, especially for the less commonly taught languages, who will be needed to replace those expected to retire over the next decade; (2) expand professional development for teachers of critical languages at both the K–12 and higher education levels, as well as the development of widely accessible critical language teaching materials and assessments for students of critical languages; and (3) step up programs in the critical languages in business education, as well as expand research and education on homeland security and risk management. ($8.5 million)

—*Sustain and strengthen other Title VI activities*, including the undergraduate foreign language and international studies, international research and studies, business and international education programs, American Overseas Research Centers, and information technology innovation. Additional funds would build and strengthen programs in critical languages, including advanced language training at home and abroad. It would also increase resources for the development of curriculum materials, assessment instruments and research, as well as obtaining from abroad and disseminating educational information about world regions. ($3.25 million)

Increase the diversity of U.S. students who major in international fields: $3 million for the Institute for International Public Policy, TVI–C—a $1.4 million increase. The Institute for International Public Policy responds to the national need for a diverse pool of well-trained, language-proficient professionals to enter the Foreign Service and related careers. The additional funds would raise the number of entering fellows by 50 percent and extend the pipeline to recruit graduate students and those working in international affairs to focus on strategic languages and issues. It also would restore and expand the capacity building grants for minority serving institutions to strengthen foreign language instruction on campus and in local secondary schools, including collaborative efforts with other Title VI grantee institutions.

Strengthen the overseas component of research and training of Americans in foreign languages and international studies: $15.6 million for Fulbright-Hays—a $3 million increase. Fulbright-Hays provides an essential overseas component for research and training of Americans in foreign languages and international studies. Overseas immersion is critical to achieving high levels of foreign language proficiency. All of the Fulbright-Hays programs require strengthening, with emphasis on increasing the number of research abroad fellowships and group projects abroad in intermediate and advanced language training in strategic world areas, and expanding curriculum development and summer seminars abroad for K–12 teachers.

APPROPRIATIONS BILL LANGUAGE

In the last 6 years, Congress has enacted language in the appropriations bill to provide these programs with more flexibility for overseas immersion opportunities for foreign language training, and to permit use of Fulbright-Hays funds, in addition to teaching, in fields including government, professional fields or international development. It also provides a 1 percent set aside for the Department of Education to carry out evaluation, outreach and dissemination activities. The Coalition recommends a continuation of the following language, but with the insert noted in bold to provide the Secretary with more flexibility in using the 1 percent set-aside.

"*Provided further*, That notwithstanding any other provision of law, funds made available in this act to carry out title VI of the Higher Education Act of 1965, as amended, and section 102(b)(6) of the Mutual Educational and Cultural Exchange Act of 1961 may be used to support visits and study in foreign countries by individuals who are participating in advanced foreign language training and international studies in areas that are vital to United States national security and who plan to apply their language skills and knowledge of these countries in the fields of government, the professions, or international development: *Provided further*, That up to 1 percent of the funds referred to in the preceding proviso may be used for program evaluation, national outreach, and information dissemination activities [*insert: that may be carried out by the Secretary or through grants and contracts to institutions of higher education or public and private nonprofit agencies and organizations]*"

Finally, the Coalition is eager to work with the subcommittee on several recommendations in the just released March 2007 National Research Council's report on these programs entitled, "International Education and Foreign Languages: Keys to Securing America's Future."

We consider our request to be a modest one for programs vital to our Nation's long-term security and economic well-being. Thank you for your consideration of our views.

PREPARED STATEMENT OF THE COALITION OF NORTHEASTERN GOVERNORS

The Coalition of Northeastern Governors (CONEG) is pleased to provide this testimony for the record to the Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies regarding fiscal year 2008 appropriations for the Low Income Home Energy Assistance Program (LIHEAP). The Governors appreciate the subcommittee's continued support for the LIHEAP program and recognize the difficult challenges facing the subcommittee in this time of severe fiscal constraints. In light of the continuously increasing cost of home energy, the Governors request that Congress provide the authorized level of $5.1 billion in regular fiscal year 2008 funding as well as contingency funds to address energy emergency situations. Funding at the authorized level will restore some of the program's purchasing power and also provide States across the country with additional resources to help our most vulnerable citizens afford to heat their homes.

Home energy prices—for heating oil, natural gas, propane and electricity—have dramatically increased in recent years. According to the Energy Information Administration, the average cost for home heating has risen from $550 during the winter of 2001–2002 to a projected $862 this year—a 56 percent increase. Low-income households, whose growth in income is far below the rise in energy prices, face the prospect of keeping their homes at unhealthy or unsafe temperatures, using unsafe alternative heating options, or accumulating high levels of home energy debt and the possibility of utility service shut-off. LIHEAP is a vital safety net for the most vulnerable of these low-income households—the elderly and disabled living on fixed incomes, and families with small children. A recent survey by the National Energy Assistance Directors' Association (NEADA) found that LIHEAP eligible low-income households spent an average of 14 percent of their annual income on residential energy before LIHEAP assistance, but 11 percent after LIHEAP benefits.

The need for home heating assistance far exceeds available Federal and State resources. LIHEAP was able to assist 5.6 million households in fiscal year 2006—the highest level in over a decade, but more than 80 percent of eligible households received no assistance. States across the country in recent years have seen significant increases in their regular LIHEAP caseloads, as well as in requests for emergency crisis from those households in imminent danger of a utility or fuel service cut-off. At the same time, recent price increases have caused the purchasing power of the LIHEAP dollar to plummet, defraying only a modest amount of a low-income household's total heating bill.

Congress provided much-appreciated additional LIHEAP funds in fiscal year 2006, but most of these funds have already been obligated, will be used for crisis cases this year, or are reserved for cooling assistance for the upcoming summer. As energy prices continue to increase the need for home energy assistance, the reduced LIHEAP Federal funding level in fiscal year 2007 is forcing many States across the country to reduce benefits, limit crisis assistance, or consider closing the program early—even as winter moratoriums on utility shut-off expire this spring.

Without additional Federal resources, the States have limited options to assist these households in need. A continued reduction in benefits could result in limited assistance if recipient households are unable to purchase the required minimum delivery of home heating oil or make the necessary payment on utility arrearages. Many States have used State resources to supplement available LIHEAP funds. Limited opportunities exist to squeeze more assistance dollars from the program, since LIHEAP administrative costs are already among the lowest of human service programs. In order to deliver maximum program dollars to households in need, States in the Northeast have incorporated various strategies to minimize the program's administrative costs including using uniform application forms to determine program eligibility, establishing a one-stop shopping approach for the delivery of LIHEAP and related programs, sharing administrative costs with other programs, and using mail recertification.

In spite of these State efforts to stretch Federal and State LIHEAP dollars, the need for the program is far too great. Increased Federal funding is vital for LIHEAP to assist the Nation's vulnerable, low-income households faced with unaffordable home energy bills. An increase in the regular LIHEAP appropriation to $5.1 billion for fiscal year 2008 in addition to contingency funds will enable States across the Nation to help mitigate the potential life-threatening emergencies and economic hardship that confront the Nation's most vulnerable citizens. With these additional funds, States can provide assistance to more households in need, offer benefit levels that provide meaningful assistance, lessen the need for emergency crisis relief, plan and operate a more efficient program, and again make optimal use of leveraging and other cost-effective programs.

We thank the subcommittee for this opportunity to share the views of the Coalition of Northeastern Governors, and we stand ready to provide you with any additional information on the importance of the Low Income Home Energy Assistance Program to the Northeast and the Nation.

PREPARED STATEMENT OF THE COLLEGE BOARD

INTRODUCTION

The College Board is a national not-for-profit association of more than 5,000 member schools, colleges, and universities. Its mission is challenging: To connect students to college success and opportunity. One of the College Board's most ambitious and important teaching and learning programs is the Advanced Placement Program (AP). Comprised of 37 college-level courses taught in high school, AP represents the highest standard of academic excellence in our Nation's schools and has become the most influential general education program in the country. A collaborative effort between motivated students, dedicated teachers, expert college professors, and committed high schools, colleges, and universities, the AP Program has allowed millions of students to take college-level courses and exams and to earn college credit or placement while still in high school since its inception in 1955. Ninety percent of the colleges and universities in the United States, as well as colleges and universities in 30 other countries, have an AP policy granting incoming students credit, placement, or both on the basis of their AP Exam grades. Many of these institutions grant up to a full year of college credit (sophomore standing) to students who earn a sufficient number of qualifying AP scores.

President Bush's request for $122 million in support for AP—including $90 million in new funding to train AP math, science, and world language teachers—will dramatically improve the quality of instruction in our Nation's schools. The ultimate outcome will be a substantial increase in the number of high school graduates who enter college with the desire and ability to succeed in science, technology, engineering, and mathematics (STEM) fields and compete in a global marketplace. Moreover, increased support for an expanded AP Program will contribute to the goal of raising standards and achievement in all of our Nation's high schools. The AP Program benefits both the students who take AP courses and those who do not take AP by promoting higher standards and better teaching in all classes. As such, a significant

investment in the expansion of AP math, science, and world language programs will have a profound effect on the overall quality of education in our Nation's schools.

ADVANCED PLACEMENT PROGRAM

AP is a time-tested program with an existing infrastructure of tens of thousands of teachers and a network of hundreds of training sites across the country. Funds invested in this program will not need to be dedicated to creating a new system for teacher professional development, course development, or the administration and scoring of assessments. That system already exists as a result of our efforts over the past 50 years, and as a result of the involvement of thousands of schools, colleges and universities in the operation of the AP Program. Thus, new Federal dollars invested in AP can go directly into teacher training and student preparation and support.

The principles and values of the AP Program can be stated quite simply:

—AP supports academic excellence. AP represents a commitment to high standards, hard work, and enriched academic experiences for students, teachers, and schools.

—AP is about equity. The AP Program should be open to all students, and we believe that every student should have access to AP courses and should be given the support he or she needs to succeed in these challenging courses.

—AP can drive school-wide academic reform. Schools that use AP as an anchor for setting high standards and raising expectations for all students see significant returns not just in terms of AP participation but in terms of increasing the overall quality and intensity of their academic programs.

Across the Nation, every State, and most school districts are exploring ways to raise standards and ensure that all students take challenging courses that prepare them for success in college and work. AP is recognized as a powerful tool for increasing academic rigor, improving teacher quality, and creating a culture of excellence in high schools. Students who take AP courses assume the intellectual responsibility of thinking for themselves, and they learn how to engage the world critically and analytically—both inside and outside of the classroom. This is an invaluable experience for students as they prepare for college or work upon graduation from high school. Moreover, schools in which AP is widely offered—and accessible to all students—experience the diffusion of higher standards throughout the entire school curriculum.

AP MATHEMATICS AND SCIENCE COURSES

Increasing rigorous math and science education in the United States will significantly boost our high school graduates' math and science proficiency, which will increase the number of students who enter college ready to succeed in programs of study leading to science, technology, engineering, and mathematics (STEM) careers. We urgently need to create those opportunities for our students. Today, only 32 percent of American undergraduates earn degrees in science and engineering, compared to 66 percent of undergraduates in Japan, 59 percent in China, and 36 percent in Germany. In 2004, China graduated 600,000 engineers, India graduated 350,000, and the United States graduated 70,000.[1]

The AP Program is an important tool in this Nation's efforts to increase its economic competitiveness. AP math and science students are much more likely than other students to major in STEM disciplines than students whose first exposure to college-level math and science courses is in college. For example:

—Sixteen percent of students who take AP Chemistry go on to major in chemistry in college. By way of contrast, only 3–4 percent of students who take general chemistry instead of AP chemistry major in that field in college.

—More than 25 percent of students who take AP Calculus go on to major in a STEM field in college, and 40 percent of students who take AP Physics major in physics in college.

Furthermore, research indicates that AP math and science courses prepare American students to achieve a level of proficiency that exceeds that of students from all other nations. For example, in the most recent TIMSS assessments, U.S. Calculus students ranked No. 15 (out of 16 countries) in the international advanced mathematics assessment. But AP Calculus students who scored a 3 or better on the AP Calculus Exam ranked first in the world. Even AP Calculus students who scored

[1] Committee on Science, Engineering and Public Policy. Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future. National Academies Press, 2006. This report notes that America appears to be on a "losing path" today with regard to our future competitiveness and standard of living.

a 1 or 2 on the AP Calculus Exam—below "passing"—were ranked second in the world. AP Physics students, as compared to other U.S. physics students and physics students internationally, were also at the top of the ranking.

Most significantly, there are many more U.S. students who could succeed in AP math and science courses—if given the chance. By utilizing an existing, diagnostic tool called AP Potential, more students could be identified as individuals who have the potential to succeed in Advanced Placement classes but may not currently have the opportunity to do so. This year we anticipate that more than 100,000 U.S. students will earn a 3 or above on the AP Calculus Exam—the score typically required for college credit. But in a national analysis of the math proficiency of students enrolled in U.S. high schools during the 2005–2006 academic year, we can identify, by name and school, an additional 500,000 students who have the same academic background and likelihood of success in AP Calculus as the 100,000 students who currently are fortunate enough to have an AP Calculus course available to them.

If we look at Biology, we see an even larger gap; we expect that about 74,000 students will earn exam grades of 3 or higher on the AP Biology Exam this year, whereas we know that at least 640,000 additional U.S. students have the academic skills that would enable them to succeed in AP Biology if they only had a course available to them and the encouragement to take on this challenge. There are hundreds of thousands of high school students in the United States who are prepared and ready to succeed in rigorous high school courses such as AP Calculus, AP Biology, AP Physics, and AP Chemistry. In many cases, the only thing preventing them from learning at this higher level is the lack of an AP teacher in their school or the lack of adequate encouragement and support to take the AP course.

CONCLUSION

AP is not for the elite, it is for the prepared. The tremendous potential of AP to drive reform in a powerful way in all of our Nation's schools is well established, and no other program has as strong an impact on overall student and teacher quality as AP. The committee's support for expanded AP math, science, and world language courses and exams will prepare many more students for the opportunity to compete in a global environment and succeed in STEM fields in college and work. We respectfully urge that you fully fund the administration's AP expansion request.

PREPARED STATEMENT OF THE COOLEY'S ANEMIA FOUNDATION

Mr. Chairman and members of the subcommittee: Thank you for the opportunity to present this testimony to the subcommittee today. My name is Frank Somma. I live in Holmdel, New Jersey and I am honored to serve as the National President of the Cooley's Anemia Foundation. As many members of this subcommittee know, Cooley's anemia, or thalassemia, is a fatal genetic blood disorder.

I could bog you down in a detailed scientific explanation of what happens physiologically when the human body cannot produce red blood cells in adequate numbers and of adequate quality to sustain life. I am not going to do that. The important thing for members of this subcommittee to remember about Cooley's anemia is that it is a fatal genetic blood disorder. Period.

I also understand that I can present you with five pages of detailed single-spaced testimony. I am not going to do that either. Instead, I am respectfully going to address the following three issues in a clear and succinct manner.

—The first is the immediate need to retain $1.94 million in the CDC's Division of Blood Disorders to fund the thalassemia blood safety surveillance network. This program works for thalassemia patients, and for all Americans, by providing a mechanism to take immediate actions to keep the blood supply safe when a threat emerges.

—The second issue is the equally critical need for this subcommittee to commit our government through the NIH—and more specifically through NHLBI—to the development of a vigorous, ethical, progressive and focused gene therapy program that is designed to cure gene disorders in the shortest possible time.

—The third issue is the urgent need to increase funding for the NIH by 6.7 percent a year for the next 3 years to assure the continuation of desperately needed research at NIDDK for the Thalassemia Clinical Research Network at NHLBI.

BLOOD SAFETY SURVEILLANCE

Mr. Chairman, when a baby is diagnosed with Cooley's anemia, or thalassemia major, the standard of treatment is to begin that child on blood transfusions. I want to be very clear here that the treatment is not to give the child a blood transfusion;

it is to begin a lifetime treatment regimen of this most invasive and dangerous intervention. Once diagnosed, our patients will receive a blood transfusion every 2 weeks for the rest of their lives.

Because Cooley's anemia patients are transfused so regularly, they represent an "early warning system" for problems in the blood supply. If there is an emerging infection or other problem with the blood supply, it is our patients that will get it first and, because of their fragile health, will likely suffer more greatly from this secondary complications.

Please understand that nearly every patient over the age of 18 today who has thalassemia major also has HIV or hepatitis C as a result of their transfusions—or did have it while they were still alive.

Blood safety is a major national issue. Surgical and trauma patients often have no choice but to be transfused. And, it is done on an emergency basis many times. Nothing is more important to the patient at the time of transfusion than that they can be confident that the blood being pumped into their veins is free from infectious agents—HIV, HCV, or something that none of us have yet heard and doctors have yet to identify.

The blood safety surveillance program is currently operating very effectively through the Division of Blood Disorders in the National Center for Birth Defects and Developmental Disability (NCBDDD) with about $1.94 million in funding. While the funding is currently in place, this subcommittee and its staff are painfully aware that CDC management attempted to eliminate it following the passage of the fiscal year 2007 Continuing Resolution.

We are respectfully urging that the subcommittee retain this funding at the $1.94 million level that currently exists in order to continue to protect Americans from unnecessary infections and diseases that may occur in the blood supply. Also, we are requesting that the subcommittee and its staff remain vigilant in protecting this program from unjustified and unjustifiable assaults.

GENE THERAPY

Mr. Chairman, as you know, in the last year or 2 we have begun to see evidence of some very good news about gene therapy. After decades of overblown promises and false starts, we can now see a pathway for scientists to follow to help make the promise of gene therapy become the reality of cures. The problem to this point in the long saga that is gene therapy has not been one of science; it has been one of expectations. As a society, we all forgot that science requires trial and error and that experiments are just that—experiments. Sometimes they succeed, but often they fail. And, when they fail, we need to analyze what happened and identify how to correct it . . . and then try again.

Today, gene therapy is advancing at a rapid pace in the rest of the world. Exciting work is being undertaken in Japan and China, in the UK and in France. Unfortunately, it is showing less progress the United States of America . . . and that is not right. We are the international leaders in scientific research and, in a field like this—fraught with financial, scientific and ethical minefields—it is essential that America demonstrate its continued leadership to the world. We set the highest ethical and moral standards on every one of these issues. We protect human subjects best. The future of gene therapy as a means of curing disease is simply too important to leave it to anyone else.

For persons with a single cell mutation disorder like thalassemia or sickle cell disease or severe combined immune deficiency (SCID), gene therapy holds tremendous promise for a cure. In fact, the CAF has recently launched the CURE Campaign: Citizens United for Research Excellence. The theme of the campaign is "It is Time to Cure Something." We are now learning so much about how to deliver healthy genes to unhealthy cells that we cannot turn back—nor can we as a Nation afford to let down the scientists in this country who have such a depth of knowledge and experience. Our friends in Europe and Asia are leaping ahead of us in this critical area of biomedical research and gene therapy.

We hope that this Congress—speaking through this subcommittee—will do what we have done and dare the NIH and its grantees to "cure something." You are investing nearly $29 billion of taxpayer money in this agency that houses the "best and the brightest" and that funds "the best and the brightest." We as Americans must never stop striving to reach previously unimaginable heights. If that means that we have to shake up the status quo and create a new funding mechanism, let's do it. But let's not continue to follow the slow going incremental, some might say "glacial" path of the past.

We need to spend our tax dollars in a coordinated and focused manner that will maximize the chances that we will unlock the secrets of how to correct single gene

defects. We are gaining direct knowledge of how to safely proceed, with an experiment currently being conducted—in France—that may be a breakthrough. It is time for the United States to step up and lead the world in this life-saving area of research.

NIH AND THE THALASSEMIA CLINICAL RESEARCH NETWORK

Mr. Chairman, 6 years ago, working closely with members of this subcommittee from both sides of the aisle, the CAF convinced the NHLBI of the need to create a Thalassemia Clinical Research Network. The purpose of the Network is to create an infrastructure that would enable the top researchers in the field to collaborate on desperately needed research projects using common protocols. Today, the Network is up and running and is the focal point for thalassemia research, most of which takes place in academic medical centers, literally spread from coast to coast.

However, there remains a cloud hanging over this, and all other, research at NIH. As the Biomedical Research and Development Price Index continues to escalate, the buying power of an NIH that has been flat-funded for 4 years continues to decrease. There would be nothing wrong with this if we had cured thalassemia, and hemophilia, and cystic fibrosis, and all other genetic and non-genetic diseases. But that is not the case.

There is an enormous amount of work to be done, treatments to be developed and cures to be found. And there is no one else to do it but our National Institutes of Health, with the support of our Congress and President.

I urge the subcommittee to make a commitment this year in this bill to a 6.7 percent increase per year for NIH for the next 3 years. This level of funding will simply bring us back to where were in fiscal year 2003 at the end of the 5 year doubling. It is time to commit to undo the damage that has been done in the last 4 years.

CONCLUSION

As I indicated at the outset, Mr. Chairman, the Cooley's Anemia Foundation has three priorities this year:

—Funding the blood safety surveillance program at CDC at $1.94 million;

—An enhanced focus on gene therapy designed to cure something; and,

—A 6.7 percent increase in NIH funding per year for 3 years.

Mr. Chairman, every night when I watch my beautiful, smart, talented 22 year old daughter Alicia suffer from the complications of thalassemia such as osteoporosis and as I watch her endure daily 8–10 hours of painful drug infusions to remove the excess iron in her system from her bi-weekly blood transfusions, I know we can do better than what we are doing now.

Please excuse my passion, but this is the United States of America. I know we can prevent this disease from happening in newborns. I know we can improve the lives of those who currently have it. And, most importantly, I know that we can cure it once and for all.

You don't need four pages of testimony from me to do that. You just need to demand the very best from the very best—our scientists, our government, and ourselves.

Thank you for your very kind attention and for all the support this committee has shown to our patients and their families over the years.

PREPARED STATEMENT OF THE CONSORTIUM OF SOCIAL SCIENCES ASSOCIATIONS

Mr. Chairman and members of the subcommittee, the Consortium of Social Science Associations (COSSA) appreciates and welcomes the opportunity to comment on the fiscal year 2008 appropriations for a number of agencies in the Department of Health and Human Services and the Department of Education. COSSA is an advocacy group promoting attention to and funding for social and behavioral science research. It is supported by more than 110 professional associations, scientific societies, universities, centers and research institutes. A list of our members is attached.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The mission of AHRQ is to promote health care quality improvement by conducting and supporting health services research that improves the outcomes, quality, access to, cost, and utilization of health care services. As the lead Federal agency charged with supporting research designed to improve healthcare, AHRQ-sponsored research provides evidence-based information that empowers healthcare deci-

sionmakers—patients, clinicians, health system leaders, and policymakers—to make informed decisions that impact the quality of healthcare services delivered.

Health services research also addresses issues of organization, financing, utilization, patient and provider behavior, quality, outcomes, effectiveness, and costs. Since fiscal year 2005, AHRQ has lost nearly $20 million in purchasing power due flat funding from Congress and inflation. As a member of Friends of AHRQ, COSSA supports the Friends' recommendation for a funding increase of at least $30 million—just .0015 percent of the $2 trillion we spent on health care annually.

This funding level would allow AHRQ to support ongoing efforts to improve the quality, safety, outcomes, access to and cost and utilization of health care services. In addition, AHRQ will be able to expand its efforts to improve patient safety, modernize health care through health information technology, develop the next generation of researchers, and evaluate the relative value of alternative technologies.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The CDC is the lead Federal agency for promoting health and safety and providing credible health information through strong partnerships, both nationally and internationally. As the command center for our Nation's public health defense system against emerging and reemerging infectious diseases, the CDC faces unprecedented challenges and responsibilities, ranging from chronic disease prevention, eliminating health disparities, bioterrorism preparedness, to combating the obesity epidemic. COSSA commends the CDC for acknowledging that as human behavior and demographics create new public health challenges, the expertise within the social and behavioral sciences will be critical in keeping the American public healthy. These behavioral factors—tobacco use, poor diet, physical inactivity, risky sexual behavior and illicit drug use—are, according to the CDC, "the underlying causes for nearly half of all deaths in the United States."

As a member of the CDC Coalition, a nonpartisan coalition of more than 100 groups committed to strengthening our Nation's prevention and health promotion programs, COSSA supports the Coalition's recommendation of a $10.7 billion appropriation for CDC (including funding for the Agency for Toxic Substances and Disease Registry, and the Vaccines for Children Program). This funding enables the agency to carry out its mission to protect and promote good health and to assure that research findings are translated into effective State and local programs. CDC's programs are crucial to the health of millions of Americans, a key to maintaining a strong public health infrastructure, and essential in protecting us from threats to our health.

The National Center for Health Statistics (NCHS), housed within CDC, provides critical information to guide actions and policies to improve the health of the American people. NCHS data document the health status of the U.S. population and identify disparities in health status and the use of health care by race/ethnicity, socioeconomic status, region, and other population characteristics. New demands for health information exceed the capacity of our current data systems. At few points in recent history has the need for information been greater.

Stagnant and reduced funding throughout most of the last decade has forced significant reduction in some of the NCHS' most important monitoring tools. Since fiscal year 2005, NCHS has lost $13 million in purchasing power due to a combination of flat funding and inflation. As a result, key NCHS programs are in jeopardy. For example, NCHS lacks resources to collect a full year's worth of vital statistics from States. Without at least $3 million in additional funding, we will become the first industrialized Nation unable to continuously collect birth, death, and other vital information. Funding shortfalls are also preventing the collection of data on many other key health care issues.

As a member of the Friends of NCHS, COSSA supports the Friends recommendation of a fiscal year 2008 funding level of $117 million for the agency, an increase of just $8 million over fiscal year 2007.

THE INSTITUTE OF EDUCATION SCIENCES (IES)

Improving the education of our children may be the most widely shared priority in the United States today. Support for other issues may come and go, but recognition of the importance of education and the government's opportunity to improve the state of education in our Nation seems only to grow. Indeed, through No Child Left Behind (NCLB), the President has made education his top domestic priority. Members from both sides of the aisle have offered legislation to reform and improve the educational system. Yet after the legislation passes, what will guide the policies that underlie the education our children receive? Most people, including the current administration, would agree that what should guide education policy is what works

best. We can accomplish finding what works best through impartial, scientific research that evaluates the efficacy of programs in an objective, systematic way and subjects findings to public scrutiny and scientific peer review.

The Education Sciences Reform Act of 2002 reauthorized the Department's educational research, statistics, and assessment activities and placed them in the newly created IES. A cornerstone of the administration's NCLB initiative is investment in research to identify effective instructional and program practices, as well as data collection needed to track student achievement and measure education reform. The new structural and management reforms underway at IES insure that the Federal investment in education research is well managed and relevant to the needs of educators and policymakers.

The $162.5 million request for research, development, and dissemination would support IES-sponsored education research, development, and dissemination, and the funding of discretionary grants and contracts that support directed and field-initiated research. The request would also include funding for the What Works Clearinghouse, which provides evidence-based information for policymakers, researchers, and educators on promising approaches and interventions, the National Library of Education, and the Education Research Information Clearinghouse (ERIC). COSSA supports increasing this amount to $180 million. This funding increase would enable IES to continue to support a diverse portfolio of directed and field-initiated research, including its eight national research and development centers. To strengthen the education research enterprise, new opportunities are needed for investigator-initiated studies that move the field forward with innovative methods and research ideas.

The $29 million increase for the National Center for Education Statistics (NCES), which COSSA strongly supports, would allow it to conduct a pilot study on the development of a postsecondary student level data system that is essential for computing postsecondary completion rates and measuring the true costs of higher education. Funds also would support a new secondary school longitudinal study, scheduled to begin in 2007, which will follow a ninth grade cohort through high school and college.

Assessment is a critical part of the President's education plan No Child Left Behind (NCLB). The fiscal year 2008 budget request includes funding NAEP and the National Assessment Governing Board. The $23.5 million increase, which COSSA supports, will allow the Department to complete preparations for implementing State-level assessments at the 12th grade level in 2009.

Part of the NCLB mission is closing the achievement gap. To this end, the President's budget would provide awards to enhance States' capacity for accurate reporting of high school graduation and dropout data, and to increase the capability of States to comply with Federal reporting requirements. The Statewide Data Systems program supports competitive awards to State educational agencies to foster the design, development, and implementation of longitudinal data systems that would enable States to use individual student data to enhance the provision of education and close achievement gaps. COSSA supports the proposed increase of $30 million for this activity in fiscal year 2008.

TITLE VI AND FULBRIGHT-HAYS

The importance of knowing about foreign cultures, economies, histories, and politics, and the ability to speak other languages besides English is critical to functioning in today's world. On March 27, the National Academies' released its report: International Education and Foreign Languages: Keys to Securing America's Future. The report concluded that the programs supported by the Department of Education—Title VI and Fulbright-Hays—were successful and useful and indicated that the country was getting internationally educated people at a small cost, because the universities are able to leverage the money from the Education Department. However, the report also proclaims that the funding for the Title VI and Fulbright-Hays programs has not kept up with the expanding pace of their mission as world conditions have changed dramatically.

The historical under-funding of Title VI and Fulbright-Hays combined with expanding needs and rising costs have contributed to the Nation's shortfall in specialists today. As the Coalition for International Education (CIE), of which COSSA is a member, has pointed out funding for key Title VI/Fulbright-Hays programs is more than 30 percent below the high point in fiscal year 1967. For example, only 1,561 or 33 percent fewer Foreign Language and Area Studies fellowships were awarded in fiscal year 2007 compared to 2,344 in fiscal year 1967. Four years of level funding combined with across-the-board cuts since fiscal year 2003 have begun to erode the earlier gains. There is an urgent need to increase funding for these pro-

grams. COSSA supports the CIE's recommendation of a $132.6 million appropriation for fiscal year 2008.

JAVITS FELLOWSHIPS AND THURGOOD MARSHALL LEGAL OPPORTUNITY GRANTS

COSSA supports increasing the funding for the Jacob Javits Fellowship Program, which provides graduate students with the funds to pursue advanced degrees in the social sciences, arts, and humanities. For many years the budget of this program has stagnated and in recent years across-the-board cuts have reduced a rather small budget even further. COSSA recommends funding at $12 million in fiscal year 2008. Providing student support for those pursuing degrees in these fields is important to the future of this country. America does not compete in a rapidly changing global environment by only supporting physicists and engineers!

COSSA also supports the restoration of funding for the Thurgood Marshall Legal Opportunity Grants to help members of underrepresented groups prepare for a legal education. It is imperative that the legal profession look like the American we have become and are becoming. That means offering opportunities to those who need a leg up to obtain a legal education. COSSA recommends funding at $3 million in fiscal year 2008.

In conclusion, COSSA acknowledges the subcommittee's history of support for these critical programs that promote health, prevent disease, and help educate a new generation of students. We hope that support will continue in fiscal year 2008.

Thank you for the opportunity to present our views.

PREPARED STATEMENT OF THE COPD FOUNDATION

AGENCY RECOMMENDATIONS

Department of Labor—Employment and Training Administration

Training Demonstration to Employ Disabled Americans.—The Foundation recommends that the Department provide increased emphasis and support for training disabled Americans. The Chronic Obstructive Pulmonary Disease (COPD) Foundation initiative that trains COPD patients to work on a hotline that provides counseling and health referral information to COPD patients across the country is a project that uses technology based training, helps SSI and SDI recipients find employment, and helps meets documented job market demand. The Foundation urges favorable consideration of this and similar initiatives to train disabled Americans.

Center for Disease Control and Prevention—National Center for Chronic Disease Prevention

COPD Self Management Demonstration.—Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death and is a chronic condition similar to diabetes that requires an aggressive self-management in order to prevent continued deterioration, hospitalization, and costly medical interventions. In view of the increasing mortality, morbidity, and cost to the Nation's health care system, the Foundation urges CDC to demonstrate and validate intervention and training protocols that are needed to improve health outcomes and reduce health care costs for COPD patients. The Foundation urges CDC to work with leading health care organizations to develop and validate self management protocols.

Center for Disease Control and Prevention—National Center for Public Health Informatics

Increasing Awareness, Early Diagnoses, and Treatment for COPD.—The National Institutes of Health launched an information campaign in January, 2007 designed to increase awareness, diagnoses, and treatment for Chronic Obstructive Pulmonary Disease (COPD). COPD is a growing epidemic, the fourth leading cause of U.S. deaths, and affects 1 in 4 Americans over the age of 45. More that 12 million people are currently diagnosed with COPD and it is estimated that another 12 million have it but remain undiagnosed despite recognizable symptoms and treatments that can control symptoms and prolong life. CDC is urged to collaborate with leading COPD health care organizations to support the effort to increase public awareness, early diagnosis, and treatment for COPD.

National Institutes of Health—National Heart, Lung, and Blood Institute—Division of Lung Diseases

Chronic Obstruction Pulmonary Disease.—Chronic Obstructive Pulmonary Disease (COPD) is a growing epidemic, the fourth leading cause of U.S. deaths, and affects one in four Americans over the age of 45. In view of these trends, it is noted that only 10 percent of the Division of Lung Disease research portfolio is focused on

COPD. The Foundation commends the Division of Lung Diseases for sponsoring several COPD workshops that have recommended additional research focused on the disease process, pathogenesis, and therapy and other recommendations. The Foundation recommends that the NHLBI aggressively pursue COPD research as recommended by these expert panels and convene a panel of leading researchers from across the country to create a COPD Research Action Plan to identify opportunities and to accelerate the pace of research.

Mr. Chairman and members of the subcommittee thank you for the opportunity to submit testimony for the record on behalf of the COPD Foundation.

THE COPD FOUNDATION

Established in 2004, the COPD Foundation has a clear mission: to develop and support programs, which improve the quality of life through research, education, early diagnosis, and enhanced therapy for persons whose lives are impacted by Chronic Obstructive Pulmonary Disease. Chronic obstructive pulmonary disease (COPD) is an umbrella term for a group of lung disorders that result in obstruction to airflow in the lung causing breathlessness. The four diseases classified under COPD are emphysema, chronic bronchitis, refractory asthma, and severe bronchiectasis. The COPD Foundation was established to speed innovations which will make treatments more effective and affordable. It also undertakes initiatives that result in expanded services for COPD patients and improves the lives of patients with COPD through research and education that will lead to prevention and someday a cure for this disease.

The COPD Foundation is led by a diverse Board of Directors that includes patients with COPD, as well as some of the most recognized professionals involved in COPD clinical practice, research and patient care. Under the board's direction, the COPD Foundation has established policies based on industry best practices from the Better Business Bureau's Wise Giving Alliance and the National Health Council in areas of governance, accountability and transparency. The first of the COPD Foundation's research initiatives is a partnership with the Scarborough family for the Richard H. Scarborough Bronchiectasis Research Fund, aimed to support translational research to halt or reverse the airways destruction of bronchiectasis.

COPD: FOURTH LEADING CAUSE OF DEATH AND RISING

Chronic Obstructive Pulmonary Disease (COPD) was the fourth leading cause of death in 2003 based on the Centers for Disease Control and Prevention's final data, which attributes 126,382 deaths to COPD for the year. Given that figure, a person dies of COPD every 4 minutes, and because of the mechanisms of this devastating disease, he or she slowly suffocates to death over several years as airway obstruction and breathlessness increase. No one knows exactly how many people in the United States have this terrible disease, but estimates range from 12 million diagnosed with another 12 million symptomatic, undiagnosed and at risk.

The decreased ability to breathe causes severe physical and mental disability in afflicted individuals. In a 2004 survey, over 50 percent of patients said that their disease limited the amount or type of work they were able to do, and of those patients nearly 80 percent were unable to work at all due to their breathlessness. Many of these individuals would otherwise have the ability to continue working for many years.

COPD cost the U.S. economy $32 billion in 2002 and it is estimated that 600 million people worldwide have the disease.

THE MEDICAL NEEDS OF THE COPD COMMUNITY HAVE GONE UNMET

While smoking is a predominant cause of COPD it is not the only cause. Other significant factors are second hand smoke, occupational dusts and chemicals, air pollution, and a genetic cause called alpha-1 antitrypsin deficiency.

The other leading causes of death have seen great improvements over the past several decades. While the mortality of COPD rose by 163 percent from 1965–1998, the mortality of coronary heart disease decreased by 59 percent and the mortality of stroke decreased by 64 percent.

Yet this fourth leading cause of death is a hidden, silent killer. There is a lack of awareness among the public that coughing and breathlessness is not a normal sign of aging. Those diagnosed with this disease are quick to blame themselves and are ashamed of their disease because of the current societal stigma. Many lack the information for proper disease self-management, which could easily prevent exacerbations and thusly, many hospital and emergency room visits.

Currently, the only therapy shown to improve survival is supplemental oxygen. There are other therapies that can improve symptoms but they do not alter the natural history of the disease.

DETECTION

COPD is fairly easy to detect: in addition to symptoms of breathlessness, cough and sputum production, spirometry is a quantitative test that measures air volume and air flow in the lung and is relatively easy and inexpensive to administer.

COPD RESEARCH

The COPD Foundation believes that significant Federal investment in medical research is critical to improving the health of the American people and specifically those affected with COPD. The support of this subcommittee has made a substantial difference in improving the public's health and well-being. While this is by no means an exhaustive list, the Foundation wishes to recognize and appreciate the efforts of the National Institutes of Health in creating the COPD Clinical Research Network, for conducting a COPD state of the science conference, and commends NHLBI for the national launch of the COPD Awareness and Education Campaign titled "COPD Learn More Breathe Better".

Chronic diseases have a profound human and economic toll on our Nation. Nearly 125 million Americans today are living with some form of chronic condition. The Foundation recognizes that the Centers for Disease Control and Prevention understands that COPD is one of the only top 10 causes of death that is on the increase, however, COPD has not been designated the resources to be a major focus of the CDC. The Foundation urges the subcommittee to encourage the CDC to expand its data collection efforts and to expand programs aimed at education and prevention of the general public and health care providers.

NIH and CDC: The Foundation requests that the National Institutes of Health in fiscal year 2008 receive an increase of 6.7 percent over fiscal year 2007 Joint Resolution Funding Levels. The COPD Foundation joins the Ad Hoc Group for Medical Research Funding, a coalition of some 300 patient and voluntary health groups, medical and scientific societies, academic research organizations and industry in making this recommendation. The fiscal year 2008 administration budget request for NIH is a $511 million cut (1.7 percent) below the final fiscal year 2007 levels. If implemented, this funding level would mean NIH's ability to conduct and support life-saving research will be cut by more than 13 percent in inflation-adjusted dollars since fiscal year 2003. The NIH, National Heart Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases and National Institute on Aging, should increase the investment in Chronic Obstructive Pulmonary Disease and the Centers for Disease Control and Prevention should initiate a Federal partnership with the COPD community to achieve the following goals:

—Promotion of basic science and clinical research related to COPD;
—Programs to attract and train the best young clinicians for the care of individuals with COPD;
—Support for outstanding established scientists to work on problems within the field of COPD research;
—Development of effective new therapies to prevent progression of the disease and control symptoms of COPD;
—Expansion of public awareness and targeted detection to promote early diagnosis and treatment.

PREPARED STATEMENT OF THE CORPS NETWORK

The Corps Network (formerly the National Association of Service and Conservation Corps or NASCC) appreciates the opportunity to submit testimony to the subcommittee about the critical need for funding AmeriCorps and other national service programs in fiscal year 2008.

We urge you to make much needed, and long overdue, investments in AmeriCorps and other national service programs supported by the Corporation for National and Community Service (CNCS).

Specifically, we recommend that the subcommittee fund:

—AmeriCorps State and National Grants at $312 million;
—The National Service Trust at $143 million;
—The National Civilian Community Corps (NCCC) at $26.7 million; and
—AmeriCorps VISTA at $95 million.

We believe that these funding levels would adequately support 75,000 AmeriCorps members ands retain the historic balance between full- and part-time service.

Established in 1985, The Corps Network is the voice of the Nation's 113 Service and Conservation Corps. Currently operating in 41 States and the District of Columbia, Corps annually enroll more than 23,000 young men and women who contribute 13 million hours of service every year. Corps annually mobilize approximately 125,000 community volunteers who contributed more than 2.4 million additional hours of service.

Service and Conservation Corps are a direct descendent of the Civilian Conservation Corps (CCC) that built parks and other public facilities still in use today. Like the legendary CCC of the 1930s, today's Corps are a proven strategy for giving young men and women the chance to change their communities, their own lives and those of their families. Service and Conservation Corps provide a wealth of valuable conservation, infrastructure improvement and human service projects. Some Corps tutor and some fight forest fires. Others complete a wide range of projects on public lands. Still others improve the quality of life in low-income communities by renovating deteriorated housing, engaging in environmental restoration, creating parks and gardens and staffing after-school programs.

Service and Conservation Corps serve young people who are most in need. Since 1985, approximately 600,000 young people have completed service in our Nation's Service and Conservation Corps. Approximately 57 percent of our Corpsmembers are young people of color, 64 percent come from families with income below the poverty line, at least 30 percent have had previous court involvement and at least 10 percent have been in foster care. More than half of all Corpsmembers enroll without a high school diploma.

Today's Corps are a proven strategy for giving young men and women, many of whom are economically or otherwise disadvantaged and out-of-work or out-of-school, the chance to change their own lives and those of their families, as well as improve their communities. Corps represent the country's largest full-time, non-federal system for youth development.

I would like to share with you three examples of why AmeriCorps funds are so important to our Nation. The Corps Network administers three AmeriCorps programs, the Gulf Coast Recovery Corps, the Civic Justice Corps and RuralResponse that address important societal problems through service.

The AmeriCorps Gulf Coast Recovery Corps:

—Assists residents impacted by the devastation of Hurricane Katrina and Rita in the long-term recovery efforts along the Gulf Coast of Mississippi.

—Deploys crews of young people (ages 18–25) from the Nation's 113 Service and Conservation Corps for 4-week projects that include rebuilding homes and structures, chopping down damaged trees near homes, removing debris, restoring trails, replanting marsh grass and trees, performing environmental restoration and other projects.

—Brings a total of 300 trained and semi-skilled volunteers to the region through the summer of 2007.

—Partners with the Hancock County Long-Term Recovery Committee, Mississippi Commission for Volunteer Service, St. Rose Delima Catholic Church in Bay St. Louis, Mississippi State Parks, U.S. Fish and Wildlife Service and other local and national organizations working in the region.

—Builds on the tradition of Corps helping communities recover from natural disasters, including the San Francisco earthquake in 1989, Hurricane Andrew in 1992, the Mississippi River floods in 1993 and the aftermath of other major hurricanes, floods, tornadoes, and wildfires.

—Will pave the way for a permanent Mississippi Corps, funded in part by the Mississippi Commission for Volunteer Service, to engage local young people in the recovery efforts.

—Is funded by the Corporation for National and Community Service's Federal AmeriCorps program.

The Civic Justice Corps (funded by AmeriCorps and the Department of Labor):

—Re-engages court-involved youth and young adults, not less than 50 percent who have been incarcerated, in their communities, the workforce, education and society as a whole, with the goal of reducing recidivism by at least 20 percent.

—Empowers Corpsmembers through a variety of service projects that meet critical community needs.

—Creates a support system that begins in the corrections facility, continues through the time in the Corps and extends 12 months after the Corps experience.

—Formalizes effective working relationships with justice agencies, employers and other partners.

—Enables Corpsmembers to earn a high school diploma or GED while preparing for careers in high-growth industries or opportunities in post-secondary education.
—Draws on the experience of Corps which enroll nearly 5,000 court-involved youth each year.
—Represents a partnership between the Cascade Center for Community Governance, the Open Society Institute, the JEHT Foundation and The Corps Network.
—Is funded by AmeriCorps in the following sites: Bend, OR; Charleston, SC; Washington, DC.
—Is funded by the U.S. Department of Labor in the following sites: Austin, TX; Camden, NJ; Denver, CO; Fremont, OH; Fresno, CA; Madison, WI; Miami, FL; Oakland, CA; Sacramento, CA; San Diego, CA and Wheaton, MD.

The RuralResponse AmeriCorps Program:
—Enables Service and Conservation Corps to bolster homeland security and disaster response capacity in underserved rural communities by filling gaps in rural emergency response networks.
—Engages young people (ages 16–25) each year in disaster response as well as traditional service and conservation projects to meet the needs of rural communities.
—Trains Corpsmembers in specific disaster preparedness and response activities such as first aid, adult and child CPR, mass care, use of global positioning systems (GPS), shelter operations, hazardous materials removal, chain saw safety and use and wildfire suppression.
—Prepares Service and Conservation Corps for long-term engagement with existing disaster response and preparedness efforts in rural communities.
—Provides a minimum wage based living allowance and an AmeriCorps Education Award (scholarship) of up to $4,725 per Corpsmember.
—Requires a 33 percent non-federal match by Service and Conservation Corps.
—Is funded by AmeriCorps at $3.6 million over 3 years in the following sites: Minnesota Conservation Corps, Quilter Civilian Conservation Corps (Fremont, OH), Vermont Youth Conservation Corps and Youth Conservation Corps, Inc. (Waukegan, IL).

Our work in the Gulf Coast Recovery Corps, the Civic Justice Corps and Rural Response embodies many of AmeriCorps' core principles including:
—Using service in creative ways to meet needs that would otherwise go unmet;
—Relying on public-private partnerships and using public dollars to attract private funds;
—A bottom-up structure in which the local community determines the projects on which we work;
—Communities demonstrate their support for projects by helping Corps meet AmeriCorps' matching requirements;
—Partnering with local government, State, and Federal land management agencies and local nonprofit organizations, including faith-based groups;
—Providing an opportunity for all Americans to serve and reconnecting disconnected youth to their communities by insuring that Corpsmembers learn life skills and job skills that enhance their employability; and
—Using the AmeriCorps Education Award to make higher education accessible to thousands of young people for whom it would otherwise be too costly.

While it is difficult to describe the "typical" Corps, successful Corps share common core elements. They:
—Rely on a model in which adult leaders serve as mentors, role models, technical trainers and supervisors for crews of 8–12 Corpsmembers;
—Provide Corpsmembers with a minimum-wage based living allowance;
—Offer classroom training to improve basic competencies, a chance to earn a GED or high school diploma, experiential and environmental service-learning-based education, generic and technical skills training, a wide range of support services, and, in many cases, an AmeriCorps post-service educational award of up to $4,725.
—Build on Corpsmembers' strengths to provide an environment in which every Corpsmember can experience success. They offer consistent contact with a caring adult, stress leadership development, creative problem-solving, and the ability to work as a member of a team; and
—Provide Corpsmembers a "second chance" to succeed in life and focus youth on the future.

A 1997 Abt Associates/Brandeis University random assignment study concluded that Youth Service and Conservation Corps are an invaluable resource for young people. According to the study, Corps generate a positive return on investment and

the youth involved were positively affected by joining a Corps. The report documents that:

—Significant employment and earnings accrue to young people who join a Corps;
—Positive outcomes are particularly striking for African-American men;
—Arrest rates drop by one third among all Corpsmembers; and
—Out-of-wedlock pregnancy rates drop among female Corpsmembers.

Abt Associates documents several factors to which the effectiveness of Corps is attributed including:

—Comprehensiveness of services;
—Supportive and dedicated program staff;
—Quality of the service projects;
—Intensity of the service experience; and
—Corpsmembers have access to an expanded social network.

It is critical for CNCS to have sufficient resources to ensure that participants in national service programs are able to continue their crucial work. Restoring our investment in AmeriCorps State and National, the National Service Trust, AmeriCorps*NCCC and AmeriCorps*VISTA, will allow more Americans of all ages and backgrounds to serve and create greater capacity to meet critical community needs.

Thank you for your consideration of these requests. If you have any questions, please do not hesitate to contact me at (202) 737–6272 or at sprouty@corpsnetwork.org.

PREPARED STATEMENT OF THE COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS

PUBLIC HEALTH WORKFORCE: INCREASING STATE AND LOCAL EPIDEMIOLOGY AND LABORATORY CAPACITY

Recommendations

—$5 million for the Office of Workforce and Career Development to support 65 CDC/Council of State and Territorial Epidemiology (CSTE) first year applied epidemiology fellows.
—$2 million increase for the National Center for Infectious Diseases to support 35 CDC/Association of Public Health Laboratories (APHL) applied research training fellows.

Building a strong public health infrastructure, particularly a trained public health workforce with sufficient epidemiologists and public health laboratory scientists—core public health professionals, will take a sustained commitment of resources over a long period of time.

The disciplines of epidemiology and laboratory science are the pillars of public health practice. States and local communities have come to rely on public health epidemiologists and laboratory scientists to investigate, monitor, and respond aggressively to public health threats. Every State's residents have become familiar with the "disease detectives" who communicate risks and provide preventive recommendations during incidents such as the recent outbreak of E. coli in spinach, seasonal influenza, West Nile virus, and epidemics of obesity, diabetes, HIV/AIDS and a host of other serious threats the public has experienced during recent years. The 2006 CSTE National Assessment of Epidemiologic Capacity shows the number and the level of training of epidemiologists is perceived as seriously deficient in most States. Federal funding has increased the number of epidemiologists engaged in bioterrorism preparedness since 2002, but has done so at the expense of State environmental health, injury and occupational health activities—shifting epidemiologists from these activities to Federal bioterrorism preparedness priorities. Those engaged in chronic disease activities have increased since 2002, but are still viewed as too low in number and training. According to the 2003 Institute Of Medicine report, Microbial Threats to Health: Emergence, Detection, and Response, rebuilding domestic public health capacity was among its highest recommendations for addressing both diseases occurring naturally and intentional release of microbial agents.

Efforts under the leadership of CDC have been made to begin addressing these gaps. CDC is supporting training fellowship programs for epidemiologists and laboratory scientists who are expected to increase State capacity and provide future leadership in these professions. CSTE applauds these efforts and proposes aggressive expansion of existing state-focused programs to increase the number of epidemiologists and public health laboratory scientists at State and local health departments. The proposed fiscal year 2008 increase will provide CSTE and APHL with

the resources to accelerate much needed expansion of the State and local workforce in these critical disciplines.

States and localities will benefit through increased numbers of highly trained epidemiologists and laboratory scientists entering employment through training programs that include the following characteristics:

—national recruiting through a partnership between CSTE and the Association of Schools of Public Health;
—orientation and training course with CDC, CSTE, and APHL faculty;
—applicant pool for State and local positions with adequate time to evaluate job performance;
—a structured, individualized training curriculum for each fellow; and
—technical and administrative support for fellows and State mentors.

The capacity and leadership legacy of these state-based programs is intended to be modeled on the success of the Epidemic Intelligence Service and provide States and localities with epidemiology and laboratory leadership for the future.

STRENGTHENING CAPACITY IN FOUR CRITICAL PUBLIC HEALTH PROGRAM AREAS

Preparing for an Influenza Pandemic

Fiscal year 2006 State and Local pandemic influenza preparedness funding is being used to: (1) create and implement, including exercising, emergency pandemic plans; (2) conduct integrated disease surveillance; (3) fund laboratory testing of influenza strains; (4) inform the public; (5) manage distribution of vaccine and antiviral medications; (6) plan for alternative facilities in the event of hospital capacity excess; (7) track vaccine and antiviral use; (8) document adverse outcomes from influenza-related medications. Continued funding at the level of $250 million in fiscal year 2008 will support these activities and help ensure that our health system is ready for the seasonal influenza epidemics and a potentially catastrophic influenza pandemic.

Epidemiologic-Laboratory Capacity (ELC Cooperative Grant Program)

CSTE strongly supports a $53 million increase for the Epidemiologic-Laboratory Capacity program at the CDC for fiscal year 2008. This increase will be instrumental in implementing the CDC plan Preventing Emerging Infectious Diseases: A Strategy for the 21st Century. This program, which supports health departments in 50 States and 6 highly populated cities/counties, was developed to repair the deteriorated surveillance and response capacity for emerging infectious diseases in health departments nationwide. Funds build capability to detect, diagnose, and prevent diseases caused by food, water and vector borne infections, vaccine preventable disease, and drug resistant infections. The early detection and prompt response to West Nile virus (WNV) in 2000 can be attributed to the foundations laid by this cooperative grant program. Funding reductions, beginning in 1998, have compromised the mission of this program and may contribute to a weakened ability to detect and respond to future disease threats. CSTE is very disappointed that the President's fiscal year 2008 budget cuts WNV funding by 45 percent. In an effort to maintain and build public health capacity, CSTE supports full funding ($110 million) for the ELC cooperative grant program in fiscal year 2008.

Terrorism Preparedness

State and Local CDC Terrorism Preparedness Grants are used to fortify health department ability to detect and investigate disease occurrence, evaluate infectious outbreaks, and rapidly access, exchange and disseminate relevant information. Funding also provides surge capacity for personnel and supplies that will be needed in the event of a terrorist attack. In fiscal year 2006, funding was cut by $100 million and remained at that level for fiscal year 2007. The President's fiscal year 2008 budget cuts funding further by $125 million. While health departments nationwide have made good progress in emergency preparedness, these funding cuts have led to a decreased epidemiology and laboratory capacity due to downsized personnel that were paid with these funds. Further staff reduction, and concomitant reduction in surveillance performed, will leave our Nation's public health system unable to provide bioterrorism threat surveillance and response. CSTE recommends full funding at the fiscal year 2005 level—$919.1 million.

Preventive Health—Health Services (PHHS) Block Grant

CSTE is disappointed that the President's fiscal year 2008 budget, once again, eliminates all funding for the PHHS Block Grant and urges restoration of funding to the fiscal year 2005 level of $131 million. This grant program was developed to allow States flexible use of funds to support objectives identified at the local level. For example, a city with increasing incidence of whooping cough (Bordatella per-

tussis) would be able to use funds to intensively track cases and prevent spread of the disease. Other cities or States may use funds to address their region-specific disease trends, such as injection drug related morbidity, sexually transmitted disease, mother-to-child diseases, or hantavirus. Because of the variation in disease prevalence across our diverse Nation, flexible funding with local allocation capacity is necessary to achieve detection, prevention, and community outreach tasks for Americans. CSTE recommends restoration of the PHHS block grant to $131 million to limit the extent of local disease epidemics spreading to becoming national disease threats.

SURVEILLANCE ISSUES: FIVE CSTE PRIORITIES

Epidemiologists working in public health agencies are responsible for monitoring trends in health and health problems, and devising prevention programs that support healthy communities. Surveillance is the foundation for developing a public health response to any disease threat—be it infectious, chronic, environmental, occupational, or injury. Surveillance is useful in (1) determining which segments of the population are at highest risk; (2) identifying changes in disease incidence rates; (3) determining modes of transmission; and (4) planning and evaluating disease prevention and control programs. For fiscal year 2008, CSTE urges Congress to provide the following increased resources for expanding surveillance of key diseases, injury and environmental health areas:

Behavioral Risk Factor Surveillance Survey (BRFSS).—Administered by CDC's Center for Chronic Disease Prevention, Health Promotion, and Genomics, the BRFSS is a primary source of information used to guide intervention, policy decisions, and budget direction at the local, State, and Federal level for multiple health conditions and chronic diseases. An increase in funding by $10 million, to $18 million, is needed to fully implement the survey. BRFSS is the primary source of information for leading health indicators for 6 areas in Health People 2010. As our Nation moves towards evidence based medicine and funding, our data source needs to be comprehensive enough to accurately reflect the health of our population. Further congressional support will improve data collection infrastructure, timely reporting, and sophisticated analysis to provide data in meaningful ways to end users nationwide.

HIV/AIDS Surveillance.—Cooperative Agreement funding to State and Local health departments for HIV/AIDS surveillance is critical to prevent new HIV infections, thereby saving an estimated $195,000 in lifetime treatment costs per individual. HIV/AIDS incidence is increasing without commensurate increases in Federal spending for surveillance. CSTE urges an increase of $35 million, to $101.3 million, for the surveillance cooperative agreements in CDC's HIV/AIDS Prevention budget (total recommendation $1,049.2 million) to address increasing HIV/AIDS incidence.

National Violent Death Reporting System (NVDRS).—Fifty thousand deaths per year in the United States are attributable to violence. The National Center for Injury Prevention and Control (NCIPC) has developed the NVDRS to collect data related to these deaths for use in development of targeted prevention and early intervention programs. Seventeen States currently are equipped with NVDRS, however increased funding will help distribute the program and personnel to all States and strengthen our Nation's ability to collect the data that will ultimately result in reduction in violent deaths. CSTE urges an increase in funding from $3.4 million to $10 million for NVDRS, administered by CDC's NCICP (total $168 fiscal year 2008 request).

Occupational Safety and Health State-Based Surveillance (NIOSH Program Announcement PAR 04–106).—In fiscal year 2005 NIOSH funded 12 States to establish Occupational Safety and Health programs that use 13 occupational health indicators to measure the burden of workplace injury and illness and make recommendations for prevention. This successful program should be expanded to all 50 States to establish a nationwide system to prevent major injuries and illnesses caused by hazardous work conditions. An increase in funding to $12.5 million, within the $300 million NIOSH budget request, will allow the expansion of this occupational surveillance to all States.

Environmental Health Tracking Grants.—There is no national surveillance system to investigate possible links between environmental exposures and a number of diseases and health conditions, as noted in the PEW Environmental Health Commission's report, America's Environmental Health Gap: Why the Country Needs a Nationwide Health Tracking Network. Most States have little capacity for tracking environmental health. Since fiscal year 2002, Congress has recognized the need for increased environmental health capacity with funding, however a significant increase

is needed to ensure that all States have the ability to track disease occurrence and adverse health conditions and their possible linkages to environmental toxins and hazards (such as the link between asbestos and mesothelioma). Funding at the $100 million level will strengthen our nations resolve to identify harmful environmental exposures and eliminate the disease burden caused by them.

PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

On behalf of the Cystic Fibrosis Foundation, and the 30,000 people with cystic fibrosis (CF), I am pleased to submit the following testimony regarding fiscal year 2008 appropriations for cystic fibrosis-related research at the National Institutes of Health (NIH) and other agencies.

ABOUT CYSTIC FIBROSIS

Cystic fibrosis is a life-threatening genetic disease for which there is currently no cure. People with CF have two copies of a defective gene that causes the body to produce abnormally thick, sticky mucus, which clogs the lungs and result in fatal lung infections. The thick mucus in those with CF also obstructs the pancreas, causing patients difficulty in absorbing nutrients in food.

The common symptoms of CF include chronic cough, wheezing or shortness of breath, excessive appetite but poor weight gain, and greasy, bulky stools. CF symptoms vary from patient to patient, due to the fact that there are more than 1,000 mutations of the CF gene.

Since its founding, the Cystic Fibrosis Foundation has maintained its focus on promoting research and improving treatments for CF. CF has been significantly transformed from a childhood death sentence into a chronic disease, which requires a rigorous daily regimen of therapy. Treatments for individuals with CF include enzymes that aid digestion, antibiotics to treat lung infections, and daily therapy to loosen the mucus in the lungs. Strict adherence to CF treatments improves the health status and quality of life for those with CF, but the regimen can be a daily challenge for patients and their families.

Through the research leadership of the Cystic Fibrosis Foundation, the life expectancy of individuals with CF has been boosted from less than 6 years in 1955 to nearly 37 years in 2005. Today, 43 percent of people with CF are 18 or older. This improvement in the life expectancy for those with CF can be attributed to research advances, which I will discuss in some detail later, and to the teams of CF caregivers who offer specialized care of the highest quality. This improvement in life expectancy is important, but we continue to loose young lives to this disease. Our progress is not nearly sufficient for those living with CF and their families, friends, and caregivers.

The promise for those with CF is in research. In the past 5 years, the Cystic Fibrosis Foundation has invested over $595 million in its medical programs of drug discovery, drug development, research, care and drug delivery aimed at life-sustaining treatments and a cure for cystic fibrosis. But a greater investment is necessary to accelerate the pace of discovery of CF therapies. This statement focuses on the investment that will be required to develop new CF treatments rapidly and efficiently and to encourage research on a cure.

SUSTAINING THE FEDERAL INVESTMENT IN BIOMEDICAL RESEARCH

This subcommittee and Congress are to be commended for their steadfast support for biomedical research, and their commitment to the National Institutes of Health (NIH), including the effort to double the NIH budget between fiscal year 1999 and fiscal year 2003. This impressive increase in funding resulted in a revolution in medical research, fueling discoveries that benefit all Americans.

However, we risk losing the research momentum the doubling generated if we fail to adequately fund the NIH so that they can capitalize on scientific advances. The Cystic Fibrosis Foundation joins the Ad Hoc Group for Medical Research to recommend increasing the NIH budget by at least 6.7 percent in fiscal year 2008. This investment will help maintain the NIH's ability to fund essential biomedical research today that will provide tomorrow's care and cures.

STRENGTHEING OUR RESEARCH INFRASTRUCTURE

It is now vital to assess our ability to translate the basic research advances of the last decade into treatment advances. The Cystic Fibrosis Foundation has been recognized for its own research approach to encompass many types of research, from basic research through Phase III clinical trials, and has created the infrastructure

required to accelerate the development of new CF therapies. As a result, we now have a pipeline of more than 25 potential therapies that are being examined to treat people with CF. Several drugs in this pipeline treat the basic defect of CF, while others attack the symptoms of the disease.

The NIH Roadmap for Medical Research provides the opportunity for the NIH to translate research into treatments for people with disease. We applaud Congress for its leadership and support for the NIH's Roadmap, which mirrors the Cystic Fibrosis Foundation's own approach to support and rewards innovation throughout the research process.

Cystic fibrosis is a disease which impacts multiple systems in the body, and as a result, several different institutes at NIH share responsibility for CF research. Having multiple responsible institutes presents roadblocks to CF research in that there can be imperfect communication among the institutes regarding research in the field. This can limit our ability to capitalize on all research opportunities. Moreover, multidisciplinary research approaches, of the sort we believe are most promising in CF, may be disadvantaged in the NIH system of review and funding.

The Cystic Fibrosis Foundation applauds NIH leaders for encouraging multidisciplinary research and Congress for directing resources to the Common Fund to finance multidisciplinary research projects. Funding pioneering multidisciplinary research is critical, but the Common Fund is also important in intangible ways, such as encouraging communication among researchers, placing a high value on trans-institute research, and breaking down barriers to communication and collaboration between institutes. We urge sufficient funding for such a multidisciplinary approach, which is most responsive to the research needs of complex diseases like CF.

FACILITATING CLINICAL RESEARCH

The Cystic Fibrosis Foundation applauds the efforts of NIH to encourage greater efficiency in clinical research. The Foundation has been a pioneer in creating a clinical trials network to achieve greater efficiency in clinical investigation. Our pioneering effort in clinical trials emerged from the necessity of a small patient population for the number of trials we are undertaking and because our patients literally cannot tolerate research delays. Yet we believe that our model should be adopted and adapted by others. We have a permanent network of clinical trial sites and have centralized and coordinated data management and analysis functions and data safety monitoring. Among the results of this outstanding network—called the Therapeutics Development Network—are the ability to achieve rapid accrual to trials and the ability to conduct multiple trials simultaneously, even in a population of 30,000 CF patients. Since the TDN's inception, it has conducted over 40 trials. Of course, the ultimate goal of a centralized clinical trials system is the acceleration of the therapeutic development process.

Although we have achieved significant efficiencies in our clinical trials system, we still encounter substantial slowdowns in the review of our multi-institutional trials by the institutional review boards (IRBs) of each of the institutions participating in the trials. We encourage Congress to urge the Department of Health and Human Services to demonstrate more aggressive leadership in persuading academic institutions to accept review by a central IRB—without insisting on parallel and often duplicative review by their own IRB—at least in the case of multi-institutional trials in rare diseases.

Pursuing New Therapies: The Cystic Fibrosis Therapeutics Development Network

The Cystic Fibrosis Foundation requests the committee allocate $3 million in Federal funding in fiscal year 2008 to support much-needed expansion of our clinical research program, the Therapeutics Development Network (TDN), through the Coordinating Center at Children's Hospital & Regional Medical Center in Seattle, Washington. This will provide a significant investment in the Cystic Fibrosis Foundation's ongoing efforts to meet the demand for testing of all the promising new therapies for cystic fibrosis.

Designating Federal funding for the Cystic Fibrosis Therapeutics Development Network will accelerate testing of new therapies for CF. The TDN plays a pivotal role in accelerating the development of new treatments to improve the length and quality of life for cystic fibrosis patients. Since the Cystic Fibrosis Foundation established this program in 1998, the TDN has evaluated 12 new products, with seven more products now in clinical trials. Opportunities exist to pursue 10 additional trials on drug candidates in the next 18 months.

The CF Foundation has adopted an innovative business approach to drug discovery and development that is emulated by other nonprofits. Lessons learned from centralization of data management and analysis and data safety monitoring in the TDN will be useful in designing clinical trial networks in other diseases. Federal

funding to support the TDN will provide special insights regarding the most efficient means of conducting clinical trials on orphan diseases.

National Center for Research Resources

The Institutional Clinical and Translational Science Awards program is an initiative of particular importance to cystic fibrosis. This NIH Roadmap program administered by the National Center for Research Resources (NCRR) encourages novel approaches to clinical and translational research, enhances the utilization of informatics and strengthens the training of young investigators. The Cystic Fibrosis Foundation has enjoyed a productive relationship with the NCRR to support our vision for improving clinical trials capacity through its early financial support of the TDN.

SUPPORTING ADDITIONAL RESEARCH AREAS

While much of this testimony has focused on clinical research, these new therapies rely on solid basic research. Although the discovery of the CF gene in 1989 was an important step forward, there is still much to be learned about the disease. As a result, the CF Foundation continues to invest in basic research on the disease to deepen our knowledge of CF and to better understand how we may intervene in the disease course. There are several research projects at NIH that are essential to this work, and for which we express our strong support.

Protein Misfolding and Mistrafficking

The Cystic Fibrosis Foundation urges the NIH to devote special focus to research in protein misfolding and mistrafficking, an area which may yield significant benefits for CF and other diseases where misfolding is an issue. We applaud both the National Heart, Lung and Blood Institute (NHLBI), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for their initiatives that target research on protein misfolding, and urge an aggressive commitment to facilitate continue exploration in this area to build upon promising discoveries. Additionally, we urge funding by the National Institute of General Medical Sciences (NIGMS) for the creation of tools and reagents and advances in techniques for precision monitoring of folding and trafficking events and for the sharing of resulting data that would complement the efforts of NIDDK- and NHLBI-funded investigations in this area.

On behalf of the Cystic Fibrosis Foundation, I thank the committee for its consideration. Congress has reason to be proud of its role in supporting NIH, which is the world's leader in biomedical research. The NIH has strong leadership to move into the new century, when we will see the translation of basic research into new treatments for many diseases. We believe the experience of the CF Foundation in clinical research can serve as a model for research on other orphan diseases, and we stand ready to work with NIH and congressional leaders.

PREPARED STATEMENT OF THE ENDOCRINE SOCIETY

The Endocrine Society would like to submit the following testimony regarding fiscal year 2008 Federal appropriations for biomedical research, with emphasis on appropriations for the National Institutes of Health. The Endocrine Society is the world's largest and most active professional organization of endocrinologists representing over 14,000 members worldwide. Our organization is dedicated to promoting excellence in research, education, and clinical practice in the field of endocrinology. The Society is comprises thousands of researchers who depend on Federal support for their careers and their scientific advances.

In April 2004 the Endocrine Society testified before the House Appropriations Committee. During this testimony the Society provided the committee with a grim picture of what might happen to NIH-funded research if the financial commitment made during the doubling period (1998–2003) was not sustained. Our testimony indicated that breakthroughs in areas of endocrine research—such as diabetes and obesity—were on the horizon after the doubling period, but that the breakthroughs were in jeopardy of being abandoned due to sharp decreases in NIH funding from Congress. Unfortunately, it seems our prognostication was correct.

Included as an addendum (Addendum A) to this testimony is an excerpt from a compelling article that appeared in the April issue of Men's Health magazine. Highlighted within this article is the story of Endocrine Society member, Alan Schneyer, Ph.D. This article examines the real life impact that reduced funding for NIH has on the Nation's researchers and their potential breakthroughs. Dr. Schneyer has been working in the field of endocrine research and has made promising discoveries

that could lead to future diabetes treatments. But as of April 2007 his lab, his research, and his employees have been shut down because his grant will no longer be funded. The great promise hoped for in 1997, at the beginning of the doubling period, has led to closed labs and unemployed scientists in 2007.

A simple glance at NIH funding trends over the last few years will show how this great promise led to great disappointment. Under the President's proposed fiscal year 2008 budget most NIH institutes and centers would see their budgets remain flat for the fourth year in a row. The proposed fiscal year 2008 NIH budget of $28.7 billion would be down $230 million from the recently finalized fiscal year 2007 budget. Worse yet, the NIH budget would fall 12 percent from 2004 to 2008 when adjusted for biomedical research inflation.

This funding downturn not only has a drastic impact on existing researchers such as Dr. Schneyer, but it is having a profound effect on future researchers as well. NIH projects the success rate for new renewal grant applications will stabilize at 20 percent in 2007 and 2008, down steeply from a high of 32 percent in fiscal year 2001. According to the American Association for the Advancement of Science, NIH expects to fund 1 in 5 applicants who apply for research funding in 2008. During the height of the doubling period NIH funded 1 in 3 applicants. As you can imagine, these trends send a chilling message to young researchers who were drawn to biomedical research during the doubling period. After years of steady support for biomedical research over the last decade, many young people were drawn into research labs, but now Federal funds are declining. As the funding declines, so too does the opportunity for young researchers. NIH is trying to address this issue with its Pathways to Independence program. This program would provide up to 5 years of support for scientists just beginning their research careers. We would encourage the committee to fully-fund the Pathways to Independence program in fiscal year 2008.

The Endocrine Society recommends that the National Institutes of Health receive $30.8 billion in fiscal year 2008. This increase of 6.7 percent will set NIH, and the researchers who depend on it for funding, on a 3-year track to recoup the losses caused by biomedical research inflation over the last 4 years.

While researchers will never guarantee cures from ongoing research, we do know that without adequate sustained Federal support the chances for breakthroughs are diminished. In fact very significant advances have been made; for example for the first time in our history death rates from cancer have started to decrease, which can be attributed to NIH funded research in previous decades. We ask that Congress stop the boom and bust funding cycles that have plagued NIH over the last 10 years and commit to a steady funding stream to keep the research of today on track to become the breakthroughs of tomorrow.

ADDENDUM A—MEN'S HEALTH—TONS OF USEFUL STUFF

THE BATTLE FOR YOUR HEALTH

As American soldiers fight terrorists overseas, another war is being lost at home: The one to cure disease and, ultimately, save your life.

Boston, MA.—The last thing Alan Schneyer, Ph.D., expected to find when he began manipulating the reproductive genes in mice was a possible cure for diabetes.

"We made these mice and thought they would be infertile, but they weren't," Schneyer tells me as we pace his sparse laboratory at Massachusetts General Hospital. "So we started looking at their other organs. Turns out, they have improved glucose tolerance and very little visceral fat. Boom! I thought, This is great. We can address a real disease."

Schneyer eyes the empty beakers, vials, and tubes, the dust beginning to gather on microscopes, tissue-holding minifridges, computer terminals. The mood is so grim I expect Edgar Allan Poe's valet to walk through the door. "Then we lost our grant. Normally you'd see six people working here. Now my fellows are gone. My technician is leaving at the end of the month. My associate works for someone else now." He looks at me and musters a half-hearted smile. "I'm out in April," he says.

Schneyer's is a familiar tale. Since a doubling of the National Institutes of Health (NIH) budget between 1997 and 2003—an increase, incidentally, that contributed to the discovery and mapping of the human genome—the agency's budget has flatlined at about $28 billion for the past 3 years, outpaced by 9 percent inflation. When funds were cut by $33 million in 2006, it marked the first time in more than 35 years that NIH appropriations actually decreased.

Schneyer, 52, is quick to note that his discovery might well have "come to a dead end." Still, with 73 million Americans either having diabetes or a high risk of it—and with the number of overweight children in America at 9 million and growing—it's frustrating to let any possible cure go unexplored. "We'll never know where my

research might have led, will we?" Schneyer says, adding that since the NIH started issuing research grants after World War II, "a good 75 percent" of discovered cures have come from government-funded programs like his—and not from drug-company labs. In fact, thanks to NIH-sanctioned research, we know that exercise promotes weight loss, high LDL cholesterol raises the risk of heart disease, chemotherapy kills cancer, and fluoride prevents tooth decay.

Now, Schneyer is left hoping for a last-minute reprieve. This is unlikely. The 2007 budget for the Department of Health and Human Services, under which both the CDC and NIH operate, shows that grant monies for "Preventive Health and Health Services," "Public Health Improvement," and "Children's Hospitals" have been slashed by almost $375 million. "Bioterrorism" funding, on the other hand, has increased to $1.7 billion, up nearly tenfold in the past 5 years.

Like many medical researchers and physicians, Schneyer is angry with the Federal Government for shifting funds away from medical research and—"ostensibly," he says—into the war on terror at home and abroad. It has not gone unnoticed in America's medical community that as Federal grants stagnate or plunge, Washington politicos have, as of January, authorized more than $315 billion—that's $6.5 billion a month, $9 million an hour—to be spent in Iraq alone.

Then there are the seemingly insane items, recently reported by Newsday, in the Department of Homeland Security's budget: $18,000 to equip the Santa Clara, California, bomb squad with Segways; $30,000 to ensure a defibrillator is on hand for every Lake County, Tennessee, high-school basketball game; $500,000 worth of security gear to the town of North Pole, Alaska, population 1,778; Kevlar vests for the police dogs of Columbus, Ohio; the list goes on.

Sitting in Schneyer's office, I motion toward the window. What would happen, I ask, if I walked into the tavern across the street and queried the first five patrons about whether Federal dollars would be better spent on body armor for soldiers, or research on the reproductive organs of mice?

"You're not framing the question correctly," he says. "Statistics indicate that two of the five men in the bar have already developed some form of cardiovascular disease. So you ask them how they feel about genetic research that might find a cure, so that their children don't die of heart disease.

"It's easy to ask why we're funding work on a mouse organ, or on a worm. Well, you take that same gene and look for a similar one in a human, and suddenly, 'Hey, it's responsible for diabetes!' It's not a question of a cure for diabetes versus body armor for soldiers. This isn't about medical science versus armor or, for that matter, school lunches, fire departments, or red lights at dangerous intersections. A smart government can fund it all."

"Where will that money come from?" I ask.

Schneyer's cheeks burn as he speaks of cost overruns in Iraq and the recent tax cuts. "Every medical-research experiment that is not done is an opportunity lost," he says. "You don't know which one is going to bring the eureka moment."

He smiles, rueful. "Our country—the president, Congress—has to decide if it's worth doing research that will lead to better health in the long run and lower costs for the next generation of Americans.

"The catchall excuse for the funding cuts is the war on terror. But al-Qaeda could attack New York, and that wouldn't reduce the number of children with diabetes in Chicago and Miami and Detroit. Researchers who are on the verge of finding cures for Alzheimer's, Parkinson's, all kinds of cancers . . . their funding is all being cut.

"That's a strange way to protect America."

PREPARED STATEMENT OF THE FAIR ALLOCATIONS IN RESEARCH FOUNDATION

The death rate in our country from AIDS has plummeted as evidenced in 2006 by the 99 percent drop in California's newly infected AIDS patients[1] from just under 10,000 to 130 (as of 2/28/07) and the 93 percent drop to 100 in all of Illinois's HIV/AIDS patients for 2004.[2] In addition, we respectfully bring to Chairman Byrd's attention that this great success includes West Virginia where AIDS deaths have dropped to 23 for their latest reporting period (2005).[3] This success against AIDS

[1] http://www.dhs.ca.gov/aids/Statistics/pdf/Stats2007/Feb07AIDSMerged.pdf Page 2, CA Office of AIDS—patients infected in 2006 who died in 2006.

[2] http://fairfoundation.org/states/illinois_AIDS_deaths.htm

[3] WVA Dept of Health, Tom Light, 304–558–1748 or http://fairfoundation.org/states/west_virginia.htm

is being repeated throughout America, yet AIDS still receives 10 percent of the entire National Institutes of Health (NIH) disease research budget.

Such exorbitant funding for AIDS has resulted in unfair allocations for all non-AIDS diseases, including the sixteen[4] that kill a million more Americans than AIDS annually. For example, cardiovascular disease kills almost a million Americans compared to 16,316 (2005)[5] for AIDS, yet the NIH is spending only $40 on each CVD patient versus $3,052 on each AIDS patient in research.[6] Diabetes kills more citizens than AIDS and breast cancer combined, yet only $50 is spent on each diabetic in research. More AIDS patients are now dying of hepatitis C than they are of AIDS,[7] and hepatitis C (HCV) affects 4–5 times as many as AIDS yet only $25 is allocated for each HCV patient.

Disease	2005 NIH research [Dollars in billions]	Deaths per disease	Dollars per patient death	Dollars per patient
HIV/AIDS	$2.930	16,316	$178,046	$3,052
Cardiovascular Dis.	2.300	930,000	2,523	40
Diabetes	1.000	73,965	14,236	50
Alzheimer's Dis.	.642	63,343	10,182	143
Prostate Cancer	.373	27,350	13,638	192
Parkinson's Dis.	.205	17,898	12,403	148
Hepatitis C	.121	12,000	10,166	25
Hepatitis B	.036	5,000	6,600	32
COPD	.066	126,128	500	5
West Nile Virus	.063	161	390,304	14,932

Regardless if the funding comparison is measured utilizing "allocation per patient," "allocation per death" or "total allocation" per disease, the great success of AIDS researchers has resulted in funding for AIDS now being disproportionate and inequitable.

In addition, hundreds of millions of dollars are raised for AIDS by celebrities and non-profit organizations (amfAR, etc.) while similar efforts do not exist for many other diseases. With the recent $37 billion stock pledge by Warren Buffett to the $29 billion Bill and Melinda Gates Foundation and Mr. Buffett's support for the Gates's bias in funding to combat HIV disease, the favoritism afforded this disease has reached excessive proportions. Indeed, Melinda Gates has stated that her fondest goal is a vaccine for HIV disease and to date the total funding by the Gates's Foundation for all HIV programs is $6.5 billion. It is anticipated that much more of the Gates Foundation will go towards combating HIV disease in the future.

When one reflects that the total NIH bio-medical research budget for every disease known to man is only $28.4 billion and 10 percent of that also goes to HIV research, one can only be dismayed at the continual favoritism afforded this illness.

The NIH has responded to The FAIR Foundation's requests to cease the favoritism afforded HIV/AIDS and to reallocate some of the present AIDS dollars to other diseases by referencing global AIDS and the fact that AIDS is communicable and destructive to the young.[8]

What are the solutions for global AIDS—more research? No, the answers to global AIDS are the same that have dropped the death rate throughout America, and they have been expressed by Presidents Clinton, Bush and the Director of the NIAID, Dr. Fauci, namely: preventive education, the drugs which converted AIDS from an acute illness into a chronic illness (HAART or Highly Active Anti-retroviral Therapy) and setting up health infrastructures.

Indeed, Dr. Fauci himself recently admitted the great success in HIV research when he stated on CNN, ". . . the scientific advancements that have been made in HIV [research] are breathtaking [with] highly effective drugs to suppress HIV to the point where what was a death sentence in the early eighties to now having patients who look and feel well, who are leading very productive, very gratifying lives . . ."

Regarding the "communicable" nature of AIDS, Congress must force realization upon the NIH that simply because an illness is "infectious" does not warrant disproportionate research funding. Patients suffering from non-communicable illnesses such as prostate disease, Alzheimer's disease, etc. should not be discriminated

[4] http://www.fairfoundation.org/thesixteen.htm
[5] http://fairfoundation.org/CDC_AIDS_death_estimates_2001-2005.pdf
[6] http://www.fairfoundation.org/factslinks.htm
[7] http://fairfoundation.org/specter_letter_hcv_in_aids_pts.pdf
[8] http://www.fairfoundation.org/nihletter.htm

against because they cannot transmit their disease to others or because its etiology is congenital or acquired by environmental causes.

In America's youth, the CDC's 2005 report States seven deaths in patients age <13, 63 under age of 19 and 677 deaths under age 30. The estimated deaths from SIDS each year is 3,000. Clearly, HIV disease is not a major factor killing our youth.

An unrecognized factor negatively impacting all non-AIDS diseases is the "compounding effect" of present NIH policy. The present funding total of each disease may be viewed as their "principal balance" for this analogy. If the present effort by 100 Members of the House to increase NIH funding by 6.7 percent is successful, the increase in AIDS funding will be approximately $194 million whereas Alzheimer's disease will receive only $43 million and Chronic Obstructive Pulmonary Disease (COPD) $4.4 million even though those two diseases kill, respectively, three and nine times more Americans than AIDS. Each year the additional increases in the "principle balance," or total funding, results in the "compounding interest effect" that increases the disproportionate funding for AIDS. Consequently, the gap in funding between AIDS and all other diseases grows even larger. Supplying greater funding to the NIH without redistribution of present inequities is unfair for non-AIDS illnesses.

The issue of AIDS favoritism is rapidly becoming a political issue. Before billions more dollars are spent on yet another preventive measure (HIV vaccine), we urge you to publicly call for a partial redistribution of the HIV excess funding to other illnesses that do not presently have effective treatments, including the 16 maladies [iii] that are killing a million more Americans than HIV disease annually.

Indeed, with the budgetary limitations resulting from our government's commitments, including supporting the war in Iraq and restoring the areas ravaged by hurricanes Katrina and Rita, necessary increases for bio-medical research funding have been non-existent. As with the common citizen whose budget is pinched, it is appropriate to reallocate existing funds, in this case some of HIV/AIDS funding to other illnesses.

Sixty-one million voters with cardiovascular disease, 21 million diabetics and millions of other constituents with non-AIDS illnesses will applaud your courageous declaration, while approximately 1 million with HIV/AIDS may be dismayed at such an announcement.

The FAIR Foundation (FAIR is an acronym for "Fair Allocations In Research) is a national organization representing thousands of members and supporters—concerned citizens—who want the success of AIDS advocates and AIDS researchers recognized with a corresponding change in the allocation priorities of the NIH with our taxpayer dollars that fund bio-medical research. Gay members of our country are present on our Board, including Ray Hill, who used to be one of this country's most strident HIV activists. Because of their great success, Ray, who has been named Houston's gay hero by that community 7 years in a row, now advocates for hepatitis C.

On behalf of our national membership we are respectfully requesting that a portion of AIDS research allocations be reevaluated and redistributed now that the existing medications and extensive prevention programs for this illness have significantly mitigated its threat.

PREPARED STATEMENT OF THE FAMILIES USA GLOBAL HEALTH INITIATIVE'S

Families USA Global Health Initiative appreciates the opportunity to submit this written testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education concerning Federal funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). Our statement today speaks to the important role that NIH and CDC play in protecting and improving health in the United States and the world.

For more than 20 years, Families USA has advocated for changes in U.S. policies to increase access to affordable health care, especially for low-income individuals. The Global Health Initiative was launched in 2006 to advocate for increased U.S. investment in research and development of medical interventions targeting infectious diseases that disproportionately affect populations in low-income countries ("global health" research).

The government must step in to support global health research and development because there is little private industry interest in filling the current void, an overwhelming human need, a long history of underfunding, and it's in our Nation's self-interest to do so.

OVERWHELMING HUMAN NEED AND HISTORIC UNDERFUNDING

Research addressing global health crises has been historically underfunded. More than 500 million people contract malaria each year. NIH spends just 0.3 percent of its budget on malaria research. CDC's malaria extramural research program was cut.

Nine million people develop active tuberculosis (TB) each year, 2 million die from TB, and extensively drug-resistant strains poses a substantial domestic and worldwide health threat. NIH spends just 0.5 percent of its budget on tuberculosis. The Global Health section of CDC's Proposed fiscal year 2008 Budget, submitted to the Congress, contains no mention of work on TB.

More than 1 billion people living in tropical and subtropical climates around the world are stricken with devastating, debilitating parasitic diseases that receive so little research funding that the World Health Organization and others in the medical community refers to these conditions as "neglected" tropical diseases.

Almost 40 million people around the world are currently infected with HIV. Only 2.5 percent of NIH's budget is devoted to research on preventative medical interventions, including vaccines and microbicides. CDC's global HIV/AIDS activities are limited primarily to support of the President's Emergency Plan for AIDS Relief (PEPFAR). Although PEPFAR is expanding access to existing HIV/AIDS treatments for many in need, PEPFAR alone will not curb the global AIDS pandemic. More than 4 million people become newly infected each year and existing treatments are becoming increasingly ineffective due to drug resistance. Vaccines and microbicides, along with improved treatments, are needed to curtail the global AIDS pandemic.

OUR NATIONAL INTEREST

When NIH and CDC are insufficiently funded, as has consistently been the case in recent years, they are forced to fight global health crises with one hand tied behind their back. This has serious health, economic, and political implications—not just internationally, but also domestically. There are also compelling diplomatic and humanitarian reasons for funding NIH's and CDC's global health work.

First, we have a national health interest in ensuring that NIH and CDC have all the resources that they need. Diseases can easily spread across international borders; epidemics abroad, including lethal strains of extremely drug-resistant TB, can lead to cases here at home. Americans who travel abroad, including our troops, are also at risk of contracting infectious diseases that are endemic in other countries.

Second, we have a national economic interest in providing NIH and CDC with all the resources that they require. In regions where HIV/AIDS, malaria, and TB prevalence are greatest, countries' entire workforces suffer from substantially reduced productivity and economic growth is hindered. With globalization, countries' economic health is intertwined. The economic toll of diseases hurts world economic growth and limits trade, and it reduces markets for U.S. goods.

Third, we have a national political interest in giving NIH and CDC the funding needed to combat infectious diseases with a massive global burden. In areas of the world where the infectious disease burden is greatest, enormous numbers of people are getting sick and dying. Populations are being decimated. The social structures of entire countries has been unraveling, paving the way for political unrest and the undermining of democracy in entire regions of the world.

Fourth, we have a national diplomatic interest, and there are strong humanitarian reasons as well, for funding NIH's and CDC's work in preventing and controlling diseases that burden millions of people around the world. As the wealthiest country on earth, we have the means to advance health and alleviate human suffering. Using our wealth to improve global health improves America's image and serves as a very effective foreign policy tool.

FUNDING RECOMMENDATIONS

All NIH Institutes and Centers

Families USA Global Health Initiative recommends 6.7 percent annual increases to NIH's total budget from fiscal year 2008 to fiscal year 2010 (including 3.7 percent adjustments each year for annual rises in biomedical inflation, plus an additional 3.0 percent each year to start to correct for the failure in recent years to keep up with inflation).

In recent years, NIH funding has fallen further and further behind the rising costs of biomedical research. This means that less research gets funded and medical progress is delayed. Only 16.7 percent of new grant applications were funded in 2006—an 83 percent failure rate. Many scientists are sitting on the sidelines, unable to develop promising ideas that could lead to an effective AIDS vaccine, im-

proved tuberculosis treatments, and other medical interventions that could improve the lives of millions worldwide.

A 6.7 percent annual increase for all NIH Institutes and Centers, for each year from fiscal year 2008 to fiscal year 2010, would adjust NIH funding for anticipated annual rises in inflation and add a modest 3.0 percent rise to help make up for losses in inflation-adjusted funding experienced by all of NIH in recent years.

Additional Increase for NIH Global Health Programs

Families USA Global Health Initiative recommends that Congress begin to rectify, over a 7 year period, historic underfunding of global health programs by increasing the National Institute of Allergy and Infectious Diseases and Fogarty International Center budgets annually by 2.9 percent for each year from fiscal year 2008 to fiscal year 2014.

This increased annual 2.9 percent investment in global health would be apart from, and in addition to, the 6.7 percent increases over the next 3 years for all NIH Institutes and Centers, and annual inflationary adjustments provided thereafter.

The National Institute of Allergy and Infectious Diseases (NIAID) has taken a leadership role in the bulk of global health research and development activities undertaken at NIH. Robust funding for NIAID is essential for addressing infectious disease crises around the globe and in the United States.

The John E. Fogarty International Center (FIC) also plays a crucial role in addressing global health challenges by facilitating collaboration between United States and international researchers through its international training and global health research capacity building programs. FIC's programs facilitate the development of medical discoveries worldwide.

Malaria and tuberculosis research, combined, comprise less than 1 percent of the National Institutes of Health's total budget. Last year, cuts to the NIH budget resulted in funding being completely cut to 11 HIV/AIDS clinical trials in the United States. FIC's fiscal year 2006 funding constituted a miniscule 0.23 percent of NIH's total budget.

A 2.9 percent additional increase for NIAID and FIC, for each year from fiscal year 2008 to fiscal year 2014—apart from and on top of the 6.7 percent annual increases for all of NIH from fiscal year 2008 to fiscal year 2010, and inflationary increases thereafter—is badly needed to make up for historic underfunding for global health research and to achieve progress in the development of new interventions for diseases devastating millions worldwide.

Centers for Disease Control and Prevention

Families USA Global Health Initiative supports the CDC Coalition's recommendation of increasing CDC's total budget to $10.7 billion in fiscal year 2008 and further recommends that Congress appropriate $512 million in fiscal year 2008 for CDC's global health work (4.8 percent of CDC's $10.7 billion total budget).

CDC's global health programs are vitally important to protecting Americans and people around the world from disease. Cuts to CDC's budget undermine both the United States and the global public health infrastructures that are crucial to rapidly responding to new disease outbreaks and combating existing global pandemics.

Yet, some of CDC's global health programs have been flat-funded for years; other global health programs can no longer carry out their critical mission due to limited funds. For instance, CDC currently has no appropriated budget for global tuberculosis activities and the malaria extramural research program had to be phased out due to insufficient funds. Moreover, failure to adequately fund CDC's global health work has broader implications for the success of other United States funded initiatives, including PEPFAR and the President's Malaria Initiative (PMI).

At a global health funding level of $512 million in fiscal year 2008, CDC would be able to support crucial global disease surveillance and control programs; perform research to improve existing medical interventions; and develop new interventions for diseases where interventions are currently lacking.

CALL FOR ACTION

Americans across the country, and people from around the world, are looking to NIH and CDC for new medical advances that will lead to a healthier tomorrow. Shortchanging NIH and CDC places America's—and the world's—health at risk. We urge the subcommittee to fund NIH and CDC at the levels specified above.

For additional information, please contact Janet Goldberg at 202–628–3030 or jgoldberg@familiesusa.org.

PREPARED STATEMENT OF FIGHT CRIME: INVEST IN KIDS

Mr. Chairman and members of the subcommittee: Thank you for the opportunity to submit this written testimony. My name is Dennis Conard and I am the Sheriff in Scott County, IA (Davenport), where I have served in law enforcement for almost 35 years. I am also a graduate of the FBI National Academy, the National Sheriffs' Institute and the Iowa Law Enforcement Academy and a member of the National Sheriffs' Association. I am also one of the 3,000 police chiefs, sheriffs, prosecutors, and victims of violence of FIGHT CRIME: INVEST IN KIDS—a non-profit anti-crime organization that has come together to take a hard-nosed look at the research about what really works to keep kids from becoming criminals.

The law enforcement leaders of FIGHT CRIME: INVEST IN KIDS know that dangerous criminals must be prosecuted and put behind bars. But we also know better than anyone that we cannot arrest and imprison our way out of the crime problem. No prison can bring back a murdered wife, mother or child, and no punishment can undo a crime victim's anguish. Fortunately, research—and our experiences on the front lines in the fight against crime—show that targeted investments can help kids get a good start in life. We could be saving thousands of lives and preventing thousands of crimes by increasing our investments in cost-effective, proven crime-prevention programs.

Four types of proven crime-prevention approaches are outlined in FIGHT CRIME: INVEST IN KIDS' "School and Youth Violence Prevention Plan":

—quality early childhood education;
—child abuse and neglect prevention programs;
—quality after-school; and
—prevention and intervention programs to get troubled kids back on track.

As you know, the first three areas fall within your Appropriations Subcommittee's jurisdiction. Since both the research and my years of experience on the front lines in the fight against crime show that these approaches help stop crime in its tracks, I urge you to increase our Nation's investments in these proven strategies for saving lives and taxpayer dollars.

EARLY CHILDHOOD EDUCATION AND CARE

By now, most people know that Head Start and quality child care help close the achievement gap. But few people are aware of the amazing impact of early education programs on later criminality. A Journal of the American Medical Association-published study of Chicago's government-funded Child Parent Centers, which have served more than 100,000 3- and 4-year-olds, showed that children who did not participate in the program were 67 percent more likely to have been retained a grade in school and 71 percent more likely to have been placed in special education. But equally impressive, the study showed that kids who did not participate were 70 percent more likely to be arrested for a violent crime by age 18. Similarly, at-risk kids who were left out of the high-quality High/Scope Perry preschool program were five times more likely to be chronic offenders (more than four arrests) by age 27 than those who participated.

By improving outcomes for kids, quality early childhood education also saves money. The High/Scope Perry Preschool program saved $17 for every $1 spent. An analysis by Arthur Rolnick of the Federal Reserve Bank of Minneapolis shows that the program's annual return on investment is 16 percent after adjusting for inflation. Seventy-five percent of that return goes to taxpayers in the form of decreased special education expenditures, crime costs and welfare payments. In comparison, the long-term average return on U.S. stocks is 7 percent after adjusting for inflation. Thus, an initial investment of $1,000 in a program like Perry Preschool is likely to return more than $19,000 in 20 years, while the same initial investment in the stock market is likely to return less than $4,000.

However, due to lack of State and Federal financial resources, there remains significant unmet need with only about half of eligible poor kids nationally served by Head Start and less than 5 percent of eligible infants and toddlers in Early Head Start. Only one in seven kids in eligible, low-income families receives help from the Child Care and Development Block Grant to pay for the quality child care that can help ensure they are on the path toward being a productive, taxpaying adult rather than a burden on taxpayers and part of our criminal justice system. Funding has been stagnant over the last several years. By the administration's own estimates, 150,000 fewer children receive child care assistance now than in 2000.

I urge Congress to:

—Increase funding for Head Start by at least $750 million to restore funding for services to kids to the fiscal year 2002 level.

—Increase discretionary funding for the Child Care and Development Block Grant by $720 million to restore funding for services to kids to the fiscal year 2002 level.

This is the first step toward meeting the unmet need and further strengthening the quality of early childhood care and education.

CHILD ABUSE AND NEGLECT PREVENTION PROGRAMS

The best available research indicates that, based on confirmed cases of abuse and neglect in just 1 year, an additional 35,000 violent criminals and more than 250 murderers will emerge as adults who would never have become violent criminals if not for the abuse or neglect they endured as kids.

Fortunately, quality, voluntary in-home parent coaching can help stop this cycle of violence. Voluntary, in-home parent coaching (or "home visiting") programs help new parents get the information, skills and support they need to be better parents and promote healthy child development. One program, the Nurse Family Partnership (NFP), has been shown to cut child abuse and neglect of at-risk children in half and reduce kids' and moms' later arrests by about 60 percent—saving an average of $28,000 (net) for each family in the program.

As a first step toward meeting this need, I urge Congress to provide:

—$100 million to expand and improve in-home coaching programs like those that would be supported under the Education Begins as Home Act (S. 667), which is expected to be enacted this year.

—$545 million (the combined mandatory and discretionary authorized level) for the Promoting Safe and Stable Families program to help communities run in-home parent coaching programs, parenting-education programs, family-strengthening services for troubled families, adoption services, and other child abuse and neglect prevention programs.

—$200 million (the authorized level) for the Child Abuse Prevention and Treatment Act to help improve State child protection services and community-based prevention services.

—$1.7 billion (rejecting the administration's proposed cuts) for the Social Services Block Grant (SSBG), the Federal Government's single largest support for child welfare services.

AFTER-SCHOOL PROGRAMS

In the hour after the school bell rings, violent juvenile crime soars and the prime time for juvenile crime begins. The peak hours for such crime are from 3:00 p.m. to 6:00 p.m. These are also the hours when children are most likely to become victims of crime, be in an automobile accident, smoke, drink alcohol, or use drugs. After-school programs that connect children to caring adults and provide constructive activities during these critical hours are among our most powerful tools for preventing crime. For example, a study compared five housing projects without Boys & Girls Clubs to five receiving new clubs. At the beginning, drug activity and vandalism were the same. But by the time the study ended, the projects without the programs had 50 percent more vandalism and scored 37 percent worse on drug activity. Despite these proven benefits, more than 14 million children nationwide still lack adult supervision after school.

The 21st Century Community Learning Centers program (21st CCLC) awards grants to communities to establish after-school programs that provide constructive activities for kids. Since being funded at $1 billion in fiscal year 2002, there have been no real funding increases for 21st CCLC. In fiscal year 2007, the program received $981 million—far below the program's $2.5 billion authorization under the No Child Left Behind Act. I urge Congress to:

—Substantially increase funding for the 21st Century Community Learning Centers to support and expand after-school programs that offer kids constructive activities during the peak hours of violent juvenile crime, 3:00 pm to 6:00 pm. Also, I urge you to authorize at least an additional $500 million for programs for at-risk middle and high school students who now experience the greatest unmet need—and are at greatest risk of perpetrating or being victims of crime.

LAW ENFORCEMENT LEADERS ARE UNITED

The members of FIGHT CRIME: INVEST IN KIDS, along with major national law enforcement associations, have adopted forceful calls for public officials to ensure access to quality early care and education, provide adequate funding to prevent child abuse and neglect, and ensure access to after-school programs. If we do not invest in research-proven crime-prevention programs for America's most vulnerable kids, many of them will grow up to become America's most wanted adults. By failing

to adequately invest in proven crime-prevention strategies, Congress is not only failing to promote the well-being of millions of kids but is also permitting the cultivation of criminals—jeopardizing the safety of all Americans for years to come.

Thank you for this opportunity to present our views on how your subcommittee can help to reduce crime and make us all safer.

PREPARED STATEMENT OF THE FOSTER GRANDPARENT PROGRAM

Mr. Chairman and members of the subcommittee, thank you for the opportunity to submit this testimony in support of fiscal year 2008 funding for the Foster Grandparent Program (FGP), the oldest and largest of the three programs known collectively as the National Senior Volunteer Corps, which are authorized by Title II of the Domestic Volunteer Service Act (DVSA) of 1973, as amended and administered by the Corporation for National and Community Service (CNS). NAFGPD is a membership-supported professional organization whose roster includes the majority of more than 350 directors, who administer Foster Grandparent Programs nationwide, as well as local sponsoring agencies and others who value and support the work of FGP.

Mr. Chairman, I would like to begin by thanking you and the distinguished members of the subcommittee for your steadfast support of the Foster Grandparent Program. No matter what the circumstances, this subcommittee has always been there to protect the integrity and mission of our programs. Our volunteers and the children they serve across the country are the beneficiaries of your commitment to FGP, and for that we thank you. I also want to acknowledge your outstanding staff for their tireless work and very difficult job they have to "make the numbers fit"—an increasingly difficult task in this budget environment.

ADMINISTRATION'S REQUEST FOR FGP

Although the number of older people in America eligible to serve as Foster Grandparent volunteers is increasing by leaps and bounds as the "Baby Boomer" cohort ages, we were extremely disappointed to learn that—instead of seeking an increase for FGP to enable FGP to engage more low-income seniors in service—the administration has proposed slashing funding for FGP by $13.387 million—a 12.1 percent cut.

IMPACT OF THE ADMINSTRATION'S PROPOSED FUNDING CUT

FGP is the only program in existence today that actively seeks out, trains, enables, places and supports the elderly poor in contributing to their communities by changing the lives of children who desperately need one-on-one attention. If enacted, this request will have a devastating effect on FGP programs nationwide:

—3,150 low-income Foster Grandparent volunteers—over 10 percent of the current volunteer complement—will be cut permanently, slashing the total number of Foster Grandparent volunteers from 30,550 to 27,400. This will happen at a time when the number of FGP volunteers has not increased appreciably in 10 years!

—Local communities will lose over 3.3 million hours of volunteer service annually.

—Approximately 35,000 fewer children with special needs will receive the critical services provided by Foster Grandparents.

—FGP will permanently lose 3,000 Volunteer Service Years (VSYs, or volunteer "slots"). For each volunteer "slot" that is cut from a Foster Grandparent Program, that program will lose approximately $4,500 from its Federal grant. In addition, at least $500 in valuable non-federal resources contributed by communities will also be lost for every volunteer position that is eliminated.

—Low-income Baby Boomers will be excluded from serving as Foster Grandparents, because there will be no funds available to hire and place new volunteers as they reach the age of 60. According to the administration on Aging, there are currently 6,000,000 low-income seniors eligible for FGP; in 20 years, there will be 13,000,000!

This cut will take FGP back 7 years, to a funding level that is more than $1 million less than its funding level in fiscal year 2001. In addition, the cut will take effect at a time when the average Federal grant for FGP has increased a miniscule $2,898—or .875 percent (seven-eighths of 1 percent!)—since fiscal year 2003. After 4 years of flat funding, this 12.1 percent cut will not only cut volunteer numbers, it will also dig deeply into funds needed to sustain quality staff and quality programs. As a result, some FGPs may actually close, and local sponsoring agencies—

short of funds themselves and unable to contribute the funds needed to make up the cut—may simply relinquish their sponsorship.

The Corporation for National and Community Service's Budget Justification states that this cut can be absorbed merely through volunteer attrition. The reality is that the majority of FGPs nationwide will be forced to cut precious volunteers from their volunteer rosters. Whether a volunteer leaves through attrition or because there is no funding for his/her position, the fact is that this budget proposal will result in 3,150 fewer low income elders serving as Foster Grandparents.

NAFGPD respectfully requests three things of the subcommittee:

(1) to provide $115.937 million for the Foster Grandparent Program in fiscal year 2008, an increase of $5.000 million over the fiscal year 2006 and fiscal year 2007 levels of funding for the program and an $18.387 million increase over the administration's fiscal year 2008 Budget Request for FGP. This critical funding will ensure the continued viability of the Foster Grandparent Program, and allow for important expansion of this unique program. Specifically, this proposal would fund a 3 percent cost of living increase for every Foster Grandparent Program as well as expansion grants to existing programs that would add 370 new low-income senior volunteers to serve 3000 additional children;

(2) to maintain current appropriations statutory language that prohibits CNCS from using funds in the bill to pay non-taxable stipend to volunteers whose incomes exceed 125 percent of the national poverty level. Congress has repeatedly over the last 7 years re-affirmed that the non-taxable stipend must be reserved for low-income volunteers. We ask that you again protect the mission of the Foster Grandparent and Senior Companion Programs—to enable low-income older people to serve their communities—by maintaining this important statutory language.

(3) to oppose administration proposals that would consolidate National and Community Service Act and DVSA accounts and set aside provisions of section 412 of the DVSA as they apply to the RSVP program (Title II, Part A), and, instead, direct that the changes proposed shall not be implemented prior to passage of a bill by the authorizing committees of jurisdiction specifying such changes.

FGP: AN OVERVIEW

Established in 1965, the Foster Grandparent Program was the first federally funded, organized program to engage older volunteers in significant service to others. It remains today the only volunteer program in existence that enables seniors living on very low incomes to serve as community volunteers by providing a small non-taxable stipend that allows volunteers to serve at little or no cost to themselves. From the 20 original programs based totally in institutions for children with severe mental and physical disabilities, FGP now comprises nearly 350 programs in every State and the District of Columbia, Puerto Rico, and the Virgin Islands. These programs are now primarily in community-based child caring agencies or organizations—where most special needs children can be found today—and are administered locally through a non-profit organization or agency and Advisory Council comprised of community citizens dedicated to FGP and its mission. FGP represents the best in Federal partnerships with local communities, with Federal dollars flowing directly to local sponsoring agencies, which in turn determine how the funds are used. Through this partnership and the flexibility of the program, FGP is able to meet the immediate needs of the local communities. This was demonstrated by Foster Grandparent Programs in communities that were impacted by the influx of Hurricane Katrina evacuees. Foster Grandparents rallied to provide services to children in shelters, child care centers, and schools.

FGP: THE VOLUNTEERS

There are currently 30,500 Foster Grandparent volunteers who give 31 million hours annually to more than 264,000 children, including 6,300 children of prisoners through 10,200 local agencies. FGP is a versatile, dynamic, and uniquely multi-purpose program. The program gives Americans 60 years of age or older who are living on incomes at or less than 125 percent of the poverty level the opportunity to serve 15 to 40 hours every week and use the talents, skills and wisdom they have accumulated over a lifetime to give back to the communities which nurtured them throughout their lives. FGP provides intensive pre-service orientation and at least 48 hours of ongoing training every year to keep volunteers current and informed on how to work with children who have special needs.

FGP: THE CHILDREN

Through our volunteers, FGP also provides person-to-person service to children and youth under the age of 21 who have special or exceptional needs, many of whom

face serious, often life-threatening challenges. The Foster Grandparent is very often the only person in a child's life who is there every day, who accepts the child, encourages him no matter how many mistakes the child makes, and focuses on the child's successes.

Special needs of children served by Foster Grandparents include AIDS or addiction to crack or other drugs; abuse or neglect; physical, mental, or learning disabilities; speech, or other sensory disabilities; incarceration and terminal illness. Of the children served, 7 percent are abused or neglected, 25 percent have learning disabilities, and 10 percent have developmental delays. FGP focuses its resources in areas where they will have the most impact: early intervention services and literacy activities. Nationally, 90 percent of the children served by Foster Grandparents are under the age of 12, with 39 percent of these children age 5 or under. Foster Grandparents work intensively with these very young children to address their problems at as early an age as possible, before they enter school. Nearly one-half of FGP volunteers serve nearly 12 million hours annually addressing literacy and emergent-literacy problems with special needs children.

Activities of the FGP volunteers with their assigned children include teaching parenting skills to teen parents; providing physical and emotional support to babies abandoned in hospitals; helping children with developmental, speech, or physical disabilities develop self-help skills; reinforcing reading and mathematics skills; and giving guidance and serving as mentors to incarcerated or other youth.

FGP: THE VOLUNTEER SITES

The Foster Grandparent Program provides child-caring agencies and organizations offering services to special-needs children with a consistent, reliable, invaluable extra pair of hands 15 to 40 hours every week to assist in providing these services. Seventy-one percent of FGP volunteers serve in public and private schools as well as sites that provide early childhood pre-literacy services to very young children, including Head Start.

FGP: COST–EFFECTIVE SERVICE

Using the Independent Sector's 2005 valuation for 1 hour of volunteer service ($18.03/hour), the value of the service given by Foster Grandparents annually is over $503 million, and represents a 4-fold return on the Federal dollars invested in FGP. The annual Federal cost for one Foster Grandparent is $3,960—less than $4.00 per hour. FGP's fiscal year 2006 Federal allocation was matched with $37.4 million in non-federal donations from States and local communities in which Foster Grandparents volunteer. This represents a non-federal match of 34 percent, or $.34 for every $1.00 in Federal funds invested—well over the 10 percent local match required by law.

NAFGPD'S FISCAL YEAR 2008 BUDGET REQUEST

Given the dramatically expanding number of low-income seniors eligible to serve and the staggering number of troubled and challenged children in America today, we respectfully request that the subcommittee provide $115.937 million for the Foster Grandparent Program in fiscal year 2008, an increase of $5.000 million over fiscal year 2006 and fiscal year 2007 funding levels. This critical funding will ensure the continued viability of the Foster Grandparent program, and allow for an expansion of this important program. It will generate opportunities for approximately 370 new low-income senior volunteers to contribute 390,000 hours of service annually to nearly 3,000 additional children with special needs through Program of National Significance (PNS) grants to existing FGPs. The requested increase would be allocated for the following purposes, in order of priority: 1st: in accordance with the Domestic Volunteer Service Act (DVSA), designate one-third of the increase over the fiscal year 2006 and fiscal year 2007 level to fund Program of National Significance (PNS) expansion grants to allow existing FGP programs to expand the number of volunteers serving in areas of critical need as identified by Congress in the DVSA.2nd: use all remaining funds to award an administrative cost increase of at least 3 percent to each existing Foster Grandparent Program in order to maintain quality, enable recruitment and sustain the work already being done by programs. The last time FGPs in the field realized any increases at all to cover the increased costs of doing business—especially in the area of transportation costs—was in fiscal year 2005; that increase amounted to a very small .84 percent, when inflationary price increases have been averaging 2–3 percent annually.

We request that no funds be provided for Senior Demonstration, and that language that expressly prohibits the payment of a non-taxable stipend to individuals whose incomes exceed 125 percent of the national poverty level continue to be in-

cluded in the appropriations statute as it has been since fiscal year 2000. This important language protects the purpose of FGP: to enable low-income elders to serve their communities at little or no cost to themselves.

The message is clear: (1) the population of low-income seniors available to volunteer 15 to 40 hours every week is increasing; (2) communities need and want more Foster Grandparent volunteers and more Foster Grandparent Programs. The subcommittee's continued investment in FGP now will pay off in savings realized later, as more seniors stay healthy and independent through volunteer service, as communities save tax dollars, and as children with special needs are helped to become contributing members of society.

Mr. Chairman, in closing I would like to again thank you for the subcommittee's support and leadership for FGP over the years. NAFGPD believes that you and your colleagues in Congress appreciate what our low-income senior volunteers accomplish every day in communities across the country.

LETTER FROM THE FSH SOCIETY, INC.

JANUARY 24, 2007.

Senator TOM HARKIN,
Chairman, Subcommittee on Labor, HHS, Education and Related Agencies U.S. Senate, Washington, DC.

DEAR HON. TOM HARKIN: I request the opportunity to testify in writing or in person before your Subcommittee on Labor, Health and Human Services, Education and Related Agencies regarding the fiscal year 2008 appropriations to the National Institutes of Health (NIH) for research on FSH muscular dystrophy.

The FSH Society requests the opportunity to update your committee on the progress made by the NIH over the past several years in FSH muscular dystrophy. Despite a growth in funding from $7 million to $75 million between 1991 and 2007 for research in muscular dystrophy across all Federal agencies, funding for our dystrophy is still anemic. The NIH now has perhaps a half dozen grants for FSH Dystrophy out of some 200 grants for muscular dystrophy in the NIH portfolio. FSHD is the third most common disease of muscle.

The NIH still needs encouragement and funding to develop a comprehensive research portfolio for FSHD. We are most appreciative of your support in this area and for the gains made thus far. It has always been an honor to participate in the hearing process.

The FSH Society, Inc. and the tens of thousands of patients it represents hope you will enable us by affording us the opportunity to present testimony to your subcommittee. It is most important to speak this year and to provide constructive input on this issue.

Sincerely,

DANIEL PAUL PEREZ,
President & CEO, FSH Society, Inc.

PREPARED STATEMENT OF THE FRIENDS OF THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

The Friends of the Health Resources and Services Administration (HRSA) is an advocacy coalition of more than 100 national organizations, collectively representing millions of public health and health care professionals, academicians and consumers. Our member organizations strongly support the programs at HRSA designed to ensure access to health services for each person in the United States.

Through its programs in thousands of communities across the country, HRSA provides a health safety net for medically underserved individuals and families, including 45 million Americans who lack health insurance; 49 million Americans who live in neighborhoods where primary health care services are scarce; African American infants, whose infant mortality rate is more than double that of whites; and the estimated 850,000 to 950,000 people living with HIV/AIDS. Programs to support the underserved place HRSA on the front lines in responding to our Nation's racial/ethnic and rural/urban disparities in health status. HRSA funding goes where the need exists, in communities all over America. We support a growing trend in HRSA programs to increase flexibility of service delivery at the local level, necessary to tailor programs to the unique needs of America's many varied communities. The agency's overriding goal is to achieve 100 percent access to health care, with zero disparities. In the best professional judgment of the members of the Friends of HRSA, to re-

spond to this challenge, the agency will require an overall funding level of at least $7.5 billion for fiscal year 2008.

The Friends of HRSA are gravely concerned about the president's budget recommendation of devastating cuts for fiscal year 2008, including over 12 program eliminations. This is in addition to the programs that were eliminated in the fiscal year 2006 and 2007 budget cycles and other programs that received deep cuts in both years.

Through its many programs and initiatives, HRSA helps countless individuals live healthier, more productive lives. In the 21st century, rapid advances in research and technology promise unparalleled change in the Nation's health care delivery system. HRSA could be well positioned to meet these new challenges as it continues to provide needed health care to the Nation's most vulnerable citizens.

The Primary Care Bureau received a $207 million increase over the fiscal year 2007 current funding level, all of which is designated for the Community Health Centers adding 342 new or expanded health center service sites and bringing the number of patients served annually to 16.3 million. Community health centers, often in partnership with National Health Service Corps clinicians, form the backbone of the Nation's safety net. More than 4,000 of these sites across the Nation provide needed primary and preventive care to over 15 million poor and near-poor Americans. HRSA primary care centers include community health centers, migrant health centers, health care for the homeless programs, public housing primary care programs and school-based health centers. Health centers provide access to high-quality, family-oriented, culturally and linguistically competent primary care and preventive services, including mental and behavioral health, dental and support services. Nearly three-fourths of health center patients are uninsured or on Medicaid, approximately two-thirds are people of color, and more than 85 percent live below 200 percent of the poverty level. 2,700 clinicians in the National Health Service Corps deliver a significant portion of the primary care services provided at health centers. Corps members work in communities with a shortage of health professionals in exchange for scholarships and loan repayments. While recent growth in the health centers program has been substantial, a significant need remains in underserved communities across the country—we encourage the committee to continue its support of existing health centers and efforts to expand the reach and scope of health centers into new communities.

Health professions and nursing education programs, authorized under Titles VII and VIII of the Public Health Service Act, are essential components of America's health care safety net, filling the gaps in the health professions' supply not met by traditional market forces. Through loans, loan guarantees, scholarships to students, and grants and contracts to academic institutions and non-profit organizations, the Title VII and VIII health professions programs are the only Federal programs designed to train providers in interdisciplinary settings to meet the needs of special and underserved populations, as well as increase minority representation in the health care workforce. The programs provide support for the training of physicians, nurses, dentists, physician assistants, nurse practitioners, public health personnel, psychologists, and other allied health providers. The final budget for fiscal year 2006 included a 51.5 percent cut to Title VII; the $40 million increase in the recently enacted fiscal year 2007 joint funding resolution does not fully recover the funding lost as a result of this devastating cut. Moreover, the President's fiscal year 2008 budget proposes an additional 94.6 percent cut to Title VII and a 29.7 percent cut to Title VIII. We are concerned that cuts to the health professions programs will exacerbate existing provider shortages in rural, medically underserved, and federally designated health professions shortage areas and impede recruitment of underrepresented minorities and students of disadvantaged backgrounds into the health professions. Adequate funding for HRSA Health Professions Programs under Title VII and VIII will help to create a prepared national workforce by working to reverse projected nationwide shortages of physicians, nurses, pharmacists, and other professionals. We strongly encourage the subcommittee to restore funding to these vital Health Professions programs.

The Maternal and Child Health Block Grant is a source of flexible funding for States and territories to address their unique needs, and remains in great need of increased funding. The Title V Maternal and Child Health Block (MCH) Grant received a $31 million cut in the fiscal year 2006 budget and stagnant funding for fiscal year 2007. The President's budget for fiscal year 2008 proposed level funding for the block grant at the fiscal year 2006 level. Greater needs among pregnant women, infants, and children, particularly those with special health care needs present daunting challenges to the State maternal and child health programs. Furthermore, if programs like the Traumatic Brain Injury program, Universal Newborn Hearing Screening, and Emergency Medical Services for Children program are eliminated,

those costs will be borne by the MCH Block Grant. Of the nearly 4 million mothers who give birth annually, almost half receive some prenatal or postnatal service from a MCH-funded program. MCH programs increase immunizations and newborn screening, reduce infant mortality and developmentally handicapping conditions, prevent childhood accidents and injuries, and reduce adolescent pregnancy.

Research indicates that 50,000 individuals die as a result of Traumatic Brain Injury (TBI) each year in the United States and an additional 80,000 survive with residual long-term impairments. Today over 5.3 million Americans are living with a TBI-related disability. TBI can strike at anyone at any time—from falls, vehicle crashes, sports injuries, violence, and other causes. HRSA's Traumatic Brain Injury program makes grants to States to coordinate, expand and enhance service delivery systems in order to improve access to services and support for persons with TBI and their families. Despite increasing numbers of soldiers returning from war with head injuries, increasing numbers of children being identified as disabled due to head injuries, and the release of an Institute of Medicine Report stating the importance of the program to brain injury survivors and their families, the administration's fiscal year 2008 budget eliminates the TBI State Grant program. We encourage the subcommittee to restore funds that were cut from the TBI State Grant program. Individuals with traumatic brain injury have an array of protection and advocacy needs, including assistance with returning to work; finding a place to live; accessing needed supports and services, such as attendant care and assistive technology; and obtaining appropriate mental health, substance abuse, and rehabilitation services.

The Children's Health Act of 2000 authorized funding for grants and programs to improve state-based newborn screening. Newborn screening is a vital public health activity used to identify and treat genetic, metabolic, hormonal and functional conditions in newborns. Screening detects disorders in newborns that, if left untreated, can cause death, disability, mental retardation and other serious illnesses. Parents are often unaware that while nearly all babies born in the United States undergo newborn screening for genetic birth defects, the number and quality of these tests vary from State to State. The March of Dimes, the American Academy of Pediatrics and the American College of Medical Genetics recommend that at a minimum, every baby born in the United States be screened for a core group of 29 treatable conditions regardless of the State in which the infant is born. Currently, Federal support for State newborn screening activities is provided through the Maternal and Child Health Block Grant, Special Projects of Regional and National Significance (SPRANS). We encourage the subcommittee to increase funding for newborn screening to assist States in improving their newborn screening programs and override the administration's proposed elimination of the universal newborn hearing screening program.

The proposed elimination of the Emergency Medical Services for Children (EMSC) program, a national initiative designed to reduce child and youth disability and death due to severe illness and injury, is also of great concern, especially in light of the recent Institute of Medicine report that highlighted significant shortcomings in pediatric emergency care. EMSC grants fund improvements to existing emergency medical services systems and to develop and evaluate improved procedures and protocols for treating children. Children are not merely small adults; they have unique and specific concerns that this programs works to address. We request that the EMSC program be funded at $25 million in fiscal year 2008.

Although the administration proposes level funding for the hospital preparedness program, we are concerned with the $13 million cut the program took in fiscal year 2007. All responders, providers and facilities must be ready to detect and respond to complex disasters, including terrorism, and HRSA must continue to support these vital hospital preparedness programs. Furthermore, HRSA's Trauma-EMS Systems Program, which is critical to ensure that our response to local, State and Federal emergencies is effective and reflects the best clinical practice in trauma and emergency medicine, was also proposed to be eliminated in fiscal year 2008. We request that the $3.5 million funding level be restored.

The Office of Rural Health Policy, which serves more than 61 million people, was cut by 89 percent in the President's budget. Although almost a quarter of the U.S. population lives in rural areas, only an eighth of our doctors work there. Because rural families generally earn less than urban families, many health problems associated with poverty are more serious, including high rates of chronic disease and infant mortality. We encourage the subcommittee to restore funding for rural health programs. Additionally, the HRSA Rural and Community Access to Emergency Devices Program provides grants to States to train lay rescuers and first responders to use AEDs and purchase and place these devices in public areas where cardiac arrests are likely to occur. We encourage the subcommittee to restore funding for this program to the fiscal year 2005 level of $8.927 million.

The HIV/AIDS Bureau received a $21 million increase in the President's 2008 request over fiscal year 2007 levels for a total of $2.1 billion. The Ryan White CARE Act programs are the largest single source of Federal discretionary funding for HIV/AIDS health care for low-income, uninsured and underinsured Americans. While we are pleased with the additional funds for HIV related drug therapies, it is insufficient to meet the needs of those seeking services. We are concerned that the cuts across the programs since fiscal year 2003 is diminishing the availability of services. These cuts have forced State, local and public health clinics' HIV/AIDS programs to stretch already thin dollars to treat existing clients while trying to provide care and treatment to those newly diagnosed. We request an increase of $682 million for Ryan White programs in fiscal year 2008. In fiscal year 2006 the AIDS Drug Assistance Programs (ADAP) received a $2 million increase. Unfortunately, by the end of fiscal year 2007 it is expected that hundreds more individuals will be added to ADAP waiting lists and that States will have had to institute other cost-containment measures such as reduced formularies, increased cost-sharing for ADAP clients and lowered eligibility requirements for enrollment.

Title X of the Public Health Service Act was enacted to provide high-quality, subsidized contraceptive care to those who cannot afford such services, to improve women's health, reduce unintended pregnancies, and decrease infant mortality and morbidity. Title X programs provide comprehensive, voluntary and affordable family planning services to millions—many of whom are uninsured—at more than 4,600 clinics nationwide. People who visit Title X funded clinics receive a broad package of preventive health services, including breast and cervical cancer screening, blood pressure checks, anemia testing, and STD/HIV screening.

A major source of HRSA's strength is its many linkages and partnerships with other Federal agencies, State, national and local organizations. For example, HRSA and the Centers for Medicare and Medicaid Services (CMS) are jointly implementing outreach on the new State Children's Health Insurance Program in addition to working together to improve data sharing and coordination, particularly on Medicaid. Work also is ongoing with the Substance Abuse and Mental Health Services Administration (SAMHSA) to integrate behavioral health and substance abuse screening, early intervention, referral and follow-up into primary health care settings funded through HRSA grants. HRSA and the Centers for Disease Control and Prevention (CDC) cooperate on a variety of disease prevention and health promotion activities.

We urge the members of the subcommittee to restore the allocations that were cut and fund the agency at a level that allows HRSA to effectively implement these important programs. The members of the Friends of HRSA are grateful for this opportunity to present our views to the subcommittee.

PREPARED STATEMENT OF THE FRIENDS OF THE NIDA COALITION

Mr. Chairman and members of the subcommittee: The Friends of the National Institute on Drug Abuse (FoN), a burgeoning coalition of over 165 scientific and professional societies, patient groups, and other organizations committed to preventing and treating substance use disorders as well as understanding the causes and public health consequences of addiction, is pleased to provide testimony in support of the NIDA's extraordinary work. Pursuant to clause 2(g)4 of House Rule XI, the Coalition does not receive any Federal funds.

Drug abuse is costly—to individuals and to our society as a whole. Smoking, alcohol abuse and illegal drugs cost this country more than $500 billion a year, with illicit drug use alone accounting for about $180 billion in health care, crime, productivity loss, incarceration, and drug enforcement. Beyond its monetary impact, drug and alcohol abuse tear at the very fabric of our society, often spreading infectious diseases and bringing about family disintegration, loss of employment, failure in school, domestic violence, child abuse, and other crimes. The good news is that treatment for drug abuse is effective and recovery from addiction is real for millions of Americans across the country. Preventing drug abuse and addiction and reducing these myriad adverse consequences is the ultimate aim of our Nation's investment in drug abuse research. Over the past three decades, scientific advances resulting from research have revolutionized our understanding of and approach to drug abuse and addiction.

Because of the critical importance of drug abuse research for the health and economy of our Nation, we write to you today to request your support for a 6.7 percent increase for NIDA in the fiscal year 2008 Labor, Health and Human Services, Education and Related Agencies Appropriations bill. That would bring total funding for NIDA in fiscal year 2008 to $1,067,389,455. Recognizing that so many health re-

search issues are inter-related, we also support a 6.7 percent increase for the National Institutes of Health overall, which would bring its total to $30.8 billion for fiscal year 2008. This work deserves continuing, strong support from Congress. Below is a short list of significant NIDA accomplishments, challenges, and successes.

Reducing Prescription Drug Abuse.—NIDA research has documented a continued increase in the number of people, especially young people, who use prescription drugs for non-medical purposes. Particular concern revolves around the inappropriate use of opioid analgesics—very powerful pain medications. Research targeting a reduction in prescription drug abuse, particularly among our Nation's youth, should continue to be a priority for NIDA.

Pain Medications and Addiction.—FoN commends NIDA for taking a leadership role in addressing issues around pain medications and addiction. The most powerful treatments available for most forms of pain are opioids. However, opioid treatment can produce negative health consequences, such as intoxication and physical dependence, and may result in opioid abuse and addiction. The prevalence of and process of how to prevent, reduce, and treat, these negative health consequences in the context of pain are not well understood. FoN is pleased that NIDA brought a focus to this important issue, in collaboration with the American Medical Association and in conjunction with the NIH Pain Consortium, via its Spring 2007 conference "Pain, Opioids, and Addiction: An Urgent Problem for Doctors and Patients."

Genes, Environment, and Development.—FoN recognizes and commends NIDA for its leadership role in launching the Genes, Environment, and Development Initiative (GEDI) with the National Cancer Institute. This initiative will support research and add to our understanding of the contribution of genetic, environmental, and developmental factors to the etiology of substance abuse and related phenotypes, and will hopefully lead to improved and tailored drug abuse and addiction prevention and treatment interventions. FoN applauds this important, cutting-edge research.

Social Neuroscience.—Research-based knowledge about the dynamic interactions of genes with environment confirms addiction as a complex and chronic disease of the brain with many contributors to its expression in individuals. FoN applauds NIDA's involvement in last year's "social neuroscience" request for applications, and this year's "genes, environment, and development initiative" request for applications.

Centers of Excellence for Physician Information.—FoN is very pleased that NIDA has created Centers of Excellence for Physician Information, and understands that these Centers will serve as national models to support the advancement of addiction awareness, prevention, and treatment in primary care practices. The NIDA Centers of Excellence will target physicians-in-training, including medical students and resident physicians in primary care specialties (e.g., internal medicine, family practice, and pediatrics). FoN also applauds NIDA for developing these centers in collaboration with the American Medical Association's Research Education Consortium.

Drug Abuse and HIV/AIDS.—NIDA understands that drug abuse and addiction continue to fuel the spread of HIV/AIDS in the United States and abroad, and that drug abuse prevention and treatment interventions can be very effective in reducing HIV risk. Research should continue to examine every aspect of HIV/AIDS, drug abuse, and addiction, including risk behaviors associated with both injection and non-injection drug abuse, how drugs of abuse alter brain function and impair decision making, and HIV prevention and treatment strategies for diverse groups. FoN applauds the Institute for holding a Spring 2007 conference titled "Drug Abuse and Risky Behaviors: The Evolving Dynamics of HIV/AIDS."

Medications Development.—FoN commends NIDA for its continued leadership in working with private industry to develop anti-addiction medications and is pleased this collaboration resulted in an effective medication for opiate addiction. FoN encourages NIDA to continue its efforts to engage the private sector in the development of anti-addiction medications, particularly for cocaine, methamphetamine, and marijuana.

Co-Occurring Disorders.—NIDA recognizes that substance abuse is a disorder that can affect the course of many other diseases. To adequately address co-occurring health problems, FoN encourages the Institute to work with other agencies to stimulate new research to develop effective strategies and to ensure the timely adoption and implementation of evidence-based practices for the prevention and treatment of co-occurring disorders.

Adolescent Brain Development—How Understanding the Brain Can Impact Prevention Efforts.—FoN notes neuroimaging research by NIDA and others showing that the human brain does not fully develop until about age 25. This adds to the rationale for referring to addiction as a "developmental disease." FoN encourages NIDA to continue its emphasis on adolescent brain development to better under-

stand how developmental processes and outcomes are affected by drug exposure, the environment, and genetics.

Translating Research Into Practice.—FoN commends NIDA for its outreach and work with State substance abuse authorities to reduce the current 15- to 20-year lag between the discovery of an effective treatment intervention and its availability at the community level. In particular, FoN applauds NIDA for continuing its work with SAMHSA to strengthen State agencies' capacity to support and engage in research that will foster statewide adoption of meritorious science-based policies and practices. FoN encourages NIDA to continue this collaboration.

Translational Research.—Ensuring Research is Adaptable and Useable. FoN commends NIDA for its broad and varied information dissemination programs. FoN also understands that the Institute continues its focus on stimulating and supporting innovative research to determine the components necessary for adopting, adapting, delivering, and maintaining effective research-supported policies, programs, and practices. As evidence-based strategies are developed, FoN urges NIDA to support research to determine how these practices can be best implemented at the community level.

Primary Care Settings and Youth.—NIDA recognizes that primary care settings are potential key points of access to prevent and treat problem drug use among young people. FoN encourages NIDA to continue to support health services research on effective ways to educate primary care providers about drug abuse and develop brief behavioral interventions for preventing and treating drug use and related health problems; and develop methods to integrate drug abuse screening, assessment, prevention and treatment into primary health care settings.

Utilizing Knowledge of Genetics and New Technological Advances to Curtail Addiction.—NIDA recognizes that not everyone who takes drugs becomes addicted. Research has shown that genetics plays a critical role in addiction, and that the interplay between genetics and environment is crucial. FoN applauds the Institute's efforts to find new and important uses for brain imaging technologies and urges the Institute to continue work in this area.

Reducing Health Disparities.—NIDA research notes that the consequences of drug abuse disproportionately impact minorities, especially African American populations. FoN is pleased to learn that NIDA continues to encourage researchers to conduct more studies in this population and to target their studies in geographic areas where HIV/AIDS is high and or growing among African Americans, including in criminal justice settings.

The Clinical Trials Network—Using Infrastructure to Improve Health.—FoN is pleased with the continued success and progress of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN). The CTN provides an infrastructure to test the effectiveness of new and improved interventions in real-life community settings with diverse populations, enabling an expansion of treatment options for providers and patients.

Drug Treatment in Criminal Justice Settings.—NIDA is very concerned about the well-known connections between drug use and crime. Research continues to demonstrate that providing treatment to individuals involved in the criminal justice system significantly decreases future drug use and criminal behavior, while improving social functioning. FoN strongly supports NIDA's efforts in this area, particularly the Criminal Justice Drug Abuse Treatment Studies (CJ–DATS).

Emerging Drug Problems.—FoN recognizes that drug use patterns are constantly changing and is pleased with NIDA's efforts to monitor drug use trends and to rapidly inform the public of emerging drug problems. FoN especially encourages NIDA to continue supporting research that provides reliable data on emerging drug trends, particularly among youth and in major U.S. cities.

Reducing Methamphetamine Abuse.—NIDA is very concerned about the continued abuse of methamphetamine across the United States. NIDA notes the advances in understanding methamphetamine abuse and addiction, and is encouraged by the growing evidence of treatment effectiveness in these populations. FoN urges NIDA to continue supporting research to address the broad medical consequences of methamphetamine abuse.

Reducing Inhalant Abuse.—NIDA understands and is alarmed that inhalant use continues to be a significant problem among our youth. FoN urges the Institute to continue its support of research on prevention and treatment of inhalant abuse, and to enhance public awareness on this issue.

Long-Term Consequences of Marijuana Use.—NIDA is concerned with the continuing widespread use of marijuana. FoN urges NIDA to continue support for efforts to assess the long-term consequences of marijuana use on cognitive abilities, achievement, and mental and physical health, as well as work with the private sector to develop medications focusing on marijuana addiction.

Blending Research and Practice.—NIDA notes that it takes far too long for clinical research results to be implemented as part of routine patient care, and that this lag in diffusion of innovation is costly for society, devastating for individuals and families, and wasteful of knowledge and investments made to improve the health and quality of people's lives. FoN applauds NIDA's collaborative approach aimed at proactively involving all entities invested in changing the system and making it work better.

Disseminating Drug Abuse and Addiction Research Information to the General Public.—FoN congratulates NIDA for its collaboration with HBO and other partners on the production of a groundbreaking documentary film on addiction. This film details the latest scientific knowledge on addiction and presents it in a compelling way for the lay public, helping people to understand addiction as a brain disease that can be successfully treated. FoN recognizes the importance of this documentary because it shows that substance abuse happens to ordinary, every day people, and that treatment can be very successful. The documentary should encourage support of those who suffer from this disease, and will reduce the stigma that so often accompanies it.

Support for Young Investigators.—NIDA recognizes the importance of, over time, replenishing the "pipeline" of researchers in the addiction field. FoN congratulates NIDA for its focus on supporting young investigators, especially in the area of clinical research. Such support is crucial to the future of this field, and the Institute should continue its efforts in this area.

Thank you, Mr. Chairman, and the subcommittee, for your support for the National Institute on Drug Abuse.

PREPARED STATEMENT OF GALLAUDET UNIVERSITY

Mr. Chairman and members of the committee: I would like to express my appreciation to you and to Congress for the generous support that we received in fiscal year 2007 during what I know are difficult times for Federal funding. I am especially grateful that Congress continues to support us during these challenging times, and I am writing in support of our appropriation request for fiscal year 2008. As I enter the first months of my presidency, I would like to introduce myself to you and discuss briefly the challenges that Gallaudet has faced during the past year and those that it will face in the near future.

In December, 2006, I was appointed interim president of Gallaudet following a lengthy protest, involving a broad segment of the Gallaudet community, against the installation of the individual appointed by Gallaudet's Board of Trustees to succeed Dr. I. King Jordan. I recently informed the University community that the 2 months since I took office on January 2, 2007 have been the most difficult and challenging of my 50 year career in education and government service (I have come out of retirement for a second time to accept this challenge). At the same time, this may be the most energized I have ever felt, as well. I do not want to minimize the seriousness of the issues that were at the heart of the protest, but I also want to assure you that I believe the Gallaudet community has never been more unified in its purpose to work together toward a future that will be worthy of Gallaudet's distinguished past.

First though, I think it is important for you to know something about the qualifications I bring to this task. I am a proud graduate of Gallaudet, having received my bachelor's degree in 1953. As I have told everyone willing to listen to my story, it was Gallaudet that prepared me to take advantage of the opportunities that eventually became open to me—Gallaudet made me what I am, and like many other deaf people I will always be grateful for that. When I left Gallaudet, I became a mathematics teacher at the New York School for the Deaf in White Plains. After earning a Master's degree from Hunter College and a Ph.D. in educational technology from Syracuse University, I was appointed director of the Kendall Demonstration Elementary School and then vice president for Pre-College Programs at Gallaudet.

Following 11 years as a Gallaudet vice president, I was appointed by President George H. W. Bush and approved by the Senate as Assistant Secretary of Education for Special Education and Rehabilitative Services, where I served as the chief oversight officer for Gallaudet and the National Technical Institute for the Deaf (NTID) until 1993. Since then, I have served for 3 years as headmaster of the New York School and, finally, for 8 years as vice president of the Rochester Institute of Technology and director of NTID. I think my career experiences have given me a unique perspective on the needs of Gallaudet University and on its relationship with the Federal Government.

I would like to address those needs briefly. Because of Congress's support for Gallaudet during recent years, we have been able to maintain a competitive pay structure for our employees while retaining the flexibility to meet the needs of a changing student body. Given the unique student population we serve and the communication skills our employees are expected to possess, retaining skilled employees is critical to our mission. Gallaudet employees received general pay increases of 2 percent in fiscal year 2003, 3 percent in fiscal year 2004, 2 percent in fiscal year 2005, and 2 percent again in fiscal year 2006 and 2007, increases that are below what Federal employees in the region received during the same timeframe, and somewhat below increases in the Consumer Price Index (CPI). During the most recent 12 month period, the national CPI–U increased by 2.1 percent and that for the Washington, DC locality increased by 2.9 percent. Given these current rates of inflation and a small erosion in the purchasing power or our employee salaries in recent years, I am projecting the need for a 3 percent general pay increase in fiscal year 2008. We are also requesting support for inflationary increases in non-salary areas, especially in the cost of utilities and benefits. In this regard, I need to point out that our benefits costs during the past several years have increased by more than 2 percent of base salaries, and we have had to fund those increases as part of our total payroll package.

The administration budget for fiscal year 2008 includes $106.998 million for Gallaudet, the same as our fiscal year 2007 and 2006 appropriations, and it would, thus, represent a second year of no funding increase. Moreover, the administration budget proposes that $600,000 of that base budget be used by the Department of Education for a major evaluation of Gallaudet's programs. As a former Federal oversight officer for Gallaudet, I understand the importance of evaluation studies, and I would welcome working in this way with the Federal Government, but I need to point out that taking these funds from our existing budget would further erode our financial base. I have carefully analyzed our fiscal year 2008 funding needs and have determined that in order to provide a 3 percent salary increase to our faculty and staff, and to meet other inflation-driven increases, we need an increase of at least 3 percent, or $3.2 million, in our appropriation for operations. I have announced a set of priorities to the Gallaudet community that are student centered and that are designed to restore Gallaudet's traditional reputation for excellence in the education of deaf students. This modest increase in our appropriation would provide substantial support for the achievement of this agenda.

In addition, I want to bring to your attention a major a problem for Gallaudet's infrastructure. During the past several years, there has been damage to dormitories serving the students of the Model Secondary School for the Deaf (MSSD) as a result of instability in the hillside site of the school's facilities. This instability is due to the construction of the facilities on an area underlain by a layer of marine clay, a problem that has been identified throughout the Washington region only during the past 20 to 30 years, following the construction of the MSSD facilities. We have discussed this problem with officials from the Department of Education in the past, but only with respect to the dormitories. During the past year, it has become evident that the main MSSD academic building is now being affected and there are threats to other buildings in the vicinity, including the Kendall Demonstration Elementary School (KDES). We have retained soil and structural engineers to assist us in assessing the current damage and the future threat, and to help us estimate costs for stabilizing the site and repairing the structural damage that has already occurred. Because of the urgent nature of the situation we have sought the support of the Department and are requesting funding to begin site stabilization from Congress in fiscal year 2008. Current estimates for stabilizing the site and repairing the existing damage are in the range of $15 to $20 million. I am requesting $7.5 million in fiscal year 2008 to support the cost of stabilizing the site. I will be making further requests to repair the damage to facilities in fiscal year 2009.

In making this request, I want to point out that Gallaudet has not asked for special funding for construction for many years. The buildings most recently constructed on the campus, the Kellogg Conference Center and the Jordan Student Academic Center were constructed with privately raised funds, as will be the Sorenson Center for Language and Communication that is currently under construction. So, I do not make this request lightly. The Model Secondary School is operated as a public school, without charging tuition and with the full support of the Federal Government. Therefore, I believe this request for support is both prudent and appropriate.

FUNDING REQUEST FOR FISCAL YEAR 2008

In our budget request to the Department of Education for fiscal year 2008, we addressed the need for inflationary increases as well as support for program development. Given the funding issues currently facing Congress, I am requesting support at this time only for our most pressing inflationary needs and the need to address the infrastructure issues I described above. Funding of our need to cover inflationary costs will provide us some budget stability, but we will continue to face the need for development and enhancement of our programs. Our strategy will be to seek alternative sources of funding for some of these program priorities and to defer development of others. We will continue to seek support for program growth from both Federal and private sources in the future.

—Inflationary costs at 3 percent—$3.2 million.

—MSSD site stabilization—$7.5 million.

My total request for fiscal year 2008 is, thus, $117.7 million; $110.2 million for operations and $7.5 million for site stabilization of the MSSD facilities.

I appreciate the challenges that Congress faces in making appropriations decisions for fiscal year 2008, but I believe experience has shown that Gallaudet provides an outstanding return on Federal dollars that are invested here, in terms of the educated and productive deaf community that the Nation enjoys as a result. Thank you.

PREPARED STATEMENT OF THE HEALTH PROFESSIONS AND NURSING EDUCATION COALITION

The members of the Health Professions and Nursing Education Coalition (HPNEC) are pleased to submit this statement for the record in support of the health professions education programs authorized under Titles VII and VIII of the Public Health Service Act. HPNEC is an informal alliance of more than 60 national organizations representing schools, programs, health professionals, and others dedicated to ensuring that Title VII and VIII programs continue to help educate the Nation's health care and public health personnel. HPNEC members are thankful for the support the subcommittee has provided to the programs, which are essential to building a well-educated, diverse health care workforce.

The Title VII and VIII health professions and nursing programs are essential components of the Nation's health care safety net, bringing health care services to underserved communities. These programs support the training and education of health care providers with the aim of enhancing the supply, diversity, and distribution of the workforce, filling the gaps in the health professions' supply not met by traditional market forces. The Title VII and VIII health professions programs are the only Federal programs designed to train providers in interdisciplinary settings to meet the needs of special and underserved populations, as well as increase minority representation in the health care workforce.

The final fiscal year 2006 Labor-HHS–Education Appropriations bill cut Title VII & VIII programs by 34.5 percent, including a 51.5 percent cut to Title VII programs. The $40 million increase provided for Title VII in the recently enacted fiscal year 2007 joint funding resolution does not restore these devastating cuts. Moreover, the President's fiscal year 2008 budget proposes an additional 94.6 percent cut to Title VII and a 29.7 percent cut to Title VIII.

HPNEC members recommend that the Title VII and VIII programs receive an appropriation of at least $550 million for fiscal year 2008. This recommendation would ensure the programs have sufficient funds to continue fulfilling their mission of educating and training a health care workforce that meets the public's health care needs.

During their 40-year existence, the Title VII and VIII programs have created a network of initiatives across the country that supports the training of many disciplines of health providers. Together, the programs work in concert with the National Health Service Corps and Community Health Centers (CHCs) to strengthen the health safety net for rural and medically underserved communities. A March 2006 study published in the Journal of the American Medical Association (JAMA) found that CHCs report high percentages of provider vacancies, including an insufficient supply of dentists, pharmacists, pediatricians, family physicians, and registered nurses; these shortages are especially pronounced in rural areas. Because Title VII and VIII programs have a successful record of training providers who serve underserved areas, the study recommends increased support for the programs as its primary means of alleviating the shortages. Further, the study serves as an important reminder that the success of CHCs is highly dependent upon a well-trained clinical staff to provide care.

HPNEC members urge the subcommittee to consider the vital need for these health professions education programs as demonstrated by the passage of the Health Professions Education Partnerships Act of 1998 (Public Law 105–392), which reauthorized the programs. The reauthorization consolidated the programs into seven general categories:

—The purpose of the Minority and Disadvantaged Health Professionals Training programs is to improve health care access in underserved areas and the representation of minority and disadvantaged health care providers in the health professions. Minority Centers of Excellence support programs that seek to increase the number of minority health professionals through increased research on minority health issues, establishment of an educational pipeline, and the provision of clinical opportunities in community-based health facilities. The Health Career Opportunity Program seeks to improve the development of a competitive applicant pool through partnerships with local educational and community organizations. The Faculty Loan Repayment and Faculty Fellowship programs provide incentives for schools to recruit underrepresented minority faculty. The Scholarships for Disadvantaged Students (SDS) make funds available to eligible students from disadvantaged backgrounds who are enrolled as full-time health professions students.

—The Primary Care Training category, including General Pediatrics, General Internal Medicine, Family Medicine, General Dentistry, Pediatric Dentistry, and Physician Assistants, provides for the education and training of primary care physicians, dentists, and physician assistants to improve access and quality of health care in underserved areas. The General Pediatrics, General Internal Medicine, and Family Medicine programs provide critical funding for primary care training in community-based settings and have been successful in directing more primary care physicians to work in underserved areas. They support a range of initiatives, including medical student training, residency training, faculty development and the development of academic administrative units. The General Dentistry and Pediatric Dentistry programs provide grants to dental schools and hospitals to create or expand primary care dental residency training programs. Recognizing that all primary care is not only provided by physicians, the primary care cluster also provides grants for Physician Assistant programs to encourage and prepare students for primary care practice in rural and urban Health Professional Shortage Areas. Additionally, these programs enhance the efforts of osteopathic medical schools to continue to emphasize primary care medicine, health promotion, and disease prevention, and the practice of ambulatory medicine in community-based settings.

—Because much of the Nation's health care is delivered in areas far removed from health professions schools, the Interdisciplinary, Community-Based Linkages cluster provides support for community-based training of various health professionals. These programs are designed to provide greater flexibility in training and to encourage collaboration between two or more disciplines. These training programs also serve to encourage health professionals to return to such settings after completing their training. The Area Health Education Centers (AHECs) provide clinical training opportunities to health professions and nursing students in rural and other underserved communities by extending the resources of academic health centers to these areas. Health Education and Training Centers (HETCs) were created to improve the supply of health professionals along the U.S.-Mexico border. They incorporate a strong emphasis on wellness through public health education activities for disadvantaged populations. Geriatric Health Professions programs support geriatric faculty fellowships, the Geriatric Academic Career Award, and Geriatric Education Centers, which are all designed to bolster the number and quality of health care providers caring for our older generations. The Quentin N. Burdick Program for Rural Health Interdisciplinary Training places an emphasis on long-term collaboration between academic institutions, rural health care agencies and providers to improve the recruitment and retention of health professionals in rural areas. The Allied Health Project Grants program represents the only Federal effort aimed at supporting new and innovative education programs designed to reduce shortages of allied health professionals and create opportunities in medically underserved and minority areas. The Graduate Psychology Education Program provides grants to doctoral, internship and postdoctoral programs in support of interdisciplinary training of psychology students with other health professionals for the provision of mental and behavioral health services to underserved populations, especially in rural and urban communities.

—The Health Professions Workforce and Analysis program provides grants to institutions to collect and analyze data on the health professions workforce to ad-

vise future decision-making on the direction of health professions and nursing programs. The Health Professions Research and Health Professions Data programs have developed a number of valuable, policy-relevant studies on the distribution and training of health professionals, including the Eighth National Sample Survey of Registered Nurses (NSSRN), the Nation's most extensive and comprehensive source of statistics on registered nurses.

—The Public Health Workforce Development programs are designed to increase the number of individuals trained in public health, to identify the causes of health problems, and respond to such issues as managed care, new disease strains, food supply, and bioterrorism. The Public Health Traineeships and Public Health Training Centers seek to alleviate the critical shortage of public health professionals by providing up-to-date training for current and future public health workers, particularly in underserved areas. Preventive Medicine Residencies provide training in the only medical specialty that teaches both clinical and population medicine to improve community health. Dental Public Health Residency programs are vital to the Nation's dental public health infrastructure. The Health Administration Traineeships and Special Projects grants are the only Federal funding provided to train the managers of our health care system, with a special emphasis on those who serve in underserved areas.

—The Nursing Workforce Development programs under Title VIII provide training for entry-level and advanced degree nurses to improve the access to, and quality of, health care in underserved areas. Health care entities across the Nation are experiencing a crisis in nurse staffing, caused in part by an aging workforce and capacity limitations within the educational system. Each year, nursing schools turn away between 42,000 and 92,000 qualified applicants at all degree levels due to an insufficient number of faculty, clinical sites, classroom space, clinical preceptors, and budget constraints. Congress responded to this dire national need by passing the Nurse Reinvestment Act (Public Law 107–205) in 2002, which increases nursing education, retention, and recruitment. The Advanced Education Nursing program awards grants to train a variety of advanced practice nurses, including nurse practitioners, certified nurse-midwives, nurse anesthetists, public health nurses, nurse educators, and nurse administrators. Workforce Diversity grants support opportunities for nursing education for disadvantaged students through scholarships, stipends, and retention activities. Nurse Education, Practice, and Retention grants are awarded to help schools of nursing, academic health centers, nurse managed health centers, State, and local governments, and other health care facilities to develop programs that provide nursing education, promote best practices, and enhance nurse retention. The Loan Repayment and Scholarship Program repays up to 85 percent of nursing student loans and offers full-time and part-time nursing students the opportunity to apply for scholarship funds. In return these students are required to work for at least 2 years of practice in a designated nursing shortage area. The Comprehensive Geriatric Education grants are used to train RNs who will provide direct care to older Americans, develop and disseminate geriatric curriculum, train faculty members, and provide continuing education. The Nurse Faculty Loan program provides a student loan fund administered by schools of nursing to increase the number of qualified nurse faculty. The Title VIII nursing programs also support the National Advisory Council on Nurse Education and Practice, which is charged with advising the Secretary of Health and Human Services and Congress on nursing workforce, education, and practice improvement issues.

—The loan programs in the Student Financial Assistance support needy and disadvantaged medical and nursing school students in covering the costs of their education. The Nursing Student Loan (NSL) program provides loans to undergraduate and graduate nursing students with a preference for those with the greatest financial need. The Primary Care Loan (PCL) program provides loans covering the cost of attendance in return for dedicated service in primary care. The Health Professional Student Loan (HPSL) program provides loans covering the cost of attendance for financially needy health professions students based on institutional determination. The NSL, PCL, and HPSL programs are funded out of each institution's revolving fund and do not receive Federal appropriations. The Loans for Disadvantaged Students (LDS) program provides grants to health professions institutions to make loans to health professions students from disadvantaged backgrounds.

These programs work collectively to fulfill their unique, three-pronged mission:

Title VII & VIII programs enhance the supply of the health professions workforce

A network of 50 Geriatric Education Centers has trained over 500,000 health practitioners in 35 health-related disciplines to better serve the burgeoning elderly population.

As the largest source of Federal funding for nursing education, the Nursing Workforce Development programs provided loan, scholarship, and programmatic support to 48,698 student nurses and nurses in fiscal year 2006.

Title VII & VIII programs improve the distribution of health care providers

A study published in the Winter 2006 issue of the Journal of Rural Health reports that up to 83 percent of family medicine residents and 80 percent of nurse practitioners who went through a program with Title VII or VIII funding chose to practice in areas with health professions shortages or medically underserved practice locations.

A study from the University of California, San Francisco shows that medical schools that receive primary care training dollars produce more physicians who work in CHCs and serve in the National Health Service Corps compared to schools without Title VII primary care funding.

Title VII & VIII programs increase the representation of minority and disadvantaged students in the health professions

A study published in the September 2006 issue of the JAMA finds that post-baccalaureate programs, which rely on Title VII among other sources of funding, are highly effective in increasing minority representation in medical school. The study concludes that enacted reductions in funding for Title VII may have negative consequences for these effective programs.

A review of physician assistant graduates from 1990–2004 reveals that graduates of Title VII supported programs were 67 percent more likely to be from underrepresented minority backgrounds than graduates of non-Title VII supported programs.

HPNEC members respectfully urge support for funding of at least $550 million for the Title VII and VIII programs, an investment essential not only to the development and training of tomorrow's health care professions but also to our Nation's efforts to provide needed health care services to underserved and minority communities. We greatly appreciate the support of the subcommittee and look forward to working with Members of Congress to achieve these goals in fiscal year 2008 and into the future.

PREPARED STATEMENT OF THE HEART RHYTHM SOCIETY

The Heart Rhythm Society (HRS) thanks you and the Subcommittee on Labor, Health and Human Services and Education for your past and continued support of the National Institute of Health, and specifically the National Heart, Lung and Blood Institute (NHLBI).

The Heart Rhythm Society, founded in 1979 to address the scarcity of information about the diagnosis and treatment of cardiac arrhythmias, is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. The Heart Rhythm Society serves as an advocate for millions of American citizens from all 50 States, since arrhythmias are the leading cause of heart-disease related deaths. Other, less lethal forms of arrhythmias are even more prevalent, account for 14 percent of all hospitalizations of Medicare beneficiaries.[1] A Our mission is to improve the care of patients by promoting research, education and optimal health care policies and standards. We are the preeminent professional group, representing more than 4,200 specialists in cardiac pacing and electrophysiology.

The Heart Rhythm Society recommends the subcommittee renew its commitment to supporting biomedical research in the United States and recommends Congress provide NIH with a 6.7 percent increase for fiscal year 2008. This increase will enable NIH and NHLBI to sustain the level of research that leads to research breakthroughs and improved health outcomes. In particular, the Heart Rhythm Society recommends Congress support research into abnormal rhythms of the heart.

HRS appreciates the actions of Congress to double the budget of the NIH in recent years. The doubling has directly promoted innovations that have improved treatments and cures for a myriad of medical problems facing our Nation. Medical research is a long-term process and in order to continue to meet the evolving chal-

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[1] Heart Rhythm Foundation, Arrhythmia Key Facts, 2004 http://www.heartrhythmfoundation.org/facts/arrhythmia.asp

lenges of improving human health we must not let our commitment wane. Furthermore, NIH research fuels innovation that generates economic growth and preserves our Nation's role as a world leader in the biomedical and biotech industries. Healthier citizens are the key to robust economic growth and greater productivity. Economists estimate that improvements in health from 1970 to 2000 were worth $95 trillion. During the same time period, the United States invested $200 billion in the NIH. If only 10 percent of the overall health savings resulted from NIH-funded research, our investment in medical research has provided a 50-fold return to the economy.[2]

Unfortunately, since the end of the doubling in 2003, funding for NIH has failed to keep pace with biomedical inflation. As a result 13 percent of NIH's purchasing power has been lost. Because of this NIH has been unable to fully fund existing multi-year grants, thus stalling life-saving discoveries. If these vacillations in funding continue, future generations of researchers will become discouraged from pursuing a career in basic science and laboratories' resources could be strained to the point of forcing lay-offs and even closure.

RESEARCH ACCOMPLISHMENTS

In the field of cardiac arrhythmias, NIH-funded research has advanced our ability to treat atrial fibrillation and thus prevent the devastating complications of stroke. Atrial fibrillation is found in about 2.2 million Americans and increases the risk for stroke about 5-fold. About 15–20 percent of strokes occur in people with atrial fibrillation. Stroke is a leading cause of serious, long-term disability in the United States and people who have strokes caused by AF have been reported as 2–3 times more likely to be bedridden compared to those who have strokes from other causes. Each year about 700,000 people experience a new or recurrent stroke and in 2002 stroke accounted for more than 1 of every 15 deaths in the United States. Ablation therapy however is providing a cure for individuals whose rapid heart rates had previously incapacitated them, giving them a new lease on life.[3]

Important advances have also been made in identifying patients with heart failure and those who have suffered a heart attack and are at risk for sudden death. The development, through initial NIH-sponsored research, and implantation of sophisticated internal cardioverter defibrillators (ICD's) in such patients has saved the lives of hundreds of thousands and provides peace of mind for families everywhere, including that of Vice-President Cheney's. A new generation of pacemakers and ICDs is restoring the beat of the heart as we grow older, permitting us to lead more normal and productive lives, reducing the burden on our families, communities and the healthcare system. Arrhythmias and sudden death affect all age groups and are not solely diseases of the elderly.

Research advances in molecular genetics have provided us the root basis for life-threatening abnormal rhythms of the heart associated with of wide range of inherited syndromes including long and short QT, Brugada syndromes, and hypertrophic cardiomyopathies. Inroads have been achieved in the identification of cardiac arrhythmias as a cause of Sudden Infant Death Syndrome (SIDS) and the genetic basis for a new clinical entity associated with sudden death of young adults was uncovered earlier this year. This knowledge has provided guidance to physicians for better detection and treatment of these sudden death syndromes reducing mortality and disability of infants, children and young adults. Individuals who survive an instance of sudden death often remain in vegetative states, resulting in a devastating burden on their families and an enormous economic burden on society. These advances have translated into sizeable savings to the health care system in the United States. Researchers are also developing a noninvasive imaging modality for cardiac arrhythmias. Despite the fact that more than 325,000 Americans die every year from heart rhythm disorders, a noninvasive imaging approach to diagnosis and guided therapy of arrhythmias, the equivalent of CT or MRI, has previously not been available.

The NIH-funded Public Access Defibrillation (PAD) Trial was also able to determine that trained community volunteers increase survival for victims of cardiac arrest. It had already been known that defibrillation, utilizing an automated external defibrillator (AED), by trained public safety and emergency medical services personnel is a highly effective live-saving treatment for cardiac arrest. A NIH-funded

[2] Murphy, KM and Topel, RH, The Value of Health and Longevity, National Bureau of Economic Research Working Paper Series, Working Paper 11405, June 2005.

[3] American Stroke Association and American Heart Association, Heart Disease and Stroke Statistics_2005 Update, 2005 http://www.americanheart.org/downloadable/heart/1105390918119HDSStats2005Update.pdf

trial however was able to conclude that placing AED's in public places and training lay persons to use them can prevent additional deaths and disabilities.[4]

Without NIH support, these life-saving findings may have taken a decade to unravel. The highly focused approach utilizing basic and clinical expertise, funded through Federal programs made these advances a reality in a much shorter time-period.

BUDGET JUSTIFICATION

These impressive strides notwithstanding, cardiac arrhythmias continue to plague our society and take the lives of loved ones at all ages, nearly one every minute of every day, as well as straining an already burdened health system. Sudden Cardiac Arrest is a leading cause of death in the United States, claiming an estimated 325,000 lives every year, or one life every 2 minutes.[5] The burden of morbidity and mortality due to cardiac arrhythmias is predicted to grow dramatically as the baby boomers age. Atrial fibrillation strikes 3–5 percent of people over the age of 65,[6] Apresenting a skyrocketing economic burden to our society in the form of healthcare treatment and delivery. Cardiac diseases of all forms increase with advancing age, ultimately leading to the development of arrhythmias. Effective drug therapy for the management of atrial fibrillation is one of the greatest unmet needs in our society today and additional research is needed to address this problem. NIH research provides the basis for the medical advances that hold the key to lowering health care costs.

The above progress we have witnessed in recent years will provide treatments for this illness, only if the resources continue to be available to the academic scientific and medical community. However, the budgets appropriated by Congress to the NIH in the past 3 years were far below the level of scientific inflation. These vacillations in funding cycles threaten the continuity of the research and the momentum that has been gained over the years. While HRS recognizes that Congress must balance other priorities, sustaining multi-year growth for the biomedical research enterprise is critical. A central objective of the doubling of the NIH budget was to accelerate solutions to human disease and disability. NIH is now engaging in the next generation of biomedical research to translate basic research and clinical evidence into new cures. Our ability to bring together uniquely qualified and devoted investigators and collaborators both at the basic science level and in the clinical arena is a vital key to our to this success. Funding models however show that a threshold exists, below which NIH will not be able to maintain its current scope and number of grants, let alone expand its programs to address new concerns and emerging opportunities. Furthermore, the United States is in danger of losing its leadership role in science and technology. The United States faces growing competition from other nations, such as China and India, which are working to invest more of their GDP's into building state-of-the art research institutes and universities to foster innovation and compete directly for the world's top students and researchers.[7]

It is for this reason that we are asking for your support to increase NIH appropriations by 6.7 percent for fiscal year 2008. The Heart Rhythm Society recommends Congress specifically acknowledge the need for cardiac arrhythmia research to prevent sudden cardiac arrest and other life threatening conditions such as sudden infant death syndrome, definitive therapeutic approaches for atrial fibrillation and the prevention of stroke, and other genetic arrhythmia conditions. Thank you very much for your consideration of our request.

If you have any questions or need additional information, please contact Nevena Minor, Coordinator, Health Policy at the Heart Rhythm Society (nminor@hrsonline.org or 202–464–3431).

Thank you again for the opportunity to submit testimony.

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[4] National Heart Lung and Blood Institute, NIH, Public Access Defibrillation by Trained Community Volunteers Increases Survival for Victims of Cardiac Arrest, November 2003 http://www.nhlbi.nih.gov/new/press/03-11-11.htm

[5] Heart Rhythm Foundation, The Facts on Sudden Cardiac Arrest, 2004 http://www.heartrhythmfoundation.org/itsabouttime/pdf/providerfactsheet.pdf

[6] Heart Rhythm Society, Atrial Fibrillation & Flutter, 2005 http://www.hrspatients.org/patients/heart disorders/atrial fibrillation/default.asp

[7] Task Force on the Future of American Innovation, The Knowledge Economy: Is the United States Losing it's Competitive Edge?, February 16, 2005.

PREPARED STATEMENT OF THE HEPATITIS FOUNDATION INTERNATIONAL

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

Continue the great strides in research at the National Institutes of Health (NIH) by providing a 6.7 percent budget increase for fiscal year 2008. Increase funding for the National Institute for Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the National Institute on Drug Abuse (NIDA) by 6.7 percent.

Continued support for the hepatitis B vaccination program for adults at the Centers for Disease Control and Prevention (CDC) as well as CDC's Prevention Research Centers by providing an 8 percent increase for CDC.

Support for the Substance Abuse and Mental Health Services Administration (SAMHSA) by providing an 8 percent increase in fiscal year 2007.

Urge CDC, NIAID, NIDDK, NIAAA, NIDA, and SAMHSA to work with voluntary health organizations to promote liver wellness, education, and prevention of both hepatitis and substance abuse.

Mr. Chairman and members of the subcommittee, thank you for your continued leadership in promoting better research, prevention, education, and control of diseases affecting the health of our Nation. I am Thelma King Thiel, Chairman and Chief Executive Officer of the Hepatitis Foundation International (HFI).

Currently, five types of viral hepatitis have been identified, ranging from type A to type E. All of these viruses cause acute, or short-term, viral hepatitis. Hepatitis B, C, and D viruses can also cause chronic hepatitis, in which the infection is prolonged, sometimes lifelong. While treatment options are available for many patients, individuals with chronic viral hepatitis B and C represent a significant number of the patients that require a liver transplant. Current treatments have limited success and there is no vaccine available for hepatitis C, the most prevalent of these diseases.

HEPATITIS B

Hepatitis B (HBV) claims an estimated 5,000 lives every year in the United States, even though therapies exist that slow the progression of liver damage. Vaccines are available to prevent hepatitis B. This disease is spread through contact with the blood and body fluids of an infected individual and from an HBV infected mother to child at birth. Unfortunately, due to both a lack in funding to vaccinate adults and the absence of an integrated preventive education strategy, transmission of hepatitis B continues to be problematic. Additionally, there are significant disparities in the occurrence of chronic HBV-infections. For example, Asian Americans represent 4 percent of the population; however, they account for more than half of the 1.3 million chronic hepatitis B cases in the United States. Current treatments do not cure hepatitis B, but appropriate treatment can help to reduce the progression to liver cancer and liver failure. Yet, many are not treated. Preventive education and universal vaccination are the best defenses against hepatitis B.

HFI supports the recommendation to increase funding by $50 million for the cost of vaccines for adults offered by the Institute of Medicine in their report, entitled "Calling the Shots: Immunization Finance Policies and Practices."

HEPATITIS C

Infection rates for hepatitis C (HCV) are at epidemic proportions. Unfortunately, many individuals are not aware of their infection until many years after they are infected. This creates a dangerous situation, as individuals who are infected unknowingly continue to spread the disease. The Center for Disease Control and Prevention estimates that there are over 4 million Americans who have been infected with hepatitis C, of which over 2.7 million remain chronically infected, with 8,000–10,000 deaths each year. Additionally, the death rate is expected to triple by 2010 unless additional steps are taken to improve outreach and education on the prevention of hepatitis C and scientists identify more effective treatments and cures. As there is no vaccine for HCV, prevention education and treatment of those who are infected serve as the most effective approach in halting the spread of this disease.

PREVENTION IS THE KEY

The absence of information about the liver and hepatitis in education programs over the years has been a major factor in the spread of viral hepatitis through unknowing participation in liver damaging activities. Adults and children need to understand the importance of the liver and how viruses and drugs can damage its abil-

ity to keep them alive and healthy. Many who are currently infected are unaware of the risks they are taking that expose them to viral infections and ultimately liver damage.

Knowledge is the key to prevention. Preventive education is essential to motivate individuals to protect themselves and avoid behaviors that can cause life-threatening diseases. Primary prevention that encourages individuals to adopt healthful lifestyle behaviors must begin in elementary schools when children are receptive to learning about their bodies. In addition to educating individuals at a critical age, schools provide access to one-fifth of the American population.

Individuals need to be motivated to assess their own risk behaviors, to seek testing, to accept vaccination, to avoid spreading their disease to others, and to understand the importance of participating in their own health care and disease management. The NIH needs to support education programs to train teachers and healthcare providers in effective communication techniques, and to evaluate the impact preventive education has on reducing the incidence of hepatitis and substance abuse.

Therefore, HFI recommends that CDC, NIAID, NIDDK, NIAAA, NIDA, and SAMHSA be urged to work with voluntary health organizations to promote liver wellness, education, and prevention of viral hepatitis, sexually transmitted diseases and substance abuse.

Only a major investment in immunization and preventive education will bring these diseases under control. All newborns, young children, young adults, and especially those who participate in high-risk behaviors must be a priority for immunization, outreach initiatives, and preventive education. We recommend that the following activities be undertaken to prevent the further spread of all types of hepatitis:

—Provide effective preventive education in our elementary and secondary schools so children can avoid the serious health consequences of risky behaviors that can lead to viral hepatitis.

—Train educators, health care professionals, and substance abuse counselors in effective communication and counseling techniques.

—Promote public awareness campaigns to alert individuals to assess their own risk behaviors, motivate them to seek medical advice, encourage immunization against hepatitis A and B, and to stop the consumption of any alcohol if they have participated in risky behaviors that may have exposed them to hepatitis C.

—Expand screening, referral services, medical management, counseling, and prevention education for individuals who have HCV, many of whom may be co-infected with HIV and Hepatitis C and/or Hepatitis B.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

HFI recommends an increase of $12 million in fiscal year 2008 for further implementation of CDC's Hepatitis C Prevention Strategy. Such an increase would bring the total funding level for the Hepatitis C Prevention Strategy to $30 million in fiscal year 2008. This increase will support and expand the development of state-based prevention programs by increasing the number of State health departments with CDC funded hepatitis coordinators. The Strategy will use the most cost-effective way to implement demonstration projects evaluating how to integrate hepatitis C and hepatitis B prevention efforts into existing public health programs.

CDC's Prevention Research Centers, an extramural research program, plays a critical role in reducing the human and economic costs of disease. Currently, CDC funds 26 prevention research centers at schools of public health and schools of medicine across the country. HFI encourages the subcommittee to increase core funding for these prevention centers, as it has been decreasing since this program was first funded in 1986. We recommend the subcommittee provide an 8 percent increase for the Prevention Research Centers program in fiscal year 2008.

Also, HFI recommends that the CDC, particularly the Division of Adolescent and School Health (DASH), work with voluntary health organizations to promote liver wellness with increased attention toward childhood education and prevention, especially through partnerships between school districts and non-governmental organizations.

INVESTMENTS IN RESEARCH

Investment in the NIH has led to an explosion of knowledge that has advanced understanding of the biological basis of disease and development of strategies for disease prevention, diagnosis, treatment, and cures. Countless medical advances have directly benefited the lives of all Americans. NIH-supported scientists remain

our best hope for sustaining momentum in pursuit of scientific opportunities and new health challenges. For example, research into why some HCV infected individuals resolve their infection spontaneously may prove to be life saving information for others currently infected. Other areas that need to be addressed are:

—Reasons why African Americans do not respond as well as Caucasians and Hispanics to antiviral agents in the treatment of chronic hepatitis C.
—Pediatric liver diseases, including viral hepatitis.
—The outcomes and treatment of renal dialysis patients who are infected with HCV and HBV.
—Co-infections of HIV/HCV and HIV/HBV positive patients.
—Hemophilia patients who are co-infected with HIV/HCV and HIV/HBV.
—The development of effective treatment programs to prevent recurrence of HCV infection following liver transplantation.
—The development of effective vaccines to prevent HCV infection.

HFI supports a 6.7 percent increase for NIH in fiscal year 2008. HFI also recommends a comparable increase of 6.7 percent in hepatitis research funding at NIAID, NIDDK, NIAAA, and NIDA.

HFI is dedicated to the eradication of viral hepatitis, which affects over 500 million people around the world. We seek to raise awareness of this enormous worldwide problem and to motivate people to support this important—and winnable—battle. Thank you for providing this opportunity to present testimony.

PREPARED STATEMENT OF THE HIV MEDICINE ASSOCIATION

The HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America represents more than 3,600 physicians, scientists and other health care professionals who practice on the frontline of the HIV/AIDS pandemic. Our members treat people with HIV/AIDS throughout the United States and the world, develop and implement effective prevention interventions, and conduct research to develop effective prevention technologies, effective vaccines and less complex and less toxic treatment regimens for use in the United States and abroad. They are medical providers that specialize in HIV medicine and work in communities across the country and in more than 150 countries outside of the United States.

The United States must sustain our three-pronged response to the AIDS pandemic—conducting research to effectively prevent and treat HIV disease; supporting programs that identify persons infected with HIV and prevent or reduce HIV transmission; and providing access to lifesaving HIV treatment to people without a reliable source of health coverage. Our past commitments resulted in our ability to develop, and provide access to, remarkable treatments that effectively suppress HIV and allow people to live healthier, more productive lives here at home and abroad. In recent years, we have been deeply concerned by our country's failure to prioritize support for domestic discretionary programs outside of defense and homeland security. The impact of our failure to invest in health care programs is already being felt and will be far-reaching and long lasting as our communities' public health infrastructures weaken and our capacity to lead the world in discovering new therapies for controlling deadly diseases such as HIV erodes.

The funding requests in our testimony largely represent the consensus of the Federal AIDS Policy Partnership (FAPP), a coalition of HIV/AIDS organizations from across the country, and are estimated to be the amounts necessary to sustain and strengthen our investment in effectively combating HIV disease.

CDC'S NATIONAL CENTER FOR HIV, STD, TB PREVENTION (NCHSTP)

HIVMA strongly supports substantial increases in funding for the National Center for HIV/AIDS, STD and TB Prevention programs at the CDC. Programs supported by NCHSTP play a critical role in reducing the 40,000 new HIV infections that still occur annually in the United States. Sufficient resources must be devoted to supporting efforts to identify people with HIV earlier in the disease so that they can be effectively linked to the medical care and treatment that prevents or delays progression to AIDS. Tuberculosis is the major cause of AIDS-related mortality worldwide. It is critical that we shore up our ability as a Nation to address tuberculosis, especially drug-resistant tuberculosis here in the United States and in the developing world. With regard to these programs, we urge at least an increase of $93 million for domestic HIV prevention programs and a funding level of $252.4 million for CDC's Division of Tuberculosis Elimination.

In the absence of an HIV vaccine, preventing new HIV transmissions is our best weapon in reducing the number of people newly infected with HIV disease each year. We strongly support the CDC guidance recommending routine HIV testing for

adults in healthcare settings, but are gravely concerned about the absence of Federal resources to assist State health departments and healthcare institutions in implementing this guidance. According to the CDC, at least 25 percent of people with HIV infection in the United States do not know it and more than 39 percent of people with HIV infection progress to AIDS within 1 year of diagnosis. The expansion of HIV testing to identify individuals who are infected with HIV, but not yet aware of their status, is vital so that they can be optimally treated early in disease progression, and can reduce risky behaviors that put others at risk for HIV transmission.

An even more robust HIV prevention budget is necessary to conduct effective surveillance, and to target uninfected individuals who engage in high-risk behaviors if we are to dramatically reduce the 40,000 new HIV infections that occur each year in the United States. We also must continue to support science-based, comprehensive programs that target people who are not HIV positive but who are at high risk for HIV infection. We are seriously concerned that the resources committed to supporting a broad-based prevention agenda have diminished while funding for unproven and unscientific abstinence-only programs has increased. We strongly encourage Congress to halt this troubling trend. Adequate resources are needed to address the high prevalence rates among vulnerable populations, e.g., men and women of color and men who have sex with men. It is short sighted to compromise these programs in order to support newer initiatives.

Funding for HIV prevention activities at the CDC should be increased by at least the $93 million recommended in the President's 2008 budget. These resources should be utilized to restore the $26 million cut in HIV prevention cooperative agreements with State and local health departments, to enhance core surveillance cooperative agreements with health departments and to expand HIV testing in critical health care venues by funding testing infrastructure, the purchase of approved testing devices, including rapid tests and confirmatory testing.

Funding for tuberculosis prevention and control must increase substantially in order to address the emerging new threat of XDR–TB. HIVMA supports the recommendation of the Advisory Council for the Elimination of Tuberculosis (ACET) for a funding level of $252.4 million for CDC's Division of Tuberculosis Elimination.

HIV/AIDS BUREAU OF THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

HIVMA supports a total commitment of $2.79 billion, an increase of $682 million for the Ryan White CARE Act program. This recommendation includes a $233 million increase for the AIDS Drug Assistance Program (ADAP) and at least an increase of $35 million for Title III (Part C).

The Health Resources and Services Administration (HRSA) oversees programs that are vital to our communities' health care safety nets—and to the ability of our clinician members to provide state-of-the-art treatment and care to patients living with HIV/AIDS. Through grants to States, cities and community clinics, CARE Act funding helps us to meet the serious and complex needs of people with HIV/AIDS who are un- or under-insured by supporting the delivery of primary medical care, prescription drugs, diagnostic tests, mental health services, substance abuse treatment, and dental services in our communities.

We strongly support a substantial increase in CARE Act funding and would propose that the majority of new funding be targeted to HIV medical care under Title III (Part C) and to the AIDS Drug Assistance Program (ADAP) to ensure that uninsured and underinsured individuals with HIV/AIDS have access to a base line of lifesaving medical care and prescription drugs regardless of where they live. Funding increases are urgently needed for Title III programs. After years of flat funding or decreases in grant awards, we estimate that these programs require an increase of $83.3 million in Federal funds. At a minimum, we urge you to include a $35 million increase for Title III, Part C programs, with this additional funding targeted to current Title III grantees with the highest demonstrated increases in patient caseloads.

Many HIV clinical programs depend on funding from multiple parts of the CARE Act to create the comprehensive services that our patients need. We strongly encourage you to support funding increases of $65 million for Title I, and $57 million for the Title II base. Resources for domestic HIV care and treatment have eroded dramatically and this trend must be reversed or AIDS mortality in the United States could increase dramatically.

NATIONAL INSTITUTES OF HEALTH (NIH)

HIVMA strongly supports at least a 6.7 percent increase for all research programs at the National Institutes of Health (NIH) including a 6.7 percent for the NIH Office

of AIDS research for fiscal year 2007. This level of increase, if sustained over several years, would halt the erosion in the Nation's medical research effort, and accelerate the pace of research that could improve the health and quality of life for millions of Americans.

The failure in recent years to adequately invest in biomedical research is taking its toll in deep cuts to clinical trials networks and significant reductions in the numbers of high quality, investigator-initiated grants that are approved. In the arena of AIDS research, virtual flat funding leads to reductions in critical research efforts to develop new therapeutics, to support the development of effective prevention technologies, and to finance vaccine development. A robust and comprehensive portfolio has been largely responsible for the dramatic gains that have been made in our knowledge about and response to the HIV virus, gains that have resulted in reductions in mortality from AIDS in the United States and other developing countries of nearly 80 percent. A continuing robust AIDS research effort is essential if we are to continue to make progress in preventing new infections, offering potent treatments with minimal toxicity, and developing a vaccine that may ultimately end the deadliest pandemic in human history. Our failure to make an adequate investment in this lifesaving research will compromise our ability to compare and evaluate optimum treatment and prevention strategies in resource-poor countries, and limit our ability to understand the appropriate role of new classes of antiretrovirals that are currently in development here at home for treatment and prevention.

The sheer magnitude of the number of people still living with HIV/AIDS in the United States and around the world—1,039,000 to 1,185,000 in the United States; 40 million globally—demands an increased investment in AIDS research if we are going to truly eradicate this devastating disease.

We also strongly support the NIH's Fogarty International Center (FIC), and believe that its programs and funding should be expanded. The FIC training programs play a critical role in developing self-sustaining health care infrastructures in resource-limited countries. By training local physicians in these countries, they are able to develop effective research programs that best address the health care, cultural and resource needs of residents in their respective countries.

Our Nation has made significant strides in responding to the HIV/AIDS pandemic here at home and around the world, but we have lost ground in recent years, particularly domestically, as funding priorities have shifted away from public health and research programs. This retreat on our past investments in AIDS research through NIH, surveillance and prevention programs through the CDC, and care and treatment through the Ryan White CARE Act program place the remarkable advancements of the past two decades in serious jeopardy. We have an opportunity to reverse this trend and to move forward with a budget that prioritizes funding for scientific discovery, public health, and care and treatment for those without resources or adequate insurance. With the support of this Congress, we have the opportunity to further limit the toll of this deadly infectious disease on our planet and to save the lives of millions who are infected or at risk of infection here in the United States and around the world.

PREPARED STATEMENT OF THE INFECTIOUS DISEASES SOCIETY OF AMERICA

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide this statement to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies concerning fiscal year 2008 Federal funding for the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). IDSA's statement speaks to the value of U.S. public health and infectious diseases research programs to the health of people in the United States and globally as well as the need to provide sufficient funding in fiscal year 2008 to sustain and improve these programs. While IDSA's leadership recognizes that current fiscal budgets are constrained due to the war in Iraq and the Federal budget deficit, we urge the subcommittee to support appropriate investments to protect all of us against the scourges wrought by infectious pathogens.

IDSA represents 8,400 infectious diseases physicians and scientists devoted to patient care, education, research, prevention, and public health. Our members care for patients of all ages with serious infections, including antibiotic-resistant bacterial infections, meningitis, pneumonia, tuberculosis, and those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, food poisoning, and HIV/AIDS, as well as emerging infections like severe acute respiratory syndrome (SARS). Housed within IDSA is the HIV Medicine Association (HIVMA), which represents more than 3,600 physicians working on the frontline of the HIV/AIDS pandemic. HIVMA members conduct research, implement prevention

programs, and provide clinical services to individuals who are infected with HIV/AIDS. IDSA and HIVMA are the principal organizations representing infectious diseases and HIV physicians in the United States.

Over the past several decades, the United States has made many significant advances in the fight against infectious diseases. For example, CDC's public health prevention and control strategies have reduced infectious diseases morbidity and mortality rates in the United States and globally. NIH-funded research and training has led to critical new discoveries while at the same time supporting economic growth in incubator sites across the country, fostering innovation and competition, and making the United States the leader in global biomedical research. Needless to say, much work remains to be done as infectious diseases remain the second leading cause of death worldwide and the third leading cause of death in the United States. Of greatest concern:

—Avian flu is an imminent threat to the United States. Despite the increased attention and progress that has been made in preparing for an influenza pandemic, the Institute of Medicine and virtually all experts conclude that the United States is woefully unprepared to sufficiently respond to pandemic flu and many gaps and challenges remain.

—Antimicrobial resistant infections have created a "silent epidemic" in communities and hospitals across the country—methicillin-resistant Staphylococcus aureus (MRSA), for example, is crippling and killing a growing number of previously healthy people including children, athletes, and military recruits as well as many elderly people; and

—On a global scale, infectious diseases annually cause 15 million deaths—HIV/AIDS, tuberculosis, and malaria alone account for one third of these deaths.

PANDEMIC AND SEASONAL INFLUENZA FISCAL YEAR 2008 FUNDING RECOMMENDATION

IDSA is deeply appreciative to the committee members for your support of increased funding for pandemic and seasonal influenza preparedness efforts as well as for the inclusion of additional pandemic influenza funding in the pending emergency supplemental appropriations bill. IDSA also applauds Congress and the administration for enacting this past December the Pandemic and All-Hazards Preparedness Act and establishing the Biomedical Advanced Research Development Authority (BARDA) within the Department of Health and Human Services. We request that Congress ensure significantly increased and sustained long-term funding to support critical activities authorized by the act. We are deeply concerned that the Federal, State, and local preparedness and response goals outlined in the act cannot be achieved without significantly increased, long-term, sustainable funding.

In addition, experts and Federal Government officials agree that the development of a pandemic vaccine is the strategy most critically needed to protect U.S. citizens from a pandemic. IDSA has proposed the establishment of a multinational Pandemic Influenza Vaccine Master Program led by the United States to outline a comprehensive approach that will systematize, coordinate, and strengthen vaccine research and development (R&D), increase production capacity, accelerate licensure, guarantee equitable global distribution, and monitor vaccine performance and safety. IDSA has proposed that a U.S. commitment of $2.8 billion is needed in fiscal year 2008 to initiate the master program and to serve as a catalyst for additional financial support from international partners. Included within our fiscal year 2008 master program proposal is a $750 million commitment for the new BARDA program. BARDA will enhance and accelerate the R&D activities necessary to produce new medical countermeasures that will protect U.S. citizens from pandemic influenza.

OTHER FISCAL YEAR 2008 FUNDING RECOMMENDATIONS

Centers for Disease Control and Prevention

IDSA recommends a total budget level of $8.7 billion for CDC's discretionary programs in fiscal year 2008 including an increase of at least $686.4 million for CDC's Infectious Diseases Program.

As part of our proposed increase in CDC's total ID Program funding, IDSA supports:

An increase of at least $50 million for CDC's Antimicrobial Resistance Program

Antimicrobial resistance is a priority funding area for IDSA in fiscal year 2008. Microbes' ability to become resistant to antimicrobial drugs not only impacts individual patients, but also can have a devastating impact on the general population as resistant microbes pass from one individual to another. A multi-pronged approach is essential to limit the impact of antibiotic resistance on patients and public

health. Our proposed increase in antimicrobial resistance funding will enable CDC to strengthen programs such as the National Healthcare Safety Network (NHSN), which generates national prevalence data to track the spread of multi-drug-resistant organisms in health care settings; expand its surveillance of clinical and prescribing data that are associated with drug-resistant infections; gather morbidity and mortality data due to resistance; educate physicians and parents about the need to protect the long-term effectiveness of antibiotics; and strengthen infection control activities across the United States. Broadening the number of CDC's extramural grants in applied research at academic-based centers also would harness the brainpower of our Nation's researchers.

An increase of at least $281 million for CDC's Immunization Program

Vaccines are one of the greatest public health successes ever achieved, helping to reduce, and in some cases eliminate, the spread of infectious diseases in the United States and abroad. In the United States, immunization of a birth cohort, or a year's worth of children born, saves 33,000 lives and $42 billion in costs. Important new vaccines have been licensed for rotavirus, pertussis, zoster, and human papillomavirus (HPV). The HPV vaccine could prevent the majority of cases of cervical cancer. Yet these new vaccines add new costs. Without additional funding of CDC's 317 Program, these vaccines will not be available to under-insured children and the infrastructure to administer vaccines and track their safety will be compromised. IDSA also is very concerned that adult immunization rates are much too low. Vaccines can be cost-saving, but new efforts are needed to make sure that access is available for all age groups. We cannot afford, however, to take scarce funds from childhood immunization to fund adult immunization—a significant new investment is required.

For these reasons, we support a total fiscal year 2008 appropriation level of $802.4 million for CDC's discretionary immunization program. This amount includes $387 million for the purchase of childhood vaccines, and $200 million for childhood immunization operations/infrastructure grants to States. In parallel fashion, as a first step toward meeting extensive needs in the adult arena, it includes $88 million for purchase of adult vaccines and $45 million for adult operations and infrastructure grants to States. Finally this amount includes $82.4 million for prevention, safety, and administrative activities.

An increase of at least $93 million for CDC's HIV Prevention Program

These additional resources should be utilized to restore cuts in HIV prevention cooperative agreements with State and local health departments, to enhance core surveillance cooperative agreements with health departments, and to expand HIV testing in critical health care venues by funding testing infrastructure and the purchase of approved testing devices, including rapid tests and confirmatory testing.

An increase of at least $252.4 million for CDC's TB Elimination Program

Recent cuts of 14 percent have eroded national tuberculosis (TB) control at a time of increased threat posed by extensively-drug resistant TB and multi-drug resistant TB. Additionally, a total of $350 million is needed across CDC as well as at the NIH to support research on TB vaccines, diagnostics, drugs, and related clinical research.

—An increase of $10 million for CDC's Public Health and Human Services Block Grant

We are concerned that the President's proposed budget once again proposes to eliminate CDC's Public Health and Human Services Block Grants, which provide States the flexibility to respond to infectious diseases outbreaks, among other events. IDSA opposes the termination of this program and instead supports a healthy increase of $10 million.

NATIONAL INSTITUTES OF HEALTH

IDSA recommends that Congress support at least a 6.7 percent increase for NIH research programs and particularly for the National Institute of Allergy and Infectious Diseases' (NIAID) AIDS research; non-AIDS, non-bioterrorism infectious diseases research, particularly antimicrobial resistance, antimicrobial therapy, and pandemic influenza research; and biodefense research. IDSA also supports a doubling of the Fogarty International Center's (FIC) budget to $134 million in fiscal year 2007.

Advancing biomedical research and maintaining the U.S. leadership in this arena requires a consistent, long-term strategy and continued strong investments. We must not be short-sighted in our approach. In light of the rise in emerging and re-emerging diseases, and particularly, the trend of previously treatable organisms evading our best drugs, IDSA urges more aggressive, sustained scientific effort and

funding dedicated not only to understanding the fundamental mechanisms of these diseases, but also support for clinical studies and translational research as a stepping stone to the development of new therapies. In addition, little research has been devoted to defining optimal antimicrobial dosing regimens, particularly related to the minimal duration of therapy necessary to cure many types of infections. Such studies require a long-term commitment and are not likely to be funded by pharmaceutical manufacturers. The consensus of many experts is that infections are frequently treated for longer periods of time than are necessary, needlessly increasing antimicrobial resistance. For this reason, IDSA urges the establishment of a Clinical Trials Network at NIH, similar to the AIDS Clinical Trials Group, devoted to defining optimal antibacterial therapy. Well-designed, multi-center randomized controlled trials that define the necessary length of therapy would create an excellent basis of evidence from which coherent and defensible recommendations could be developed.

IDSA also is concerned that NIH research project grant funding has steadily declined after peaking in 2004—the average award would be 8.4 percent smaller in 2008 than in 2004. IDSA fears that we are discouraging and potentially sacrificing an entire generation of young scientists if they conclude that NIH grants are unattainable. Sustainable and predictable funding is needed in this area. Finally, IDSA supports a doubling of FIC's budget. FIC oversees vital programs which train health professionals in resource-limited countries about how best to attack AIDS, tuberculosis, malaria, and other infectious diseases.

CONCLUSION

Today's investment in infectious disease research, prevention, and treatments will pay significant dividends in the future by dramatically reducing health care costs and improving the quality of life for millions of Americans. In addition, U.S. leadership in infectious diseases research and prevention will translate into worldwide health benefits. We urge the subcommittee to continue to demonstrate leadership and foresight in this area by appropriating the much-needed resources outlined above in recognition of the lives and dollars that ultimately will be saved.

PREPARED STATEMENT OF THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

Provide a 6.7 percent increase for fiscal year 2008 to the National Institutes of Health (NIH) budget. Within NIH, provide proportional increases of 6.7 percent to the various institutes and centers, specifically, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Office of Research on Women's Health (ORWH).

Accelerate funding for extramural clinical and basic functional gastrointestinal disorders (FGID) and motility disorders research at NIDDK.

Continue to urge NIDDK to develop a strategic plan on irritable bowel syndrome (IBS) with the purpose of setting research goals, determining improved treatment options for IBS sufferers, and assisting in recruitment of new investigators to conduct IBS research.

Urge the National Institute of Child Health and Human Development (NICHD) and NIDDK to continue to support research into fecal and urinary incontinence, including the development of a standardization of scales to measure incontinence severity and quality of life and to develop strategies for primary prevention of fecal incontinence associated with childbirth.

Provide funding to NIDDK and the National Cancer Institute (NCI) for increased research on the causes of esophageal cancer.

Thank you for the opportunity to present this written statement regarding the importance of functional gastrointestinal and motility disorders research. IFFGD has been serving the digestive disease community for 15 years. We work to broaden the understanding of functional gastrointestinal and motility disorders in adults and children. IFFGD raises awareness on disorders and diseases that many people are uncomfortable and embarrassed to discuss. The prevalence of fecal incontinence and irritable bowel syndrome or IBS, as well as a host of other gastrointestinal disorders affecting both adults and children, is underestimated in the United States. These conditions continue to remain hidden in our society. Not only are they misunderstood, but the burden of illness and human toll has not been fully recognized.

Since its establishment, IFFGD has been dedicated to increasing awareness of functional gastrointestinal and motility disorders, among the public, health profes-

sionals, and researchers. While maintaining a high level of public education efforts, IFFGD has also become recognized for our professional symposia. We consistently bring together a unique group of international multidisciplinary investigators to communicate new knowledge in the field of gastroenterology. Next month IFFGD will be hosting our Seventh International Symposium on Functional Gastrointestinal Disorders, bringing scientists, researchers, and clinicians from across the world together to discuss the current science and opportunities on IBS and other functional gastrointestinal and motility disorders. Also, in November 2002, we hosted a conference on fecal and urinary incontinence, the proceedings of which were published in Gastroenterology, the official journal of the American Gastroenterological Association (AGA). The IFFGD has also been working with the National Institute of Child Health and Human Development (NICHD), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the Office of Medical Applications of Research (OMAR) in the NIH Office of the Director on the NIH State of the Science Conference on Fecal and Urinary Incontinence to beheld in December 2007.

The majority of the diseases and disorders we address have no cure. We have yet to completely understand the pathophysiology of the underlying conditions. Patients face a life of learning to manage a chronic illness that is accompanied by pain and an unrelenting myriad of gastrointestinal symptoms. The costs associated with these diseases are enormous; estimates range from $25–$30 billion annually. The human toll is not only on the individual but also on the family. Economic costs spill over into the workplace. In essence, these diseases reflect lost potential for the individual and society. The IFFGD is a resource that provides hope for hundreds of thousands of people as they try to regain as normal a life as possible.

IRRITABLE BOWEL SYNDROME (IBS)

IBS strikes people from all walks of life. It affects 25 to 45 million Americans and results in significant human suffering and disability. This chronic disease is characterized by a group of symptoms, which include abdominal pain or discomfort associated with a change in bowel pattern, such as loose or more frequent bowel movements, diarrhea, and/or constipation. Although the cause of IBS is unknown, we do know that this disease needs a multidisciplinary approach in research and often treatment.

IBS can be emotionally and physically debilitating. Due to persistent bowel unpredictability, individuals who suffer from this disorder may distance themselves from social events, work, and even may fear leaving their home.

In the House and Senate fiscal years 2004, 2005, 2006, and 2007 Labor, Health and Human Services, and Education Appropriations bills, Congress recommended that NIDDK develop an IBS strategic plan. The development of a strategic plan on IBS would greatly increase the institute's progress toward the needed research on this functional gastrointestinal disorder, as well as serve to advance our understanding of this disease, determine improved treatment options for IBS sufferers, and assist in recruiting new investigators to conduct IBS research. NIDDK is formulating an action plan for digestive diseases through the National Commission on Digestive Diseases and has indicated that IBS will be included as a component of this overall plan. IBS must be given sufficient attention, however, in order to increase the functional gastrointestinal disorders (FGID) and motility disorders research portfolio at NIDDK.

FECAL INCONTINENCE

At least 6.5 million Americans suffer from fecal incontinence. Incontinence is neither part of the aging process nor is it something that affects only the elderly. Incontinence crosses all age groups from children to older adults, but is more common among women and in the elderly of both sexes. Often it is a symptom associated with various neurological diseases and many cancer treatments. Yet, as a society, we rarely hear or talk about the bowel disorders associated with spinal cord injuries, multiple sclerosis, diabetes, prostate cancer, colon cancer, uterine cancer, and a host of other diseases.

Damage to the anal sphincter muscles; damage to the nerves of the anal sphincter muscles or the rectum; loss of storage capacity in the rectum; diarrhea; or pelvic floor dysfunction can cause fecal incontinence. People who have fecal incontinence may feel ashamed, embarrassed, or humiliated. Some don't want to leave the house out of fear they might have an accident in public. Most attempt to hide the problem for as long as possible. They withdraw from friends and family, and often limit work or education efforts. Incontinence in the elderly burdens families and is the primary

reason for nursing home admissions, an already huge social and economic burden in our increasingly aged population.

In November 2002, the IFFGD sponsored a consensus conference—"Advancing the Treatment of Fecal and Urinary Incontinence Through Research: Trial Design, Outcome Measures, and Research Priorities." Among other outcomes, the conference resulted in six key research recommendations:

—More comprehensive identification of quality of life issues associated with fecal incontinence and improved assessment and communication of treatment outcomes related to quality of life.

—Standardization of scales to measure incontinence severity and quality of life.

—Assessment of the utility of diagnostic tests for affecting management strategies and treatment outcomes.

—Development of new drug compounds offering new treatment approaches to fecal incontinence.

—Development and testing of strategies for primary prevention of fecal incontinence associated with childbirth.

—Further understanding of the process of stigmatization as it applies to the experience of individuals with fecal incontinence.

The IFFGD has been working with the NICHD, NIDDK, and OMAR on a NIH State of the Science Conference on Fecal and Urinary Incontinence that is scheduled to take place in December 2007. The goal of this conference will be to assess the state of the science and outline future priorities for research on both fecal and urinary incontinence; including, the prevalence and incidence of fecal and urinary incontinence, risk factors and potential prevention, pathophysiology, economic and quality of life impact, current tools available to measure symptom severity and burden, and the effectiveness of both short- and long-term treatment. Once the conference is completed, NIH must prioritize implementation of the recommendations of this important conference.

GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Gastroesophageal reflux disease, or GERD, is a common disorder affecting both adults and children, which results from the back-flow of acidic stomach contents into the esophagus. GERD is often accompanied by persistent symptoms, such as chronic heartburn and regurgitation of acid. But sometimes there are no apparent symptoms, and the presence of GERD is revealed when complications become evident. One uncommon complication is Barrett's esophagus, a potentially pre-cancerous condition associated with esophageal cancer. Symptoms of GERD vary from person to person. The majority of people with GERD have mild symptoms, with no visible evidence of tissue damage and little risk of developing complications. There are several treatment options available for individuals suffering from GERD.

Gastroesophageal reflux (GER) affects as many as one-third of all full term infants born in America each year. GER results from an immature upper gastrointestinal motor development. The prevalence of GER is increased in premature infants. Many infants require medical therapy in order for their symptoms to be controlled. Up to 25 percent of older children and adolescents will have GER or GERD due to lower esophageal sphincter dysfunction. In this population, the natural history of GER is similar to that of adult patients, in whom GER tends to be persistent and may require long-term treatment.

GASTROPARESIS

Gastroparesis, or paralysis of the stomach, refers to a stomach that empties slowly. Gastroparesis is characterized by symptoms from the delayed emptying of food, namely: bloating, nausea, vomiting or feeling full after eating only a small amount of food. Gastroparesis can occur as a result of several conditions, including being present in 30 percent to 50 percent of patients with diabetes mellitus. A person with diabetic gastroparesis may have episodes of high and low blood sugar levels due to the unpredictable emptying of food from the stomach, leading to diabetic complications. Other causes of gastroparesis include Parkinson's disease and some medications, especially narcotic pain medications. In many patients the cause of the gastroparesis cannot be found and the disorder is termed idiopathic gastroparesis. Over the last several years, as more is being found out about gastroparesis, it has become clear this condition affects many people and the condition can cause a wide range of symptoms of differing severity.

FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS AND THE NATIONAL INSTITUTES OF HEALTH

The International Foundation for Functional Gastrointestinal Disorders recommends an increase of 6.7 percent to the budget of NIH, and a 6.7 percent increase for NIDDK and NICHD. However, we request that this increase for NIH does not come at the expense of other Public Health Service agencies.

We urge the subcommittee to provide the necessary funding for the expansion of the NIDDK's research program on FGID and motility disorders. This increased funding will allow for the growth of new research on FGID and motility disorders at NIDDK, a strategic plan on IBS, and increased public and professional awareness of FGID and motility disorders. In addition, we urge the subcommittee to continue to support and provide adequate funding to the Office of Research on Women's Health (ORWH) under the NIH Office of the Director, particularly for their Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCORs) program and the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program. The ORWH supports important research into IBS.

A primary tenant of IFFGD's mission is to ensure that clinical advancements concerning GI disorders result in improvements in the quality of life for those affected. By working together, this goal will be realized and the suffering and pain millions of people face daily will end. Thank you.

PREPARED STATEMENT OF THE JEFFREY MODELL FOUNDATION

Mr. Chairman and members of the subcommittee: Thank you for the opportunity to testify before you today. I am Vicki Modell and, along with my husband Fred, we created the Jeffrey Modell Foundation in 1987 in memory of our son, who died at the age of 15 as a result of a life long battle against one of the estimated 140 primary immunodeficiency (PI) diseases.

Today I wish to discuss with you two important initiatives for the Congress, the CDC, and the Jeffrey Modell Foundation to collaborate on that will achieve the following:

—Continue to educate and raise awareness about primary immunodeficiency diseases among physicians, other health care providers, and the public through a highly successful program that has, to date, generated $10 private for every $1 public invested; and

—Launch a pilot program that will extend newborn screening to Severe Combined Immune Deficiency, the most lethal of all PI diseases, saving lives and saving money.

The Jeffrey Modell Foundation is an international organization located in New York City. In its 21 years of existence, the Foundation has grown into the premier advocacy and service organization on behalf of people afflicted with primary immunodeficiency diseases. As a demonstration of the extent to which the JMF leads in the field, please consider the following:

—The Foundation has established Jeffrey Modell Research and Diagnostic Centers at 34 academic and teaching hospitals in the United States and abroad.

—The Foundation conducts a national physician education and public awareness campaign, currently funded with approximately $2.5 million appropriated by this committee to the Centers for Disease Control and Prevention (CDC) and awarded to the JMF. To date, the Foundation has leveraged the Federal money to generate in excess of $75 million in donated media and corporate contributions with almost 250,000 placements/airings on television, radio, print, and other public media, as well as a 30-minute program produced for PBS. CME physician symposia have been held at leading academic teaching hospitals throughout the Nation. It has also included mailings to physicians in a variety of specialist and generalist fields, including pediatrics and several pediatric specialties, family practice, and internal medicine, as well as to school nurses, clinical and registered nurses and daycare centers throughout the United States.

—In addition, the Foundation has long been a provider of direct patient services such as KIDS Days that give young people a chance to meet and share experiences with others similarly situated in their communities in a fun atmosphere that encourages a feeling of normalcy in patients.

First and foremost, Mr. Chairman, I am here today to thank you and all the members of this committee. Over the last 10 years that we have been coming to Washington, we have been given the opportunity to build a partnership with the Congress, the Centers for Disease Control and Prevention, the National Institutes of Health, the Health Resources and Services Administration, as well as with our own supporters in the private sector, including the pharmaceutical and biotechnology in-

dustries, and other concerned donors. We believe that we have maximized the benefits for patients from the support that this subcommittee has afforded the Foundation.

CENTERS FOR DISEASE CONTROL AND PREVENTION

This subcommittee is currently funding CDC with $2.5 million for physician education and public awareness of primary immune deficiencies. The Jeffrey Modell Foundation operates the program under a contract with CDC. Since the campaign's inception, it has generated more than $75 million in donated media, including television and radio spots, magazine ads, billboards, airport signs and other print media, as well as other corporate support. Every $1 provided by the committee has been leveraged into more than $10 of private money for this education and awareness program.

In a national survey conducted on behalf of the Foundation, funded by a grant from the CDC, one in three Americans state that they have heard of Primary Immunodeficiency. When 502 pediatricians and family practice physicians were asked about PI, 85 percent of physicians consider PI to be rare or extremely rare (1 in 5,000–10,000 patients). However, the National Institutes of Health cites the prevalence of 1 in 500. This disparity shows how much education the medical community still needs.

The progress being made by the campaign is significant. As reported by the Foundation's Centers for Primary Immunodeficiencies, there has been a 79 percent increase in the number of diagnosed patients, a 58 percent increase in the number of patients receiving treatment, and a 57 percent increase in patients referred to JMF specialized centers. These increases are reflected on an annual basis for each year of the campaign. The most meaningful statistic is that there has been an annual 256 percent increase in the number of diagnostic tests performed, showing that the campaign is raising patients' and physicians' awareness of PI. The campaign has generated over 6 million hits to the JMF website annually, 500,000 unique visits to the JMF website annually and over 12,000 calls to the JMF hotline, further evidence of the campaign's effectiveness.

Two years ago the subcommittee increased the CDC funding for the campaign by approximately $500,000 in order to expand the campaign to target the underserved minority population. Research shows that the incidence of PI does not vary between races or among ethnic groups. To reach its intended audience, the minority campaign must run ads on different radio stations and television networks and have space in different print media. Since the program's launch, the campaign has leveraged the $1 million in Federal funds to generate over $17 million in donated media and has had almost 60,000 airings/placements.

We respectfully request that this subcommittee continue to fund this program at $2.5 million in fiscal year 2008 (the level requested in the President's budget), allowing the Foundation to continue both the original education and awareness program and the targeted minority campaign.

QUALITY OF LIFE AND ECONOMIC IMPACT STUDY

In 2006, the Foundation set out to examine the impact of early diagnosis in a rigorous manner. Physician experts at the 118 Jeffrey Modell Diagnostic and Referral Centers were contacted. Each of the Centers was asked to examine patient records 1 year prior to diagnosis and for the year following diagnosis and treatment. The data, which included 532 patient records, was collected by the Foundation and reviewed by members of the Foundation's Medical Advisory Board.

The results of the study clearly demonstrate that the quality of life of undiagnosed patients is significantly lower than that of diagnosed patients. Undiagnosed patients suffer from chronic infections an average of 44.7 days per year compared to 12.6 days for diagnosed patients. On average, undiagnosed patients are treated with antibiotics 166.2 days per year compared to 72.9 days per year. Undiagnosed patients spend 14.1 more days of the year in hospitals than diagnosed patients. Also, the study found that undiagnosed patients missed 33.9 days of work or school compared to only 8.9 days missed by diagnosed patients.

Besides being sicker, requiring more care, and more time out of the workforce, ultimately, an undiagnosed patient costs the healthcare system $102,552 per year compared to $22,610; diagnosing a patient with PI saves $79,942 per year. According to NIH, there are as many as 500,000 undiagnosed patients in this country; these undiagnosed patients cost the healthcare system approximately $40 billion annually. These costs underscore the important of early identification and treatment for PI patients.

NEWBORN SCREENING PROGRAM

Mr. Chairman, our dedication to the importance of early diagnosis has led us to field of newborn screening. And here we have an opportunity for the action of this subcommittee to save lives, literally. Severe combined immune deficiency (SCID) is the most severe form of PI and is fatal, if an infant is not diagnosed and treated within the first year of life. Within the first few months of life, the infant will suffer from one or more serious infections, including pneumonia, meningitis or bloodstream infections.

Newborn screening is the solution to this life-threatening condition. Last fall the Foundation sponsored a meeting in conjunction with the CDC Foundation to examine the state of the science regarding newborn screening for SCID. We learned at that meeting that doctors can diagnose SCID with 99 percent accuracy; and we learned that they can treat it with a 95 percent success rate using bone marrow transplantation to restore the immune system before the infant develops any serious infections. If a diagnosis of SCID is made within the infant's first 2 months of life, treating SCID costs under $10,000. However, by the 9th or 10th month of life, if the infant survives that long, the costs of transplantation and other medical complications are over $1 million and the success rate falls dramatically.

Based on discussions at last fall's meeting at the CDC, both Wisconsin and New York are prepared to begin a pilot program to screen newborns for SCID. In Wisconsin, a collaboration between the Children's Hospital of Wisconsin, the Medical College of Wisconsin and the Wisconsin State Laboratory of Hygiene has been established to begin the program by replicating the State's current screening model for cystic fibrosis. The Wisconsin State Laboratory of Hygiene currently runs 300–500 tests per day, 6 days a week, easily accommodating all the newborns in the State. Screening tests are conducted between the 3rd and 7th day of life, and a report is delivered by the lab to the pediatrician within 7 days. New York State health officials are going to monitor Wisconsin's program to determine how the screen needs to be altered to handle New York's 250,000 live births a year.

To start this pilot, both the Children's Hospital of Wisconsin and the Foundation each contributed to this effort. The Foundation has estimated that it will cost approximately $560,000 per State to begin screening for SCID. Once the pilot program demonstrates efficacy, SCID screening will cost a maximum of between $6.50 and $7 per child.

To support the efforts of Wisconsin and New York, we respectfully request that this subcommittee increase funding for CDC's Environmental Health Laboratory program by $750,000, specifically to fund the pilot program to screen newborns for SCID in Wisconsin and New York. We anticipate that this will be a one-time cost. Once the pilot is evaluated and methods are proven, States will be able to add this test to their screening panel.

CONCLUSION

With the support the Jeffrey Modell Foundation has received from this subcommittee, we have been able to increase significantly the public's awareness of PI and most importantly, thanks to your support, we have been able to save lives. The Federal Government's investment in this campaign is producing results far beyond anything that even we had anticipated. Many more children are being tested and treated; lives are being saved.

We understand that the subcommittee must make difficult decisions in this fiscal environment. However, the Foundation's education and awareness campaign has been recognized as a model collaborative program that has successfully leveraged Federal dollars in a manner rarely seen. We now know the financial burden an undiagnosed patient places on the healthcare system; there is no reason to spend $40 billion annually on the treatment of undiagnosed patients. For every Federal dollar spent on the campaign and research, the potential to save lives increases exponentially. This is precisely the kind of public-private partnership that should be encouraged. It works. It saves lives. And, it is the best example of bringing scientific advances to every citizen regardless of their station in life.

After 5 years of funding for the campaign, we believe it is time for this subcommittee to take the next step with us and financially support newborn screening for SCID. The science shows the screening is accurate and the treatment is successful and cost effective. Diagnosing, transplanting and curing just one baby will make the all of our efforts worthwhile; but, there is no reason to stop at one. We will continue to advocate for the expansion of this pilot program and eventually the inclusion of the screen for SCID on every State's list of required newborn screening.

Thank you, Mr. Chairman, for the opportunity to present this testimony to the subcommittee.

PREPARED STATEMENT OF THE LUPUS FOUNDATION OF AMERICA

SUMMARY

The Lupus Foundation of America (LFA) is the Nation's leading non-profit voluntary health organization dedicated to improving the diagnosis and treatment of lupus, supporting individuals and families affected by the disease, increasing awareness of lupus among health professionals and the public, and finding the causes and cure. LFA respectfully calls upon Congress to provide the following allocations in the fiscal year 2008 Labor-Health and Human Services-Education (LHHS) appropriations measure to reduce and prevent suffering from lupus:

—$3.25 million for the National Lupus Patient Registry (NLPR) at the National Center for Chronic Disease Prevention and Health Promotion within the Centers for Disease Control and Prevention (CDC) to sustain current epidemiological efforts and expand the registry to seven sites. Such an expansion would ensure that the registry includes all forms of lupus and all affected populations, particularly African Americans, Hispanics, and Asian Americans, who are disproportionately at-risk for—and have worse outcomes associated with—lupus.

—$30.8 billion (a 6.7 percent increase) for the National Institutes of Health (NIH) to support lupus research. Specifically, we urge the subcommittee to provide a 6.7 percent increase to each of the following institutes and centers, which play an integral role in lupus research: NCMHD, NHGRI, NHLBI, NIAID, NIAMS, NIDDK, NIEHS, and NINDS. Moreover, we respectfully call on Congress to move to provide a 33 percent increase for lupus research for each of the next three fiscal years.

—$1 million in new funding for the HHS Office on Women's Health to support a sustained national lupus education and awareness campaign. These educational efforts would be directed toward healthcare professionals who diagnose and treat people with lupus, with an emphasis on reaching those individuals at highest risk—women of color—a health disparity that remains unexplained.

BACKGROUND ON LUPUS

As you may know, lupus—a debilitating, chronic autoimmune disease that causes inflammation and tissue damage to virtually any organ system—affects as many as 2 million Americans. Since lupus is a systemic disease, it can cause significant disability and even death. Lupus can be particularly difficult to diagnose because its symptoms are similar to those of many other diseases, and major gaps exist in understanding the causes and consequences of the disease. Lupus affects women nine times more often than men and disproportionately impacts women of color. Our scientific advisors note that lupus is the prototypical autoimmune disease and indicate that finding answers to questions about lupus also may provide understanding about other autoimmune diseases affecting 22 million Americans. Tragically, there have been no new drugs approved by the Food and Drug Administration specifically for lupus in nearly 40 years. Currently, there is no cure for lupus; available treatments can lead to damaging side effects and can adversely impact quality of life. LFA maintains that the Nation must significantly increase its attention to—and investment in—lupus research, education, and awareness to help ensure that much-needed progress is made in lupus diagnosis and treatment—eventually achieving a cure.

CDC NATIONAL LUPUS PATIENT REGISTRY

LFA respectfully requests that the subcommittee provide $3.25 million in fiscal year 2008 to the CDC National Lupus Patient Registry (NLPR). The NLPR plays an integral role in lupus epidemiological studies which provide important insight into the disease. The establishment of the NLPR was the first nationwide step in the CDC's effort to assess the prevalence and incidence of lupus. The NLPR serves as a conduit for the collection of valid and reliable data for epidemiological studies to better understand and measure the burden of illness, assess the social and economic impact of the disease, and stimulate additional private investment by industry in the development of new, safe, and effective therapies—and hopefully a cure—for lupus.

Currently, the NLPR involves two study sites—in Georgia and Michigan. The information collected through the Emory University School of Medicine and the Michigan Department of Community Health (in collaboration with the University of Michigan) stems from a multi-pronged approach using data from laboratory tests, interviews with physicians who treat lupus patients, hospital data, and other sources. While the data gleaned from the current sites are important and useful, unfortunately—due to limited resources—the NLPR does not include information on

all forms of lupus and all populations affected by the disease. This constrained scope, depth, and breadth of the NLPR limits its utility to researchers and does not allow for adequate exploration of the health disparities apparent among those diagnosed with lupus.

Existing epidemiological data on lupus are decades old and no longer reliable. Population-based epidemiological studies of lupus must be conducted at strategically-located sites throughout the Nation that will provide accurate data on all forms of lupus (i.e. systemic lupus, primary discoid lupus, drug-induced lupus, neonatal lupus, antiphospholipid antibodies) and the disparity among the various racial and ethnic populations. The LFA and its scientific and medical advisors recommend that the NLPR be expanded to an additional five sites, which should represent the populations that are disproportionately affected by lupus—principally African Americans, Hispanics, Asian Americans, and Native Americans. To that end, LFA urges the subcommittee to provide $3.25 million in fiscal year 2008 and to include language in the report accompanying the fiscal year 2008 LHHS measure that encourages the CDC to create a common data entry and management system across all study sites, to collaborate with a consortium of academic health centers with an expertise in lupus epidemiology, and ensure adequate numbers and locations of study sites and sufficient numbers of individuals of all racial and ethnic backgrounds.

RESEARCH FOR BETTER TREATMENTS AND A CURE

The LFA has long been concerned about the inadequate levels of Federal investment in lupus research. Unfortunately, during the doubling of NIH funding, lupus did not receive its proportional increase; now that NIH funding has flattened, lupus research is in danger of falling even further behind. However, after a tragic 40 year dearth of specific new treatments to manage this debilitating and devastating disease, lupus researchers are on the brink of major discoveries that could substantially advance lupus research, leading to better treatments, and possibly a cure.

To achieve these much-needed breakthroughs, LFA maintains that Federal research funding must be increased significantly. It is important to note that level or decreased NIH funding could bring to a standstill clinical trials and large observational studies, and could curtail research on those at highest risk for lupus, women of color. Furthermore, insufficient Federal funding also could slow much-needed genetic research, when we are just discovering the critical components that may contribute to lupus and its adverse effects. Therefore, it is critical that biomedical researchers be provided the necessary resources to continue seeking answers to the questions that will lead to safer and more effective lupus treatments. To that end, LFA has joined with the broader public health and research communities in supporting an overall 6.7 percent increase for the NIH in fiscal year 2008. LFA has identified a number of NIH institutes and centers whose research activities are critical to identifying improved treatments and a cure for lupus, and as noted above, we urge that each of these entities receive a 6.7 percent increase in fiscal year 2008: NCMHD, NHGRI, NHLBI, NIAID, NIAMS, NIDDK, NIEHS, NIDDK and NINDS. We urge Congress to move to provide a 33 percent increase for lupus research for each of the next 3 fiscal years.

NIAMS.—Lupus affects the skin, bones, joints, and connective tissue. NIAMS is integral to making gains in lupus treatment and identifying a cure. LFA asks that the subcommittee encourage NIAMS to significantly expand research related to lupus, with a particular focus on understanding the underlying mechanisms of disease, gene-gene and gene-environmental interactions, lupus and kidney disease, biomarkers, pediatric research, environmental factors, and factors related to health disparities and comorbidities associated with lupus.

NIAID.—Lupus is a dysfunction of the immune system which warrants greater examination. LFA's scientific and medical advisors maintain that NIAID has an integral and more significant role to play in lupus research. To that end, LFA respectfully requests that the subcommittee urge NIAID to take a leadership role in lupus research and expand and intensify genetic, clinical, and basic research related to lupus, with a particular focus on gene-gene and gene-environmental interactions, biomarkers, pediatric research, environmental factors, and factors related to health disparities and comorbidities associated with lupus.

NCMHD.—Nine out of 10 people with lupus are women; lupus is two to three times more common among women of color than Caucasian women. Lupus mortality has increased over the past 3 years and is higher among older African American women. We urge the subcommittee to encourage NCMHD to collaborate with extramural researchers and LFA to ensure that these terrible disparities receive the attention—and interventions—they deserve.

NHGRI.—Lupus likely is a polygenetic disease. As such, LFA asks the subcommittee to encourage NGHRI to undertake efforts to help identify the gene(s) associated with lupus.

NHLBI.—Lupus attacks the heart, lungs, blood, and blood vessels. LFA encourages the subcommittee to urge NHLBI to expand and intensity research on lupus, with a special emphasis on lupus and early onset of cardiovascular disease.

NIEHS.—Lupus disease activity can be triggered by certain environmental factors. LFA encourages the subcommittee to urge NIEHS to undertake additional lupus related research activities to help identify environmental factors, biomarkers, and gene-environmental interactions associated with the disease.

NIDDK.—Lupus causes lupus nephritis—inflammation of the kidneys. LFA asks the subcommittee to urge NIDDK to undertake studies into this condition, which is one of the most serious manifestations of lupus.

NINDS.—Lupus attacks the blood vessels in the brain, causing seizures, psychosis, and stroke. LFA urges the subcommittee to encourage NINDS to expand its research related to lupus.

INCREASED AWARENESS AND EDUCATION FOR BETTER OUTCOMES

Too many affected individuals and their health professionals remain unaware of the signs and symptoms of lupus, delaying correct diagnoses and often leading to poorer outcomes. Therefore, the LFA's medical advisors recommend a sustained national lupus education campaign to improve awareness and education of the public and health professionals to reduce and prevent suffering from lupus. LFA respectfully requests the subcommittee provide $1 million in new fiscal year 2008 funding to the Office on Women's Health to support this important endeavor. LFA welcomes the opportunity to work with HHS staff and others to ensure the campaign's success.

SUMMARY

LFA very much appreciates the opportunity to submit written testimony on fiscal year 2008 funding for lupus research, epidemiological studies, education and awareness efforts. We understand that the Nation faces unprecedented fiscal challenges; however, LFA has serious concerns that without new Federal investments, we will not make the necessary progress in lupus-related biomedical research and epidemiology at such a promising time. LFA stands ready to work with the subcommittee and others in Congress to reduce and prevent suffering from lupus.

PREPARED STATEMENT OF THE LYMPHOMA RESEARCH FOUNDATION

I am Melanie Smith, director of Public Policy and Advocacy for the Lymphoma Research Foundation (LRF). On behalf of the lymphoma survivors, researchers, and caregivers who are represented by LRF, I would like to express our appreciation for the opportunity to submit a statement to the House Appropriations Subcommittee for Labor, Health and Human Services, and Education. We will focus our remarks on the opportunities and challenges in lymphoma research and the potential for extending and improving the lives of those who are diagnosed with lymphoma.

LRF is the Nation's largest lymphoma-focused voluntary health organization devoted exclusively to funding lymphoma research and providing patients and healthcare professionals with critical information on this disease. LRF's mission is to eradicate lymphoma and serve those touched by this disease. To that end, we have developed a research program through which we fund leading lymphoma researchers at outstanding academic institutions. LRF-funded research focuses on understanding the basic mechanisms of lymphoma as well as enhancing the available treatments for the disease. To date, LRF has funded more than $34.7 million in lymphoma research.

LRF is especially proud of its 3-year initiative to provide more than $21 million for a special mantle cell lymphoma program comprised of eighteen clinical and/or laboratory-based projects in North America and Europe. The program is aimed at identifying curative therapies for mantle cell lymphoma. Because mantle cell lymphoma is a form of lymphoma for which treatment options have been limited and survival much too short, this intensive and aggressive research effort is critically important.

THE BURDEN OF LYMPHOMA AND NEED FOR NEW TREATMENTS

Lymphoma is the most commonly diagnosed hematologic cancer and the third most common childhood cancer. Although lymphoma experts hail the lymphoma

therapeutic advances of the last decade for dramatically changing lymphoma treatment and care, these new treatments do not eliminate the pressing need for additional therapeutic research. The numbers underscore the need for a continued commitment to lymphoma research. In 2007, approximately 71,380 Americans will be diagnosed with lymphoma. It is estimated that 63,190 will be diagnosed with non-Hodgkin lymphoma (NHL), and that 18,660 will die from NHL. Also in 2007, it is expected that 8,190 cases of Hodgkin lymphoma will be diagnosed, and 1,070 Americans will die from the disease. Nearly half a million Americans are living with lymphoma.

The treatment advances of recent years have not boosted the survival rate for NHL as dramatically as we had hoped. The 5-year survival rate is 63 percent and the 10-year survival rate is only 49 percent. The 5-year survival rate for Hodgkin lymphoma is 86 percent and the 10-year survival rate is 81 percent.

Still another issue must be remembered when we are evaluating the progress that has been made in the fight against Hodgkin lymphoma and NHL. There is an increasing body of knowledge about the long-term effects of treatment for cancer, but there is a need for additional research to understand the effects of cancer therapies, develop strategies to minimize or address these effects, and develop therapies that are accompanied by fewer side effects. A study published in a recent edition of the Journal of the National Cancer Institute underscored the challenges facing Hodgkin lymphoma patients; according to the report of a British research team, Hodgkin lymphoma patients may have an increased rate of myocardial infarction for up to 25 years after undergoing treatment. The cardiotoxicity can be attributed to the radiotherapy, anthracyclines, and vincristine used in Hodgkin lymphoma therapy.

ADVANCES IN LYMPHOMA RESEARCH

In the last decade, there have been a number of significant advances in lymphoma research that have contributed to deeper understanding of the disease and its progression and fostered the development of new treatments. Knowledge about the diversity of lymphoma has contributed to the effort to target treatment regimens to specific forms of the disease. In addition, we are learning more about the link between environmental factors and infections—chemicals, toxins, drugs, infectious agents such as hepatitis C and Epstein Barr virus, and the gastric pathogen *Helicobacter pylori*—and many forms of lymphoma.

Recent lymphoma treatment advances are a monoclonal antibody (rituximab) that blocks a specific protein on B lymphocytes and a radioactively labeled monocolonal antibody (tositumomab) that may prolong remission in follicular lymphoma patients. Studies suggest that bortezomib, which inhibits an enzyme complex that plays a role in regulating cell function and growth, will shrink tumors in patients with mantle cell lymphoma. Finally, research is underway on additional immunotherapies, including therapeutic vaccines for lymphoma.

One of the key areas of inquiry is the identification of the best combinations of treatments, including rituximab. Investigators are also considering whether to treat low-grade follicular lymphoma immediately or to continue the current approach of "watch and wait." Stem cell transplantation remains an important part of lymphoma treatment, but additional research may contribute to refinements in the procedure and better results for lymphoma patients.

There are a number of new therapies in development with the hope of prolonging life and providing a better quality of life. In addition, long-term and late effects of treatment are a concern. Lymphoma patients may be at risk for developing second cancers, and investigation of these risks is critical and may contribute to better management of currently available therapies.

ROLE OF LRF IN LYMPHOMA RESEARCH

By supporting outstanding investigators considering a wide range of topics in lymphoma research, LRF contributes significantly to progress in the field. In 2003, LRF made a determination that it would tackle one of the most challenging forms of non-Hodgkin lymphoma, mantle cell lymphoma, with an aggressive and well-coordinated research program that focuses on this rare form of non-Hodgkin lymphoma (NHL) affecting only 6–10 percent of NHL patients.

Since 2003, LRF has dedicated more than $21 million to the Mantle Cell Lymphoma Research Initiative, and with those funds has supported a range of critical research efforts, including:

—Hosting the preeminent scientific meeting focused exclusively on mantle cell lymphoma.

—Formation of the Mantle Cell Lymphoma Consortium to stimulate collaboration among its members to accelerate the pace of finding cures for the disease.

—Launching of an MCL web site and awarding the first set of correlative clinical trials grants.

—Inclusion of nearly 100 scientists in the network of mantle cell researchers.

The Mantle Cell Lymphoma Consortium may serve as a research model for focusing on other forms of lymphoma, and LRF is moving ahead with additional targeted initiatives.

ROLE OF NIH IN LYMPHOMA RESEARCH

LRF will continue to play a strong and creative role in funding lymphoma research, fostering cutting edge initiatives that hold the promise of making a meaningful and positive change in the lives of those living with lymphoma. Although the Foundation's efforts will continue and even expand, its work must be undertaken in collaboration with NIH. This is not only because of the magnitude of the NIH cancer research budget but also because of the potential for NIH to provide leadership among all elements of the research and development community, including NIH intramural researchers, academic researchers, private foundations, industry, and the Food and Drug Administration (FDA).

We understand that the substantial increases in NIH funding that Congress approved between 1999 and 2003 will not be replicated in the foreseeable future. However, we urge that Congress provide an increase of 6.7 percent for NIH in fiscal year 2008, an increase that will simply protect the recent investment in NIH and permit additional research progress. Advances in cancer research have contributed to improvements in survival, but these advances have generally been incremental and have required a sustained funding commitment.

We urge that Congress protect NIH funding and strive to provide an increase in funding to allow researchers to pursue promising avenues of research. LRF recommends that NIH strengthen its lymphoma research program by several actions:

—The National Cancer Institute (NCI) should boost its support for translational and clinical lymphoma research. NCI should support research efforts aimed at evaluating the most appropriate utilization of new therapies, including the best possible combinations of therapies.

—NCI should also enhance its support for correlative studies of tumor biology and treatment response, as well as its investment in research on the late and long-term effects of lymphoma treatments.

—NCI should expand its research effort focused on understanding the complex interaction among environmental, viral, and immunogenetic factors that are involved in the initiation and promotion of lymphoma.

—Although NCI has historically been the lead institute in funding lymphoma research, other institutes, including the National Heart, Lung, and Blood Institute (NHLBI), National Institute on Aging (NIA), and National Institute of Environmental Health Sciences (NIEHS), should also evaluate and improve their lymphoma research programs. A lymphoma-focused initiative to investigate environmental/viral links is warranted.

NCI is developing a plan for the implementation of the recommendations of its Clinical Trials Working Group. To date, most implementation efforts have concentrated on the planning and management of NCI-sponsored clinical trials. We urge NCI to act on recommendations of the Working Group that focused on strengthening patient participation in clinical trials. Increasing the rate of participation in clinical trials is a key element in accelerating the pace of cancer clinical research and the development of new treatments.

We also recommend that NCI consider actions that would encourage the utilization of a centralized institutional review board (IRB), an effort that could contribute to a streamlining of the review of new clinical trials and minimize delays in the clinical trials process. NCI has tested a central IRB, and that IRB or another might be utilized by cancer researchers for review and approval of their protocols. Encouragement from NCI regarding the utilization of a centralized IRB could contribute to a more rapid acceptance among researchers.

We have detailed some impressive advances in lymphoma treatment, but the research task is far from complete. Much more research must be undertaken to ensure proper utilization of existing therapies, and new therapies are needed for a number of different forms of lymphoma. We look forward to the continued commitment of Congress to lymphoma research. As we seek to strengthen our private sector investment in research, we hope that the public-private lymphoma research partnership will continue.

PREPARED STATEMENT OF THE MARCH OF DIMES FOUNDATION

The 3 million volunteers and 1,400 staff members of the March of Dimes Foundation appreciate the opportunity to submit the Foundation's Federal funding recommendations for fiscal year 2008. The March of Dimes is a national voluntary health agency working to improve the health of mothers, infants and children by preventing birth defects, premature birth and infant mortality through research, community services, education, and advocacy.

The volunteers and staff of the March of Dimes urge the subcommittee to provide the funding increases recommended below. Of particular note, one of the last actions of the 109th Congress was unanimous approval of the PREEMIE Act (Public Law 109–450). The March of Dimes commends Congress for recognizing the growing health crisis of preterm birth and calls on the subcommittee to fund two major provisions of the act: (1) expansion of CDC activities related to preterm birth, which are outlined in the CDC section of this testimony and (2) a Surgeon General's Conference and report on preterm birth. In order to convene a Surgeon General's conference on preterm birth and produce a widely disseminated report, $1,000,000 in fiscal year 2008 funding is needed. The conference and report will establish a public-private research and education agenda to accelerate the development of new strategies for preventing preterm birth.

NATIONAL INSTITUTES OF HEALTH (NIH)

The March of Dimes joins the larger research community in recommending a 6.7 percent increase in funding for the NIH bringing total Federal support to just over $30 billion. The 6.7 percent increase was calculated by the biomedical inflator of 3.7 percent and lost purchasing power which is 3 percent. Since the doubling of NIH's budget was completed in 2003, the agency has lost 13 percent of its purchasing power. With all the threats to children's health it is imperative to increase the overall investment in medical research.

Office of the Director

The March of Dimes was extremely pleased that Congress included $69 million for the National Children's Study (NCS) in the fiscal year 2007 Joint Funding Resolution, allowing for implementation of the next phase of the study. The Foundation urges the subcommittee to include within the Office of the Director $111 million ($42 million in new funding) for the NCS in fiscal year 2008. While the amount may seem substantial, it is dwarfed by the cost of treating the diseases and conditions the study is designed to address. Approximately 1 year after the full study is underway researchers will begin a thorough review of data pertaining to premature birth and pregnancy outcomes and, using this data, will focus on an array of serious pediatric health problems. This landmark study holds the potential to dramatically enhance understanding of the causes of preterm birth, birth defects, and infant mortality as well as numerous other childhood diseases and conditions.

National Institute of Child Health and Human Development (NICHD)

The March of Dimes recommends a 6.7 percent increase for NICHD in fiscal year 2008 and an increase of at least $100 million over the next 5 years to boost prematurity-related research. In recent years, the NICHD has made a major commitment to enhance our understanding of the factors that result in premature birth and to develop strategies to prolong pregnancy so that infants are not born too soon. But additional research is needed.

Since 1981, the preterm birth rate has increased 30 percent resulting in more than half a million premature births in 2005—or 1 in 8. Preterm birth is the leading cause of death in the first month of life and, for those babies who do survive, 1 in 5 experience life long health problems including cerebral palsy, mental retardation, chronic lung disease, and vision and hearing loss. Preterm labor can happen to any pregnant woman, and the causes of nearly half of all premature births are not yet known.

This growing problem of preterm births was brought into sharp focus by the 2006 Institute of Medicine (IOM) report entitled, "Preterm Birth: Causes, Consequences and Prevention." The IOM found that the annual economic burden associated with preterm birth in the United States was at least $26.2 billion, or $51,600 per infant born preterm. In 2003, the national hospital bill alone for the care of these babies exceeded $18 billion, half of which was borne by Medicaid and other public programs and the remainder was charged to employers and families.

Safe Motherhood/Infant Health

The National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health works to promote optimal reproductive and infant health. The March of Dimes recommends an $8 million increase, as authorized in the PREEMIE Act, for CDC to increase epidemiological research on preterm labor and delivery, which is vital to ultimately preventing preterm birth.

Specifically, these additional funds will enable CDC to conduct additional epidemiological studies on preterm birth, including the relationship between prematurity, birth defects and developmental disabilities. These new funds will also make possible the establishment of systems for the collection of maternal-infant clinical and biomedical information that is linked with the Pregnancy Risk Assessment Monitoring System (PRAMS). Increasing CDC's research activities related to preterm birth will bring the Nation closer to improving screening and early detection and finding new interventions for women at risk for preterm labor.

National Center on Birth Defects and Developmental Disabilities (NCBDDD)

Of particular interest to the March of Dimes is NCBDDD's birth defects program that includes surveillance, research and prevention activities. For fiscal year 2008, the March of Dimes requests an increase of $10 million to support surveillance and research and an additional $2 million for folic acid education. In the March of Dimes professional judgment, these modest increases are vital to making progress in reducing the incidence of birth defects.

In the United States, about 3 percent of all babies are born with a major birth defect. Birth defects are the leading cause of infant mortality accounting for more than 20 percent of all infant deaths every year. Children with birth defects who survive may experience lifelong physical and mental disabilities, and are at increased risk for developing other health problems. In fact, birth defects contribute substantially to the Nation's health care costs. According to CDC, the lifetime economic cost of caring for infants born each year with 1 of the 18 most common birth defects exceeds $8 billion.

The causes of nearly 70 percent of birth defects are unknown and it is therefore critical that the subcommittee increase funding for the National Birth Defects Prevention Study. This groundbreaking CDC initiative is being carried out by 9 regional Centers for Birth Defects Research and Prevention located in Arkansas, California, Georgia, Iowa, Massachusetts, New York, North Carolina, Texas, and Utah. Each of these centers identify infants with major birth defects; interview mothers about medical history, environmental exposures, and lifestyle before and during pregnancy; and collect DNA samples to study gene-environment interactions. This study has nearly 11 years worth of data and DNA samples collected. Due to funding limitations, CDC has yet to be able to analyze the DNA samples to identify genetic risk factors. In addition, without increased funding the CDC will be forced to decrease the number of centers participating in the study.

NCBDDD also provides funding to assist States with community-based birth defects tracking systems, programs to prevent birth defects and improve access to health services for children with birth defects. Surveillance forms the backbone of a vital, functional and responsive public health network. Additional resources are sorely needed to help States seeking assistance.

Finally, NCBDDD is conducting a national public and health professions education campaign designed to increase the number of women taking folic acid. CDC estimates that up to 70 percent of neural tube defects (NTDs), serious birth defects of the brain and spinal cord including anencephaly and spina bifida could be prevented if all women of childbearing age consume 400 micrograms of folic acid daily, beginning before pregnancy. Since 1996, the rate of NTDs in the United States has decreased by 26 percent. Unfortunately, according to a recent analysis conducted by CDC folate concentrations among non-pregnant women of child bearing age decreased by 16 percent from 1999–2000 through 2003–2004. Clearly, women are still not receiving an adequate level of folic acid and increased resources to CDC for the expansion of its folic acid education campaign is needed.

National Center for Health Statistics

The National Center for Health Statistics (NCHS) provides data essential for both public and private research and programmatic initiatives. The National Vital Statistics System and the National Survey on Family Growth, for example, is the principal source of information on the utilization of prenatal care and on birth outcomes, including preterm delivery, low birthweight and infant mortality. The current funding level threatens the collection of vital information and more specifically NCHS

lacks the resources to collect a full year's worth of vital statistics from States. Without at least $3 million in additional funding we will become the first industrialized Nation unable to collect birth, death and other vital statistics. The March of Dimes supports a funding level of $117 million, an increase of $8 million over fiscal year 2007, to ensure that NCHS continues its role in monitoring our Nation's health.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

Newborn Screening

Newborn screening is a vital public health activity used to identify and treat genetic, metabolic, hormonal and functional conditions in newborns. Screening detects disorders in newborns that, if left untreated, can cause death, disability, mental retardation and other serious illnesses. Parents are often unaware that while nearly all babies born in the United States undergo newborn screening for genetic birth defects, the number and quality of these tests vary from State to State. The March of Dimes, the American Academy of Pediatrics and the American College of Medical Genetics recommend that at a minimum, every baby born in the United States be screened for a core group of 29 treatable conditions regardless of the State in which the infant is born. Only 11 States and the District of Columbia currently screen for all 29 of these conditions.

Currently, Federal support for State newborn screening activities is provided through the Maternal and Child Health Block Grant, Special Projects of Regional and National Significance (SPRANS). The March of Dimes recommends full funding of the MCH Block Grant at the authorized level of $850 million. In addition, the Foundation urges that $9 million of SPRANS funding be set-aside for newborn screening activities (an increase of $3 million over fiscal year 2007). In the March of Dimes professional judgment, this funding will allow for the continuation of the Regional Genetic Service and Newborn Screening Collaboratives that focus on the maldistribution of genetic services and resources and bring services closer to local communities. It would also enable HRSA to improve the capacity of States to: (1) provide screening, counseling, testing, and special services for newborns and children at risk for heritable disorders; (2) educate health professionals and parents on the availability and importance of newborn screening; and (3) support States with technical assistance on the acquisition and use of new technologies and newborn screening services.

FISCAL YEAR 2008 FEDERAL FUNDING RECOMMENDATIONS

[In millions of dollars]

Program	Fiscal year 2007 funding	March of Dimes fiscal year 2008 recommendation
National Institutes of Health (Total)	28,879	30,813
National Children's Study	69	111
National Institute of Child Health & Human Development	1,253	1,337
National Human Genome Research Institute	486	519
National Center on Minority Health and Disparities	199	212
Center for Disease Control and Prevention (CDC)	6,095	7,800
Save Motherhood/Infant Health (NCCDPHP)	44	52
Birth Defects Research & Surveillance	15	25
Folic Acid Education Campaign	2	4
Immunization	520	802.4
Polio Eradication	101	101
National Center for Health Statistics	109	117
Health Resources and Services Administration (Total)	6,884	7,500
Maternal and Child Health Block Grant	693	850
Newborn Screening	6	9
Newborn Hearing Screening	10	10
Consolidated (Community) Health Centers	1,988	2,188
Healthy Start	102	102
Agency for Healthcare Research and Quality	319	350

PREPARED STATEMENT OF MEHARRY MEDICAL COLLEGE

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

$300 million for the Title VII Health Professions Training programs, including:
—$33.6 million for the Minority Centers of Excellence.
—$35.6 million for the Health Careers Opportunity program.
$250 million for the National Institutes of Health's National Center on Minority Health and Health Disparities.
$169 million for the National Center for Research Resources Extramural Facilities Construction program.
—$6.7 percent increase for Research Centers for Minority Institutions.
—$119 million for Extramural Facilities construction.
$65 million for the Department of Health and Human Services' Office of Minority Health.
$65 million for the Department of Education's Strengthening Historically Black Graduate Institutions program.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Wayne J. Riley, president and CEO of Meharry Medical College in Nashville, Tennessee. I have previously served as vice-president and vice dean for health affairs and governmental relations and associate professor of medicine at Baylor College of Medicine in Houston, Texas and as assistant chief of medicine and a practicing general internist at Houston's Ben Taub General Hospital. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

Mr. Chairman, time and time again, you have encouraged your colleagues and the rest of us to take a look at our Nation and evaluate our needs over the next 10 years. I want to say that minority health professional institutions and the Title VII Health Professionals Training programs address a critical national need. Persistent and sever staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. If you take minorities as a whole, Minority health professional institutions and the Title VII Health Professions Training programs address this critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example, African Americans represent approximately 15 percent of the U.S. population while only 2–3 percent of the Nation's healthcare workforce is African American.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the

underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Institutions that cultivate minority health professionals have been particularly hard-hit as a result of the cuts to the Title VII Health Profession Training programs in fiscal year 2006 and fiscal year 2007 Funding Resolution passed earlier this Congress. Given their historic mission to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The cuts to the Title VII Health Professions Training programs amount to a loss of core funding at these institutions and have been financially devastating.

Mr. Chairman, I feel like I can speak authoritatively on this issue because I received my medical degree from Morehouse School of Medicine, a historically black medical school in Atlanta. I give credit to my career in academia, and my being here today, to Title VII Health Profession Training programs' Faculty Loan Repayment Program. Without that program, I would not be the president of my father's alma mater, Meharry Medical College, another historically black medical school dedicated to eliminating healthcare disparities through education, research and culturally relevant patient care.

In fiscal year 2008, funding for the Title VII Health Professions Training programs must be restored to the fiscal year 2005 level of $300 million, with two programs—the Minority Centers of Excellence (COEs) and Health Careers Opportunity Program (HCOPs)—in particular need of a funding restoration. In addition, the National Institutes of Health (NIH)'s National Center on Minority Health and Health Disparities (NCMHD), as well as the Department of Health and Human Services (HHS)'s Office of Minority Health (OMH), are both in need of a funding increase.

MINORITY CENTERS OF EXCELLENCE

COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions (the Medical and Dental Institutions at Meharry Medical College; The College of Pharmacy at Xavier University; and the School of Veterinary Medicine at Tuskegee University) to the training of minorities in the health professions. Congress later went on to authorize the establishment of "Hispanic", "Native American" and "Other" Historically black COEs.

Presently the statute is configured in such a way that the "original four" institutions compete for the first $12 million in funding, "Hispanic and Native American" institutions compete for the next $12 million, and "Other" institutions can compete for grants when the overall funding is above $24 million. For funding above $30 million all eligible institutions can compete for funding.

However, as a consequence of limited funding for COEs in fiscal year 2006 and fiscal year 2007, "Hispanic and Native American" and "Other" COEs have lost their support. Out of 34 total COEs in fiscal year 2005, only 4 now remain due to the cuts in funding.

For fiscal year 2008, I recommend a funding level of $33.6 million for COEs.

HEALTH CAREERS OPPORTUNITY PROGRAM (HCOP)

HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional.

Collectively, the absence of HCOPs will substantially erode the number of minority students who enter the health professions. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. If HCOPs continue to lose Federal support, then these numbers will drastically decrease. It is estimated that the number of minority students admitted to health professional schools will drop by 25–50 percent without HCOPs. A reduction of just 25 percent in the number of minority students admitted to medical school will produce approximately 600 fewer minority medical students nationwide.

As a result of cuts in the fiscal year 2006 and fiscal year 2007 Labor-HHS Appropriations process, only 4 out of 74 total HCOPs currently receive Federal funding. As president of Meharry, I feel this loss as we were one of the 70 institutions who lost their HCOP grants.

For fiscal year 2008, I recommend a funding level of $35.6 million for HCOPs.

NATIONAL INSTITUTES OF HEALTH (NIH): EXTRAMURAL FACILITIES CONSTRUCTION

Mr. Chairman, if we are to take full advantage of the recent funding increases for biomedical research that Congress has provided to NIH over the past decade, it is critical that our Nation's research infrastructure remain strong. The current authorization level for the Extramural Facility Construction program at the National Center for Research Resources is $250 million. The law also includes a 25 percent set-aside for "Institutions of Emerging Excellence" (many of which are minority institutions) for funding up to $50 million. Finally, the law allows the NCRR Director to waive the matching requirement for institutions participating in the program. We strongly support all of these provisions of the authorizing legislation because they are necessary for our minority health professions training schools.

Unfortunately, funding for NCRR's Extramural Facility Construction program was completely eliminated in the fiscal year 2006 Labor-HHS bill, and no funding was restored in the funding resolution for fiscal year 2007. In fiscal year 2008, please restore funding for this program to its fiscal year 2004 level of $119 million, or at a minimum, provide funding equal to the fiscal year 2005 appropriation of $40 million.

RESEARCH CENTERS IN MINORITY INSTITUTIONS

The Research Centers at Minority Institutions program (RCMI) at the National Center for Research Resources has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2008.

STRENGTHENING HISTORICALLY BLACK GRADUATE INSTITUTIONS—DEPARTMENT OF EDUCATION

The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, section 326) is extremely important to MMC and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2008, an appropriation of $65 million (an increase of $7 million over fiscal year 2007) is suggested to continue the vital support that this program provides to historically black graduate institutions.

National Center on Minority Health and Health Disparities

The National Center on Minority Health and Health Disparities (NCMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NCMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NCMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NCMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the Minority Centers of Excellence program.

For fiscal year 2008, I recommend a funding level of $250 million for the NCMHD.

Department of Health and Human Services' Office of Minority Health (OMH)

Specific programs at OMH include:

(1) Assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals,

(2) Assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers,

(3) Supporting conferences for high school and undergraduate students to interest them in health careers, and

(4) Supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

The OMH has the potential to play a critical role in addressing health disparities. Unfortunately, the OMH does not yet have the authority or resources necessary to support activities that will truly make a difference in closing the health gap between minority and majority populations.

For fiscal year 2008, I recommend a funding level of $65 million for the OMH.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, Meharry Medical College along with other minority health professions institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. Meharry and other minority health professions schools seek to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity as we have done for 1,876.

Thank you, Mr. Chairman, for this opportunity.

PREPARED STATEMENT OF THE MOREHOUSE SCHOOL OF MEDICINE

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

$300 million for the Title VII Health Professions Training programs, including:

—$33.6 million for the Minority Centers of Excellence.

—$35.6 million for the Health Careers Opportunity program.

$250 million for the National Institutes of Health's National Center on Minority Health and Health Disparities.

Support for the National Center for Research Resources Extramural Facilities Construction program.

—$6.7 percent increase for Research Centers for Minority Institutions.

—$119 million for Extramural Facilities Construction.

$65 million for the Department of Health and Human Services' Office of Minority Health.

$65 million for the Department of Education's Strengthening Historically Black Graduate Institutions program.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. John E. Maupin, president of Morehouse School of Medicine (MSM) in Atlanta, Georgia. I have previously served as President of Meharry Medical College, executive vice-president at Morehouse School of Medicine, as director of a community health center in Atlanta, and deputy director of health in Baltimore, Maryland. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

Mr. Chairman, time and time again, you have encouraged your colleagues and the rest of us to take a look at our Nation and evaluate our needs over the next 10 years. I want to say that minority health professional institutions and the Title VII Health Professionals Training programs address a critical national need. Persistent and sever staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. Morehouse is a private school with a very public mission of educating students from traditionally underserved communities so that they will care for the underserved. Mr. Chairman, I would like to share with you how your committee can help us continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural

and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Institutions that cultivate minority health professionals, like MSM, have been particularly hard-hit as a result of the cuts to the Title VII Health Profession Training programs in fiscal year 2006 and fiscal year 2007 Funding Resolution passed earlier this Congress. Given their historic mission to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The cuts to the Title VII Health Professions Training programs amount to a loss of core funding at these institutions and have been financially devastating.

Mr. Chairman, I feel like I can speak authoritatively on this issue because I received my medical degree from Meharry Medical College, a historically black medical and dental school in Nashville, Tennessee. I have seen first hand what Title VII funds have done to minority serving institutions like Morehouse and Meharry. I compare my days as a student to my days as president, without that Title VII, our institutions would not be here today. However, Mr. Chairman, since those funds have been cut in the last 2 fiscal years, we are standing at a cross roads. This committee has the power to decide if our institutions will go forward and thrive, or if we will continue to try to just survive. We want to work with you to eliminate health disparities and produce world class professionals, but we need your assistance.

In fiscal year 2008, funding for the Title VII Health Professions Training programs must be restored to the fiscal year 2005 level of $300 million, with two programs—the Minority Centers of Excellence (COEs) and Health Careers Opportunity Program (HCOPs)—in particular need of a funding restoration. In addition, the National Institutes of Health (NIH)'s National Center on Minority Health and Health Disparities (NCMHD), as well as the Department of Health and Human Services (HHS)'s Office of Minority Health (OMH), are both in need of a funding increase.

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However, as a consequence of limited funding for COEs in fiscal year 2006 and fiscal year 2007, "Hispanic and Native American" and "Other" COEs have lost their support. Out of 34 total COEs in fiscal year 2005, only 4 now remain due to the cuts in funding. MSM lost its COE funding as well, which was a devastating blow to our School.

For fiscal year 2008, I recommend a funding level of $33.6 million for COEs.

HEALTH CAREERS OPPORTUNITY PROGRAM (HCOP)

HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary

schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional.

Collectively, the absence of HCOPs will substantially erode the number of minority students who enter the health professions. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. If HCOPs continue to lose Federal support, then these numbers will drastically decrease. It is estimated that the number of minority students admitted to health professional schools will drop by 25–50 percent without HCOPs. A reduction of just 25 percent in the number of minority students admitted to medical school will produce approximately 600 fewer minority medical students nationwide.

As a result of cuts in the fiscal year 2006 and fiscal year 2007 Labor-HHS Appropriations process, only 4 out of 74 total HCOPs currently receive Federal funding. As president of MSM, I am proud to say we competed well enough to be one of those four; however, those who have the same mission as ours must have this funding as well.

For fiscal year 2008, I recommend a funding level of $35.6 million for HCOPs.

NATIONAL INSTITUTES OF HEALTH (NIH): EXTRAMURAL FACILITIES CONSTRUCTION

Mr. Chairman, if we are to take full advantage of the recent funding increases for biomedical research that Congress has provided to NIH over the past decade, it is critical that our Nation's research infrastructure remain strong. The current authorization level for the Extramural Facility Construction program at the National Center for Research Resources is $250 million. The law also includes a 25 percent set-aside for "Institutions of Emerging Excellence" (many of which are minority institutions) for funding up to $50 million. Finally, the law allows the NCRR Director to waive the matching requirement for institutions participating in the program. We strongly support all of these provisions of the authorizing legislation because they are necessary for our minority health professions training schools.

Unfortunately, funding for NCRR's Extramural Facility Construction program was completely eliminated in the fiscal year 2006 Labor-HHS bill, and no funding was restored in the funding resolution for fiscal year 2007. In fiscal year 2008, please restore funding for this program to its fiscal year 2004 level of $119 million, or at a minimum, provide funding equal to the fiscal year 2005 appropriation of $40 million.

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The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to MMC and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2008, an appropriation of $65 million (an increase of $7 million over fiscal year 2007) is suggested to continue the vital support that this program provides to historically black graduate institutions.

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The OMH has the potential to play a critical role in addressing health disparities. Unfortunately, the OMH does not yet have the authority or resources necessary to support activities that will truly make a difference in closing the health gap between minority and majority populations.

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Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, Morehouse School of Medicine along with other minority health professions institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. MSM and other minority health professions schools seek to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity as we have since our founding day.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE TO END HOMELESSNESS

The National Alliance to End Homelessness (the Alliance) is a nonpartisan, nonprofit organization that has several thousand partner agencies and organizations across the country. These partners are local faith-based and community-based nonprofit organizations and public sector agencies that provide homeless people with shelter, transitional and permanent housing, and services such as substance abuse treatment, job training, and physical health and mental health care. In addition, we have supported over 160 State and local entities who have completed 10 year plans to end homelessness. The Alliance represents a united effort to address the root causes of homelessness and challenge society's acceptance of homelessness as an inevitable by-product of American life.

Overview—Our recent research report, Homelessness Counts, estimates that 744,313 people are homeless on any given night. This includes 98,452 families. Fifty-six percent of the total were living in shelters or transitional housing and 44 percent were unsheltered. This report illustrates that far too many people are homeless and many are not being reached by existing programs. This is inexcusable given that we know what interventions work and several communities are making progress toward ending homelessness. These interventions, such as housing first for families and permanent supportive housing, couple housing with an appropriate level of services for the family or individual. Therefore, not only does the Department of Housing and Urban Development play a role in ending homelessness, so do the Departments of Labor, Health and Human Services, and Education. We call on Congress and all Federal agencies to adequately fund the programs that assist States and local entities in developing permanent housing and the necessary social services to once and for all end homelessness for all Americans.

GOALS

1. *Moving Forward to End Homelessness*.—Communities across America are working toward ending homelessness. Communities are using Federal, State, and local funds to help homeless persons maintain housing. It is important that this progress not be undermined. To this end, the Alliance recommends the following:

—Allocate an additional $80 million for services in permanent supportive housing within SAMHSA's Center for Mental Health Services.

—Increase funding to Projects for Assistance in Transition from Homelessness (PATH) to $58.3 million.

—Increase the Runaway and Homeless Youth Act Programs to $140 million.

—Provide a $200 million increase in the Community Health Center program within Health Resource Services Administration. This would result in the Health Care for the Homeless programs receiving $190 million.
—Fund Education for Homeless Children and Youth services at its full authorized level of $70 million.
—Increase funding for the Homeless Veterans Reintegration Program to $50 million.

2. *Connecting Homeless Families, Individuals, and Youth to Mainstream Services*.—People experiencing homelessness also depend on mainstream programs such as the ones below to live day to day and once housed, remain housed. The Alliance recommends the following to meet this goal:
—Fund the Social Services Block Grant at $1.7 billion, the same funding level as fiscal year 2006.
—Reject cuts and fund the Community Services Block Grant at $700 million
—Appropriate $60 million in education and training vouchers for youth exiting foster care under the Safe and Stable Families Program.

GOAL 1—MOVING FORWARD TO END HOMELESSNESS

Support Services for Permanent Supportive Housing Projects

The Alliance recommends allocating an additional $80 million for services in permanent supportive housing within SAMHSA's Center for Mental Health Services. The administration has set a goal of ending chronic homelessness by 2012 and joined with Congress to set a goal of creating 150,000 additional units of permanent supportive housing. According to the Alliance's report, Homelessness Counts, 23 percent of those who are homeless on any given night meet the chronic homelessness definition of being homeless for long periods of time or repeatedly. These people need access to housing and support services. The Alliance and our partners believe the Department of Health and Human Services needs to raise its commitment to provide the services necessary to end homelessness. Therefore, we are proposing this increase in SAMHSA funding to help communities provide services to 16,000 new units of permanent supportive housing.

PROJECTS FOR TRANSITION ASSISTANCE FROM HOMELESSNESS (PATH)

The Alliance recommends that Congress increase PATH funding to $58.3 million and adjust the funding formula to increase allocation for small States and territories.

The PATH program provides access to mental health services for homeless people with serious mental illnesses. PATH focuses on outreach to eligible consumers, followed by help in ensuring that those consumers are connected with mainstream services, such as Supplemental Security Income (SSI), Medicaid and welfare programs. Under the PATH formula grant, approximately 30 States share in the program's annual appropriations increases. The remaining States and territories receive the minimum grant of $300,000 for States and $50,000 for territories. These amounts have not been raised since the program was authorized in 1991. To account for inflation, the minimum allocation should be raised to $600,000 for States and $100,000 for territories. Amending the minimum allocation requires a legislative change. If the authorizing committees do not address this issue, we hope that appropriators will explore ways to make the change through appropriations bill language.

RUNAWAY AND HOMELESS YOUTH PROGRAMS

The Alliance recommends funding the Runaway and Homeless Youth Act (RHYA) programs at $140 million. RHYA programs support cost-effective, community and faith-based organizations that protect youth from the harms of life on the streets. The problems of homeless and runaway youth are addressed by the Administration for Children and Families within HHS, which operates coordinated competitive grant programs like RHYA. The RHYA programs can either reunify youth safely with family or find alternative living arrangements. RHYA programs end homelessness by: engaging youth living on the street with Street Outreach Programs, quickly providing emergency shelter and family crisis counseling through the Basic Centers, or providing supportive housing that helps young people develop lifelong independent living skills through Transitional Living Programs. Recently, the Congressional Research Service issued a report complimenting the good work of RHYA programs but detailing the gaps in services due to limited funding. It is essential that Congress increase this program.

COMMUNITY HEALTH CENTERS AND HEALTH CARE FOR THE HOMELESS (HCH) PROGRAMS

The Alliance recommends a $200 million increase to the Community Health Centers Program which would result in funding the HCH programs at $190 million.

Persons living on the street suffer from health problems resulting from or exacerbated by the condition of being homeless, such as hypothermia, frostbite, and heatstroke. In addition, they often have infections of the respiratory and gastrointestinal systems, tuberculosis, vascular diseases such as leg ulcers, and hypertension.[1] Health care for the homeless programs are vital to prevent these conditions from becoming fatal. Congress allocates 8.7 percent of the Consolidated Health Centers account for Health Care for the Homeless (HCH) projects. The HCH program has achieved significant success since its inception in 1987, but the health care needs of Americans experiencing homelessness each year far exceed the service capacity of Health Care for the Homeless grantees.

EDUCATION FOR HOMELESS CHILDREN AND YOUTH

The Alliance recommends funding Education for Homeless Children and Youth (EHCY) at its full authorized level of $70 million. The most important potential source of stability for homeless children is school. The mission of the Education for Homeless Children and Youth program is to ensure that these children can continue to attend school and thrive. The Education for Homeless Children and Youth program, within the Department of Education's Office of Elementary and Secondary Education, removes obstacles to enrollment and retention by establishing liaisons between schools and shelters and providing funding for transportation, tutoring, school supplies, and the coordination of statewide efforts to remove barriers.

HOMELESS VETERANS REINTEGRATION PROGRAM (HVRP)

The Alliance recommends that Congress increase HVRP funding to $50 million.

HVRP, within the Department of Labor's Veterans Employment and Training Service (VETS), provides competitive grants to community-based, faith-based, and public organizations to offer outreach, job placement, and supportive services to homeless veterans. HVRP is the primary employment services program accessible by homeless veterans and the only targeted employment program for any homeless subpopulation. It is estimated that this program only reaches about two percent of the overall homeless veteran population. An appropriation at the authorized level of $50 million would enable HVRP grantees to reach approximately 19,866 homeless veterans.

GOAL 2—CONNECTING HOMELESS FAMILIES, INDIVIDUALS AND YOUTH TO MAINSTREAM SERVICES

Social Services Block Grant (SSBG)

The Alliance recommends that Congress fully restore SSBG funding to its fiscal year 2006 level of $1.7 billion. SSBG funds are essential for programs dedicated to ending homelessness. In particular, youth housing programs and permanent supportive housing providers often receive State, county, and local funds which originate from the SSBG. As the U.S. Department of Housing and Urban Development has focused its funding on housing, programs that provide both housing and social services have struggled to fund the service component of their programs. This gap is often closed using Federal programs such as SSBG.

Community Services Block Grant (CSBG)

The Alliance recommends that Congress fully restore CSBG funding to its fiscal year 2006 level of $630 million. Funding cuts for the CSBG will destabilize the progress communities have made toward ending homelessness by not only ending services directly provided by CSBG funds but limiting a community's ability to access other Federal dollars such as those provided by HUD. Community Action Agencies (CAAs) are directly involved in housing and homelessness services. In several communities, CAAs lead the Continuum of Care (CoC). CoCs coordinate local homeless service providers and the community's McKinney-Vento Homeless Assistance Grant application process with the Department of Housing and Urban Development.

In the fiscal year 2004 Community Services Block Grant Information Systems report published by the U.S. Department of Health and Human Services, CAAs reported administering $207.4 million in section 8 vouchers, $30 million in section 202

[1] Harris, Shirley N, Carol T. Mowbray and Andrea Solarz. Physical Health, Mental Health and Substance Abuse Problems of Shelter Users. Health and Social Work, Vol. 19, 1994.

services[2] and $271.1 million in other Department of Housing and Urban Development (HUD) programs which includes homeless program funding.[3]

Foster Youth Education and Training Vouchers

The Alliance recommends that Congress appropriate $60 million in education and training vouchers for youth exiting foster care under the Safe and Stable Families Program. The Education and Training Voucher Program offers funds to foster youth and former foster youth to enable them to attend colleges, universities and vocational training institutions. Students may receive up to $5,000 a year for college or vocational training education. The funds may be used for tuition, books, housing, or other qualified living expenses. Given the large number of people experiencing homelessness who have a foster care history, it is important to provide assistance such as these education and training vouchers to stabilize youth, prevent economic crisis, and prevent possible homelessness.

CONCLUSION

Homelessness is not inevitable. As communities implement plans to end homelessness, they are struggling to find funding for the services homeless and formerly homeless clients need to maintain housing. The Federal investments in mental health services, substance abuse treatment, employment training, youth housing, and case management discussed above will help communities create stable housing programs and change social systems which will end homelessness for millions of Americans.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH (NAEVR)

EXECUTIVE SUMMARY

NAEVR requests fiscal year 2008 NIH funding at $31 billion, or a 6.7 percent increase over fiscal year 2007, to balance the biomedical inflation rate of 3.7 percent and to maintain the momentum of discovery. Although NAEVR commends the leadership's actions in the 110th Congress to increase fiscal year 2007 NIH funding by $620 million, this was just an initial step in restoring the NIH's purchasing power, which has declined by more than 13 percent since fiscal year 2005. That power would be eroded even further under the President's proposed fiscal year 2008 budget. NAEVR commends NIH Director Dr. Zerhouni who has articulately described his agenda to foster collaborative, cost-effective research and to transform the healthcare research and delivery paradigm into one that is predictive, preemptive, preventive, and personalized. NIH is the world's premier institution and must be adequately funded so that its research can reduce healthcare costs, increase productivity, improve quality of life, and ensure our Nation's global competitiveness.

NAEVR requests that Congress make vision health a top priority by funding the NEI at $711 million in fiscal year 2008, or a 6.7 percent increase over fiscal year 2007. This level is necessary to fully advance the breakthroughs resulting from NEI's basic and clinical research that are resulting in treatments and therapies to prevent eye disease and restore vision. Vision impairment/eye disease is a major public health problem that is growing and which disproportionately affects the aging and minority populations, costing the United States $68 billion annually in direct and societal costs, let alone reduced independence and quality of life. Adequately funding the NEI is a cost-effective investment in our Nation's health, as it can delay, save, and prevent expenditures, especially to the Medicare and Medicaid programs.

FUNDING THE NEI AT $711 MILLION IN FISCAL YEAR 2008 ENABLES IT TO LEAD TRANS–INSTITUTE VISION RESEARCH THAT MEETS NIH'S GOAL OF PREEMPTIVE, PREDICTIVE, PREVENTIVE, AND PERSONALIZED HEALTHCARE

Funding NEI at $711 million in fiscal year 2008 represents the eye and vision research community's judgment as that necessary to fully advance breakthroughs resulting from NEI's basic and clinical research that are resulting in treatments and therapies to prevent eye disease and restore vision.

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[2] Section 202 is dedicated to housing from elderly and disabled individuals and families.

[3] U.S. Department of Health and Human Services, Administration of Children and Families. The Community Services Block Grant fiscal year 2004 Statistical Report. Prepared by the National Association for State Community Services Programs.

NEI research responds to the NIH's overall major health challenges, as set forth by Dr. Zerhouni: an aging population; health disparities; the shift from acute to chronic diseases; and the co-morbid conditions associated with chronic diseases (e.g., diabetic retinopathy as a result of the epidemic of diabetes). In describing the predictive, preemptive, preventive, and personalized approach to healthcare research, Dr. Zerhouni has frequently cited NEI-funded research as tangible examples of the value of our Nation's past and future investment in the NIH. These include:

—Dr. Zerhouni has cited as a breakthrough the collaborative Human Genome Project/NEI-funded discovery of gene variants strongly associated with an individual's risk of developing age-related macular degeneration (AMD), the leading cause of blindness (affecting more than 10 million Americans) which increasingly robs seniors of their independence and quality of life. These variants, which are responsible for about 60 percent of the cases of AMD, are associated with the body's inflammatory response and may relate to other inflammation-associated diseases, such as Alzheimer's and Parkinson's disease. As NEI Director Dr. Paul Sieving has stated, "One of the important stories during the next decade will be how Alzheimer's disease and macular degeneration fit together."

—Dr. Zerhouni has cited the NEI-funded Age-Related Eye Disease Study (AREDS) as a cost-effective preventive measure. In 2006, NEI began the second phase of the AREDS study, which will follow up on initial study findings that high levels of dietary zinc and antioxidant vitamins (Vitamins C, E and beta-carotene) are effective in reducing vision loss in people at high risk for developing advanced AMD—by a magnitude of 25 percent.

—NEI has funded research, along with the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI), into factors that promote new blood vessel growth (such as Vascular Endothelial Growth Factor, or VEGF). This has resulted in anti-VEGF factors that have been translated into the first generation of ophthalmic drugs approved by the Food and Drug Administration (FDA) to inhibit abnormal blood vessel growth in "wet" AMD, thereby stabilizing vision loss. Current research is focused on using treatments singly and in combination to improve vision or prevent further vision loss due to AMD. As part of its Diabetic Retinopathy Clinical Research Network, NEI is also evaluating these drugs for treatment of macular edema associated with diabetic retinopathy.

Although these breakthroughs came directly from the past doubling of the NIH budget, their long-term potential to preempt, predict, prevent, and treat disease relies on adequately funding NEI's follow-up research. Unless its funding is increased, the NEI's ability to capitalize on the findings cited above will be seriously jeopardized, resulting in "missed opportunities" that could include:

—Following up on the AMD gene discovery by developing diagnostics for early detection and promising therapies, as well as to further study the impact of the body's inflammatory response on other degenerative eye diseases.

—Fully investigating the impact of additional, cost-effective dietary supplements in the AREDS study, singly and in combination, to determine if they can demonstrate enhanced protective effects against progression to advanced AMD.

—Following up with further clinical trials on patients with the "wet" form of AMD, as well as patients with diabetic retinopathy, using the new anti-angiogenic ophthalmic drugs singly and in combination to halt disease progression and potentially restore vision.

In addition, NEI research into other significant eye disease programs, such as glaucoma and cataract, will be threatened, along with quality of life research programs into low vision and chronic dry eye. This comes at a time when the U.S. Census and NEI-funded epidemiological research (also threatened without adequate funding) both cite significant demographic trends that will increase the public health problem of vision impairment and eye disease.

VISION IMPAIRMENT/EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM THAT IS INCREASING HEALTHCARE COSTS, REDUCING PRODUCTIVITY, AND DIMINISHING QUALITY OF LIFE

The 2000 U.S. Census reported that more than 119 million people in the United States were age 40 or older, which is the population most at risk for an age-related eye disease. The NEI estimates that, currently, more than 38 million Americans age 40 and older experience blindness, low vision or an age-related eye disease such as AMD, glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million Americans by year 2020. The economic and societal impact of eye disease is increasing not only due to the aging population, but to its dispropor-

tionate incidence in minority populations and as a co-morbid condition of other chronic disease, such as diabetes.

Although the NEI estimates that the current annual cost of vision impairment and eye disease to the United States is $68 billion, this number does not fully quantify the impact of direct healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. The continuum of vision loss presents a major public health problem and financial challenge to both the public and private sectors.

In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer. As a result, Federal funding for the NEI is a vital investment in the health, and vision health, of our Nation, especially our seniors, as the treatments and therapies emerging from research can preserve and restore vision. Adequately funding the NEI can delay, save, and prevent expenditures, especially those associated with the Medicare and Medicaid programs, and is, therefore, a cost-effective investment.

NAEVR urges fiscal year 2008 NIH and NEI funding at $31 billion and $711 million, respectively.

ABOUT NAEVR

Founded in 1997, NAEVR is a non-profit advocacy organization comprised of a coalition of 55 professional, consumer, and industry organizations (see list below) involved in eye and vision research. NAEVR's goal is to achieve the best vision for all Americans through advocacy and public education about the value and cost-effectiveness of eye and vision research sponsored by the NIH, NEI, and other Federal research entities.

Advanced Medical Optics; Alcon Laboratories, Inc.; Allergan, Inc.; AMD Alliance International; American Academy of Ophthalmology; American Academy of Optometry; American Association for Pediatric Ophthalmology and Strabismus; American Assoc. of Ophthalmic Pathologists; American Diabetes Association; American Glaucoma Society; American Ophthalmological Society; American Society of Retina Specialists; American Optometric Association; American Society of Cataract and Refractive Surgery; American Uveitis Society; Association for Research in Vision and Ophthalmology; Association of Schools and Colleges of Optometry; Association of University Professors of Ophthalmology; Association of Vision Science Librarians; Bausch & Lomb; Blinded Veterans Association; Discovery Eye Foundation; Eli Lilly & Company; Eye Bank Association of America; EyeSight Foundation of Alabama; Fight for Sight; Foundation Fighting Blindness; Genentech, Inc.; Glaucoma Research Foundation; Inspire Pharmaceuticals, Inc.; ISTA Pharmaceuticals, Inc.; Juvenile Diabetes Research Foundation Intl.; Lighthouse International; Lions Clubs Intl. Foundation; Macular Degeneration Partnership; Natl. Vision Rehabilitation Assoc.; Novartis; Ocular Microbiology and Immunology Group; Pfizer Inc.; Prevent Blindness America; Prevention of Blindness Society of Metropolitan Washington; Research to Prevent Blindness; Santen, Inc.; Second Sight; Sjogren's Syndrome Foundation; Tear Film and Ocular Surface Society; The Cornea Society; The Glaucoma Foundation; The Macula Society; The Retina Society; Vision Council of America; Vision Share, The Consortium of Eye Banks; Vistakon, Johnson & Johnson Vision Care, Inc.; Women in Ophthalmology; and Women's Eye Health Task Force.

PREPARED STATEMENT OF THE NATIONAL AREA HEALTH EDUCATION CENTERS ORGANIZATION

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

$300 million for the Title VII Health Professions Training programs.

$33 million for area Health Education Centers.

$4.371 million for Health Education and Training Centers.

The National Area Health Education Centers Organization (NAO) is the professional organization representing Area Health Education Centers (AHECs) and Health Education and Training Centers (HETCs).

AHECs and HETCs are two of the Title VII Health Professions Training programs. The Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce and eliminating the disparities in our Nation's healthcare system. These programs help address healthcare disparities by employing strategies such as providing training for students in rural and underserved areas, interaction with faculty role models

who serve in rural and underserved areas and placement services to foster and encourage students to work in these areas.

AHECs develop and support the community based training of health professions students, particularly in rural and underserved areas. They also provide continuing education and other services that improve the quality of community-based healthcare. HETCs use the infrastructure of AHECs to address the needs of diverse populations with persistent and severe unmet health needs. In 5 border and 6 non-border States, HETCs train and support Community Health Workers (CHWs) to provide healthcare services and information to their communities.

Nationwide, AHECs and HETCs support health professional training in almost 25,000 community based practice settings, and over 47,000 health professional students receive training at these sites. Furthermore, over 339,000 health professionals receive continuing education through AHECs and HETCs. AHECs and HETCs perform these education and training services through collaborative partnerships with Community Health Centers (CHCs) and the National Health Service Corps (NHSC).

COMMUNITY HEALTH CENTERS AND THE NATIONAL HEALTH SERVICE CORPS

CHCs are dedicated to providing preventative and ambulatory healthcare to uninsured and underinsured populations. A March 2006 study published in the Journal of the American Medical Association (JAMA) found that CHCs report high percentages of provider vacancies, including an insufficient supply of dentists, pharmacists, pediatricians, family physicians and registered nurses. These shortages are particularly pronounced in CHCs that serve rural areas. Because the Title VII Health Professions Training programs (including AHECs and HETCs) have a successful record of training providers to work in underserved areas, the study recommends increased support for the Title VII Health Professions Training programs as the primary means of alleviating the health professions shortage in rural CHCs. The study serves as an important reminder that the success of CHCs is highly dependent upon a well-trained clinical staff to provide care. Thirty-eight percent of AHEC training sites are CHCs, and 26 percent of the health professionals who receive continuing education through HETCs are employed at CHCs. Another 36 percent are employed at NHSC sites.

AHECs and HETCs also undertake a variety of programs related to the placement and support of NHSC scholars and loan repayment recipients. NHSC scholars and loan repayment recipients commit to practicing in an underserved area, and are focused on improving health by providing comprehensive team-based healthcare that bridges geographic, financial and cultural barriers. As contractors of the NHSC Student/Resident Experiences and Rotations in Community Health (SEARCH) program, AHECs and HETCs help to expand the NHSC by placing students and residents in rotations in rural areas. These students and residents are then far more likely to return to the rural area as a NHSC scholar or loan repayment recipient. This is because health professionals who spend part of their training providing care for rural and underserved populations are 3 to 10 times more likely to practice in rural and underserved areas after graduation or program completion.

COMMUNITY HEALTH WORKERS

Like NHSC scholars and loan repayment recipients, CHWs aim to respond to local health problems with effective and culturally sensitive strategies. They provide health services in their communities and specifically address healthcare disparities by working to improve health literacy. CHWs are uniquely suited to these tasks because they come from, and live in, the same communities as their patients. They also speak the same language as their non-English speaking patients.

An October 2006 study by the Health Resources and Services Administration (HRSA) entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" shows the importance of the CHWs. This study found that minority health professionals disproportionately serve minority and other medically underserved populations, minority populations tend to receive better care from practitioners of their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their own language.

HETCs are the only Federal program mandated to recruit, train and support CHWs. In 2004–2005 HETCs provided the initial training and continuing education for over 5,000 CHWs. But the Fiscal Year 2006 and Fiscal Year 2007 Labor-Health and Human Services (HHS)-Education Appropriations bills zeroed out the funding for HETCs. Unless funding is restored, HETCs will no longer be able to recruit, train or support CHWs.

JUSTIFICATION FOR FUNDING RECOMMENDATIONS

By improving the quality, geographic diversity and diversity of the healthcare workforce, the United States can eliminate healthcare disparities. In order to continue the progress that the Title VII Health Professions Training programs (including AHECs and HETCs) have already made towards this goal, an additional Federal investment is required. NAO recommends that the Title VII Health Professions Training programs are funded at $300 million in fiscal year 2008, including $33 million for AHECs and $4.371 million for HETCs.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS

The National Association of Children's Hospitals thanks the subcommittee for the opportunity to submit a statement for the hearing record in support of the Children's Hospitals' Graduate Medical Education (CHGME) Program in the Health Resources and Services Administration.

On behalf of the Nation's 60 independent children's teaching hospitals, N.A.C.H. very much appreciates the subcommittee's early commitment to provide Federal GME funding for these hospitals. In 1999, 2000, and 2006, Congress authorized and reauthorized the CHGME program to give independent children's teaching hospitals a level of Federal support for their teaching programs, which seeks to be comparable to what adult teaching hospitals receive from Medicare.

We appreciate very much the continuation of $297 million for CHGME in the final Fiscal Year 2007 Continuing Resolution, the same level as Congress appropriated for fiscal year 2006. The fiscal year 2007 appropriation marks the first time since Congress first agreed to appropriate $305 million for CHGME in fiscal year 2004 that the program's funding has not been reduced due to across-the-board spending cuts in health and human services.

CHGME has Been a Success.—CHGME support to children's hospitals now approaches about 80 percent of the level of Medicare GME support to adult hospitals. CHGME has made it possible for children's hospitals to strengthen their training of pediatric physicians at a time of national shortages, without having to sacrifice the hospitals' clinical or research programs. And it has enabled the hospitals to achieve strong financial positions, which are essential to their ability to fulfill their capital intensive missions.

For fiscal year 2008, we respectfully request $330 million, the annual authorization level that Congress enacted and the president signed into law last year. It would make up for the erosion in funding for the CHGME program over the last 4 years and address the cost of inflation. It is important in a program with both wage-related and medical teaching costs. Full funding would ensure the hospitals will have the resources necessary to train and educate the Nation's pediatric workforce.

N.A.C.H. AND CHILDREN'S HOSPITALS

N.A.C.H. is a not-for-profit trade association, representing more than 135 children's hospitals. They include independent acute care children's hospitals, children's hospitals within larger medical centers, and independent children's specialty and hospitals. N.A.C.H. helps its members fulfill their missions of clinical care, education, research and advocacy for all children.

Children's hospitals are regional and national centers of excellence for children with serious and complex conditions. They are centers of biomedical and health services research for children and are the major training centers for pediatric researchers, as well as a significant number of children's doctors. They also are major safety net providers, serving a disproportionate share of children from low-income families, and they are advocates for the public health of all children.

Although they represent less than 5 percent of all hospitals in the country, the three major types of children's hospitals provide 41 percent of the inpatient care for all children, 42 percent of the inpatient care for children assisted by Medicaid, and most hospital care for children with serious conditions.

BACKGROUND: THE NEED FOR CHGME

While they account for less than 1 percent of all hospitals, independent children's teaching hospitals alone train 35 percent of all pediatricians, half of all pediatric specialists and the majority of pediatric researchers. They provide required pediatric rotations for many other residents and train more than 4,800 resident FTEs annually. Shortages of pediatric specialists across the Nation only heighten the importance of these hospitals.

Prior to initial funding of the CHGME program for fiscal year 2000, the eligible hospitals were facing enormous challenges to their ability to maintain their training programs. The increasingly price competitive medical marketplace was resulting in more and more payers failing to cover the costs of care, including the costs associated with teaching.

Because they see few if any Medicare patients, independent children's hospitals were essentially left out of Medicare GME, which had become the one major source of GME financing for other teaching hospitals. They received only 1/200th (or less than 0.5 percent) of the Federal GME support that all other teaching hospitals received under Medicare. This lack of GME financing, combined with financial challenges stemming from their other missions, threatened their teaching programs, as well as other services.

Safety Net Institutions.—Independent children's hospitals are a significant part of the health care safety net for low-income children, which puts them at financial risk. In fiscal year 2005 children assisted by Medicaid were, on average, 55 percent of all inpatient days of care. Yet, Medicaid average, paid only 78 percent of costs. Without disproportionate share hospital payments, Medicaid would pay even less. Medicaid payment shortfalls for outpatient and physician care are even greater.

The independent children's hospitals also are essential providers of care for seriously and chronically ill children. They devote more than 75 percent of their care to children with one or more chronic or congenital conditions. They provide the majority of inpatient care to children with many serious illnesses—from children with cancer or cerebral palsy, for example, to children needing heart surgery or organ transplants. In some regions, they are the only source of pediatric specialty care. The severity and complexity of illness and the services these institutions must maintain to assure access to this quality care for all children are often poorly reimbursed.

Lastly, many of the independent children's hospitals are a vital part of the emergency and critical care services in their regions. They are part of the emergency response system that must be in place for public health emergencies. Expenses associated with disaster preparedness add to their continuing costs in meeting children's needs.

Mounting Financial Pressures.—The CHGME program, and its relatively quick progress to full funding in fiscal year 2002, came at a critical time. In 1997, when Congress first considered establishing CHGME, a growing number of independent children's hospitals had financial losses; many more faced mounting financial pressures. More than 10 percent had negative total margins, more than 20 percent had negative operating margins, and nearly 60 percent had negative patient care margins. Some of the Nation's most prominent children's hospitals were at financial risk. Thanks to CHGME, these hospitals have been able to maintain and strengthen their training programs.

Pediatric Workforce.—The important role CHGME plays in the continual development of our Nation's pediatric workforce is not lost on the larger pediatric community, including the American Academy of Pediatrics and Association of Medical School Pediatric Department Chairs. They support CHGME and recognize it is critical not only to the future of the individual hospitals but also to provision of children's health care and advancements in pediatric medicine. This year, the chairs of more than 40 medical school pediatric departments have endorsed full funding for the program, regardless of whether they are affiliated with a CHGME hospital. For example, the pediatric leadership of Iowa has endorsed full funding for CHGME, even though Iowa's own children's hospitals do not receive CHGME funding, because it is so important to the institutions around the country from which Iowa recruits pediatric subspecialists.

CONGRESSIONAL RESPONSE

In the absence of movement toward broader GME financing reform, Congress in 1999 authorized the Children's Hospitals' GME discretionary grant program to address the existing inequity in GME financing for the independent children's hospitals. The legislation was reauthorized in 2000 through fiscal year 2005 and provided $285 million for fiscal year 2001 and such sums as necessary in the years beyond. Congress passed the initial authorization as part of the "Healthcare Research and Quality Act of 1999." It passed the first 5-year reauthorization as part of the "Children's Health Act of 2000." Last year, it passed the second 5-year reauthorization as part of the "Children's Hospital GME Support Reauthorization Act of 2007," which authorized $330 million for each of the 5 years, through fiscal year 2011.

With this subcommittee's support, Congress appropriated initial funding for CHGME in fiscal year 2000, before the enactment of its authorization. Following en-

actment, Congress moved substantially toward full funding for the program in fiscal year 2001 and completed that goal, providing $285 million in fiscal year 2002, $290 million in fiscal year 2003, $303 million in fiscal year 2004, $301 million in fiscal year 2005, $297 million in fiscal year 2006, and $297 million in fiscal year 2007. (In the fiscal year 2004, 2005, 2006, the funding levels are net of across-the-board cuts in discretionary funding. For example, Congress appropriated $305 million for fiscal year 2004; the net appropriation, after cut, was $303 million.)

Health Resources and Services Administration.—The CHGME funding is distributed through HRSA to 60 children's hospitals according to a formula based on the number and type of full-time equivalent residents trained, in accordance with Medicare rules, as well as the complexity of care and intensity of teaching the hospitals provide. Consistent with the authorization, HRSA allocates the annual appropriation in monthly payments to eligible hospitals.

CHGME'S SUCCESS

The annual CHGME appropriations represent an extraordinary achievement for the future of children's health and the Nation's independent children's teaching hospitals:

—Thanks to CHGME, the Federal Government has made substantial progress in providing more equitable Federal GME support to independent children's hospitals. They now receive about 80 percent of the level of Federal GME support that Medicare provides to other teaching hospitals. It is still not equity, but it is dramatic improvement from the 0.5 percent of 1998.

—Thanks to CHGME, children's hospitals have been able to make a substantial improvement in their contribution to the Nation's pediatric workforce, without having to sacrifice their clinical or research missions. Between 2000 and 2004, without the CHGME hospitals being able to increase the numbers of general pediatric residents they trained, the Nation would have experienced a net decline in the number of new pediatricians. During the same period, CHGME hospitals also accounted for more than 80 percent of the new pediatric subspecialty programs and more than 60 percent of the new pediatric subspecialists trained.

—Thanks to CHGME, children's hospitals have been able to achieve strong, financial positions. According to Moody's Investor Services, before 2000, children's hospitals tended to have negative to break-even financial margins. Since then, they have improved their margins and CHGME is one of the major reasons.

FISCAL YEAR 2008 REQUEST

N.A.C.H. respectfully requests that the subcommittee provide equitable GME funding for independent children's hospitals by providing $330 million in fiscal year 2008, the full authorization level. Such funding is vital for a program that has wage-related and medical teaching costs and experienced 3 years of reductions due to across-the-board cuts before fiscal year 2007.

Adequate, equitable funding for CHGME is an ongoing need. Children's hospitals train new pediatric residents and researchers every year. Children's hospitals have appreciated very much the support they have received, including the attainment of the program's authorized full funding level in fiscal year 2002 and continuation of full funding with an inflation adjustment in fiscal year 2003 and fiscal year 2004. Congress can restore this progress by providing $330 million in fiscal year 2008.

Continuing equitable CHGME funding is more important than ever in light of continued budget pressures in many States for reductions in Medicaid spending. Because children's hospitals devote a substantial portion of their care to children from low-income families, they are especially affected by Medicaid. Support for a strong investment in GME at children's hospitals is also consistent with the concern Congress has expressed for the health and well-being of children—through education, health and social welfare programs. And it is consistent with the subcommittee's emphasis on the importance of investment in the National Institutes of Health for which we are grateful.

The CHGME funding has been essential to the ability of the independent children's hospitals to sustain their GME programs. At the same time, it has enabled them to do so without sacrificing support for other critically important services that also rely on hospital subsidy, such as many specialty and critical care services, child abuse prevention and treatment services, services to low-income children with inadequate or no coverage, mental health and dental services, and community advocacy, such as immunization and motor vehicle safety campaigns.

In conclusion, CHGME is a success. It is an invaluable investment in children's health. The future of pediatric medicine and children's access to pediatric care de-

pends on it. N.A.C.H. is joined by the American Academy of Pediatrics, American Hospital Association and others in recommending $330 million for fiscal year 2008.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

On behalf of more than 1,000 Health Center organizations across the country serving more than 16 million patients, the National Association of Community Health Centers (NACHC) is pleased to submit this statement for the record, and to thank the subcommittee for its continued support and investment in the Health Centers program.

ABOUT HEALTH CENTERS

Over more than 40 years, the Health Centers program has grown from a small demonstration project providing desperately needed primary care services in underserved communities to one of the fundamental elements of our Nation's health care safety net. Funding was approved in 1965 for the first two Neighborhood Health Center demonstration projects, one in Boston, Massachusetts, and the other in Mound Bayou, Mississippi.

Today, Health Centers serve as the primary health care safety net for many communities across the country and the Federal grant program enables more low-income and uninsured patients to receive care each year. Health Centers currently serve as the family doctor for one in eight uninsured individuals, and one in every five low-income children. Health Centers are helping thousands of communities address a range of increasing (and costly) health problems, including prenatal and infant health development, chronic illnesses including diabetes and asthma, mental health, substance addiction, domestic violence and HIV/AIDS.

Federal law requires that every Health Center be governed by a community board with a patient majority—a true patient democracy. Health Centers are required to be located in a federally designated Medically Underserved Area (MUA), and must provide a package of comprehensive primary care services to anyone who comes in the door, regardless of their ability to pay. Because of these characteristics, the insurance status of Health Center patients differs dramatically from other primary care providers. As a result, the role of public dollars is substantial. Federal grant dollars, which make up roughly one-quarter of Health Centers' operating revenues, are intended to cover the costs of serving uninsured patients; just over 40 percent of revenues are from reimbursement through Federal insurance programs, principally Medicare and Medicaid. The balance of the revenues are from State and community partnerships, privately insured individuals, and patient's ability to pay.

The Health Centers program is administered by the Bureau of Primary Health Care (BPHC) at the Health Resources and Services Administration (HRSA), within the U.S. Department of Health and Human Services (HHS).

FUNDING BACKGROUND

We greatly appreciate that the subcommittee has approved substantial funding increases for the Health Centers program over the past several years, the result of which has been a broad expansion effort enabling Health Centers to serve many of those that remain underserved in our country. Since 2001, in addition to the overall funding increase, the subcommittee has provided specific increases in funding to stabilize existing centers, as well as to meet the goals of the President's initiative—to significantly impact health care delivery in 1,200 communities through new or expanded Health Centers. With the funding provided in fiscal year 2007, that goal will be met this year.

The Health Centers program has succeeded in expanding access to primary and preventive care services in underserved communities across the country. The Office of Management and Budget rated the Health Centers program as one of the top 10 Federal programs, and the best competitive grant program within all of HHS.

Yet despite this record expansion, hundreds of communities have submitted applications since fiscal year 2002 that received high ratings, but could not be funded due to lack of funds. There is clearly a tremendous need and a tremendous desire to expand Health Center services to new communities. With additional resources, Health Centers stand ready to provide low-cost, highly effective care to millions more uninsured and underserved individuals and families.

FISCAL YEAR 2008 AND BEYOND: TOWARD 30 MILLION PATIENTS BY 2015

In his fiscal year 2008 budget proposal, President Bush requested a total funding level of $1.988 billion for the Health Centers program. While this represents a slight increase over the President's request in fiscal year 2007, it is essentially the same as the enacted level for fiscal year 2007, as Congress funded the program above the President's request last year. NACHC is requesting an increase of $200 million for fiscal year 2008, for a total funding level of $2.188 billion.

In order to truly serve those in need across the country, Health Centers must expand their operations and develop new centers in areas of need. This request represents the next step, an investment in a longer-term plan to provide a health care home in a Health Center to 30 million Americans by 2015, and to eventually bring access to care in a Health Center to every American who needs it within 15 years. We hope to work with the subcommittee to guide this investment around several priorities. First, in the face of rising costs of care and a rising percentage of new patients without insurance coverage, a significant and strategic investment in existing Health Centers is needed to allow them to meet the demand for their services in the communities they serve today. Second, new and expanded Health Centers should be brought to communities with little or no access to care through planning grants and new access point funding targeted to those communities most in need. Lastly, in order to make a comprehensive range of necessary services available at every Health Center, funding should be made available to add mental health, oral health and pharmacy services in high need communities.

In 2005, President Bush called for "a Community Health Center in every poor county" in America. NACHC supports the goal of bringing care to those areas of the country with high poverty and no current access to a Health Center. However, NACHC has expressed the preference that such an expansion address the lack of access in the neediest communities of the country, and that eligibility for new funding not be limited to certain geographic areas such as counties. Further, the President's budget includes proposed legislative language waiving the statutorily designated proportionality requirements for Migrant, Public Housing and Homeless Health Centers in order to implement this second expansion initiative. NACHC strongly opposes this change.

In addition to the expansion efforts, it is critical that Federal funding for Health Centers keep pace with the growing cost of delivering care. NACHC requests that the subcommittee designate $59 million of any increase in funding to be used to make base grant adjustments for existing centers, allowing an average increase of 3 percent in current Health Center grants. Under the subcommittee's leadership, Congress has provided base grant adjustments for existing centers in 6 out of the 8 previous fiscal years, including $25 million in fiscal year 2007. A recent study by NACHC found that in the 2 years that these adjustments were not included in the Health Centers appropriation, the number of patient visits per grantee actually decreased.

NACHC appreciates the subcommittee's leadership in stabilizing the Federal Tort Claims Act (FTCA) judgment fund for Health Centers in past years. For fiscal year 2008, the President has requested that $44,000,000 be appropriated for this purpose. This is $500,000 below last year's level. NACHC supports maintaining the judgment fund at a total funding level of $44,500,000.

In 1997, Congress authorized and began funding the HRSA Loan Guarantee Program (LGP) for the construction, renovation, and modernization of Health Centers. Demand for this guarantee program has accelerated significantly in the last several years. NACHC expects that at the current rate of usage, the remaining credit subsidy will be entirely used during calendar year 2008. In response that the success of this program, NACHC is requesting an additional $5 million be provided until expended for additional loan guarantees. The LGP has proven to be a vital resource for Health Centers across the country—in particular, those on the Gulf Coast—as they seek financing to fund the facilities necessary to accommodate the growth in patient visits resulting from recent expansion efforts.

Finally, in addition to increased funding for the Health Centers program, expanding access to vital preventive and primary health care in underserved communities will also depend on commensurate growth in a number of high-priority programs, including:

—$150 million for the National Health Service Corps, the largest single source of health professionals for Health Centers. Such an increase will enable the NHSC to place an additional 800 medical professionals;

—$450 million for Health Professions Training Programs under Title VII/VIII, including $30 million for Area Health Education Centers (AHECs); and

—$250 million for Title III of the Ryan White AIDS Program, which provides grants to Health Centers and other primary care providers for outpatient early intervention services.

CONCLUSION

America's Health Centers are grateful to the subcommittee for its ongoing efforts to support and stabilize the Health Centers program and to expand health centers' reach into more than 5,000 communities nationwide. As a result of those efforts, more than 16 million people have access to the affordable, effective primary care services that our Nation's Health Centers provide.

We respectfully ask that the subcommittee continue that investment, as the work of caring for our uninsured and medically underserved is far from complete. A recent NACHC study found that some 56 million Americans are still without regular access to primary care. America's Health Centers look forward to meeting that need and rising to the challenge of providing a health care system that works for all Americans. We look forward to working with you over the coming year to move toward that goal.

If you need any additional information or have any questions related to Health Centers or NACHC, please do not hesitate to contact me or John Sawyer, Assistant Director of Federal Affairs, at (202) 331–4603, or via email at jsawyer@nachc.com.

PREPARED STATEMENT OF THE NATIONAL CENTER FOR VICTIMS OF CRIME

The National Center for Victims of Crime submits this testimony to urge members of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies to fully fund the Rape Prevention and Education (RPE) Grant program at $80 million. Rape crisis centers rely on this money to educate their communities about the prevention of sexual abuse and assault. RPE Grant funds provide the foundation for crucial efforts to end sexual violence.

As the leading national resource and advocacy organization for victims of crime, the National Center understands the vital necessity of sexual assault education and outreach programs for victims and their communities. Every day, our Helpline staff speaks to sexual assault victims and connects them with local services. We also work with rape crisis centers and State sexual assault coalitions across the country who have all described to us their desperate struggles to meet their communities' needs. They report that without greater RPE Grant program funding, they cannot continue their education and prevention efforts.

PREVALENCE OF RAPE AND SEXUAL ASSAULT

The incidence of sexual assault in this country remains unconscionably high. The latest National Crime Victimization Survey reports that 191,670 people were raped or sexually assaulted in 2005.[1] The crime of sexual violence affects people of all backgrounds and ages—children and adults, males and females. Approximately 1 in 6 women and 1 in 33 men in America have experienced an attempted or completed rape as a child or adult.[2] Young adults and teens are particularly at risk, with people aged 16 to 24 being raped at significantly higher rates than any other age group,[3] and nearly 5 percent of college women being sexually assaulted during any given calendar year.[4]

IMPACT ON VICTIMS, FAMILIES, AND COMMUNITIES

Sexual assault exacts a terrible cost on individual victims, their families, and our Nation. The annual cost of sexual assault to victims is approximately $26 million.[5] Moreover, victims of sexual violence experience higher rates of depression, anxiety disorders, mental illness, addiction, eating disorders, and self-esteem problems than non-victims. Rape survivors are six times more likely to commit suicide than victims of other crimes.[6]

Workplaces and communities are also affected when victims suffer. Rape victims face a loss of economic productivity through unemployment, underemployment, and

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[1] Bureau of Justice Statistics, U.S. Dept. of Justice, Criminal Victimization 2005 (Sept. 2006).
[2] Id.
[3] Id.
[4] Fisher, Cullen, & Turner, Nat'l Inst. of Justice & Bureau of Justice Statistics, the Sexual Victimization of College Women (2000).
[5] Bureau of Justice Statistics, U.S. Dept. of Justice, Criminal Victimization 2005 (Sept. 2006).
[6] Arthur H. Green, M.D., Sexual Abuse: Immediate and Long-Term Effects and Intervention, 32 J. AM. ACAD. Child Adolescent Psychiatry. 5, (Sept. 1993).

absence from work. According to the Centers for Disease Control and Prevention (CDC), 21 percent of victims who have been raped by an intimate partner report losing time from work as a result of their victimization.[7]

PURPOSES OF THE RAPE PREVENTION AND EDUCATION GRANT PROGRAM

Understanding the far-reaching impact of sexual violence and the importance of prevention, Congress established the CDC's Rape Prevention and Education Program through the Violence Against Women Act of 1994. RPE funding provides formula grants to States and territories to support rape prevention and education programs conducted by rape crisis centers, State sexual assault coalitions, and other public and private nonprofit entities. Funding is used for:

—Educational seminars for professionals, the public, schools, colleges, and universities;
—Hotline operations;
—Education and training programs aimed at preventing sexual violence at colleges and universities; and,
—Education about date rape drugs.

These education and outreach activities are crucial not only to help change public attitudes and behaviors, but also to train allied professionals on issues related to sexual violence so they can better understand victims and make appropriate referrals.

RPE funding also supports the National Sexual Violence Resource Center (NSVRC), a project operated by the Pennsylvania Coalition Against Rape (PCAR). NSVRC provides information, materials, and resources on sexual violence to policy makers, Federal, and State agencies, college campuses, State, territory and tribal sexual assault coalitions, the media, and the public.

EDUCATIONAL SEMINARS AND TRAININGS

Rape prevention and education efforts make crucial contributions to ending sexual violence by helping to change attitudes about rape and reduce the isolation of victims. Educational efforts around the country include:

—Kansas: During the 2005 fiscal year, RPE Grant-funded projects provided 2,212 educational sessions to 15,010 students and 267 professionals.
—Mississippi: Over the past 5 years, RPE projects conducted a total of 1,923 community education sessions with 66,422 participants. In addition, the Mississippi Coalition Against Sexual Assault offered a training program for home health workers, nursing home employees, and others in contact with the elderly population to help them identify and respond to signs of abuse and assault.
—Pennsylvania: During the 2006 fiscal year, the PCAR provided 24,213 sexual assault education programs to students and 3,469 prevention education programs to the community.

Many of these educational sessions and trainings, like those conducted in Mississippi, focused on increasing awareness of sexual violence in underserved and at-risk communities. Such outreach also consistently results in an increased number of victims contacting local rape crisis centers for services and support. However, as operation costs increase and funding levels have stagnated, such remarkable efforts cannot expand and grow to reach these vulnerable populations.

HOTLINE OPERATIONS

The RPE Grant program also provides crucial support for State and local hotlines, which offer 24-hour crisis intervention, referrals, and information about sexual violence. Importantly, hotline operations allow trained advocates and rape crisis counselors to reach more physically or culturally isolated communities. Recent successes include:

—Massachusetts: Funds from the RPE Grant program permit rape crisis centers across Massachusetts to provide 24-hour hotline services for victims of sexual assault and their families. The program also supports Llamanos, a Spanish-language, toll-free, sexual assault hotline for Latino survivors and their families. Llamanos also provides training for 13 rape crisis centers, five community health organizations, and eight additional community-based agencies serving the Latino population. Together, these hotline services received more than 12,000 calls in the past fiscal year.

[7] Nat'l Ctr. for Injury Prevention and Control, Costs of Intimate Partner Violence Against Women in the United States (Atlanta, Ga., 2003).

—Louisiana: Since Hurricane Katrina struck in 2005, the RPE Grant-funded Louisiana Foundation Against Sexual Assault (LaFASA) has provided hotline services specifically for hurricane victims who were sexually assaulted in the aftermath of the storm. Witnesses, survivors, and their families can call and receive support, counseling, and referral information.

PREVENTING SEXUAL VIOLENCE IN SCHOOLS AND ON COLLEGE CAMPUSES

Recognizing that attitudes and beliefs regarding sexual violence are formed early in life, many RPE grantees emphasize education and prevention programs for young people. As youths become aware of the frequency of acquaintance rape, they can and do broaden their efforts to protect themselves, from merely locking doors against strangers to taking precautions with those they know. RPE-funded programs, in collaboration with students and campus personnel, have developed and continue to implement sexual violence prevention programs for schools across the Nation. These programs aim to reduce first-time male perpetration of sexual violence, address norms and beliefs that support or condone sexual violence, and empower bystanders to respond constructively when they recognize abusive relationships. Examples of these programs include:

—*Iowa*.—During the 2006 fiscal year, community prevention specialists conducted 4,599 educational sessions for a total of 71,521 students in grades pre-K through 12. In addition, 244 sexual violence prevention sessions were offered to 14,128 students at Iowa colleges and State universities. After one Iowa event, some female students who had repeatedly endured degrading harassment from fellow classmates came forward to report the incidents to campus authorities, who intervened.

—*California*.—The RPE Grant program funds MyStrength, California's innovative statewide social marketing campaign. This program, which follows a national evidence-based model targeting 14- to 18-year-old males, aims to help prevent first-time perpetration of sexual violence.[8]

—*Indiana*.—The Communities Against Rape Initiative (CARe) is a statewide collaboration supported by the RPE Grant program that helps develop and implement rape prevention curricula for rural, urban, and suburban schools. Since its founding in 1997, CARe has trained more than 1,000 Indiana teachers to use the curricula. Pre- and post-test results from more than 4,600 students show positive changes in students' knowledge and attitudes about rape.[9]

All these remarkable programs and initiatives report that even with such successes, much more could be done to raise awareness about sexual violence in local communities if RPE funding were increased. For instance, the California Coalition Against Sexual Assault (CALCASA) reports that if the national RPE Program were fully funded, the MyStrength campaign could saturate the State with marketing materials, and MyStrength clubs could be sustained in hundreds of high schools throughout California. Such efforts would advance our fight to end sexual violence against men, women, and children.

DRUG-FACILITATED SEXUAL VIOLENCE

Drug-facilitated rape is staggeringly pervasive in this country. A recent report from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) shows that more than 70,000 students between the ages of 18 and 24 survive an alcohol or drug-related sexual assault each year.[10] Drugs are used to render victims incapable of providing consent for sexual activity or defending themselves against rape. Because detection and prosecution remain difficult, the best means to prevent these crimes is education. The RPE Grant program funds efforts to raise public awareness of the risk and symptoms associated with Rohypnol, gamma-hydroxybutyrate (GHB), and other common date rape drugs.

RAPE PREVENTION AND EDUCATION FUNDING MUST BE INCREASED

Program after program has told the National Center that due to lack of funding they are unable to expand their outreach efforts, staff and volunteers have been taxed to the limit, and they are unable to reprint popular educational materials. Without full funding, these programs cannot make continued progress against sex-

[8] Learn more about the MyStrength campaign at http://www.mystrength.org (accessed March 28, 2007).

[9] For more information about the CARe initiative, visit http://www.four-h.purdue.edu/care/main.html (accessed March 28, 2007).

[10] Task Force of the Nat'l Advisory Council on Alcohol Abuse and Alcoholism, National Institutes of Health, A Call to Action: Changing the Culture of Drinking at U.S. Colleges (2002).

ual violence. Although the Violence Against Women Act of 2005 (VAWA) reauthorized the Rape Prevention and Education Grant program at $80 million, funding for the past several years has remained at approximately $42 million.[11]

When Congress reauthorized the Rape Prevention and Education Grant program as part of VAWA, it recognized the importance of this program in reducing sexual victimization. The National Center calls on Congress to honor its commitment to preventing rape by providing full funding for the Rape Prevention and Education Grant program for the 2008 fiscal year.

PREPARED STATEMENT OF THE NATIONAL CHILD ABUSE COALITION

The National Child Abuse Coalition, committed to strengthening the Federal response to the protection of children and the prevention child abuse and neglect, urges fiscal year 2008 funding for the Child Abuse Prevention and Treatment Act (CAPTA) programs at the authorized level of $200 million:

—CAPTA basic State grants at $84 million;

—CAPTA community-based prevention grants at $80 million; and

—CAPTA research and demonstration grants at $36 million.

Basic State Grants.—At current funding, child protection agencies are unable to serve close to half the abused and neglected children in their caseloads.

CAPTA funds programs have not kept pace with the needs of communities for supporting families and protecting children. States are hard pressed to treat children or protect them from further harm. In 2004, according to the most recent HHS data, an estimated 3 million reports of possible abuse and neglect were made to States, and almost 900,000 of these reports were substantiated. In 2004, just over 40 percent of the child victims received no services following a substantiated report of maltreatment: suspected abuse reported, report investigated, report substantiated, case closed. Almost 1,500 children died as a result of abuse or neglect. The most endangered are the youngest: more than 80 percent of children who were killed were under age 4.

CAPTA's Basic State Grants help States protect children. The Nation's child welfare system has long been stretched beyond capacity. No State passed the test when measured against the HHS Child and Family Service Reviews to evaluate a State's performance in protecting children. Federal officials repeatedly cited States for certain deficiencies: significant numbers of children suffering abuse or neglect more than once in a 6-month period; caseworkers not visiting children often enough to assess needs; and not providing promised medical and mental health services.

Funding CAPTA State grants at $84 million would enable State child protective services to expand post-investigative services for child victims, shorten the time to the delivery of services, and increase services to other at-risk families.

Community-Based Prevention Grants.—For every Federal dollar spent on foster care and adoption subsidies, we spend less than 13 cents in Federal child welfare funding on preventing and treating child abuse and neglect.

Annual direct costs of child abuse and neglect in the United States total over $24 billion in hospitalizations, chronic health and mental health care, child welfare services, law enforcement, and courts. Indirect costs from special education, other health and mental health care, crime, and lost productivity, total more than $94 billion annually.[1] Community services to prevent child abuse are far less costly than the damage inflicted on children from abuse and neglect. A GAO evaluation of child abuse prevention efforts found "total Federal costs of providing prevention programs for low-income populations were nearly offset after 4 years."[2]

CAPTA's Prevention Grants help States to develop community-based prevention services, including parenting education, home visiting services, and respite care. We spend billions of dollars every year on foster care to protect the children who have been the most seriously injured; we can do a much better job at protecting children before the damage is so bad that we have no other choice than to remove them from their homes. Funding CAPTA prevention grants at $80 million would help communities support proven, cost-effective approaches to preventing child abuse and neglect.

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[11] Passed as part of the Violence Against Women Act 2005 Reauthorization, Public Law 109–162.

[1] Fromm, S. (2001). Total Estimated Cost of Child Abuse and Neglect in the United States. Prevent Child Abuse America.

[2] U.S. General Accounting Office (1992). Child Abuse: Prevention Programs Need Greater Emphasis (GAO/HRD–92–99).

Discretionary Research and Demonstration Grants.—Current funding levels short-change community efforts to develop innovative programs to serve children and families and to improve our knowledge about child maltreatment.

We urge Congress to approve the President's proposed increase of $10 million to support home visitation programs, with funds available to promote an array of research- and evidence-based home visitation models that enable communities to provide the most appropriate services suited to the families needing them.

The U.S. Advisory Board on Child Abuse and Neglect recommended as the highlight of its 1991 report, Creating Caring Communities, the establishment of universal voluntary home visitor services. The Centers for Disease Control (CDC) Task Force on Community Preventive Services in its 2003 report evaluating the effectiveness of strategies for preventing child maltreatment "recommends early childhood home visitation for prevention of child abuse and neglect in families at risk for maltreatment, including disadvantaged populations and families with low-birth weight infants."[3]

Research evidence supports the value of a range of early childhood home visitation models using professionals, nurses, paraprofessionals, and trained volunteers from the community in improving parenting and family health and preventing child maltreatment.

For example, results from the randomized trial of the Healthy Families New York program based on the Healthy Families America model using Family Support Workers (specially trained paraprofessionals who live in the target community and share the same language and cultural background as program participants) showed that the program had positive effects in the areas of parenting and child abuse and neglect, birth outcomes, and health care. According to the research team analyzing the Healthy Families program in New York, the results for the subgroup of participants who resemble the clients typically served by the Nurse Family Partnership (NFP) model of home visiting by nurses are similar to those found in randomized trials of NFP.[4]

In another randomized trial, adolescent mothers who received case management services and Parents as Teachers (PAT) home visitors were significantly less likely to be subjected to child abuse investigations than control group mothers who received neither case management nor PAT home visitation.[5] Randomized trials of the Parent-Child Home Program, a home visitation early literacy and parenting program model, show significant ongoing positive effects on parents' interaction with their children, in contrast to control group families examined before and after completion of the program.[6]

In another study of home visiting models funded by CDC, researchers concluded from a literature review of evaluations of home visitation programs that where randomized trials might not always be feasible, non-randomized studies are important to validate research or provide stronger evidence when the randomized trial is compromised. In its review of evaluations of various models, the report found that the evaluated programs reduced child maltreatment by approximately 39 percent, overall.[7]

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[3] Hahn, R.A., Bilukha, O.O., Crosby, A., Fullilove, M.T., Liberman, A., Moscicki, E.K., et al. (2003). First reports evaluating the effectiveness of strategies for preventing violence: Early childhood home visitation. Center for Disease Control, Morbidity and Mortality Weekly Report, 52, 109.

[4] DuMont, K., et al. (2006). Healthy Families New York Randomized Trial: Impacts on Parenting After the First Two Years. New York State Office of Children and Families. Working Paper Series.

[5] Wagner, M.M. & Clayton, S.L. (1999). The Parents as Teachers Program: Results from Two Demonstrations. The Future of Children: Home Visiting: Recent Program Evaluations, 9(1), 91–115.

[6] Joint Dissemination Review Panel of U.S. Department of Education. (1978). Unanimous Approval of Research Findings, 1967–1978, Mother-Child Home Program of Verbal Interaction Project. Freeport, NY: Verbal Interaction Project.

O'Hara, J.M. & Levenstein, P. (1981). Second Year Progress Report: 9/15/80–9/14/81: Tracing the Parent-Child Network. Final Report, Grant No. NIEG 800042, National Institute of Education, U.S. Department of Education.

Levenstein, P., O'Hara, J.M., & Madden, J. (1983) , "The Mother-Child Home Program of the Verbal Interaction Project", in Consortium for Longitudinal Studies, ed., As the Twig is Bent Hillsdale, NJ: Lawrence Erlbaum Associates.

Levenstein, P. & O'Hara, J.M., (1993) "The necessary lightness of mother-child play", in K.B. MacDonald, eds., Parents and Children Playing Albany, NY: State University of New York Press.

[7] Hahn, R., et al. (2005). Home Visiting Programs to Prevent Child Abuse: Taking Silver and Bronze Along With Gold. U.S. Centers for Disease Control and Prevention. Child Abuse and Neglect: The International Journal. Vol. 29, p. 215–218.

Funding research and program innovations at $36 million, as the President requests, would provide support for a diversity of home visitation models, as well as the field-initiated research, training, technical assistance, and data collection also authorized by CAPTA out of this money.

CHILD WELFARE SPENDING: A FAILURE TO INVEST

Our failure to invest in our child protective service system and community-based programs for preventing child maltreatment has created a spending gap of almost $17 billion in services to intervene on behalf of children. Current available data peg Federal, State, and local dollars for child protective services and preventive services at only about $3.1 billion of the estimated $20.2 billion total cost of what we ought to be spending.

According to the Urban Institute, States reported spending $22 billion on child welfare in 2002, and they could categorize how $17.4 billion of the funds were used.[8] Of that amount, $10 billion was spent for out-of-home placements, $1.7 billion on administration, $2.6 billion on adoption, and $3.1 billion (about 18 percent) on all other services, including prevention, family preservation and support services, and child protective services.

Failure to invest in a working child protection system results in a national failure to keep children free from harm. The cost to child protective services in 2002 of investigating the 1.745 million children who were screened in for investigations, plus the expense that would have been incurred if services had been provided to all of the 896,000 substantiated child victims (as well as to the 708,000 children in unsubstantiated reports who also received some services), totals $7.2 billion. Second, consider the cost of preventive services—$13 billion if offered to the 3 million child maltreatment victims identified in the HHS National Incidence Study III. That's a total cost of $18.4 billion. Yet, in 2002, States spent only $3.1 billion in Federal, State, and local funds on protective and preventive services for children. Our national child welfare policy represents a morally unacceptable failure to invest in this system.

These are conservative cost figures. When adjusted to account for inflation, data indicate that investigations by child protective service agencies cost approximately $1,011 per case. The cost per case to provide basic in-home services such as homemaker assistance or family counseling is $3,360.[9] These costs are low to start with. Pay scales in child welfare are generally low and noncompetitive—significantly lower, for example, than salaries for teachers, school counselors, nurses and public-health social workers[10]—which brings these costs in at a low level.

What does the spending gap mean? States report having difficulty in recruiting and retaining child welfare workers,[11] because of issues like low salaries, high caseloads, insufficient training and limited supervision, and the turnover of child welfare workers—estimated to be between 30 and 40 percent annually nationwide.[12] The average caseload for child welfare workers is double the recommended level, and obviously much higher in many jurisdictions.[13] Because our system is weighted toward protecting the most seriously injured children, we wait until it gets so bad that we have to step in. Far less attention in policy or funding is directed at preventing harm to children from ever happening in the first place or providing the appropriate services and treatment needed by families and children victimized by abuse or neglect.

Increasing funding for CAPTA's basic State grants and community-based prevention grants will help to begin to address the current imbalance. It is time to invest additional resources to work in partnership with the States to help families and prevent children from being abused and neglected.

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[8] Scarcella, C.A. (2004). The Cost of Protecting Vulnerable Children IV: How Child Welfare Funding Fared during the Recession, Washington, DC. Urban Institute.

[9] Courtney, M.E. (1998). "The Costs of Child Protection in the Context of Welfare Reform". The Future of Children, Vol. 8, No. 1.

[10] U.S. General Accounting Office (2003). HHS Could Play a Greater Role in Helping Child Welfare Agencies Recruit and Retain Staff (GAO–03–357).

[11] U.S. General Accounting Office (1995). Child Welfare: Complex Needs Strain Capacity to Provide Services (GAO/HEHS–95–208).

[12] U.S. General Accounting Office (2003). HHS Could Play a Greater Role in Helping Child Welfare Agencies Recruit and Retain Staff (GAO–03–357).

[13] Alliance for Children and Families, American Public Human Services Association, Child Welfare League of America (2001). The child welfare workforce challenge: Results from a preliminary study. Dallas.

THE CASE FOR PREVENTION

Our present system of treating abused and neglected children and offering some help to troubled families is overworked and inadequate to the task. Hundreds of thousands of children are currently identified as having been abused, but receive no services to prevent further abuse. We must focus attention on children and families known to the system in order to prevent reoccurrence of abuse, as well as provide services to families earlier, before problems become severe. Putting dollars aside for prevention is sound investing, not luxury spending.

We know that child abuse prevention fights crime, because research has shown us that victims of child abuse are more likely to engage in criminality later in life, and that childhood abuse increases the odds of future delinquency and adult criminality overall by 40 percent.[14] We know that preventing child maltreatment helps to prevent failure in school. Typically abused and neglected children suffer poor prospects for success in school, exhibiting poor initiative, language and other developmental delays, and a disproportionate amount of incompetence and failure.[15] Ensuring that children are ready to learn means ensuring that children are safe at home. We know that preventing child abuse can help to prevent disabling conditions in children. Physical abuse of children can result in brain damage, mental retardation, cerebral palsy, and learning disorders.[16]

Research conducted by CDC in collaboration with Kaiser Permanente shows us that childhood abuse is linked with behaviors later in life which result in the development of chronic diseases that cause death and disability, such as heart disease, cancer, chronic lung and liver diseases, and skeletal fracture, and that the adult victims of child maltreatment are more likely suffer from depression and suicide attempts.[17]

Community-based services to overburdened families are far less costly than the damage inflicted on children that leads to outlays for child protective services, law enforcement, courts, foster care, health care and the treatment of adults recovering from child abuse. A range of services, such as voluntary home-visiting, family support services, parent mutual support programs, parenting education, and respite care contribute to a community's successful strategy to prevent child abuse and neglect.

National Child Abuse Coalition Member Organizations: Alliance for Children and Families, American Academy of Pediatrics, American Bar Association, American Humane Association, American Professional Society on the Abuse of Children, American Psychological Association, Association of University Centers on Disabilities, Boys and Girls Clubs of America, CHILD Inc., Child Welfare League of America, Children's Defense Fund, First Star, General Federation of Women's Clubs, National Alliance of Children's Trust and Prevention Funds, National Association of Children's Hospitals, National Association of Counsel for Children, National Association of Social Workers, Nat'l. Center for Child Traumatic Stress, National Center for State Courts, National CASA Association, National Education Association, National Exchange Club Foundation, National PTA, National Respite Coalition, Parents Anonymous, Prevent Child Abuse America, Voices for America's Children.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR OSTEOPOROSIS AND RELATED BONE DISEASES

Mr. Chairman and members of the committee: The National Coalition for Osteoporosis and Related Bone Diseases (Bone Coalition) is pleased to have the opportunity to present our views on the fiscal year 2008 budget for the National Institutes of Health (NIH). We are appreciative of your continued support of the NIH. The Federal investment made to date has allowed for new research opportunities to be pursued that hold the potential to prevent and one day possibly cure diseases such as osteoporosis, osteogenesis imperfecta and Paget's disease of bone.

The leaders of the Coalition are the National Osteoporosis Foundation, the Amerian Society for Bone and Mineral Research, the Osteogenesis Imperfecta Foundation and the Paget Foundation for Paget's Disease of Bone and Related Disorders.

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[14] C.S. Widom (1992). The Cycle of Violence. Washington, DC: National Institute of Justice.

[15] S.R. Morgan (1976). The Battered Child in the Classroom. Journal of Pediatric Psychology.

[16] H.P. Martin & M.A. Rodeheffer (1980). The Psychological Impact of Abuse in Children. In: G.J. Williams. Traumatic Abuse and Neglect of Children at Home. Baltimore, MD: Johns Hopkins University Press.

[17] V.J. Felitti, R.F. Anda, et al. (1998). Relationship of Childhood Abuse and Household Dysfunction to Many of the Leading Causes of Death in Adults. The Adverse Childhood Experiences (ACE) Study. American Journal of Preventive Medicine.

Throughout our existence, the Coalition has remained committed to reducing the impact of bone disease through expanded biomedical, clinical, epidemiological and behavioral research.

Bone health is integral to the overall health and well being of the Nation's population. The bony skeleton is a remarkable organ that not only serves a structural function, providing mobility, support, and protection for the soft tissues, but also functions as a reservoir or storehouse for essential minerals and growth factors. It may even potentially act as an endocrine organ.

The 2004 Surgeon General's Report on Bone Health and Osteoporosis calls bone health an "often overlooked aspect of physical health" and further States that "[a] healthy skeletal system with strong bones is essential to overall health and quality of life. Yet, today, far too many Americans suffer from bone diseases and fractures."

Bone diseases such as osteoporosis, osteogenesis imperfecta, and Paget's disease of bone remain a major public health problem in this country and the financial, physical and psychosocial consequences of bone diseases significantly diminish quality of life and burden society.

Osteoporosis.—Is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures, particularly of the hip, spine, and wrist. This is due to several factors such as the aging of our population, increased use of steroids and other drugs that have deleterious affects on bone, and increased immobilized patients and nursing home populations. Over 10 million Americans have osteoporosis, the majority of whom (80 percent) are women; 34 million more have low bone mass and are at increased risk for the disease. The estimated national direct expenditures for osteoporosis and related fractures total $18 billion each year in 2002 dollars.

Paget's Disease of Bone.—The second most prevalent bone disease after osteoporosis—is a chronic skeletal disorder that may result in enlarged or deformed bones in one or more regions of the skeleton. Excessive bone breakdown and formation can result in bone that is dense, but fragile. Complications may include arthritis, fractures, bowing of limbs, neurological complications, and hearing loss if the disease affects the skull. Prevalence in the population ranges from 1.5 percent to 8 percent depending on the person's age and geographical location. Paget's disease primarily affects people over 50.

Osteogenesis Imperfecta.—Causes brittle bones that break easily due to a problem with collagen production. For example, a cough or sneeze can break a rib, rolling over can break a leg. Besides fragile bones, people with OI may have hearing loss, brittle teeth, short stature, skeletal deformities, and respiratory difficulties. OI affects between 20,000 to 50,000 Americans. In severe cases fractures occur before and during birth. In some cases, an affected child can suffer repeated fractures before a diagnosis can be made. Undiagnosed OI may result in accusations of child abuse.

Cancer Metastasis to Bone.—A frequent complication of cancer is its spread to bone (bone metastasis) that occurs in up to 80 percent of patients with myeloma and 70 percent of patients with either breast or prostate cancer—causing severe bone pain and pathologic fractures. Only 20 percent of breast cancer patients and 5 percent of lung cancer patients survive more than 5 years after discovery of bone metastasis.

Musculoskeletal Trauma and Skeletal Pain.—Of the 60 million Americans injured annually, more than one-half incur injuries to the musculoskeletal system. In the United States, back pain is a major reason listed for lost time from work and sports injuries are increasing in "weekend warriors" of both sexes. In our military, bone trauma is now accounting for over 50 percent of all combat injuries.

HOW HAS BONE RESEARCH HELPED PEOPLE?

NIH-supported research in bone health has led to important discoveries and has generated new treatments and pharmaceutical products.

—Research has taught us that those with low bone mass are at risk for osteoporosis. These individuals can then address their risk with exercise, diet, other behavioral and lifestyle changes, and medication.
—Research has decreased fracture risk and extended the lifespan to normal for people with OI.
—Research has identified drugs which improve the quality of life of people whose cancer has metastasized to bone.
—Research has led us to develop simple, non-invasive and accurate tests that can determine bone mass and help predict fracture risk.
—Research has identified and demonstrated a variety of drugs that can reduce bone loss and fractures, and even build new bone. Thirty years ago, there was no treatment for osteoporosis.

—Research has helped us to understand the need for weight-bearing exercise to build and maintain bone in order to reduce fracture risk. Falling can be reduced by strength-building exercise that increases balance and flexibility.
—Research has led to the discovery of a recessive form of osteogenesis imperfecta, providing new possibilities for prevention, treatment and a cure. But much remains to be done.

FUTURE OPPORTUNITIES FOR BONE RESEARCH

Osteoporosis.—Research has the potential to add important new information to our understanding of osteoporosis.
—Therapies such as calcium supplementation and physical activity need to be explored to help chronically ill children reach and maintain peak bone mass.
—Data on the beneficial and/or adverse effects of bone therapies such as bisphosphonates in children as well as adults with many chronic diseases such as diabetes, inflammatory arthritis and osteogenesis imperfecta are almost nonexistent and are sorely needed.
—The pathophysiology of bone loss in diverse populations needs to be studied in order to develop targeted therapies to improve bone density and bone quality.
—Racial differences in bone and the origin of racial differences in fracture patterns need to be identified to understand important determinants of fracture and their underlying biology.
—Patients at risk for fracture who do not meet current criteria for osteoporosis need to be identified. In addition, the effects of current and developing osteoporosis treatments on these patients need to be studied.
—Research into gene targeting which could cure osteogenesis imperfecta is a few short years away from human trials. Continued research into drug therapies is needed to improve bone quality, allowing people with osteogenesis imperfecta to live independently.

Congenic and Genetic Disease of Bone.—Thousands of children and adolescents nationwide suffer from musculoskeletal disorders and malformations, many of which have devastating effects on mortality and disability. Diseases such as osteogenesis imperfecta, fibrous dysplasia, osteopetrosis, and Paget's disease are caused by poorly understood genetic mutations. In Paget's disease, underlying genetic defects can also be exacerbated by environmental factors. Increased research on the role of the environmental and genetic factors in the development of Paget's disease could lead to the identification of new therapeutic targets for the disease. The science of genetics has led to tremendous advances in our understanding of numerous systems that affect bone health, but little of this technology is being applied to bone research. Knowledge of complex gene pathways must be used to deepen our understanding of bone biology to gain better insight into the causes of these debilitating diseases. Research is needed that:
—Focuses on mechanisms of preventing fractures and improving bone quality and correcting malformations, on innovations in surgical and non-surgical approaches to treatment, on physical factors that affect growth, and on genetic defects that cause bone disease.
—Expands research on skeletal stem cell biology and the genetics and pathophysiology of rare disorders such as fibrous dysplasia, melhoreostosis, XLinked hypophosphatemic rickets and fibrodysplasia ossificans progressiva.

Cancer Metastasis to Bone.—Immune response plays a role in cancer metastasis. Osteoimmunology—the study of the relationships between the immune system and bone homeostasis—is an emerging area of research and may help scientists prevent and treat the spread of cancer to bone. Research is needed to:
—Determine mechanisms and to identify, block and treat cancer metastasis to bone.
—Expand research on osteosarcoma to improve survival and quality of life and to prevent metastatic osteosarcoma in children and teenagers who develop this cancer.
—Expand research on tumor dormancy as it relates to bone metastasis.

Musculoskeletal Trauma and Skeletal Pain.—Research is needed to better understand the epidemiology of back pain, improve on existing diagnostic techniques for back pain, as well as to develop new ones. Furthermore, expanded research is needed to improve diagnostic and therapeutic approaches to significantly lower the impact of musculoskeletal traumas, and on research on accelerated fracture healing, the use of biochemical or physical bone stimulation, the role of hematopoietic niches to preserve bone stem cells, the use of mesenchymal bone stem cells, and biomaterials and biologicals in bone repair and regeneration, and research into repair of nonunion fractures in osteogenesis imperfecta.

Bone Strength.—Research is also needed in the area of bone strength. Although bone mineral density has been a useful predictor of susceptibility to fracture, other properties of the skeleton contribute to bone strength, such as geometry and composition. At this time, little is understood as to how these properties influence bone strength. However, research clearly indicates that exercise that causes mechanotransduction plays a key role in the maintenance of bone; and loss of bone due to immobilization as occurs in patients in hospitals and nursing homes may be preventable with therapies that mimic mechanotransduction. Bone strength is also influenced by the amount of mineral, however, how the bone becomes mineralized is not well understood. Understanding this process should assist in prevention of pathologic mineralization as occurs in hardening of the arteries that causes heart attacks. Research, including research on bone structure and periosteal biology, is needed which will achieve identification of the parameters that influence bone strength and lead to better prediction for prevention and treatment of bone diseases such as osteoporosis, osteogenesis imperfecta, bone loss due to kidney disease, and hardening of the arteries.

To move this research forward, Congress must provide sufficient funding to the National Institutes of Health to sustain the robust research atmosphere in which to address the challenges in the bone field. Research must continue to be accelerated in order to improve the health of the Nation.

RECOMMENDATION

The National Coalition for Osteoporosis and Related Bone Diseases supports:

—a 6.7 percent increase in funding for the National Institutes of Health as recommended by the Ad Hoc Group for Medical Research, the Campaign for Medical Research, the Federation of American Societies for Experimental Biology, the National Health Council, and Research!America.

—a 6.7 percent increase for the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the lead institute for bone research.

—increased funding for NIA, NIDCR, NIDDK, NCI and NICHD, other Institutes that also fund bone-related research, as well as additional support for bone programs at NIBIB and NCAM.

Thank you for the opportunity to submit our statement regarding the fiscal year 2008 budget for the National Institutes of Health.

PREPARED STATEMENT OF THE NATIONAL CONSUMER LAW CENTER ON BEHALF OF OUR LOW-INCOME CLIENTS [1]

The Federal Low Income Home Energy Assistance Program (LIHEAP) [2] is the cornerstone of government efforts to help needy seniors and families avoid hypothermia in the winter and heat stress (even death) in the summer. We are in a sustained period of much higher household energy prices and expenditures and the demand for this program is growing as increases in energy prices far outstrip the ability of low income households to pay. In light of the crucial safety net function of this program in protecting the health and well-being of low-income seniors, the disabled and families with very young children, we respectfully request that LIHEAP be fully funded at its authorized level of $5.1 billion for fiscal year 2008 and that advance funding of $5.1 billion be provided for the program in fiscal year 2009.

COST OF HOME ENERGY REMAINS AT RECORD HIGH LEVELS

Residential heating expenditures remain at record high levels. According to the Department of Energy's Energy Information Administration's March 2007 Short-Term Energy Outlook, this winter's average residential heating expenditures are projected to be 53 percent higher for heating oil, 29.6 percent higher for natural gas, 39.4 percent higher for propane, and 18.6 percent higher for electricity than the averaged expenditures for 2000–2005. This U.S. Department of Energy short-term forecast of residential heating expenditures shows that, on average, residential bills are still among the highest on record. The cost of electricity, used for both heating and cooling, has been increasing rapidly due, in part, to increases in the price of natural gas used to generate electricity in many power plants and the lifting of price caps in States that restructured their electric markets.

In a brief span of time, energy bills have walloped low-income households. In 2008, LIHEAP eligible households are predicted to spend, depending on the type of

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[1] Mass Union of Public Housing Tenants and Pennsylvania Utility Law Project.

[2] 42 U.S.C. §§ 8621 et seq.

heating fuel used, 63 percent more on their total residential energy bills than in 2001 if they used heating oil, 36 percent more if they used natural gas, 47 percent more if they used propane and 34 percent more if they use electricity. The effect of these continually rising prices on low-income households is devastating.

STATES' DATA ON ELECTRIC AND NATURAL GAS DISCONNECTIONS AND ARREARAGES SHOW THAT MORE HOUSEHOLDS ARE FALLING BEHIND

Not surprisingly, the steady and dramatic rise in residential energy costs has resulted in increases in electric and natural gas arrearages and disconnections. For example, utility service disconnections in Rhode Island increased by over 92 percent between the years 2000 and 2006. Similarly, the gap between service disconnections and reconnections increased, suggesting increased durations of service loss and greater numbers of households that do not regain access to service under their own accounts.[3]

Although there are winter utility shut-off moratoria in place for many States, not every home is protected against energy shut-offs in the middle of winter. As we approach the lifting of winter shut-off moratoria, we expect to see a wave of disconnections as households are unable to afford the cost of the energy bills.

Iowa.—Despite milder winter temperatures this winter, the continued high cost of natural gas has set back a record number of low-income households in Iowa. In February 2007, the number of low-income households with past due energy accounts was the second highest on record for this time of year since these data have been tracked. As an indication of the effect of long term effect of rising home energy prices, the total number of LIHEAP households in arrears in February 2007 was 80 percent higher than 5 years ago at this point in time and 151 percent higher than in February 1999. The total amount of arrearages of LIHEAP households has also grown sharply due to the increase in prices. By February 2007, the total amount of LIHEAP household arrears had increased 42 percent from the same period 5 years ago and 163 percent compared to arrears in February 1999. The total number of LIHEAP households served in fiscal year 2007 is expected to remain at the record high level of fiscal year 2006, yet the program received $16 million less under the fiscal year 2007 appropriations. In order to serve the increased demand for LIHEAP this heating season the program reduced benefits by 30 percent and redirected LIHEAP funds normally dedicated to the summer pre-purchase of deliverable fuels (a program component that maximizes purchasing power).[4]

Ohio.—In Ohio, the number of households entering into the State's low-income energy affordability program, the Percentage of Income Payment Program (PIPP), increased 13 percent from January 2006 to January 2007. The increase is an even more dramatic 64 percent between January 2002 and January 2007. The total dollar amount owed (arrearage) by low-income PIPP customers increased 8 percent from January 2006 to January 2007 and 62 percent when comparing PIPP customer arrears from January 2002 to January 2007. The National Energy Assistance Directors Association estimates that the number of households applying for energy assistance in fiscal year 2007 is likely to remain at fiscal year 2006 levels, for Ohio that would mean an estimated 30 percent more households when compared to Ohio households that received heating assistance in fiscal year 2002.[5]

Pennsylvania.—Utilities in Pennsylvania that are regulated by the Pennsylvania Public Utility Commission (PA PUC) have established universal service programs that assist utility customers in paying bills and reducing energy usage. Even with these programs, electric and natural gas utility customers find it difficult to keep pace with their energy burdens. The PA PUC estimates that more than 19,700 households entered the current heating season without heat-related utility service—this number includes about 3,700 households who are heating with potentially unsafe heating sources such as kerosene or electric space heaters and kitchen ovens. In mid-December 2006 an additional 9,000 residences where electric service was previously terminated were vacant and over 7,500 residences where natural gas

[3] Calculated from data provided by the Rhode Island Public Utilities Commission.

[4] Iowa Bureau of Energy Assistance, National Energy Assistance Directors' Association's "LIHEAP Survey Results—Status of fiscal year 2007 Program Funding (March 7, 2007) and the National Energy Assistance Directors' Association, "The Low Income Home Energy Assistance Program: Providing Heating and Cooling Assistance to Low-Income Families During a Period of High Energy Prices (February 9, 2007). NEADA documents are available at www.neada.org.

[5] Public Utilities Commission of Ohio, National Energy Assistance Directors' Association's "LIHEAP Survey Results—Status of Fiscal Year 2007 Program Funding (March 7, 2007), the National Energy Assistance Directors, "Est. Total Households Receiving LIHEAP Heating Assistance by State—Projected Applications for Fiscal Year 2006 (2/13/06) and "Estimated Total Households Receiving LIHEAP Heating Assistance by State Actuals in 2002, 2003; Projected in 2004." NEADA documents are available at www.neada.org.

service was terminated were vacant. In 2006, the number of terminations increased 32 percent compared with terminations in 2004. As of February 2007, 18.9 percent of residential electric customers and 16.3 percent of natural gas customers were overdue on their energy bills. The National Energy Assistance Directors Association estimates that the number of households applying for energy assistance in fiscal year 2007 is likely to remain at fiscal year 2006 levels, for Pennsylvania that would mean an estimated increase of over 354,065 LIHEAP households from in fiscal year 2005 levels. However, in fiscal year 2007 Pennsylvania is experiencing a 34 percent reduction in LIHEAP funding compared to levels in fiscal year 2006. This reduction in funding has resulted in a 32 percent cut to the average LIHEAP crisis benefit from $422 in fiscal year 2006 to $285 in fiscal year 2007 (year to date).[6]

LIHEAP IS A CRITICAL SAFETY NET PROGRAM FOR THE ELDERLY, THE DISABLED AND HOUSEHOLDS WITH YOUNG CHILDREN

In fiscal year 2006, 5.7 million households received LIHEAP heating assistance, the highest number of households served in 13 years. Preliminary estimates by the National Energy Assistance Directors' Association are that fiscal year 2007 participation rates will remain near the same record levels as in fiscal year 2006.[7] Yet, energy prices have been on a continued upward climb. These two trends cut into the ability of the LIHEAP program to help protect our most vulnerable citizens from extreme weather conditions that cause illness, physical harm and even death.

Recent national studies have documented the dire choices low-income households are faced with when energy bills are unaffordable. Because adequate heating and cooling are tied to the habitability of the home, low-income families will go to great lengths to pay their energy bills. Low-income households faced with unaffordable energy bills cut back on necessities such as food, medicine and medical care.[8] The U.S. Department of Agriculture recently released a study that shows the connection between low-income households, especially those with elderly persons, experiencing very low food security and heating and cooling seasons when energy bills are high.[9] A pediatric study in Boston documented an increase in the number of extremely low weight children, age 6 to 24 months, in the 3 months following the coldest months, when compared to the rest of the year.[10] Clearly, families are going without food during the winter to pay their heating bills, and their children fail to thrive and grow.

When people are unable to afford paying their home energy bills, dangerous and even fatal results occur. Families resort to using unsafe heating sources, such as space heaters, ovens and burners, all of which are fire hazards.[11] In the summer, the inability to afford cooling bills can result in heat-related deaths and illness. The loss of essential utility services can be devastating, especially for poor families that can find themselves facing hypothermia in the winter, hyperthermia in the summer, eviction, property damage from frozen pipes, the use of dangerous alternative sources of heat.

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[6] Pennsylvania Public Utility Commission Bureau of Consumer Services, National Energy Assistance Directors' Association's "LIHEAP Survey Results—Status of Fiscal Year 2007 Program Funding (March 7, 2007) and National Energy Assistance Directors' Association, "The Low Income Home Energy Assistance Program: Providing Heating and Cooling Assistance to Low-Income Families During a Period of High Energy Prices (February 9, 2007). NEADA documents are available at http://www.neada.org.

[7] National Energy Assistance Directors' Association, Talking Points in Support of Additional Federal and State Grant Funding for Energy Assistance (Jan. 19, 2007) available at www.NEADA.org.

[8] See e.g., National Energy Assistance Directors' Association, 2005 National Energy Assistance Survey, Tables in section IV,G (September 2005) (To pay their energy bills, 20 percent of LIHEAP recipients went without food, 35 percent went without medical or dental care, 32 percent did not fill or took less than the full dose of a prescribed medicine). Available at http://www.neada.org/comm/surveys/NEADA_2005_National_Energy_Assistance_Survey.pdf.

[9] Mark Nord and Linda S. Kantor, Seasonal Variation in Food Insecurity Is Associated with Heating and Cooling Costs Among Low-Income Elderly Americans, The Journal of Nutrition, 136 (Nov. 2006) 2939–2944.

[10] Deborah A. Frank, MD et al., Heat or Eat: The Low Income Home Energy Assistance Program and Nutritional and Health Risks Among Children Less Than 3 years of Age, AAP Pediatrics v.118, no.5 (Nov. 2006) e1293-e1302. See also, Child Health Impact Working Group, Unhealthy Consequences: Energy Costs and Child Health: A Child Health Impact Assessment Of Energy Costs And The Low Income Home Energy Assistance Program (Boston: Nov. 2006).

[11] John R. Hall, Jr., Home Heating Fire Patterns and Trends (In 2003 there were over 53,000 heating-equipment related home fires resulting in 260 deaths (73 percent of the deaths involved portable space heaters) and 1,260 injuries and $494 million in property damage), National Fire Protection Association (Nov. 2006).

LIHEAP is an administratively efficient and effective targeted health and safety program that works to bring fuel costs within a manageable range for vulnerable low-income seniors, the disabled and families with young children. LIHEAP must be fully funded at its authorized level of $5.1 billion in fiscal year 2008 in light of the steady increase in home energy costs and the increased need for assistance to protect the health and safety of low income families by making their energy bills more affordable. In addition, fiscal year 2009 advance funding would facilitate the efficient administration of the State LIHEAP programs. Advanced funding provided certainty of funding levels to States to set income guidelines and benefit levels before the start of the heating season. States can also plan the components of their program year (e.g., amounts set aside for heating, cooling and emergency assistance, weatherization, self-sufficiency and leveraging activities).

PREPARED STATEMENT OF THE NATIONAL COUNCIL OF SOCIAL SECURITY MANAGEMENT ASSOCIATIONS

Chairman Harkin, Senator Specter and members of the subcommittee, my name is Richard Warsinskey and I represent the National Council of Social Security Management Associations (NCSSMA). I have been the manager of the Social Security office in Downtown Cleveland, Ohio for nearly 12 years and have worked for the Social Security Administration for 31 years. On behalf of our membership, I am pleased to have the opportunity to submit this written testimony to the subcommittee.

The NCSSMA is a membership organization of nearly 3,400 Social Security Administration (SSA) managers and supervisors who provide leadership in over 1,300 Field Offices and Teleservice Centers throughout the country. We are the front-line service providers for SSA in communities all over the Nation. We are also the Federal employees with whom many of your staff members work to resolve problems and issues for your constituents who receive Social Security retirement benefits, survivors or disability benefits, or Supplemental Security Income. From the time our organization was founded over 36 years ago, the NCSSMA has been a strong advocate of efficient and prompt locally delivered services nationwide to meet the variety of needs of beneficiaries, claimants, and the general public. We consider our top priority to be a strong and stable Social Security Administration, one that delivers quality and prompt community based service to the people we serve—your constituents.

IMPACT OF SSA'S APPROPRIATED FUNDING LEVEL ON SSA FIELD OFFICES & TELESERVICE CENTERS

For fiscal year 2008, the President has proposed an increase for SSA of approximately $304 million over the final level of funding for fiscal year 2007. And yet, staffing levels in offices across the country are being cut. In fact, SSA will lose about 4,000 positions from the beginning of fiscal year 2006 to fiscal year 2008. The most significant staffing losses in SSA have occurred in the agency's Field Offices. Field Offices have lost about 2,300 positions in the past 18 months and about 1,200 positions since September 2006. The vast majority of these losses have been in the most critical positions in the Field: Claims Representatives and Service Representatives. All of this comes after 5 years of reductions to the President's Budget Requests, which total $720.0 million, and about 8,000 work years. It is interesting to note that while total Executive Branch Employment is expected to increase 2.1 percent from fiscal year 2006 to fiscal year 2008, SSA's employment is expected to decrease by 6.2 percent.

In 2007, an average of 858,000 people are visiting Social Security Administration Field Offices every week. At the same time, Field Offices are also being overwhelmed by business-related telephone calls. SSA Field Offices are receiving approximately 68 million business related phone calls a year. This is in addition to the 44 million phone calls handled by live agents that are received by SSA's 1–800 number on an annual basis. The fact that the public can't get through to SSA on the telephone is creating an overwhelming amount of walk-in traffic in many Field Offices. Waiting times in many Field Offices are running 2 to 3 hours long. Some visitors are even experiencing wait times of over 4 hours.

SSA is also facing a retirement wave as many of its employees were hired around the time SSA took over the Supplemental Security Income (SSI) program in 1974. It is important for the agency to be able to replace this wealth of experience. It can take up to 4 years before newly hired Claims Representatives become fully proficient in the very complicated programs SSA administers.

The impact of inadequate resources in recent years is apparent in the severe cutbacks in processing Continuing Disability Review cases and SSI Redeterminations. For every $1 spent on a Continuing Disability Review, $10 is saved. SSA currently has a backlog of 1.3 million Continuing Disability Review cases. The agency also saves $7 for every $1 spent on an SSI redetermination. SSA was unable to process over 2.0 million of these cases in the past few years due to the lack of resources.

In recent months I have received hundreds of messages from SSA Field Office management describing how the stress in their offices is incredible. Health problems are growing. It truly is a dire situation. I would like to share with you part of a communication I received from a member of Field Office management:

"We have lost five employees recently. Two had strokes in the office in the last month and it may have been due to all the stress. Another employee is retiring next month. We are simply being hammered with work. The number of people visiting our office is well beyond our capacity to handle them. About 30.0 percent of our visitors live outside our service area. We don't receive staff for these extra visitors and the loss of staff has made it an impossible situation.

"We really have a very dedicated and wonderful staff. But so many are about to have a breakdown. We are just desperate to get help."

Even if SSA receives the funding increase recommended by the President for fiscal year 2008, staffing will be cut because SSA's expenditures continue to increase in several areas. Salaries and benefit costs, including those for the Disability Determination Services, rent, and security costs, are totaling more than the annual increases in appropriated funds. And for fiscal year 2007, SSA's final level of funding was just enough to avoid an agency-wide furlough. Although a furlough was avoided, the agency will be faced with limited hiring for the entire year after only being able to replace one out of three staffing losses last year.

As a result, the fiscal year 2008 President's budget request will provide fewer, not additional, resources for SSA. Therefore, we are in strong support of the additional funding recommended in the Fiscal Year 2008 Senate Budget Resolution. These additional funds would be a major step in restoring SSA's service to appropriate levels.

SURVEY OF OUR MEMBERS

Our association just completed a survey of our members. Over 2,000 responded. The gravity of the losses in the Field Offices can be seen in an answer to one question. The question was: " Do you have enough staff to keep workloads current?" Only 3.2 percent answered "yes" to this question.

The losses in staff in Field Offices are having a significant impact on our ability to provide good service. In answer to the question: "What percent of the time are Field Offices able to provide prompt telephone service?" nearly 63 percent said they can only do this 50 percent or less of the time. Nearly a third said they can provide prompt telephone service less than 25 percent of the time. The impact of these staffing losses can also be seen in the increased waiting times for the public. In answer to the question as to whether waiting times had increased in the past 2 years, 80 percent said "yes" and nearly a third said the waiting times were significantly longer.

DISABILITY BACKLOGS

It is also important to note that receiving prompt service is not the case for hundreds of thousands of claimants that have filed for Social Security and SSI Disability benefits. There are currently over three quarter of a million hearings pending. And at the moment, it is taking 510 days, on average, for a hearings decision. Nearly 300,000 hearings have been pending over a year. SSA estimates that the hearings backlog could grow to 1 million cases by 2010 if additional resources are not provided for SSA.

SSA also has a total of about 1.4 million disability cases pending at the initial claims, reconsideration, and hearings levels. We estimate about 125,000 of these cases belong to veterans and about half of these are pending at the hearings level.

Every day SSA Field Offices and Teleservice Centers throughout the country are being contacted by people regarding the status of their hearings as I am sure most congressional offices are. Many of these people are desperate and have insufficient funds to live on and the delays only add to their sense of hopelessness.

At the beginning of this decade there were only about 311,000 hearings pending, and the average time for processing was just 274 days. So the pending cases have grown 130.0 percent in 6 years, and the average time to process a case has increased by 234 days. These long waits occur after most claimants have passed the first two stages of their claim, having received an initial decision and a reconsideration. By this point, over 200 days on average have already passed by.

THE IMPACT OF THE BABY BOOMERS RETIRING

Next year, in 2008, the first of 78 million baby boomers will be eligible for Social Security retirement. So there will be a steady rise in retirement claims with SSA—along with an increasing number of contacts by these retirees with SSA once they start receiving benefits.

At the end of 2006, there were 40.3 million people receiving retirement and survivor benefits. This figure is expected to rise by about 1 million a year over the next 10 years and accelerate after this. SSA took about 3.3 million retirement and survivor claims last year. So we are looking at a significant increase in work for SSA offices.

THE COMMISSIONER'S BUDGET

Because SSA is an independent agency, the Commissioner is required by law to prepare an annual budget request for SSA, which is submitted by the President to Congress without revision, together with the President's budget request for SSA. This budget request reflects what the Commissioner has evaluated as the level of funding necessary to meet the agency's service delivery improvements and fiscal stewardship responsibilities through 2012. The Commissioner's budget request also factors in that SSA has received less than the President's recommended level of funding in recent years, thus leading to the need for additional resources in the future to meet the full service delivery plan. The budget amount submitted by the Commissioner of Social Security for fiscal year 2008 is $10.44 billion. This $10.44 billion is $843 million more than what the President requested. The difference between these proposed funding levels is significant. Of more significance is the difference between the final funding levels approved by Congress for SSA in comparison to the budget requests submitted in recent years by the Commissioner. Inadequate levels of resources have contributed to the growing inability of SSA to provide adequate levels of service.

SOCIAL SECURITY TRUST FUND

The Social Security Trust Fund currently totals approximately $2.0 trillion. The Social Security Trust Fund is intended to pay benefits to future beneficiaries and finance the operations of the Social Security Administration. The additional funding for SSA proposed in the fiscal year 2008 Senate Budget Resolution represents about 1/65th of 1 percent of $2 trillion. Don't the workers who have paid into this trust fund with their taxes deserve to receive due consideration and the very benefits they have paid for in a timely manner?

The Social Security Trust Fund contains the necessary resources to make up the difference between the level requested by SSA's Commissioner and the President. Yet, because of the levels of service that SSA and its various components that process disability claims are currently able to provide, many of these taxpayers must wait so long for service that they die before a decision is made on their case. They never receive the benefits that they have paid for. This also applies to receiving good service in Social Security Administration Field Offices—it currently is not at the level it ought to be and people are not receiving what they have paid for and what they deserve.

CONCLUSION

The NCSSMA believes that the American public wants and deserves to receive good and timely service for the tax dollars they have paid to receive Social Security. We urge approval of at least the amount included in the Fiscal Year 2008 Senate Budget Resolution, and encourage you to consider providing the level of funding requested by the Commissioner of Social Security. This additional funding would certainly begin the necessary process to restore the levels of service that the public deserves from SSA.

On behalf of the members of the NCSSMA, I thank you again for the opportunity to submit this written testimony to the subcommittee. Our members are not only dedicated SSA employees, but they are also personally committed to the mission of the agency and to providing the best service possible to the American public. We respectfully ask that you consider our comments and would appreciate any assistance you can provide in ensuring that the American public receives the necessary service that they deserve from the Social Security Administration.

PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for the opportunity to submit testimony to this subcommittee regarding the appropriation for the Corporation for Public Broadcasting (CPB). As the president and CEO of the National Federation of Community Broadcasters, I speak on behalf of 250 community radio stations and related organizations across the country. Nearly half our members are rural stations and half are controlled by people of color. In addition, our members include many of the new Low Power FM stations that are putting new local voices on the airwaves. NFCB is the sole national organization representing this group of stations which provide service in the smallest communities of this country as well as the largest metropolitan areas.

In summary, the points we wish to make to this subcommittee are that NFCB:

—Requests $440 million in funding for CPB for fiscal year 2010;
—Requests $40 million in fiscal year 2008 for conversion of public radio and television to digital broadcasting;
—Requests $27 million in fiscal year 2008 for replacement of the radio interconnection system;
—Requests that advance funding for CPB is maintained to preserve journalistic integrity and facilitate planning and local fundraising by public broadcasters;
—Reject the administration's proposal to rescind $107.35 million of already-appropriated 2008 CPB funds;
—Supports CPB activities in facilitating programming and services to Native American, African American and Latino radio stations;
—Supports CPB's efforts to help public radio stations utilize new distribution technologies and requests that the subcommittee ensure that these technologies are available to all public radio services and not just the ones with the greatest resources.

Community Radio fully supports $440 million in Federal funding for the Corporation for Public Broadcasting in fiscal year 2010. Federal support distributed through CPB is an essential resource for rural stations and for those stations serving communities of color. These stations provide critical, life-saving information to their listeners and are often in communities with very small populations and limited economic bases, thus the community is unable to financially support the station without Federal funds.

In larger towns and cities, sustaining grants from CPB enable Community Radio stations to provide a reliable source of noncommercial programming about the communities themselves. Local programming is an increasingly rare commodity in a Nation that is dominated by national program services and concentrated ownership of the media.

For over 30 years, CPB appropriations have been enacted 2 years in advance. This insulation has allowed pubic broadcasting to grow into a respected, independent, national resource that leverages its Federal support with significant local funds. Knowing what funding will be available in advance has allowed local stations to plan for programming and community service and to explore additional non-governmental support to augment the Federal funds. Most importantly, the insulation that advance funding provides "go[es] a long way toward eliminating both the risk of and the appearance of undue interference with and control of public broadcasting." (House Report 94–245.)

For the last few years, CPB has increased support to rural stations and committed resources to help public radio take advantage of new technologies such as the Internet, satellite radio and digital broadcasting. We commend these activities which we feel provide better service to the American people but want to be sure that the smaller stations with more limited resources are not left out of this technological transition. We ask that the subcommittee include language in the appropriation that will ensure that funds are available to help the entire public radio system utilize the new technologies, particularly rural and minority stations.

NFCB commends CPB for the leadership it has shown in supporting and fostering the programming services to Latino stations and to Native American stations. For example, Satélite Radio Bilingüe provides 24 hours of programming to stations across the United States and Puerto Rico addressing issues in Spanish of particular interest to the Latino population. At the same time, Native Voice One (NV1) is distributing programming for the Native American stations. There are now over 33 stations controlled by and serving Native Americans.

Two years ago CPB funded the establishment of the Center for Native American Public Radio (CNAPR). After 2 years in operation, CNAPR has helped with the renewal of licenses and expansion of the interconnection system to all Native stations and has raised the possibility of Native Nations owning their own, locally controlled station. In the process of this work, it was recognized that radio would not be avail-

able to all Native Nations and broadband and other new technologies would be necessary. CNAPR has been repositioned as Native Public Media and is working hard to double the number of Native stations within the next 3 years. These stations are critical in serving local isolated communities (all but one are on Indian Reservations) and in preserving cultures that are in danger of being lost. CPB's 2003 assessment recognized that ". . . Native Radio faces enormous challenges and operates in very difficult environments." CPB funding is critical to these rural, minority stations. CPB's funding of the Intertribal Native Radio Summit in 2001 helped to pull these isolated stations together into a system of stations that can support each other. The CPB assessment goes on to say "Nevertheless, the Native Radio system is relatively new, fragile and still needs help building its capacity at this time in its development." Native Public Media promises to leverage additional, new funding to ensure that these stations can continue to provide essential services to their communities.

CPB also funded a Summit for Latino Public Radio which took place in September 2002 in Rohnert Park, California, home of the first Latino Public Radio station. These Summits have expanded the circle of support for Native and Latino Public Radio and identified projects that will improve efficiency among the stations through collaborations and explore new ways of reaching the target audiences.

CPB plays a very important role for the public and Community Radio system; they are the convener of discussions on critical issues facing us as a system. They support research so that we have a better understanding of how we are serving listeners, and they provide funding for programming, new ventures, expansion to new listeners, and projects that improve the efficiency of the system. This is particularly important at a time when there are so many changes in the radio and media environment with new distribution technologies and media consolidation. An example of this support is the grant that NFCB received to update and publish our Public Radio Legal Handbook online. This provides easy-to-read information to stations about complying with governmental regulations so that stations can function legally and use their precious resources for programming instead of legal fees.

Finally, Community Radio supports $40 million in fiscal year 2008 for conversion to digital broadcasting by public radio and television. It is critical that this digital funding be in addition to the on-going operational support that CPB provides. The President's proposal that digital money should be taken from the fiscal year 2008 CPB appropriation would effectively cut stations' grants by over 25 percent. This would have a devastating impact on stations trying to recover from hard economic times. And it would come at a time when the local voices of community and public radio are especially important to notify and support people during emergency situations and to help communities deal with the loss of loved ones—things that commercial radio is no longer able to do because of media consolidation.

While public television's digital conversion needs are mandated by the FCC, public radio is converting to digital to provide more public service and to keep up with commercial radio. The Federal Communications Commission has approved a standard for digital radio transmission and to allow multicasting. CPB has provided funding for 554 transmitters to convert to digital and is working with radio transmitter and receiver manufacturers to build in the capacity to provide a second channel of programming. Most exciting to public and community radio is the encouraging results of tests that National Public Radio has conducted, with funding from CPB, that indicate that stations can broadcast at least three high-quality signals, even while they continue to provide the analog signal. The development of second and third audio channels will potentially double or triple the service that public radio can provide, particularly in service to unserved and underserved communities. This initial funding still leaves nearly 250 radio transmitters that will ultimately need to convert to digital or be left behind.

Federal funds distributed by the CPB should be available to all public radio stations eligible for Federal equipment support through the Public Telecommunications Facilities Program (PTFP) of the National Telecommunications and Information Agency of the Department of Commerce. In previous years, Federal support for public radio has been distributed through the PTFP grant program. The PTFP criteria for funding are exacting, but allow for wider participation among public stations. Stations eligible for PTFP funding and not for CPB funding include small-budget, rural and minority controlled stations and the new Low Power FM service.

Community Radio strongly supports funding for the public radio interconnection system. Public Radio pioneered the use of satellite technology to distribute programming. The new ContentDepot system that the Public Radio Satellite System is launching continues this tradition of cutting edge technology. The satellite capacity that supports this system must be renewed and upgrades are necessary at the sta-

tions and the network operations level. Interconnection is vital to the delivery of the high quality programming that public broadcasting provides to the American people.

This is a period of tremendous change. Digital is transforming the way we do things; new distribution avenues like digital satellite broadcasting and the Internet are changing how we define the business we are in; and, the concentration of ownership in commercial radio makes public radio in general, and Community Radio in particular, more important as a local voice than we have ever been. New Low Power FM stations are providing new local voices in their communities. Community radio is providing essential local emergency information, programming about the local impact of the major global events taking place, culturally appropriate information and entertainment in the language of the native culture, as well as helping to preserve cultures that are in danger of dying out. During the natural disasters of the last couple of years, radio proved once again to be the most dependable and available medium to get emergency information to the public.

During these challenging times, the role of CPB as a convener of the system becomes even more important. The funding that it provides will allow the smaller stations to participate along with the larger stations which have more resources, as we move into a new era of communications.

Thank you for your consideration of our testimony.

PREPARED STATEMENT OF THE NIH TASK FORCE OF THE BIOENGINEERING DIVISION

The NIH Task Force of the Bioengineering Division of the Basic Engineering Group of the Council on Engineering of ASME ("Task Force"), is pleased to provide comments on the bioengineering-related programs in the National Institutes of Health (NIH) fiscal year 2008 budget request. The ASME Bioengineering Division is focused on the application of mechanical engineering knowledge, skills and principles to the conception, design, development, analysis and operation of biomechanical systems.

IMPORTANCE OF BIOENGINEERING

Bioengineering is an interdisciplinary field that applies physical, chemical and mathematical sciences and engineering principles to the study of biology, medicine, behavior, and health. It advances knowledge from the molecular to the organ systems level, and develops new and novel biologics, materials processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health. Bioengineers have employed mechanical engineering principles in the development of many life-saving and life-improving technologies, such as the artificial heart, prosthetic joints and numerous rehabilitation technologies.

BACKGROUND

The NIH is the world's largest and most eminent organization dedicated to improving health through medical science. During the last 50 years, NIH has played a leading role in the major breakthroughs that have increased average life expectancy by 15 to 20 years.

The NIH is comprised of different Institutes and Centers that support a wide spectrum of research activities including basic research, disease- and treatment-related studies, and epidemiological analyses. The missions of individual Institutes and Centers focus on either a particular organ (e.g. heart, kidney, eye), a given disease (e.g. cancer, infectious diseases, mental illness), or a stage of life (e.g. childhood, old age), or may encompass crosscutting needs (e.g., sequencing of the human genome and the National Institute of Biomedical Imaging and Bioengineering (NIBIB)).

The total fiscal year 2008 NIH budget request is $28.85 billion, which represents a $330 million (1.1 percent) reduction from the $29.18 billion approved in the fiscal year 2007 continuing joint resolution. While the Task Force is grateful to Congress for the unexpected $600 million boost to NIH as it wrapped up the fiscal year 2007 appropriations, we are greatly concerned about the decrease in funding for fiscal year 2008. Research and development is expected to account for 97 percent of the total fiscal year 2008 NIH budget, or $28.3 billion. With this, the administration estimates that a total of 10,188 new, competing research project grants (RPGs) could be supported, which is an increase of 566 RPGs over fiscal year 2007. While the overall fiscal year 2008 budget decreased compared to fiscal year 2007, the budgets allotted to some institutes and centers actually increased, while all others decreased. The largest increase went to the National Institute of Allergy and Infec-

tious Disease (NIAID), which will receive $4.59 billion, a total that includes a $200 million contribution to the Global Fund for HIV/AIDS.

The NIH Roadmap for biomedical research will receive $486 million in fiscal year 2008, which is an increase of $3 million from fiscal year 2007. Each institute and center will be required to contribute 1.3 percent of its fiscal year 2008 budget to the NIH Roadmap initiative. Since all institutes and centers were freed of their obligation to transfer 1.2 percent of their budgets to this initiative in fiscal year 2007, an effective 2.5 percent reduction in the budget of each will hence result.

NIBIB RESEARCH FUNDING

The administration's fiscal year 2008 budget requests $300 million for the NIBIB, an increase of $4 million or 1.3 percent from the fiscal year 2007 continuing joint resolution. Taking into account the 3.7 percent inflation rate (as estimated by the Bureau of Economic Analysis) this effectively amounts to a decrease in funding by 2.4 percent. However, the number of research project applications to NIBIB continues to grow (a 5 percent increase was noted in fiscal year 2006 over fiscal year 2005, for example). The decrease in the NIBIB budget combined with the increase in the number of NIBIB extramural research grant applications will result in a sharp decrease in the success rate for bioengineering-related grants. In fact, the success rate for applications to the NIBIB is already one of the lowest among all NIH institutes and centers (17 percent in fiscal year 2006 versus 20 percent in fiscal year 2005).

TASK FORCE RECOMMENDATIONS

The Task Force is concerned that bioengineering-based research continues to constitute a small portion of the total NIH budget. Yet there is an increasing need for advanced engineering concepts to be applied to basic and translational biomedical problems for the potential of recent biological advances to be realized. Moreover, the United States is rapidly falling behind our counterparts in the European Union and Pacific Rim with regards to bioengineering advances. Our request for increased bioengineering funding addresses these critical issues. The Task Force wishes to emphasize that, in many cases, bioengineering-based solutions to health care problems result in a reduction in health care costs. Therefore, we strongly urge Congress to provide increased funding for bioengineering within the NIBIB and across NIH.

The NIBIB requires exceptional and urgent consideration for funding increases in the coming years due to its fiscal year 2006 application success rate of only 17 percent, which is sure to decrease even further for fiscal year 2007 and fiscal year 2008 given the proposed budget estimates. This rate is below average with respect to the NIH as a whole and is a direct manifestation of the continued growth of the bioengineering field outpacing funding increases to the NIBIB.

While the Task Force supports new Federal proposals that seek to double Federal research and development in the physical sciences over the next decade, we believe that strong Federal support for bioengineering and the life sciences is especially essential to the health and competitiveness of the United States. The disturbing trend in the inflation rate outpacing the NIBIB budget increase rate will begin to reverse the tremendous gains the United States has made in the bioengineering field over the last decade. Four years of falling budgets are a sharp contrast from the 15 percent annual increases during the NIH doubling period and will have a long-lasting, deleterious impact.

ASME International is a non-profit technical and educational organization with 125,000 members worldwide. The Society's members work in all sectors of the economy, including industry, academic, and government. This statement represents the views of the ASME NIH Task Force of the Bioengineering Division and is not necessarily a position of ASME as a whole.

PREPARED STATEMENT OF THE NATIONAL LEAGUE FOR NURSING

The National League for Nursing is the sole organization representing leaders in nursing education and nurse faculty across all the types of nursing programs in the United States. With more than 1,100 nursing schools and health care agencies, some 20,000 individual members comprising nurses, educators, administrators, public members, and 18 constituent leagues, the National League for Nursing is the premier organization—established 114 years ago—dedicated to excellence in nursing education that prepares the nursing workforce to meet the needs of our diverse populations in an ever-changing health care environment. The NLN appreciates this opportunity to discuss the status of nursing education and the damage that could

ensue to patients and our Nation's health care by the ill-considered cuts aimed at Title VIII.

The NLN endorses the subcommittee's past policy strategies for health care capacity-building through nursing education. We likewise respect your recognition of the requisite role nurses play in the delivery of cost-efficient health care services and the generation of quality health outcomes.

We are disturbed, however, that the 7-year and counting nursing shortage is outpacing the level of Federal resources and investments that have been expended by Congress to help alleviate the nationwide nursing scarcity. The NLN is gravely concerned that the administration's proposed fiscal year 2008 appropriations for nursing education are inconsistent with the health care reality facing our Nation. The President's budget proposes a decrease of funding of $44 million (or 29 percent) for the Title VIII—Nursing Workforce Development Programs. This budget cut will diminish training and development, a shortsighted and hazardous course of action that potentially further jeopardizes the delivery of health care for the people in the United States.

As the nursing community has pointed out many times before, more than three decades ago during another less serious nursing shortage, Congress appropriated $153 million for nurse education programs. In today's dollars, that amount would be worth more than $615 million—four times the amount the Federal Government currently is spending on Title VIII programs.

The National League for Nursing contends that the Federal strategy should be to broaden, not curtail, Title VIII initiatives by increasing investments to be consistent with national demand. We urge the subcommittee to fund the Title VIII programs at a minimum level of $200 million for fiscal year 2008. The NLN also advocates that section 811 of Title VIII—Advanced Education Nursing Program—be restored and funded at an augmented level equal to the other Title VIII programs.

NURSE SHORTAGE AFFECTED BY FACULTY SHORTAGE

The subcommittee is well aware that today's nursing shortage is real and unique from any experienced in the past with an aging workforce and too few people entering the profession at the rate necessary to meet growing health care requirements. NLN research provides evidence of a strong correlation between the shortage of nurse faculty and the inability of nursing programs to keep pace with the demand for new registered nurses (RNs). Without faculty to educate our future nurses, the shortage cannot be resolved.

The NLN's Nursing Data Review 2004–2005.—Baccalaureate, Associate Degree, and Diploma Program revealed that graduations from RN programs contributed an estimated 84,878 additional prospective nurses to the RN labor supply falling far short of the Nation's demands. In its biennial 10-year employment projections for 2004–2014, the U.S. Department of Labor's Bureau of Labor Statistics (BLS) reported that over the next 10 years, about 70,000 new RN jobs and 50,000 replacement jobs will accrue each year, for a total of 120,000 RN job openings per year. Multiply that annual sum by 10 years, and BLS's model-based findings estimate that 1.2 million new RN workers will be needed from 2004–2014. This growth represents a 29 percent projected change over the next 10 years.

The NLN's 2004–2005 data review shows that nursing school applications surged in recent years, rising more than 59 percent over the past decade. The 2004–2005 academic year was no exception as almost 25,000 additional applications were submitted to nursing schools at all degree levels. Nonetheless, an estimated 147,000 qualified applications were turned away owing in large part to the lack of faculty necessary to teach additional students. Alarmingly too, this NLN review determined that new admissions fell by more than 27 percent in 2004–2005 after 2 years of reported increases. The significant dip in admissions seems to mark a turning point, reinforcing that a key priority in tackling the nurse shortage has to be scaling up the capacity to accept qualified applicants.

TRENDS STRESSING FACULTY SHORTAGE

It is not surprising that the problem of nurse faculty vacancies often is described as acute and as exacerbating the national nurse-workforce shortfall. The NLN's research, reported in its Nurse Educators 2006: A Report of the Faculty Census Survey of RN and Graduate Programs, indicated that the nurse faculty vacancies in the United States continued to grow even as the numbers of full- and part-time educators increased. The estimated number of budgeted, unfilled, full-time positions countrywide in 2006 was 1,390. This number represents a 7.9 percent vacancy rate in baccalaureate and higher degree programs, which is an increase of 32 percent

since 2002; and a 5.6 percent vacancy rate in associate degree programs, which translates to a 10 percent rise in the same period.

The data in the 2006 faculty census survey describe several trends, of which the following three are critical:

AGING OF THE FACULTY POPULATION

Nursing programs responding to the survey indicated that almost two-thirds of all full-time nurse faculty members were 45- to 60-years old and likely to retire in the next 5 to 15 years. A mean of 1.4 full-time faculty members per program left their positions in 2006, with 24 percent of these departures due to retirement. It is an open question where schools of nursing will find replacements for these experienced individuals.

DECREASE IN DOCTORALLY PREPARED FACULTY

Data show that nurse faculty are less well-credentialed in 2006 than they were 4 years earlier when the last NLN faculty census was conducted. A little over 43 percent of full-time baccalaureate and higher degree program faculty hold earned doctorates; whereas only 6.6 percent of associate degree program full-time faculty and 0.7 percent of diploma program full-time faculty are doctorally prepared. The overwhelming majority of the full-time faculty in associate degree (83 percent) and diploma (92.6 percent) programs hold the master's degree as their highest earned credential. The master's degree was the most common credential among part-time faculty members.

INCREASE IN PART-TIME FACULTY

Nearly 45 percent of the estimated mean number of faculty full-time equivalents are part-time faculty. Nationwide, the mean number of faculty members per institution had grown to 14.9 full-time and 12.1 part-time faculty in 2006, compared to 12.3 full-time and 7.4 part-time in 2002. The estimated number of part-time baccalaureate faculty has grown 72.5 percent since 2002. Over 58 percent of baccalaureate and higher degree programs and almost half of associate degree programs (47.5 percent) reported hiring part-time faculty as their primary strategy to compensate for unfilled, budgeted, full-time positions. While the use of part-time faculty allows for greater flexibility, often they are not an integral part of the design, implementation, and evaluation of the overall nursing program.

THE FEDERAL FUNDING REALITY

Today's undersized supply of appropriately prepared nurses and nursing faculty does not bode well for our Nation, where the shortages are deepening health disparities, inflated costs, and poor quality of health care outcomes. Congress moved in the right policy direction in passing the Nurse Reinvestment Act in 2002. That act made Title VIII programs a comprehensive system of capacity-building strategies to develop nurses by providing schools of nursing with grants to strengthen programs, through such activities as faculty recruitment and retention efforts, facility and equipment acquisition, clinical lab enhancements, and loans, scholarships and services that enable students to overcome obstacles to completing their nursing education programs. Yet, as the HRSA Title VIII data show, it is abundantly clear that Congress must step up in providing critical attention and significantly more funding to this ongoing systemic problem.

Nursing Education Loan Repayment Program.—In fiscal year 2005, with 4,465 applicants to the Title VIII Nursing Education Loan Repayment Program, 803 awards were made (599 initial 2-year awards and 204 amendment awards), or 18 percent of applicants received awards. In fiscal year 2006, there were 4,222 applicants to the program; 615 awards were made (373 initial 2-year awards and 242 amendment awards) with 14.6 percent of applicants receiving awards.

Nursing Scholarship Program.—In fiscal year 2005, 3,482 applications were submitted to the Nursing Scholarship Program, and 212 awards, or 6.1 percent of the applicants received scholarships. In fiscal year 2006, there were 3,320 applicants to the same program and 218, or 6.6 percent, awards were.

Advanced Education Nursing (AEN) Program.—This program supports the graduate education that is the foundation to professional development of advanced practice nurses, whether with clinical specialties or with a specialty in teaching. In fiscal year 2005, AEN supported 11,949 graduate nursing students across the specialties. The President's proposed fiscal year 2008 budget eliminates this program, which is fundamental to appropriately preparing future nursing faculty, the engine of the workforce pipeline. AEN must be restored and fully funded in order to prevent the

Nation from losing ground in the effort to remedy the nurse and nurse faculty shortages.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

We would be remiss in not acknowledging that nursing research is an integral part of the effectiveness of nursing care. NINR provides the knowledge base for improving the quality of patient care and reducing health care costs and demands. Critical to enhancing research within the nursing profession is the infrastructure development that increases the pool of nurse investigators and nurse educators, expands programs to develop partnerships between research-intensive environments and smaller colleges and universities, and promotes career development for minority researchers. Yet, as noted by the expanding list of non-nursing journals that publish the investigator findings of NINR-sponsored research, an investment in NINR goes far beyond just the nursing community and produces research results for all health care providers.

The relatively small investment made by the Federal Government in NINR is well justified for the outcomes received. For example, NINR has supported research that:

—Led to nursing intervention enabling excellent metabolic control in diabetic adolescents;

—Devised ways to sustain reduced high blood pressure in young African-American men;

—Reduced the burdens of caregivers of persons with dementia or other chronic care needs; and

—Developed a successful, national model for Spanish speakers in a community-based Arthritis Self-Management Program.

As the only organization that collects data across all levels of the nursing education pipeline, the NLN can state with authority that the nursing shortage in this country will not be reversed until the concurrent shortage of qualified nurse educators is addressed. Without adequate faculty, there are simply too few spots in nursing education programs to train all the qualified applicants out there. This challenge requires millions of dollars of increased funding for the professional development of nurses. The NLN urges Congress to strengthen existing Title VIII nurse education programs by funding them at a minimum level of $200 million for fiscal year 2008.

Your support will help ensure that nurses exist in the future who are prepared and qualified to take care of you, your family, and all those in this country who will need our care.

PREPARED STATEMENT OF THE NATIONAL MARFAN FOUNDATION

Chairman Harkin, ranking member Specter, and members of the subcommittee, the National Marfan Foundation thanks you for the opportunity to submit testimony regarding the fiscal year 2008 budget for the National Heart, Lung and Blood Institute, the National Institute of Arthritis, Musculoskeletal and Skin Diseases, and the Centers for Disease Control and Prevention. We are extremely grateful for the subcommittee's strong support of the NIH and CDC, particularly as it relates to life threatening genetic disorders such as Marfan syndrome. Thanks to your leadership, we are at a time of unprecedented hope for Marfan syndrome patients and their families.

It is estimated that 200,000 people in the United States are affected by the Marfan syndrome or a related disorder. Marfan syndrome is a genetic disorder of the connective tissue that manifests itself in many areas of body, including the heart, eyes, skeleton, lungs and blood vessels. It is a progressive condition that can cause deterioration in each of these body systems. The most serious and life-threatening aspect of the syndrome however, is a weakening of the aorta. The aorta is the largest artery that takes oxygenated blood to the body from the heart. Over time, many Marfan syndrome patients experience a dramatic weakening of the aorta which can cause the vessel to dissect and tear.

Fortunately, early surgical intervention can prevent a dissection and strengthen the aorta and the aortic valves. If preventive surgery is performed before a dissection occurs, the success rate of the procedure is over 95 percent. Unfortunately, if surgery is initiated after a dissection has occurred, the success rate drops below 50 percent. Aortic dissection is a leading killer in the United States, and 20 percent of the people it affects have a genetic predisposition, like Marfan syndrome, to developing the complication.

Fortunately, new research offers hope that a commonly prescribed blood pressure medication, losartan, might be effective in preventing this frequent and devastating event.

NATIONAL HEART LUNG AND BLOOD INSTITUTE

As NHLBI Director Dr. Elizabeth Nabel told the subcommittee during her appearance at the April 20th hearing on the "Burden of Chronic Disease" there is landmark clinical trial underway sponsored by NHLBI's Pediatric Heart Network to determine the effects of losartan on aortic growth:

"After the discovery that Marfan syndrome is associated with the mutation in the gene encoding a protein called fibrillin-1, researchers tried for many years, without success, to develop treatment strategies that involved repair of replacement of fibrillin-1. Recently, a major breakthrough occurred with the discovery that one of the functions of fibrillin-1 is to bind to another protein, TGF-beta, and regulate its effects. After careful analysis revealed aberrant TGF-beta activity in patients with Marfan syndrome, researchers began to concentrate on treating Marfan syndrome by normalizing the activity of TGF-beta. Losartan, which is known to affect TGF-beta activity, was tested in a mouse model of Marfan syndrome. The results, published only last April, showed that drug was remarkably effective in blocking the development of aortic aneurysms, as well as lung defects associated with the syndrome.

Based on this promising finding, the NHLBI Pediatric Heart Network, is now undertaking a clinical trial of losartan in patients with Marfan syndrome. About 600 patients aged 6 months to 25 years will be enrolled and followed for 3 years. This development illustrates the outstanding value of basic science discoveries, and identifying new directions for clinical applications. Moreover, the ability to organize and initiate a clinical trial within months of such a discovery is testimony to effectiveness of the NHLBI Network in providing the infrastructure and expertise to capitalize on new findings as they emerge."

Dr. Hal Dietz, the Victor A. McKusick professor of genetics in the McKusick-Nathans Institute of Genetic Medicine at the Johns Hopkins University School of Medicine, and the director of the William S. Smilow Center for Marfan Syndrome Research, is the driving force behind this groundbreaking research. Dr. Dietz uncovered the role that fibrillin-1 and TGF-beta play in aortic enlargement, and demonstrated the benefits of losartan in halting aortic growth in mice. He is the reason we have reached this time of such promise, and we are proud to have supported his cutting-edge research for many years.

We are also extremely grateful to Dr. Nabel and her colleagues at NHLBI for their leadership in advancing the losartan clinical trial. The Pediatric Heart Network, lead by Dr. Lynn Mahony and Dr. Gail Pearson, has demonstrated tremendous skill and dedication in facilitating this complex trial in a very short timeframe. We deeply value their hard work and commitment. NMF is a proud partner with NHLBI in supporting this promising research. The Foundation is actively supporting patient travel costs, and funding ancillary studies to the trial focused on additional manifestations of the Marfan syndrome that might be impacted losartan.

Finally, we are excited that NHLBI has formed a "Working Group on Research in Marfan Syndrome and Related Conditions" jointly sponsored by the NMF. The panel is chaired by Dr. Dietz and comprised of experts in all aspects of basic and clinical science related to the syndrome. The mission of the Working Group is to identify current research opportunities and challenges with a 5–10 year horizon, and to make recommendations for areas that require leadership by the NHLBI in order to move forward. We look forward to partnering with NHLBI to advance the goals outlined by the Working Group.

In order to support the important mission of the NHLBI, and its activities related to Marfan syndrome, NMF joins with the Ad Hoc Group for Medical Research, the Campaign for Medical Research, the Federation of American Societies for Experimental Biology, the National Health Council, and Research!America in recommending a 6.7 percent for NIH overall and NHLBI specifically in fiscal year 2008.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCKULOSKELETAL AND SKIN DISEASES

NMF is proud of its longstanding partnership with the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Dr. Steven Katz has been a strong proponent of basic research on Marfan syndrome during his tenure as NIAMS director and has generously supported several "Conferences on Heritable Disorders of Connective Tissue." Moreover, the Institute has provided invaluable support for Dr. Dietz's mouse model studies. The discoveries of fibrillin-1, TGF-beta, and their role

in muscle regeneration and connective tissue function were made possible in part through collaboration with NIAMS.

As the losartan clinical trail moves forward, we hope to expand our partnership with NIAMS to support ancillary studies that fall under the mission and jurisdiction of the Institute. One of the areas of great interest to researchers and patients, is the role that losartan may play in strengthening muscle tissue in Marfan patients. In response to our request for proposals for ancillary studies grants, NMF received applications focused on this area that scored extremely well under the peer review of our Scientific Advisory Board. We appreciate the subcommittee's ongoing support of NIAMS and our collaboration with the Institute on these emerging research opportunities.

To support the mission of the Institute in fiscal year 2008, NMF recommends a 6.7 percent increase for NIAMS.

CENTERS FOR DISEASE CONTROL AND PREVENTION

We are grateful for the subcommittee's encouragement last year of collaborations between the CDC and the Marfan syndrome community. One of the most important things we can do to prevent untimely deaths from aortic aneurysms is to increase awareness of Marfan syndrome and related connective tissue disorders. Education and prevention are two of the cornerstone missions of the Foundation. However, despite our efforts to raise awareness among the general public and the health care community, we know of too many families who have lost a loved one because they did not know that they were affected.

Recently, the NMF leadership traveled to Atlanta to visit with the Centers for Disease Control and Prevention to explore potential partnerships in the area of awareness and prevention of aortic dissections. We look forward to working with the National Center on Birth Defects and Developmental Disabilities (NCBDD) to prevent needless loss of life from the cardiovascular complications associated with Marfan syndrome. We applaud the leadership of the NCBDD's Division of Human Development and Disability for their interest in this area and appreciate the subcommittee's support of this partnership. We have discussed a number of potential collaborations with the CDC focused on the need for early diagnosis and treatment of Marfan syndrome, in order to enhance the quality and length of life for patients.

In order to support the important work of the CDC, NMF joins with the "CDC Coalition" in recommending an appropriation of $10.7 billion for the agency in fiscal year 2008. We would also encourage a corresponding percentage increase for the NCBDD and its Division of Human Development and Disability.

ABOUT THE NATIONAL MARFAN FOUNDATION

The NMF is a non-profit voluntary health organization founded in 1981. NMF is dedicated to saving lives and improving the quality of life for individuals and families affected by the Marfan syndrome and related disorders. The Foundation has three major goals: (i) to provide accurate and timely information about the Marfan syndrome to affected individuals, family members, physicians and other health professionals; (ii) to provide a means for those with Marfan syndrome and their relatives to share in experiences, to support one another and to improve their medical care and (iii) to support and foster research.

PREPARED STATEMENT OF THE ARCH NATIONAL RESPITE COALITION

Mr. Chairman, I am Jill Kagan, Chair of the ARCH National Respite Coalition, a network of respite providers, family caregivers, State and local agencies and organizations across the United States who support respite. This statement is presented on behalf of the undersigned organizations, many of which are members of the Lifespan Respite Task Force, a coalition of over 80 national and more than 100 State and local groups who supported the passage of the Lifespan Respite Care Act (Public Law 109–442). Together, we are requesting that the subcommittee include funding for the newly enacted Lifespan Respite Care Act in the fiscal year 2008 Labor, HHS and Education Appropriations bill at its modestly authorized level of $40,000,000. We join the 17 Members of the Senate who, along with Senator Hillary Rodham Clinton (D-NY) and Senator John Warner (R-VA), are sending a letter to the subcommittee making this same request.

WHO NEEDS RESPITE?

A national survey found that 44 million family caregivers are providing care to individuals over age 18 with disabilities or chronic conditions (National Alliance for

Caregiving [NAC] and AARP, 2004). In 2001, the last year Federal data were collected, 9,400,000 children under age 18 were identified with chronic or disabling conditions (National Survey of Children with Special Health Care Needs, U.S. Health Resources and Services Administration, 2001). These surveys suggest that a conservative estimate of the Nation's family caregivers probably exceeds 50 million.

Compound this picture with the growing number of caregivers known as the "sandwich generation" caring for young children as well as an aging family member. It is estimated that between 20 and 40 percent of caregivers have children under the age of 18 to care for in addition to a parent or other relative with a disability. And in the United States, 6,700,000 children, with and without disabilities, are in the primary custody of an aging grandparent or other relative other than their parents.

These family caregivers are providing about 80 percent of all long-term care in the United States. It has been estimated that in the United States these family caregivers provide $306,000,000,000 in uncompensated care, an amount comparable to Medicare spending in 2004 and more than twice what is spent nationwide on nursing homes and paid home care combined (Presentation by P.S Arno, PhD, Albert Einstein College of Medicine, January 2006).

WHAT IS RESPITE NEED?

State and local surveys have shown respite to be the most frequently requested service of the Nation's family caregivers, including the most recent study, "Evercare Study of Caregivers in Decline" (Evercare and NAC, 2006). Yet respite is unused, in short supply, inaccessible, or unaffordable to a majority of the Nation's family caregivers. The 2004 survey of caregivers found that despite the fact that the most frequently reported unmet needs were "finding time for myself," (35 percent), "managing emotional and physical stress" (29 percent), and "balancing work and family responsibilities" (29 percent), only 5 percent of family caregivers were receiving respite (NAC and AARP, 2004).

Barriers to accessing respite include reluctance to ask for help, fragmented and narrowly targeted services, cost, and the lack of information about how to find or choose a provider. Even when respite is an allowable funded service, a critically short supply of well trained respite providers may prohibit a family from making use of a service they so desperately need.

Twenty of 35 state-sponsored respite programs surveyed in 1991 reported that they were unable to meet the demand for respite services. In the last 15 years, we suspect that not too much has changed. A recent study conducted by the Family Caregiver Alliance identified 150 family caregiver support programs in all 50 States and Washington, DC funded with State-only or State/Federal dollars. Most of the funding comes through the Federal National Family Caregiver Support Program. As a result, programs are administered by local area agencies on aging and primarily serve the elderly. And again, some programs provide only limited respite, if at all. Only about one-third of these 150 identified programs serve caregivers who provide care to adults age 18–60 who must meet stringent eligibility criteria. As the report concluded, "State program administrators see the lack of resources to meet caregiver needs in general and limited respite care options as the top unmet needs of family caregivers in the States."

The 25 State respite coalitions and other National Respite Network members confirm that long waiting lists or turning away of clients because of lack of resources is still the norm.

While most families take great joy in helping their family members to live at home, it has been well documented that family caregivers experience physical and emotional problems directly related to their caregiving responsibilities. Three-fifths of family caregivers age 19–64 surveyed recently by the Commonwealth Fund reported fair or poor health, one or more chronic conditions, or a disability, compared with only one-third of non-caregivers (Ho, Collins, Davis and Doty, 2005). A study of elderly spousal caregivers (aged 66–96) found that caregivers who experience caregiving-related stress have a 63 percent higher mortality rate than noncaregivers of the same age (Schulz and Beach, December 1999).

Supports that would ease their burden, most importantly respite care, are too often out of reach or completely unavailable. Even the simple things we take for granted, like getting enough rest or going shopping, become rare and precious events. One Massachusetts mother of a seriously ill child spoke to the demands of constant caregiving: "I recall begging for some type of in-home support. It was during this period when I fell asleep twice while driving on the Massachusetts Turn-

pike on the way to appointments at Children's Hospital. The lack of respite put our lives and the lives of everyone driving near me at risk."

Restrictive eligibility criteria also preclude many families from receiving services or continuing to receive services they once were eligible for. A mother of a 12-year-old with autism was denied additional respite by her State DD (Developmental Disability) agency because she was not a single mother, was not at poverty level, wasn't exhibiting any emotional or physical conditions herself, and had only one child with a disability. As she told us, "Do I have to endure a failed marriage or serious health consequences for myself or my family before I can qualify for respite? Respite is supposed to be a preventive service."

For the millions of families of children with disabilities, respite has been an actual lifesaver. However, for many of these families, their children will age out of the system when they turn 21 and they will lose many of the services, such as respite, that they currently receive. In fact, 46 percent of U.S. State units on aging identified respite as the greatest unmet need of older families caring for adults with lifelong disabilities. An Alabama mom of a 19-year-old-daughter with multiple disabilities who requires constant care recently told us about her fears at a respite summit in Alabama. "My daughter Casey has cerebral palsy, she does not communicate, she is incontinent she eats a pureed diet, she utilizes a wheelchair, she is unable to bathe or dress herself. At 5 feet 5 inches and 87 pounds I carry her from her bedroom to the bathroom to bathe her, and back again to dress her. Without respite services, I do not think I could continue to provide the necessary long-term care that is required for my daughter. As I age, I do wonder how much longer I will be able to maintain my daily ritual as my daughter's primary caregiver."

Disparate and inadequate funding streams exist for respite in many States. But even under the Medicaid program, respite is allowable only through State waivers for home and community-based care. Under these waivers, respite services are capped and limited to narrow eligibility categories. Long waiting lists are the norm.

Respite may not exist at all in some States for adult children with disabilities still living at home, or individuals under age 60 with conditions such as ALS, MS, spinal cord or traumatic brain injuries, or children with serious emotional conditions. In Tennessee, a young woman in her twenties gave up school, career and a relationship to move in and take care of her 53 year-old mom with MS when her dad left because of the strain of caregiving. She went for years providing constant care to her mom with almost no support. Now 31, she wrote, "And I was young—I still am—and I have the energy, but—it starts to weigh. Because we've been able to have respite care, we've developed a small pool of people and friends that will also come and stand in. And it has made all the difference."

RESPITE BENEFITS FAMILIES AND IS COST SAVING

Respite has been shown to improve the health and well-being of family caregivers that in turn helps avoid or delay out-of-home placements, such as nursing homes or foster care, minimizes the precursors that can lead to abuse and neglect, and strengthens marriages and family stability.

The budgetary benefits that accrue because of respite are just as compelling, especially in the policy arena. Delaying a nursing home placement for just one individual with Alzheimer's or other chronic condition for several months can save government long-term care programs thousands of dollars. Moreover, data from an ongoing research project of the Oklahoma State University on the effects of respite care found that the number of hospitalizations, as well as the number of medical care claims decreased as the number of respite care days increased (fiscal year 1998 Oklahoma Maternal and Child Health Block Grant Annual Report, July 1999). A Massachusetts social services program designed to provide cost-effective family-centered respite care for children with complex medical needs found that for families participating for more than 1 year, the number of hospitalizations decreased by 75 percent, physician visits decreased by 64 percent, and antibiotics use decreased by 71 percent (Mausner, S., 1995).

In the private sector, a study by Metropolitan Life Insurance Company and the National Alliance for Caregivers found that U.S. businesses lose from $17,100,000,000 to $33,600,000,000 per year in lost productivity of family caregivers (MetLife and National Alliance for Caregiving, 2006). In an Iowa survey of parents of children with disabilities, a significant relationship was demonstrated between the severity of a child's disability and their parents missing more work hours than other employees. They also found that the lack of available respite care appeared to interfere with parents accepting job opportunities. (Abelson, A.G., 1999) Offering respite to working family caregivers could help improve job performance and employers could potentially save billions.

LIFESPAN RESPITE CARE PROGRAM WILL HELP

The Lifespan Respite Care Act is based on the success of statewide Lifespan Respite programs in four States: Oregon, Nebraska, Wisconsin and Oklahoma. Michigan passed State Lifespan Respite legislation in 2004 but has not provided the funding to implement the program, and a State Lifespan Respite bill is currently pending in the Arizona State legislature.

Lifespan Respite, which is a coordinated system of community-based respite services, helps States use limited resources across age and disability groups more effectively, instead of each separate State agency or community-based organization being forced to constantly reinvent the wheel or beg for small pots of money. Pools of providers can be recruited, trained and shared, administrative burdens can be reduced by coordinating resources, and the savings used to fund new respite services for families who may not currently qualify for any existing Federal or State program.

The State Lifespan Respite programs provide best practices on which to build a national respite policy. The programs have been recognized by prominent policy organizations, including the National Conference of State Legislatures, which recommended the Nebraska program as a model for State solutions to community-based long-term care. The National Governors Association and the President's Committee for People with Intellectual Disabilities also have highlighted lifespan respite systems as viable solutions. And most recently, the White House Conference on Aging recommended enactment of the Lifespan Respite Care Act to Congress.

The purpose of the new law is to expand and enhance respite services, improve coordination, and improve respite access and quality. Under a competitive grant program, States would be required to establish State and local coordinated Lifespan Respite care systems to serve families regardless of age or special need, provide new planned and emergency respite services, train and recruit respite workers and volunteers and assist caregivers in gaining access to services. Those eligible would include family members, foster parents or other adults providing unpaid care to adults who require care to meet basic needs or prevent injury and to children who require care beyond that required by children generally to meet basic needs.

The Federal Lifespan Respite program would be administered by the U.S. Department of Health and Human Services [HHS], which would provide competitive grants to statewide agencies through Aging and Disability Resource Centers working in collaboration with State respite coalitions or other State respite organizations. The program is authorized at $40,000,000 in fiscal year 2008 rising to $95,000,000 in fiscal year 2011.

No other Federal program mandates respite as its sole focus. No other Federal program would help ensure respite quality or choice, and no current Federal program allows funds for respite start-up, training or coordination or to address basic accessibility and affordability issues for families. We urge you to include $40,000,000 in the fiscal year 2008 Labor, HHS, Education appropriations bill so that Lifespan Respite Programs can be replicated in the States and more families, with access to respite, will be able to continue to play the significant role in long-term care that they are fulfilling today.

NATIONAL ORGANIZATIONS

American Association of People with Disabilities; American Association on Intellectual and Developmental Disabilities; American Dance Therapy Association;American Network of Community Options and Resources; American Psychological Association; Association of University Centers on Disabilities; Autism Society of America; Bazelon Center for Mental Health Law; Christopher and Dana Reeve Foundation; Chronic Illness Coalition; Easter Seals; Epilepsy Foundation; Family Voices; Generations United; National Association of Councils on Developmental Disabilities; National Association for Home Care and Hospice; National Association of Social Workers; National Association of State Head Injury Administrators; National Council on Aging; National Down Syndrome Congress; National Down Syndrome Society; National Family Caregivers Association; National Gerontological Nursing Association; National Multiple Sclerosis Society; National Organization For Empowering Caregivers; National Rehabilitation Association; National Respite Coalition; National Spinal Cord Injury Association; Older Women's League; Paralyzed Veterans of America; The ALS Association; The Arc of the United States; United Cerebral Palsy; Well Spouse Association; Wilson's Disease Association.

STATE AND LOCAL ORGANIZATIONS

Alabama Lifespan Respite Resource Network; Allegheny County Respite Care Coalition, Pittsburgh, PA; Arizona Lifespan Respite Coalition (in formation); Catholic

Family and Child Services, Yakima, WA; East Central Alabama United Cerebral Palsy; Easter Seals of Southern Georgia; Families Together, Inc., Wichita, Kansas; Family Voices Vermont; Illinois Respite Coalition; Iowa Respite and Crisis Care Coalition; Kansas Respite Coalition; Louisiana Developmental Disabilities Council; Maryland Respite Care Coalition; Michigan Respite Resource Network; Nebraska Respite Coalition; New Jersey Family Support Center; New Jersey Lifespan Respite Task Force; North Carolina Respite and Crisis Care Coalition; Oklahoma Respite Resource Network; Parent to Parent of Vermont; Partnership for People with Disabilities, Virginia Commonwealth University; Pennsylvania Respite Coalition; Respite and Crisis Care Coalition of Washington; Respite Care Association of Wisconsin; South Carolina Respite Coalition; Tennessee Respite Coalition; Tennessee Voices for Children; The Arc of King County, WA; United Cerebral Palsy of Huntsville and Tennessee Valley, Huntsville, AL; United Cerebral Palsy of Pennsylvanial; and Virginia Respite Resource Project.

PREPARED STATEMENT OF THE NATIONAL SLEEP FOUNDATION

SUMMARY OF FISCAL YEAR 2008 RECOMMENDATIONS

Provide a $10,000,000 increase in funding in fiscal year 2008 to the Centers for Disease Control and Prevention (CDC) to undertake data collection activities and create awareness and training programs related to sleep, sleep disorders and the consequences of sleep deprivation to improve public health and safety.

Encourage CDC to continue to take a leadership role in partnering with other Federal agencies and voluntary health organizations in the National Sleep Awareness Roundtable to create collaborative sleep education and public awareness initiatives. In view of CDC's success with similar initiatives, encourage the CDC to financially support the Roundtable and its initiatives.

Provide direction and funding of $1,000,000 to United States Surgeon General to develop and implement steps leading to the development of a report on sleep and sleep disorders in order to call attention to the public health impact of inadequate and disorder sleep in order to protect and advance the health and safety of the Nation.

Mr. Chairman and members of the subcommittee, thank you for allowing me to submit testimony on behalf of the National Sleep Foundation (NSF). I am Dr. Barbara Phillips, Chair of the NSF Board of Directors and professor at the University of Kentucky College of Health, Department of Preventive Medicine. NSF is an independent, non-profit organization that is dedicated to improving public health and safety by achieving understanding of sleep and sleep disorders, and by supporting sleep-related education, research, and advocacy. We work with sleep specialists and other health care professionals, researchers, patients and drowsy driving victims throughout the country as well as collaborate with many government, voluntary organizations and corporations to prevent health and safety problems related to sleep deprivation and untreated sleep disorders.

Sleep problems, whether in the form of medical disorders or related to work schedules and a 24/7 lifestyle, are ubiquitous in our society. It is estimated that sleep-related problems affect 50 to 70 million Americans of all ages and socioeconomic classes. Sleep disorders are common in both men and women; however, important disparities in prevalence and severity of certain sleep disorders have been identified in minorities and underserved populations. Despite the high prevalence of sleep disorders, the overwhelming majority of sufferers remain undiagnosed and untreated, creating unnecessary public health and safety problems, as well as increased health care expenses. Surveys conducted by the National Sleep Foundation show that more than 60 percent of adults have never been asked about the quality of their sleep by a physician, and fewer than 20 percent have ever initiated such a discussion.

Additionally, Americans are chronically sleep deprived as a result of demanding lifestyles and a lack of education about the impact of sleep loss. Sleepiness affects vigilance, reaction times, learning abilities, alertness, mood, hand-eye coordination, and the accuracy of short-term memory. Sleepiness, as a result of untreated disorders or sleep deprivation, has been identified as the cause of a growing number of on-the-job accidents and automobile crashes.

According to the National Highway Traffic Safety Administration's 2002 National Survey of Distracted and Drowsy Driving Attitudes and Behaviors, an estimated 1.35 million drivers have been involved in a drowsy driving crash in the past 5 years. According to NSF's 2006 Sleep in America poll, 51 percent of all adolescents who drive report that they have driven drowsy at least once in the past year. In

fact, 15 percent of drivers in 10th to 12th grades say they drive drowsy once a week or more! A large number of academic studies have linked work accidents, absenteeism, and poor school performance to sleep deprivation and circadian effects.

The recent Institute of Medicine (IOM) report, Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem, found the cumulative effects of sleep loss and sleep disorders represent an under-recognized public health problem and have been associated with a wide range of negative health consequences, including hypertension, diabetes, depression, heart attack, stroke, and at-risk behaviors—all of which represent long-term targets of the Department of Health and Human Services (HHS). Moreover, the personal and national economic impact is staggering. The IOM estimates that the direct and indirect costs associated with sleep disorders and sleep deprivation total hundreds of billions of dollars annually.

Sleep science and government reports have clearly demonstrated the importance of sleep to health, safety, productivity and well-being, yet studies continue to show that millions of Americans are at risk for serious health and safety consequences of untreated sleep disorders and inadequate sleep. Unfortunately, despite recommendations in numerous Federal reports, there are no on-going national educational programs regarding sleep and fatigue issues aimed at the general public, health care professional, underserved communities or at-risk groups.

NSF believes that every American needs to understand that good health includes healthy sleep, just as it includes regular exercise and balanced nutrition. We must elevate sleep to the top of the national health agenda. We need your help to make this happen.

Our biggest challenge is bridging the gap between the outstanding scientific advances we have seen in recent years and the level of knowledge about sleep held by health care practitioners, educators, employers, and the general public. Because resources are limited and the challenges great, we think creative and new partnerships are needed to fully develop sleep awareness, education, and training initiatives. Consequently, the NSF is spearheading two important initiatives to raise public and physician awareness of the importance of sleep to the health, safety and well-being of the Nation.

First, for the last 3 years, Congress has recommended that the CDC support activities related to sleep and sleep disorders. As a result, CDC's National Center for Chronic Disease Prevention and Health Promotion has been collaborating with more than twenty voluntary organizations and Federal agencies to form the National Sleep Awareness Roundtable (NSART), which was officially launched in March of this year. NSART is currently working through four task forces—public awareness, research, patient access to care, and public policy—to develop a National Action Plan. This document will address what is required to organize a successful collaboration to implement effective public and professional awareness and education initiatives to improve sleep literacy and healthy sleep behaviors. NSART is seeking to expand its membership by reaching out to new organizations and State and Federal agencies that are interested in raising awareness of sleep issues and implementing NSART's National Action Plan.

The CDC has taken initial steps to begin to consider how sleep affects public health issues, but it needs appropriate resources to take additional actions, as recommended by the IOM and other governmental reports. Currently, the CDC budget does not include a line item for sleep-related activities.

With adequate resources, the CDC could:

—Add sleep-related items to established surveillance systems to build the evidence base for the prevalence of sleep disorders and their co-morbidities in order to increase awareness of these issues on the national, State, and local levels.

—Support the development of targeted approaches for delivering messages to promote sleep, along with exercise and nutrition, as a healthy behavior, and for increasing public and professional education and awareness regarding the public health impact of untreated sleep disorders and chronic sleep loss.

—Develop training materials for health care professionals regarding the signs and symptoms of sleep disorders, as well as countermeasures for drowsy driving and workplace accidents related to sleep loss, shift work, and long work hours.

—Increase and enhance fellowship opportunities to attract promising researchers at universities and colleges across the country to conduct epidemiological activities and health cost assessments regarding sleep.

NSF and members of the National Sleep Awareness Roundtable believe that a partnership with CDC is critical to address the public health impact of sleep and sleep disorders. We hope that the committee will provide funding of $10,000,000 to the CDC to begin programs as outlined here and to support efforts developed by

NSART through a cooperative agreement similar to other roundtables in which CDC participates.

Second, at the National Institutes of Health's Frontiers of Knowledge in Sleep and Sleep Disorders conference in 2004, the U.S. Surgeon General acknowledged widespread illiteracy in our country regarding sleep loss and untreated sleep disorders. He emphasized that sleep problems are easily related to the three top areas of the national health agenda: prevention, preparedness, and health disparities. Prevention of some of our Nation's most pressing health problems would be fostered by attending to sleep disorders. Sleep deprivation and fatigue are major barriers to maximizing preparedness and response in times of crisis. Finally, like many health and safety concerns, access to knowledge and medical care for sleep problems is beyond the reach of many Americans.

For the last 2 years, Congress has directed the Office of the Surgeon General to help promote sleep as a public health concern through the development of a Surgeon General's Report on Sleep and Sleep Disorders, in order to call attention to the importance of sleep and develop strategies to protect and advance the health and safety of the Nation. The Surgeon General has expressed interest in addressing this issue through the development of a conference or workshop on how sleep impacts public health, but currently lacks the funding to proceed.

Therefore, NSF respectfully requests that the committee provide direction and $1,000,000 in funding to the Office of the Surgeon General to develop a workshop and a call to action related to sleep and public health, in preparation for a Report on Sleep and Sleep Disorders.

The IOM report includes important recommendations that support the sprit of these efforts and other specific actions to be taken by the CDC and the Office of the Surgeon General to raise awareness of sleep health and sleep disorders and to collect surveillance data to evaluate future education and intervention initiatives. CDC and the Surgeon General must receive direction and appropriate funding in order to continue partnering with voluntary health organizations and State and Federal agencies to increase support for initiatives that help ensure the health and safety of all Americans.

Thank you again for the opportunity to present you with this testimony.

PREPARED STATEMENT OF THE NATIONAL TECHNICAL INSTITUTE FOR THE DEAF

Mr. Chairman and members of the committee: I am pleased to present the fiscal year 2008 budget request for the National Technical Institute for the Deaf, one of eight colleges of the RIT, in Rochester, NY. We serve the university needs of approximately 1,100 deaf/hard-of-hearing students from across the nation and 150 hearing students, on a campus of over 14,000 students. Created by Congress, we provide postsecondary technical education to prepare deaf/hard-of-hearing students for successful employment.

NTID has fulfilled this mandate with distinction for 39 years.

BUDGET REQUEST

NTID's fiscal year 2008 request is $60,757,000. This consists of $59,052,000 for continuing operations and $1,705,000 for construction projects initiating replacement of aging mechanical systems. The NTID request and the President's are shown below.

	Operations	Construction	Total
NTID request	$59,052,000	$1,705,000	$60,757,000
President's Request	55,349,000	913,000	56,262,000
Difference	3,703,000	792,000	4,495,000

We are respectfully requesting that the committee restore the appropriation to the NTID requested level. Our operations request does not include additional funding for new academic programs or headcount. Instead, we are committed to fund all program improvements and increases in headcount, if any, through the reallocation of existing resources.

We commit because we have consistently minimized requests. From fiscal year 2003 to fiscal year 2007 we saved of $6.2 million by increasing revenues and reducing/reallocating headcounts. These difficult savings controlled budget requests while allowing expansion in areas such as speech-to-test services for deaf/hard-of-hearing students who do not know sign language.

We are proud of those accomplishments; however, those actions leave limited flexibility regarding what we respectfully submit is inadequate funding proposed in the President's budget. Significant reductions threaten our vitality, and leave us with options such as the following:

1. *Not Funding Technology Needs*.—Student curricula demand state-of-the-art technology updates to prepare students for jobs. For deaf/hard-of-hearing students, technology to support the delivery of instruction is critical. We spend $1,000,000/year for technology; eliminating that would reduce programming development and quality.

2. *Not Supporting Endowment Allocations*.—The Education of the Deaf Act authorizes matching private donations from appropriations, to reduce dependence on Federal funds. In fiscal year 2006, NTID matched over $900,000; we do not want to stop this practice.

3. *Not Supporting Outreach Efforts, Which Impact Future Enrollment*.—Approximately $542,000 supports six programs designed to: attract junior/senior high school students to NTID; create a Community College Referral Program; and establish a Summer English Institute. All are designed to increase future enrollments.

4. *It Does Not Include a Fair Labor Standards Act (FLSA) Lawsuit Against RIT With a $2.5 Million Settlement Proposal Announced in March, 2007*.—It affects 170 current RIT employees including about 140 NTID employees (mostly sign language interpreters), and others who have worked for NTID within the last 6 years. A proportion of the settlement may be paid by NTID in fiscal year 2008; the exact amount is to be determined.

With the reclassification of positions from exempt-from-overtime to non-exempt-from-overtime, we expect an increase in our compensation expenses. The financial impact is to be determined; however, its impact is immediate, beginning April 16, 2007.

5. *It Does Not Recognize the Effect of Inflation and the Impact of Freezing Positions*.—NTID budgeted a 3 percent salary increase in fiscal year 2007, but the RIT increase was 3.5 percent; we follow RIT per our Department of Education agreements. At level fiscal year 2008 funding we will consider freezing open positions, including those we have aggressively filled such as speech-to-text services which expanded in response to an Office of Civil Rights ruling.

NTID expenses are driven by inflationary pressures. We must fund salary, health care, and energy costs increases, and the rising costs of RIT services, which are subject to the same pressures. Taken together, these costs represent over 80 percent of NTID's total expenditures.

The President's request for fiscal year 2008 ignores inflationary increases and returns to fiscal year 2006 levels. Our requested increase of $3,703,000 in fiscal year 2008 operations over that fiscal year 2006 level is the equivalent of having obtained an increase of 3.3 percent both from fiscal year 2006 to fiscal year 2007 (which we did not receive) and from fiscal year 2007 to fiscal year 2008. We believe these requests are supported by the rationale above on the negative impact of various potential reductions.

Regarding construction, the President's request partially funds the $1.7 million needed to replace mechanical heating, ventilation, and air-conditioning systems (well past their expected lives in 40 year old buildings) and the delivery of energy to NTID buildings. The systems have been well maintained but on-going maintenance difficulties dictate replacement at this time.

ENROLLMENT

Total enrollment is at 1,250 for school year 2006–2007 (fiscal year 2007), and was 1,256 students last year. NTID anticipates maintaining or increasing enrollment for school year 2007–2008 (fiscal year 2008). A 5-year summary of student enrollment follows.

NTID ENROLLMENTS—5 YEAR NUMBERS

School Year	Deaf/Hard-of-Hearing Students				Hearing Students			Grand Total
	Undergrad	Grad RIT	MSSE	Subtotal	Interpreting Program	MSSE	Subtotal	
2002–3	1,093	29	16	1,138	65	28	93	1,231
2003–4	1,064	45	41	1,150	92	28	120	1,270
2004–5	1,055	42	49	1,146	100	35	135	1,281
2005–6	1,013	53	38	1,104	116	36	152	1,256
2006–7	1,017	47	31	1,095	130	25	155	1,250

The number of students studying in our interpreting program has grown substantially, the number in our graduate secondary teacher preparation program—MSSE—has fluctuated (totaling both MSSE columns above), and the sub-total of deaf/hard-of-hearing students has declined from 1,138 in 2002–2003 to 1,095 in 2006–2007, a decline of 43 students. However, the decline in enrollment of deaf/hard-of-hearing students parallels almost one-for-one the drop in international students from 90 enrolled in 2002–2003 to 42 enrolled in 2006–2007, a decline of 48 students. A change in the Education of the Deaf Act increased the surcharge on tuition for international students from 50 percent to 100 percent, resulting in the significant decline.

INCREASING NUMBERS OF STUDENTS WITH SECONDARY DISABILITIES

NTID is working with significantly increased numbers of students with disabilities in addition to deafness. The table shows the number and percent of students receiving services from the RIT Disability Services Office, which serves students with physical or mental impairments that limit one or more major life activities. Their services assure equal access to education based upon legal foundations established by Federal law—the Rehabilitation Act of 1973 including section 504, and the Americans with Disabilities Act of 1990.

NUMBER AND PERCENT OF STUDENTS RECEIVING SECONDARY DISABILITY SERVICES

Year	Number	Percent
1998–1999	33	3.0
1999–2000	57	5.0
2000–2001	82	7.6
2001–2002	78	7.2
2002–2003	97	8.6
2003–2004	95	8.7
2004–2005	110	10.3
2005–2006	129	12.7

While we are unable to calculate the additional budgetary costs, it is clear that services are increasing significantly year-by-year, with associated increased costs.

STUDENT ACCOMPLISHMENTS

Our recently reported placement rate indicates that 95 percent of NTID's fiscal year 2005 graduates in the labor force were employed (using the methodology of the Bureau of Labor Statistics) in jobs commensurate with the level of their academic training. Over the last 5 years, a large proportion (83 percent) were employed in science, engineering, business, and visual communications.

In fiscal year 2005, new research conducted with the Social Security Administration and Cornell University examined 10,196 graduates and withdrawals spanning 25 years. It shows that graduation from NTID has significant economic benefits over a lifetime of work. Baccalaureate graduates earn, on average during their peak earning years, $12,020 more per year than students who attend, but withdraw without a degree; sub-baccalaureate graduates earn $4,762 more. Students who withdraw experience twice the rate of unemployment as graduates.

NTID clearly makes a significant, positive difference in the earnings, and in turn in the lives of those who graduate.

While 60 percent of students attending NTID receive benefits through the Supplemental Security Income program (SSI), by the time they are at age 50, less than 3 percent of graduates continue to draw SSI benefits. Graduates also access Social Security Disability Insurance (SSDI), fundamentally an unemployment benefit, at far lesser rates than withdrawals. By age 50, withdrawals were twice as likely to be receiving SSDI as degree graduates.

A large percentage of non-graduates will continue to depend heavily on Federal income support throughout their lives. But NTID graduation significantly reduces dependence on welfare programs. Considering the added taxes graduates pay as a result of their increased earnings, and the savings derived from reduced dependency on the Federal income support programs, the Federal investment in NTID returns significant societal dividends.

NTID BACKGROUND

Academic Programs.—NTID offers high quality, career-focused, associate degree programs that lead to placement in well-paying technical careers. A cooperative edu-

cation component ties closely to high demand employment opportunities. We are expanding transfer associate degree programs to better serve the higher achieving segment of our student population who seek bachelors and masters degrees in an increasingly demanding marketplace. These transfer programs provide for seamless transition to baccalaureate studies. Finally, we support students in RIT baccalaureate programs. One of NTID's greatest strengths is its outstanding track record of assisting high-potential students to gain admission to and to graduate from the other colleges of RIT at rates that are better than their hearing peers.

Research.—The research program and agenda are guided and organized according to these general research areas: Language and Literacy, Teaching and Learning, Socio-cultural Influences, Career Development, Technology Integration, and Institutional Research. All benefit enrolled students as well as deaf/hard-of-hearing adults throughout the country.

Outreach.—Extended outreach activities to junior and senior high school students, expand their horizons regarding a college education.

Student Life.—The new Student Development Center, funded by a $2.0 million gift from a private individual and $1.5 million fiscal year 2005 Federal appropriations has been occupied. Our activities foster student leadership and community service, and providing opportunities to explore other educational interests.

SUMMARY

The fiscal year 2008 request will allow NTID to continue its mission of preparing deaf/hard-of-hearing people to enter the workplace and society and compete with their hearing peers. Our alumni have demonstrated that they can achieve full independence and become contributing members of society; they can earn a living and live a satisfying life as a result of the postsecondary education received at NTID. Collaborative research between NTID and the Social Security Administration shows that NTID graduates over their lifetimes are employed at a much higher rates, earn substantially more (therefore paying significantly more in taxes), and participate at a much lower rate in Federal welfare programs.

We are hopeful that the members of the committee will agree that NTID, with its outstanding record of service to deaf/hard-of-hearing people, remains deserving of their support and confidence.

PREPARED STATEMENT OF THE NATIONAL TUBERCULOSIS CONTROLLERS ASSOCIATION

The National Tuberculosis Controllers Association (NTCA) is pleased to submit our recommendations for TB control programs in the Labor Health and Human Services and Education Appropriations subcommittee purview.

The National Tuberculosis Controllers Association (NTCA) is a membership organization composed of persons who are working, or have worked in Tuberculosis Control programs in the United States and it's Pacific Affiliated Islands. Membership is also extended to our partners in other TB-related organizations and to any other persons who have interest in Tuberculosis control issues.

The United States is now facing unprecedented threats in our progress towards the goal of eliminating TB and even our fundamental responsibility to control TB, due to regressive cuts to programs that are essential to contain the disease and prevent the creation of new highly dangerous strains of drug resistance.

PREVALENCE OF TB IN THE UNITED STATES

Tuberculosis (TB) is a disease caused by a bacterium that is spread through the air—that is, it is spread from person-to-person by sharing the air that we breathe. Infection affects some people immediately, but for many, it becomes "dormant," to become active at a later time. It is estimated that one-third of the world's population is infected with TB in this latent form, and indeed, these people form a reservoir of a disease that kills more than 2 million adults and children each year (~1 every 15 seconds) and remains the leading cause of human death from an infectious disease today.

In the United States, efforts to control the disease following its resurgence in the early 1990's have created a public health infrastructure that has been able to achieve that goal in many sectors. At the heart of this endeavor is the Centers for Disease and Control's (CDC) Division of TB Elimination (DTBE), which coordinates prevention and control activities to States through cooperative agreement awards to support categorical infrastructure. Following interim analyses, the Institute of Medicine (IOM) declared in its 2000 report, Ending Neglect, the Elimination of Tuberculosis in the United States, that TB could be eliminated as a public health problem

in the United States by 2010. The 13,767 cases reported in 2006 represent the lowest absolute number of cases ever recorded in our country. But we are far from TB elimination. The lower numbers have again lulled us into a false sense of security, and as Federal support once again is being withdrawn, we are facing another potential and more dangerous challenge to our public's health.

The majority of U.S. TB cases come from outside U.S. borders. Fifty-five percent of 2006 TB cases were non-U.S. born, but the majority of these individuals have resided in the United States for more than 5 years and are citizens. Twenty States reported increases in TB cases in 2006 over 2005, with the District of Columbia recording the highest TB case rate (12.6/100,000) in the Nation.

White, U.S.-born people no longer make up the majority of TB cases in the United States—TB now embraces racial and ethnic minorities as never before. African Americans have 8 times the risk of developing TB as whites; Hispanics and Asians have 8 and 21 times the risk, respectively. Our health systems have been slow to adapt to the needs of these populations.

CHALLENGES TO TB CONTROL

In its November 2005 statement, CDC recognized 5 critical challenges to controlling TB in the United States. Addressing each challenge requires intact and fully functional local public health systems that are able to reach people at-risk, unique to populations in individual States and to the disease. Our State and local TB programs are losing the front-line, experienced staff that provide adequate case management to persons with active (and infectious) TB and ensure safe completion of treatment (at least 6–9 months of multiple medications), preventing the emergence of drug resistance among those who do not take medications appropriately. As programs lose funding, it is these essential, "core" services that are being compromised, or even eliminated entirely.

The Division of TB Elimination has been level-funded for at least 12 years; in 2006, our State and local programs were asked to absorb a real cut of 4.8 percent in Federal funding. The impact has been stealthy, but clear. These are examples:

In Massachusetts, 77 percent of reported TB cases are foreign-born, and among this group, about 95 percent are drug-resistant. The State also has fewer staff resources to handle these cases since nine field staff positions (21 percent of the work force) have been lost since 2002.

In New York City, 1,185 patients had to be managed by 26 fewer nurses and field staff (an 18 percent cut).

California has more than 20 percent of our national cases, 2,800, of whom 78 percent are foreign-born. California reports an 11 percent rate of drug resistance and yet had to deal with a 9 percent reduction in its Federal support versus 2005.

California and New York both reported cases of the new Extensively Drug-Resistant (XDR)-TB strain in 2006. These strains are virtually resistant to current treatment regimens and are associated high levels of mortality.

In December, Dr. Michael Fleenor, Chair of the National Advisory Committee on the Elimination of Tuberculosis, wrote to Secretary Leavitt and to CDC Director Gerberding to express concerns of the Council concerning the current negative impact of these funding reductions and to point out the urgent need to address these concerns in light of the new strains of XDR–TB. XDR–TB is produced by the failure to effectively treat individuals with other multidrug resistant TB (MDR TB) strains. Each of the 118 MDR TB cases reported in the United States in 2005 has the potential to become XDR TB without the expertise and infrastructure to cure the disease through directly observed treatment. Make no mistake—XDRTB is already in the United States and only our public health infrastructure prevents the production of more cases!

The resurgence of tuberculosis and the emergence of Multi-Drug Resistant TB (MDRTB), organisms resistant to the two most effective drugs in the 1990's resulted from a collapse of the same infrastructure that we have since struggled to re-create, and are in the process of disassembling once again at this very moment. In short, we are being set up to fail. Earlier this year, U.S. Assistant Surgeon General and DTBE Director, Dr. Kenneth Castro warned the TB control community to anticipate a further reduction of 25 percent in Federal support for TB control over the next 5 years. Such a reduction bodes poorly for sustained efforts to control the disease, and, in the face of emerging XDR–TB, is a potential disaster.

There is another lethal disease, to which governmental response was, on balance, both swift and appropriate, and from which we can learn: SARS. XDR–TB is, in many ways imminently more dangerous than SARS. While both are virtually untreatable, have extremely high death rates and are transmissible from person to person, TB unlike SARS, has both a human reservoir and a state of Latent Infec-

tion. TB, both regular and XDR, can lie dormant, only to emerge months or years later and spread person to person. Yet today we are facing funding cutbacks rather than vitally needed increases to keep our defensive infrastructure intact against TB.

In order to put our domestic situation in proper context. Basic and applied research is sorely needed to help us understand the complex interactions between the TB organism and human beings which gives rise to latent and active disease. Research will provide insights as to how we might reduce the length, complexity, and toxicity of our currently limited drugs; it will provide us with tools to diagnose TB disease and dormant infection quickly; and it will help us understand how to reach people at-risk to prevent TB from developing. Laboratories must have better tools to identify and report drug resistance cheaply and quickly. And we must use our understanding and our resources to assist other countries in controlling the disease and preventing the emergence of active disease in those with dormant infection—for the world's problem truly is our problem too.

The CDC DTBE clearly has demonstrated its ability to work closely with State and local public health TB programs to address issues of TB control. This association and cooperative partnership is responsible for the successes we have achieved over the past 15 years and it should be reinforced by assuring adequate support for the unprecedented challenges we are now facing. The current funding level of $137.4 million for DTBE actually represents a 23 percent decrease over the past decade, adjusted for inflation. The NTCA recommends that the committee adopt the National Coalition for the Elimination of Tuberculosis's recommendation of an increase of $390.6 million in project funding for the CDC's Division of Tuberculosis Elimination for a total of $528 million in fiscal year 2008. This includes:

—To Maintain Control of Core Activities and Regional Medical Training and Consultation Centers (RTMCC's)—$185 million

—Preparedness & Outbreak Response Capacity for XDR TB—$45 million.

—Accelerating the Decline—$75 million.

—For Research and Development of New Tools, Drugs and Diagnostics—$110 million.

—For Intensified Support for Action to Accelerate Control (ISAAC). Includes Enhancements to Surveillance, Laboratory, Border Health, Health Disparities, Evaluation, and Research Translation (Turning Research Into Practice)—$113 million.

CONCLUSION

Clearly, the responsibility for TB control is a shared one. The CDC DTBE has an excellent track record of working closely with State and local health departments, providers and communities; the successful control of TB among residents of New Orleans during the hurricane is a recent example. Without the expertise and public health infrastructure that was in place, the 130 TB cases that were distributed from New Orleans to emergency shelters across the United States would have led to multiple outbreaks of TB. However, the ongoing budget cuts at the CDC directly impair TB prevention and control core activities within the States and seriously compromise a remarkable successful relationship. We have seen this pattern before. We know this will leave us once again at risk of an even more deadly epidemic of tuberculosis. The NCTA appreciates the opportunity to submit this statement to the subcommittee.

PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2008

A 6.7 percent increase for the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Continue to expand the NIDDK's Nephrotic Syndrome (NS) and Focal Segmental Glomerularsclerosis (FSGS) research portfolios by aggressively supporting grant proposals in this area and creating a Glomerular Diesease Registry.

Encourage the National Center for Minority Health and Health Disparities (NCMHD) to initiate studies into the incidence and cause of NS and FSGS in minority populations.

Mr. Chairman and members of the subcommittee, the NephCure Foundation (NCF) is grateful for the opportunity to present testimony before you. NCF is a nonprofit organization that is driven by a panel of respected medical experts and a dedicated band of patients and families that work together to save kidneys and also lives. NCF is the only non-profit organization exclusively devoted to fighting idiopathic nephrotic syndrome (NS) and focal segmental glomerulosclerosis (FSGS).

Now in our sixth year, the NephCure Foundation continues to work tirelessly to support glomerular disease research.

FSGS: ONE FAMILY'S STORY

Bradly Grizzard, was diagnosed with focal segmental glomerulosclerosis (FSGS) in 2002. In May of 2005, his mother donated one of her kidneys to him.

FSGS is one of a cluster of glomerular diseases that attack the tiny filtering units contained in each human kidney, known as nephrons. Glomerular disease attacks the portion of the nephron called the glomerulus, scarring and often destroying these filters. Currently, scientists do not know why glomerular injury occurs, and there is no known cure for these diseases.

Upon diagnosis, an FSGS patient's health often takes a rapid downward plunge at and it is extremely difficult to make a comeback. Bradly was a star football player at his high school and was being recruited by college football coaches before FSGS attacked his body. When his kidneys failed, he was forced to give up football, as well as juggle college classes with several hours of dialysis a day. He was lucky that his mother's kidney was a match, but even so, the first few hospitals that they approached refused to perform the transplant. They were eventually able to find a doctor and a hospital that was willing to perform the operation, and the transplanted kidney is now working well. Even though Bradly is now feeling much stronger, he must remain on costly immunosuppressant drugs for the rest of his life. These drugs cause many unpleasant side effects and medical complications.

Sadly, Bradly's story is far from unique. There are thousands of people in this country who have had their lives disrupted due to the sudden onset of FSGS. Furthermore, although kidney transplants have been very successful for thousands of FSGS patients, many patients end up rejecting the transplanted kidney. A large percentage of patients even see the FSGS comes back and attacks the transplanted kidney. In either case, the patient must then again rely on daily dialysis as a means of survival. There are thousands of young people who are in a race against time, hoping for a treatment that will save their lives. The NephCure Foundation today raises its voice to speak for them all, asking you to take specific actions that will aid our mission to find the cause and cure of NS/FSGS.

First and foremost, we join the Ad Hoc Group for Medical Research Funding in asking for a 6.7 percent increase for the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

MORE RESEARCH IS NEEDED

Little progress has been made on finding the cause of or the cure for FSGS. Scientists tell NCF that much more research needs to be done on the basic science behind the disease.

NCF is thankful that the NIDDK is continuing to work with us on the FSGS clinical trial. Currently, 150–175 patients nationwide are enrolled in the trial. Recently, the steering committee charged with providing programmatic direction to the trial decided on several changes which would accelerate progress. NCF is also working with the NIDDK to cosponsor ancillary basic biological material studies of the enrolled patients.

NCF is pleased to learn that the NIDDK is intending to re-release the program announcement (PA) entitled, "Exploratory Basic Research in Glomerular Disease" (PA–06–228). After being originally introduced as a R21 PA in March of 2006, PA–06–228 was rescinded along with all other non-clinical R21 programs when they were folded into the general NIH wide solicitation. NCF is optimistic that re-issuing this PA under the RO1 mechanism, as intended, will stimulate significant research into glomerular diseases.

As health information technology continues to advance, disease registries and databases are fast becoming a crucial resource and vital source of information. The basic understanding of numerous conditions has been greatly improved by compiling patient information and disease data. At this time, no such registry exists for glomerular diseases. NCF has been informed by researchers and scientists that such a registry would greatly increase the clinical knowledge of NS and FSGS.

We ask the committee to encourage the NIDDK to help find the cause and the cure for glomerular disease by continuing its support for the FSGS clinical trial and the ancillary basic biological material studies. We also ask the NIDDK to continue to add glomerular disease to program announcements. Additionally, we would like the committee to recommend that the NIDDK place a high priority on any initiatives that seek to establish a glomerular disease registry.

TOO LITTLE EDUCATION ABOUT A GROWING PROBLEM

When glomerular disease strikes, the resulting nephrotic syndrome causes a loss of protein in the urine and edema. The edema often manifests itself as puffy eyelids, a symptom that many parents and physicians mistake as allergies. With experts projecting a substantial increase in nephrotic syndrome in the coming years, there is a clear need to educate pediatricians and family physicians about glomerular disease and its symptoms.

NCF has conducted numerous education programs. A national FSGS conference was held in Philadelphia from June 3–4, 2006. This conference sought to provide attendees with the most up to date information on this disease. Through speakers, information sessions, and informal conversations with other patient families, attendees realized that they are not alone and will be further energized for the effort to find a cause and a cure for FSGS.

Also, last summer, the NIDDK sponsored a working group scientific conference. This working group advised NIDDK on animal models, reagents, and other resources for the study of glomerular disease.

NCF also applaud the work of the NIDDK in establishing the National Kidney Disease Education Program (NKDEP), and we seek your support in urging the NIDDK to make sure that glomerular disease remains a focus of the NKDEP.

We ask the committee to encourage the NIDDK to have glomerular disease receive high visibility in its education and outreach efforts, and to continue these efforts in conjunction with the NephCure Foundation's work. These efforts should be targeted towards both physicians and patients.

GLOMERULAR DISEASE STRIKES MINORITY POPULATIONS

Nephrologists tell NCF that glomerular disease strikes a disproportionate number of African-Americans. No one knows why this is, but some studies have suggested that a genetic sensitivity to sodium may be partly responsible. DNA studies of African Americans who suffer from FSGS may lead to insights that would benefit the thousands of African Americans who suffer from kidney disease.

NCF asks that the NIH pay special attention to why this disease affects minority populations to such a large degree. NCF wishes to work with the NIDDK and the National Center for Minority Health and Health Disparities (NCMHD) to encourage the creation of programs to study the high incidence of glomerular disease within the African-American population.

There is also evidence to suggest that the incidence of glomerular disease is higher among Hispanic-Americans than in the general population. An article in the February 2006 edition of the NIDDK publication Recent Advances and Emerging Opportunities, discussed the case of Frankie Cervantes, a 6 year old boy of Mexican and Panamian descent. Frankie has FSGS, and like Bradly, received a transplanted kidney from his mother. We applaud the NIDDK for highlighting FSGS in their publication, and for translating the article about Frankie into both English and Spanish. Only through similar efforts at cross-cultural education can the African-American and Hispanic-American communities learn more about glomerular disease.

We ask the committee to join with us in urging the NIDDK and the National Center for Minority Health and Health Disparities (NCMHD) to collaborate on research that studies the incidence and cause of this disease among minority populations. We also ask that the NIDDK and the NCMHD undertake culturally appropriate efforts aimed at educating minority populations about glomerular disease.

Thank you again for this opportunity and please contact us if you have any questions or require additional information.

PREPARED STATEMENT OF NTM INFO AND RESEARCH

AGENCY RECOMMENDATIONS

CDC: NTMIR requests a $7,000,000 allocation in the budget to enable CDC, Infectious Diseases HIV/AIDS, STD and TB Prevention Program to launch an external partnership to develop and implement a public health education and outreach initiative to promote NTM education for health care providers and the general public. Further NTMIR requests that CDC develop specific epidemiology studies regarding prevalence, geographic, demographic and host specific data regarding NTM infection in the population.

NIH: NTMIR requests an allocation in the budget to enable NIH, NHLBI to advance diagnostics and treatments for patients suffering from pulmonary Nontuber-

culous Mycobacteria (NTM) disease. NTMIR further requests that NHLBI issue a program announcement or other appropriate mechanism to ensure the initiation of grant proposals

NIH: NTMIR requests an allocation in the budget to enable NIH, NIAID to collaborate further with NHLBI, the advocacy community and other Federal agencies to advance the understanding of NTM by establishing a national registry of patients and to issue a program announcement, an NIH partnership funding program or other appropriate mechanism to ensure the initiation of grant proposals and other activities in NTM.

Thank you for the opportunity to submit a statement on behalf of NTM Info & Research and all the patients suffering with pulmonary NTM disease.

WHAT IS PULMONARY NONTUBERCULOUS MYCOBACTERIAL DISEASE (NTM)?

NTM is an infectious disease considered to be of environmental origin as these bacteria are ubiquitous in the water and soil that surround us. Although NTM is diagnosed by the same basic test used to diagnose traditional tuberculosis (TB), it is significantly more difficult to treat. NTM progressively diminishes lung capacity, with all the attendant negative consequences in life.

Unfortunately, even though TB has a significantly high profile, NTM does not because education and awareness have been lacking. Furthermore, there is growing evidence that NTM is many times more prevalent than TB in the United States. For example, the State of Florida Infectious Disease Laboratory reports receiving over twice as many specimens that are NTM positive for every one that is positive for TB. Even more startling, the Agency for Health Care Administration for Florida hospital patient discharges shows almost 9 times the number of patients with the primary diagnosis of NTM versus those with TB.

Doctors in leading treating facilities are reporting that even though NTM is not reportable, they are seeing more NTM patients than TB patients. A current report from Toronto, Ontario indicates that the prevalence may be six times higher than the older data we have in the United States.

NTM is not limited to one strain and has certain strains that are inherently resistant to drug therapy, and in all cases multiple drugs are required on a lengthy to permanent basis. A significant number of patients require short- to long-term intravenous medication and this is a particular hardship for the elderly because Medicare does not cover in-home therapy. Medicare recipients must be hospitalized one to three times a week driving treatment costs significantly higher than in alternate settings.

NTM INFO & RESEARCH (NTMIR)

NTMIR was founded through a partnership of concerned patients and interested physicians who see increasing numbers of people affected by this devastating disease. NTMIR was created to expand professional awareness, diagnosis and treatment, facilitate research and provide patient support. Our mission is a public/private partnership to advance the science and the outcomes for countless patients with NTM disease.

NTMIR has already demonstrated a track record of success since it commenced its activities just 3 years ago. These include, successful implementation of the NTMInfo.org website and online support group, patient education throughout the country through the replication of an NTM information pamphlet, initiating professional education and Grand Round lectures to increase professional education both for specialists and family physicians, establishment of a partnership of cooperation with public health in the State of Florida and with the American Lung Association of Florida. NTMIR negotiated an agreement between a major pharmaceutical company, the FDA and a division of HRSA to provide an urgently needed drug for patients who could not otherwise obtain it, some of whom might have died without it.

Fern Leitman's Story

In September 1996, shortly after lung surgery, Fern's health deteriorated to the point where her doctors suggested that her children be called. Fern was rushed to a procedure room to put a bronchoscope into her lungs to see what was happening.

NTM can affect any one of us . . . but for some unknown reason it affects more women than men.

Fern's normal morning routine starts with pulmonary therapy to clear her airways. Then there is a sinus wash. With breakfast, Fern takes five different oral drugs and IV medicines. In addition, there are inhaled medicines. The total time from awakening to being able to leave the house is usually 4 hours.

THE NEEDS OF NTM PATIENTS HAVE GONE UNMET—MORE CAN BE DONE NOW!

While tuberculosis is often known to appear in inner cities and immigrant populations, NTM knows no such boundaries. However, current epidemiologic data is not available. The latest data that we have from the Centers for Disease Control was collected in the 1980's and we urgently need newer data. Current data from the University of Toronto suggests that the prevalence may be six times higher than our older information. We have no reason to believe that Toronto is any different than Chicago, Miami or any other major U.S. city.

PREPARED STATEMENT OF THE ONCOLOGY NURSING SOCIETY

OVERVIEW

The Oncology Nursing Society (ONS) appreciates the opportunity to submit written comments for the record regarding fiscal year 2008 funding for cancer and nursing related programs. ONS, the largest professional oncology group in the United States, composed of more than 35,000 nurses and other health professionals, exists to promote excellence in oncology nursing and the provision of quality care to those individuals affected by cancer.

This year more than 1,444,920 Americans will be diagnosed with cancer, and more than 565,000 will lose their battle with this terrible disease. Despite these grim statistics, significant gains in the War Against Cancer have been made through our Nation's investment in cancer research and its application. Research holds the key to improved cancer prevention, early detection, diagnosis, and treatment, but such breakthroughs are meaningless, unless we can deliver them to all Americans in need. Moreover, a recent survey of ONS members found that the nursing shortage is having an adverse impact in oncology physician offices and hospital outpatient departments. Some respondents indicated that when a nurse leaves their practice, they are unable to hire a replacement due to the shortage—leaving them short-staffed and posing scheduling challenges for the practice and the patients.

To ensure that all people with cancer have access to the comprehensive, quality care they need and deserve, ONS advocates ongoing and significant Federal funding for cancer research and application, as well as funding for programs that help ensure an adequate oncology nursing workforce to care for people with cancer. The Society stands ready to work with policymakers at the local, State, and Federal levels to advance policies and programs that will reduce and prevent suffering from cancer and sustain and strengthen the Nation's nursing workforce. We thank the subcommittee for its consideration of our fiscal year 2008 funding request detailed below.

SECURING AND MAINTAINING AN ADEQUATE ONCOLOGY NURSING WORKFORCE

Oncology nurses are on the front lines in the provision of quality cancer care for individuals with cancer—administering chemotherapy, managing patient therapies and side-effects, working with insurance companies to ensure that patients receive the appropriate treatment, providing counseling to patients and family members, and engaging in myriad other activities on behalf of people with cancer and their families. Cancer is a complex, multifaceted chronic disease, and people with cancer require specialty-nursing interventions at every step of the cancer experience. People with cancer are best served by nurses specialized in oncology care, who are certified in that specialty. Overall, age is the number one risk factor for developing cancer. Approximately 77 percent of all cancers are diagnosed at age 55 and older.

As the overall number of nurses will drop precipitously in the coming years, we likely will experience a commensurate decrease in the number of nurses trained in the specialty of oncology. With an increasing number of people with cancer needing high-quality health care, coupled with an inadequate nursing workforce, our Nation could quickly face a cancer care crisis of serious proportion, with limited access to quality cancer care, particularly in traditionally underserved areas. A study in the New England Journal of Medicine found that nursing shortages in hospitals are associated with a higher risk of complications—such as urinary tract infections and pneumonia, longer hospital stays, and even patient death. Without an adequate supply of nurses, there will not be enough qualified oncology nurses to provide the quality cancer care to a growing population of people in need, and patient health and well-being could suffer.

Further, of additional concern is that our Nation also will face a shortage of nurses available and able to conduct cancer research and clinical trials. With a shortage of cancer research nurses, progress against cancer will take longer because

of scarce human resources coupled with the reality that some practices and cancer centers resources could be funneled away from cancer research to pay for the hiring and retention of oncology nurses to provide direct patient care. Without a sufficient supply of trained, educated, and experienced oncology nurses, we are concerned that our Nation may falter in its delivery and application of the benefits from our Federal investment in research.

ONS has joined with others in the nursing community in advocating $200 million as the fiscal year 2008 funding level necessary to support implementation of the Nurse Reinvestment Act and the range of nursing workforce development programs housed at the U.S. Health Resources and Services Administration (HRSA). Enacted in 2002, the Nurse Reinvestment Act (Public Law 107–205) included new and expanded initiatives, including loan forgiveness, scholarships, career ladder opportunities, and public service announcements to advance nursing as a career. Despite the enactment of this critical measure, HRSA fails to have the resources necessary to meet the current and growing demands for our Nation's nursing workforce. For example, in fiscal year 2006 HRSA received 4,222 applications for the Nurse Education Loan Repayment Program, but only had the funds to award 615 of those applications. Also, in fiscal year 2006 HRSA received 3,320 applications for the Nursing Scholarship Program, but only had funding to support 218 awards.

While a number of years ago one of the biggest factors associated with the shortage was a lack of interested and qualified applicants, due to the efforts of the nursing community and other interested stakeholders, the number of applicants is growing. As such, now one of the greatest factors contributing to the shortage is that nursing programs are turning away qualified applicants to entry-level baccalaureate programs, due to a shortage of nursing faculty. According to the American Association of Colleges of Nursing (AACN), U.S. nursing schools turned away 42,866 qualified applicants from baccalaureate and graduate nursing programs in 2006, due to insufficient number of faculty. The nurse faculty shortage is only expected to worsen with time, as half of the RN workforce is expected to reach retirement age with in the next 10 to 15 years. At the same time, significant numbers of faculty are expected to retire in the coming years, with insufficient numbers of candidates in the pipeline to take their places. If funded sufficiently, the components and programs of the Nurse Reinvestment Act will help address the multiple factors contributing to the nursing shortage.

The nursing community opposes the President's fiscal year 2008 budget proposal that decreases nursing workforce funding by $44 million—a cut which eliminates all funding for advanced nursing education programs. With additional funding in fiscal year 2008, these important programs will have much-needed resources to address the multiple factors contributing to the nationwide nursing shortage, including the shortage of faculty—a principal factor contributing to the current shortage. Advanced nursing education programs play an integral role in supporting registered nurses interested in advancing in their practice and becoming faculty. As such, these programs must be adequately funded in the coming year.

ONS strongly urges Congress to provide HRSA with a minimum of $200 million in fiscal year 2008 to ensure that the agency has the resources necessary to fund a higher rate of nursing scholarships and loan repayment applications and support other essential endeavors to sustain and boost our Nation's nursing workforce. Nurses—along with patients, family members, hospitals, and others—have joined together in calling upon Congress to provide this essential level of funding. One Voice Against Cancer (OVAC), a collaboration of more than 45 national nonprofit organizations representing millions of Americans, and the National Coalition for Cancer Research (NCCR), is a non-profit organization comprised of 26 national organization, also advocate $200 million for the Nurse Reinvestment Act in fiscal year 2008. ONS and its allies have serious concerns that without full funding, the Nurse Reinvestment Act will prove an empty promise, and the current and expected nursing shortage will worsen, and people will not have access to the quality care they need and deserve.

SUSTAIN AND SEIZE CANCER RESEARCH OPPORTUNITIES

Our Nation has benefited immensely from past Federal investment in biomedical research at the National Institutes of Health (NIH). ONS has joined with the broader health community in advocating a 6.7 percent increase ($32.831 billion) for NIH in fiscal year 2008. This will allow NIH to sustain and build on its research progress, resulting from the recent doubling of its budget, while avoiding the severe disruption to that progress that would result from a minimal increase. Cancer research is producing extraordinary breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for cancer patients. We

have seen extraordinary advances in cancer research, resulting from our national investment, which have produced effective prevention, early detection and treatment methods for many cancers. To that end, ONS calls upon Congress to allocate $5.131 billion to the National Cancer Institute (NCI) in fiscal year 2008 to support the battle against cancer.

The National Institute of Nursing Research (NINR) supports basic and clinical research to establish a scientific basis for the care of individuals across the life span—from management of patients during illness and recovery, to the reduction of risks for disease and disability and the promotion of healthy lifestyles. These efforts are crucial in translating scientific advances into cost-effective health care that does not compromise quality of care for patients. Additionally, NINR fosters collaborations with many other disciplines in areas of mutual interest, such as long-term care for older people, the special needs of women across the life span, bioethical issues associated with genetic testing and counseling, and the impact of environmental influences on risk factors for chronic illnesses, such as cancer. ONS joins with others in the nursing community in advocating a fiscal year 2008 allocation of $150 million for NINR.

BOOST OUR NATION'S INVESTMENT IN CANCER PREVENTION, EARLY DETECTION, AND AWARENESS

Approximately two-thirds of cancer cases are preventable through lifestyle and behavioral factors and improved practice of cancer screening. Although the potential for reducing the human, economic, and social costs of cancer by focusing on prevention and early detection efforts remains great, our Nation does not invest sufficiently in these strategies. In 2005, the United States spend over $2.0 trillion in healthcare—$6,683 for every man, woman, and child; however we only allocate approximately 1 percent of that amount for population-based prevention efforts. The Nation must make significant and unprecedented Federal investments today to address the burden of cancer and other chronic diseases, and to reduce the demand on the healthcare system and diminish suffering in our Nation both for today and tomorrow.

As the Nation's leading prevention agency, the Centers for Disease Control and Prevention (CDC) plays an important role in translating and delivering, at the community level, what is learned from research. Therefore, ONS joins with our partners in the cancer community—including OVAC—in calling on Congress to provide additional resources for the CDC to support and expand much-needed and proven effective cancer prevention, early detection, and risk reduction efforts. Specifically, ONS advocates the following fiscal year 2008 funding levels for the following CDC programs: $250 million for the National Breast and Cervical Cancer Early Detection Program; $65 million for the National Cancer Registries Program; $25 million for the Colorectal Cancer Prevention and Control Initiative; $50 million for the Comprehensive Cancer Control Initiative; $25 million for the Prostate Cancer Control Initiative; $5 million for the National Skin Cancer Prevention Education Program; $10 million for the Ovarian Cancer Control Initiative; $6 million for the Geraldine Ferraro Blood Cancer Program; $145 million for the National Tobacco Control Program; and $65 million for the Nutrition, Physical Activity, and Obesity Program.

CONCLUSION

ONS maintains a strong commitment to working with Members of Congress, other nursing societies, patient organizations, and other stakeholders to ensure that the oncology nurses of today continue to practice tomorrow, and that we recruit and retain new oncology nurses to meet the unfortunate growing demand that we will face in the coming years. By providing the fiscal year 2008 funding levels detailed above, we believe the subcommittee will be taking the steps necessary to ensure that our Nation has a sufficient nursing workforce to care for the patients of today and tomorrow and that our Nation continues to make gains in our fight against cancer.

PREPARED STATEMENT OF PARENT PROJECT MUSCULAR DYSTROPHY

Chairman Harkin, ranking member Specter, and members of the committee: I want to thank you for this opportunity to submit testimony for the written record. My name is Pat Furlong, Co-Founder and CEO of Parent Project Muscular Dystrophy (PPMD) and the mother of two sons who battled Duchenne Muscular Dystrophy (DMD).

The past year has been historical for PPMD and the entire Duchenne and Becker Muscular Dystrophy (DBMD) Community. Right now, a drug that holds tremendous

potential for a percentage of patients suffering not only from Duchenne but from other neurological conditions, like Cystic Fibrosis, is in a Phase 2 clinical trial, and has received Fast Track designation from the Food and Drug Administration (FDA). We all waited anxiously and were relieved when PTC Therapeutics reported an increase presence of dystrophin in Duchenne patients involved in the initial Phase 2 clinical trial, and we are very hopeful more good news will be on the way. While the drug in question—PTC 124—is being developed by a private entity, I can say with confidence that we would not have reached this milestone if not for the significant investments made into DMD research by the National Institutes of Health (NIH).

It is for this very reason that NIH's investments into Duchenne and Becker research must not only be sustained but strengthened. All six Senator Paul Wellstone MD Research Centers of Excellence are in operation, and the Muscular Dystrophy Coordinating Committee (MDCC) is working to advance the government-wide MD agenda.

At the Centers for Disease Control and Prevention (CDC), active surveillance of Duchenne is taking place in five States, and we are making progress toward developing a DMD Patient Registry, replete with evidence-based care considerations, In addition, PPMD has partnered with the CDC on an education and outreach initiative that has produced materials that help explain Duchenne to children, enable doctors to offer accurate and timely diagnoses, and help parents ensure their children get the care they need and deserve. Through the pilot work in Mississippi, CDC and PPMD have taken concrete steps to educate people on the early warning signs of DBMD so patients get the earliest diagnosis possible.

I want to continue to urge the committee to support Federal funding for DBMD. Specifically, we are seeking:

—A $2.5 million increase in MD activities at the CDC. Of this increase:
  —$2.25 million should be dedicated to advancing efforts to develop and launch an International DBMD Patient Registry.
  —$250,000 should be used to continue the successful joint CDC/PPMD Education & Outreach initiative, bringing the total for this project to $1 million.
—Increased funding at the NIH to ensure the continued support of the six MD Centers of Excellence and other research initiatives focused on DBMD.

We are very well aware of the significant budgetary pressures—both internal and external—that you will be dealing with this year. That's why we believe we have put forth a reasonable request that seeks the funding necessary to sustain and advance the successes attained to date. Without such an investment, we fear we will lose ground and not receive the greatest return on investment possible.

On behalf of all families impacted by Duchenne and Becker MD, I thank you for your past support. I urge your panel and the entire Senate to continue to lead the way in providing critically needed dollars to support DBMD research at the NIH and patient support and related initiatives at the CDC.

PREPARED STATEMENT OF THE PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

Chairman Harkin, ranking member Specter, and members of the subcommittee: People for the Ethical Treatment of Animals (PETA) is the world's largest animal rights organization, with 1.6 million members and supporters. We greatly appreciate the opportunity to submit testimony regarding the fiscal year 2008 appropriations for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The following national animal and health protection organizations support these comments: The American Anti-Vivisection Society, the Alternatives Research and Development Foundation, In Defense of Animals, and the Physicians Committee for Responsible Medicine.

As you are aware, Federal regulatory agencies require most chemicals and many other products to undergo tests that measure their toxicity levels. Unfortunately, most of these tests involve the suffering and death of animals. Other problems include agencies needlessly duplicating each other's tests, lack of innovation (e.g., relying on outdated and flawed test methods developed decades ago), and underutilization of scientific expertise outside of the U.S. Government (e.g., ignoring better methods used in other countries).

ICCVAM was created in 1997 to solve the three regulatory testing problems of animal suffering, wasteful duplication, and lack of innovation. It was made a permanent committee under the National Institute of Environmental Health Sciences in 2000.

Contrary to its ostensible purpose, however, ICCVAM has become a major obstacle to the adoption of more sophisticated and accurate test methods—in many cases,

methods that have been widely adopted by the rest of the industrialized world. Instead, ICCVAM is clinging to decades-old animal-poisoning tests that were never proven relevant to humans to begin with.

This causes two major problems. First, animals are being harmed needlessly when non-animal tests could be adopted instead. Second, public health is being undermined, as non-animal test methods have been demonstrated to be more accurate, more sensitive, and more protective of public health.[1]

In addition, test methods that use animals render our Federal agencies impotent in their efforts to regulate health and environmental hazards because the fact that these methods are not human-relevant leads to continual—and successful—court challenges on the part of industry.

ICCVAM's counterpart in Europe—the European Centre for the Validation of Alternative Methods (ECVAM)—has developed and validated a number of non-animal methods. Yet ICCVAM fails to even adopt the ECVAM-validated methods, becoming a bottleneck for the adoption of new methods in the United States.[2]

Worse, ICCVAM and its lead agency, the U.S. Environmental Protection Agency (EPA), have repeatedly and blatantly violated both the letter and the spirit of a major tenet of the Organization for Economic Cooperation and Development (OECD) Council Decision, of which the United States is a member. The OECD's 1981 Mutual Acceptance of Data in the Assessment of Chemicals provides that: "[D]ata generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment."

Presented below are five specific recent examples:

1. Skin Corrosion Testing.—Two types of non-animal tests for skin corrosion, the Transcutaneous Electrical Resistance method (OECD 430) and human skin model studies (OECD 431), were successfully validated in partnership with ECVAM and endorsed by ECVAM's Scientific Advisory Committee (ESAC) in 1998, accepted by EU regulators in June 2000, and published as OECD Test Guidelines in April 2004. The OECD specifically accepts the tests as part of a strictly non-animal weight-of-evidence assessment of skin corrosion. Yet ICCVAM arbitrarily insists on confirmatory testing in rabbits of any negative results.

2. Phototoxicity Testing.—The cell-based 3T3 Neutral Red Uptake Phototoxicity Test is also ECVAM validated, ESAC endorsed, and codified in both EU regulations and as an OECD Test Guideline (OECD 432). However, the regulatory acceptance of this method in the United States remains uncertain.

3. Ocular Testing.—In 2005, ICCVAM reviewed several non-animal methods to replace the infamous Draize test, in which chemicals are dripped into the eyes of restrained (though not anesthetized) rabbits. These methods (which use actual animal eyes from slaughterhouses) have been accepted by some countries for more than a decade and are currently accepted throughout the EU through mutual acceptance of data. Nevertheless, ICCVAM has placed severe restrictions on their use.

4. Acute toxicity testing.—ICCVAM convened an international workshop in 2000 to discuss a non-animal (cell-based) method that had the potential to replace acute toxicity testing in animals. Acute toxicity testing, otherwise known as lethal poisoning, means taking a group of animals and forcing them to ingest or inhale a toxic

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[1] For example, in 1971, scientists Weil and Scala examined the reliability of data from eye irritancy tests—in which chemicals are dripped into rabbits' eyes—and concluded that, because of significant variability in test results from day to day and lab to lab, this test should not be used as a standard regulatory toxicity study (Weil CS and Scala RA. 1971. Toxicol. Appl. Pharmacol. 17: 276–360). In 1986, Freeberg and colleagues studied 281 cases of accidental human eye exposure to 14 household products and compared the outcome with the results of rabbit eye irritation tests. They found that the animal test failed to correctly predict the human eye response more than half (52 percent) of the time (Freeberg FE and others. 1986. J. Toxicol. Cutaneous & Ocular Toxicol. 5: 115–23). A few years later, Koch and colleagues at the U.S. Food and Drug Administration stated that there was no clear relationship between the rabbit eye response and the exposure of the human eye to chemicals or products and that the Draize test is "plagued" with a lack of reproducibility. (Koch WH. 1989. Cutaneous & Ocular Toxicol. 8: 17–22). The Multicenter Evaluation of In Vitro Cytotoxicity (MEIC) study examined the results of rat and mouse "lethal dose" toxicity studies—in which groups of animals are force-fed massive doses of a chemical until half of them convulse and die. The researchers found that rodent lethal dose tests were, at best, 65 percent predictive of acute toxicity in humans. By contrast, the MEIC study found that a "battery" of four non-animal tests using human cells was able to predict human toxicity with 84 percent accuracy (U.S. National Toxicology Program Interagency Centre for the Evaluation of Alternative Toxicological Methods. 2000 Sep. The Multicenter Evaluation of In Vitro Cytotoxicity (MEIC)—Summary).

[2] In its 10-year history, it has validated only one non-animal test method that originated in the United States.

substance in increasing amounts until half of the animals die. Although this method is almost universally recognized as an extremely cruel, crude, and imprecise test method that causes a tremendous amount of animal suffering, it remains the backbone of regulatory testing.

The workshop resulted in a report stating that that the cell-based methods could be used immediately to reduce the numbers of animals killed and that, within 3 years—given the proper funding and effort—the method could be validated as a full replacement measure. It is now 7 years later, and ICCVAM has made no progress in implementing the cell-based methods even as a reduction measure and has cynically ignored its potential as a replacement measure.

5. Pyrogenicity (Fever-Inducing) Testing.—According to a March 2006 European Union press release, ECVAM "approved six new alternative testing methods that will reduce the need for certain drugs and chemicals to be tested on animals. The new tests use cell cultures rather than animals to establish the toxicity of cancer drugs and identify contaminated drugs." Five of the tests replace the use of animals in pyrogenicity testing (for fever-inducing bacteria) for which hundreds of thousands of rabbits are currently used every year.

Despite the fact that these methods were less expensive than animal tests and that, as stated in the news release, "the tests approved . . . will not only reduce the number of animals needed for testing, but will also increase the accuracy of the tests, thereby making the products concerned safer" (emphasis added), ICCVAM's peer review panel concluded that the methods were not valid as replacements for the rabbit test.

RECOMMENDATIONS

ICCVAM follows a double standard that sets ever-increasing hurdles for every non-animal method while accepting every animal test as the unquestioned gold standard. Companies are now attempting to circumvent ICCVAM, submitting their data from non-animal test methods directly to the relevant agency to consider, knowing that it is pointless to send a non-animal method to ICCVAM for review.

If Congress is to continue funding ICCVAM, the agency must be held accountable for its failures to date and be required to fulfill its mandate "to establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness" (Public Law 106–545). At the very least, there should be reciprocity between ECVAM and ICCVAM and ICCVAM should be required to expeditiously adopt non-animal test methods developed and validated in Europe.

In its 2007 appropriations, Congress included report language that required ICCVAM to develop a 5-year plan to "identify areas of high priority for new and revised non-animal and alternative assays or batteries of those assays to create a path forward for the replacement, reduction and refinement of animal tests" by November 15, 2007 (House Report 109–15). In December 2006, PETA, The Humane Society of the United States, and other national animal protection organizations submitted extensive comments to NIEHS regarding essential components of this plan.

We respectfully request that the committee include the following report language for fiscal year 2008: "The committee understands that the American animal protection community has submitted recommendations for items to be included in ICCVAM's 5-year plan to identify areas of high priority for new and revised non-animal and alternative assays or batteries of those assays to create a path forward for the replacement, reduction and refinement of animal tests. The committee requests that these recommendations be adopted by ICCVAM or, upon presentation of the plan to the committee by November 15, 2007, an explanation of any exclusions of the aforementioned recommendations be included."

Thank you for your consideration of our request.

PREPARED STATEMENT OF THE POPULATION ASSOCIATION OF AMERICA/ASSOCIATION OF POPULATION CENTERS

INTRODUCTION

Thank you, Chairman Harkin, ranking member Specter, and other distinguished members of the subcommittee, for this opportunity to express support for the National Institutes of Health (NIH) and the National Center for Health Statistics (NCHS)—two agencies important to our organizations.

BACKGROUND ON THE PAA/APC AND DEMOGRAPHIC RESEARCH

The PAA is a scientific organization comprised of over 3,000 population research professionals, including demographers, sociologists, statisticians, and economists. The APC is a similar organization comprised of over 30 universities and research groups that foster collaborative demographic research and data sharing, translate basic population research for policy makers, and provide educational and training opportunities in population studies.

Demography is the study of populations and how or why they change. Demographers, as well as other population researchers, collect and analyze data on trends in births, deaths, and disabilities as well as racial, ethnic, and socioeconomic changes in populations. Major policy issues population researchers are studying include the demographic causes and consequences of population aging, trends in fertility, marriage, and divorce and their effects on the health and well being of children, and immigration and migration and how changes in these patterns affect the ethnic and cultural diversity of our population and the Nation's health and environment.

The NIH mission is to support research that will improve the health of our population. The health of our population is fundamentally intertwined with the demography of our population. Recognizing the connection between health and demography, the NIH supports population research programs primarily through the National Institute on Aging (NIA) and the National Institute of Child Health and Human Development (NICHD).

NATIONAL INSTITUTE ON AGING

According to the Census Bureau, by 2029, all of the baby boomers (those born between 1946 and 1964) will be age 65 years and over. As a result, the population age 65–74 years will increase from 6 percent to 10 percent of the total population between 2005 and 2030. This substantial growth in the older population is driving policymakers to consider dramatic changes in Federal entitlement programs, such as Medicare and Social Security, and other budgetary changes that could affect programs serving the elderly. Further, the macroeconomic and global impact of population aging on competitiveness in the world economy is becoming a bigger issue—as illustrated during the recent Global Summit on Aging sponsored by NIA and the State Department. To inform this debate, policymakers need objective, reliable data about the antecedents and impact of changing social, demographic, economic, and health characteristics of the older population. The NIA Behavioral and Social Research (BSR) program is the primary source of Federal support for research on these topics.

In addition to supporting an impressive research portfolio, that includes the prestigious Centers of Demography of Aging Program, the NIA BSR program also supports several large, accessible data surveys. Two such surveys, the National Long-Term Care Survey (NLTCS) and the Health and Retirement Study (HRS) have become seminal sources of information to assess the health and socioeconomic status of older people in the United States.

By using NLTCS data, investigators identified the declining rate of disability in older Americans first observed in the mid-1990s. In 2006, an analysis of the latest data found the prevalence of chronic disability among people 65 and older fell from 26.5 percent in 1982 to 19 percent in 2004/2005. The findings suggest that older Americans' health and function continue to improve at a critical time in the aging of the population. If it continues, this trend could have momentous impact on reducing the need for costly long-term care.

In 2006, NIA announced a 6-year renewal of the HRS. The HRS, now entering its 15th year, has tracked 27,000 people, and has provided data on a number of issues, including the role families play in the provision of resources to needy elderly and the economic and health consequences of a spouse's death. The Social Security Administration recognizes and funds the HRS as one of its "Research Partners" and posts the study on its home page to improve its availability to the public and policymakers. HRS is particularly valuable because its longitudinal design allows researchers: (1) the ability to immediately study the impact of important policy changes such as Medicare Part D; and (2) the opportunity to gain insight into future health-related policy issues that may be on the horizon, such as recent HRS data indicating an increase in pre-retirees self-reported rates of disability.

With additional support in fiscal year 2008, the NIA BSR program could fully fund its existing centers and support its ongoing surveys. Additional support would allow NIA to expand the centers' role in understanding the domestic macroeconomic as well as the global competitiveness impact of population aging and fully fund initiatives in fiscal year 2008 addressing financial challenges faced by older Americans.

NIA could also use additional resources to support individual investigator awards by precluding an 18 percent cut in competing awards, improving its funding payline, and sustaining training and research opportunities for new investigators.

NATIONAL INSTITUTE ON CHILD HEALTH AND HUMAN DEVELOPMENT

Since its establishment in 1968, the NICHD Center for Population Research has supported research on population processes and change. Today, this research is housed in the Center's Demographic and Behavioral Sciences Branch (DBSB). The Branch encompasses research in four broad areas: family and fertility, mortality and health, migration and population distribution, and population composition. In addition to funding research projects in these areas, DBSB also supports a highly regarded population research infrastructure program and a number of large database studies, including the Fragile Families and Child Well Being Study and National Longitudinal Study of Adolescent Health.

NICHD-funded demographic research has consistently provided critical scientific knowledge on issues of greatest consequence for American families: work-family conflicts, marriage and child bearing, childcare, and family and household behavior. However, in the realm of public health, demographic research is having an even larger impact, particularly on issues regarding adolescent and minority health. For example, in 2006, researchers with the National Longitudinal Study of Adolescent Health, reported findings illustrating that by the time they reach early adulthood (age 19–24), a large proportion of American youth have begun the poor practices contributing to three leading causes of preventable death in the United States: smoking, poor diet and physical inactivity, and alcohol abuse. This study is striking in that it found the health situation of young people—in terms of behavior, health conditions, and access to and use of care—deteriorates markedly between the teen and young adult years. The study reinforces the importance of educating young people about adopting healthy lifestyles after they leave high school and the parental home.

Understanding the role of marriage and stable families in the health and development of children is another major focus of the NICHD DBSB. Consistently, research has shown children raised in stable family environments have positive health and development outcomes. Therefore, NICHD supports research to elucidate factors that contribute to family formation and strong partnerships. Recent findings have identified factors that can destabilize relationships between new parents. These factors include serious health or developmental problems of the parents' child, lower earnings, less education, and a father who has other children with different mothers. A new study published in 2006 produced the first measures of multi-partnered fertility (having children by more than one partner) in U.S. urban areas. The study found that in 59 percent of unmarried couples with a new baby, at least one parent had a child from another relationship. Previous research demonstrates multi-partnered fertility has potentially serious implications for both child well-being and marriage promotion efforts because of the demands of existing commitments and relationships. Policymakers and community programs can use these findings to support unstable families and improve the health and well being of children.

With additional support in fiscal year 2008, NICHD could restore full funding to its large-scale surveys, which serve as a resource for researchers nationwide. Furthermore, the Institute could apply additional resources toward improving its funding payline, which has gone from the 20th percentile range in 2003 to the 15th percentile in January 2007. Additional support could be used to preclude cuts of 17 percent to 22 percent in applications approved for funding and to support and stabilize essential training and career development programs necessary to prepare the next generation of researchers.

NATIONAL CENTER FOR HEALTH STATISTICS

Located within the Centers for Disease Control (CDC), the National Center for Health Statistics (NCHS) is the Nation's principal health statistics agency, providing data on the health of the U.S. population and backing essential data collection activities. Most notably, NCHS funds and manages the National Vital Statistics System, which contracts with the States to collect birth and death certificate information. NCHS also funds a number of complex large surveys to help policy makers, public health officials, and researchers understand the population's health, influences on health, and health outcomes. These surveys include the National Health and Nutrition Examination Survey, National Health Interview Survey, and National Survey of Family Growth. Together, NCHS programs provide credible data necessary to answer basic questions about the State of our Nation's health.

The President's fiscal year 2008 budget requests $109.9 million in program funds for National Center for Health Statistics. This recommendation represents an increase of $900,000 over the fiscal year 2007. Despite this modest increase, if enacted, the President's request would only allow NCHS to purchase 10 months of vital statistics data. Recently, PAA and APC joined 150 other organizations in sending a letter (http://www.chsr.org/nchsletterhouse031507.pdf) to the House and Senate Appropriations Committees expressing concern about this matter and asking that NCHS receive $117 million in fiscal year 2008, an $8 million increase over its fiscal year 2007 level. Without at least $3 million in additional funding, the United States will become the first industrialized Nation unable to continuously collect birth, death, and other vital information. The full $8 million increase is necessary to not only restore integrity and stability to the vital statistics program, but also to restore other important data collection and analysis initiatives and to modernize systems NCHS uses to manage and protect its data.

RECOMMENDATIONS

PAA and APC join the Ad Hoc Group for Medical Research in supporting an fiscal year 2008 appropriation of $30.8 billion, a 6.7 percent increase over the fiscal year 2007 appropriation, for the NIH. We also urge the subcommittee to include language in the fiscal year 2008 bill allowing the National Children's Study to continue and to appropriate $111 million for NCS in fiscal year 2008 through the NIH Office of the Director.

PAA and APC, as members of the Friends of NCHS, support a fiscal year 2008 appropriation of $117 million, a 7 percent increase over the fiscal year 2007 appropriation, for the NCHS. This funding is needed to maintain the Nation's vital statistics system and to sustain and update the agency's major survey operations.

Thank you for considering our requests and for supporting Federal programs that benefit the field of demographic research.

PREPARED STATEMENT OF PROJECT R&R: RELEASE AND RESTITUTION FOR CHIMPANZEES IN U.S. LABORATORIES

Project R&R, whose advisory board of chimpanzee experts includes 12 organizations with a combined membership of 500,000, respectfully submits testimony on our funding priority.

We request that Federal funding for breeding chimpanzees for research, or for projects that require breeding, be terminated. We do so for the following reasons:

—A "surplus" of chimpanzees has resulted from over-breeding in the 1980s for HIV/AIDS research and later findings that they are a poor HIV/AIDS model.[1]
—There are enough chimpanzees to address existing federally funded research.[2]
—As a result of the "surplus," the government funds a national sanctuary system.[3]
—The current population costs in excess of about $11 million Federal per year.
—Breeding more chimpanzees increases taxpayers' financial burden.
—Expansion of the population compounds existing concerns about their quality of care.
—While there is a breeding moratorium, NIH still funds research projects requiring breeding.[4]
—The public is concerned about the use of chimpanzees in research.

BACKGROUND

Of an estimated 1,300 chimpanzees in laboratories in the United States today, approximately 850 are federally owned or supported. In the mid-1990s, the National Research Council (NRC) made recommendations to address the "surplus" that included a moratorium on breeding federally-owned or supported chimpanzees for at least 5 years[5] (implemented in 1995). The National Advisory Research Resources Council, which advises NCRR on funding activities, policies, and program, met on 09/15/05 and recommended that NCRR extend the moratorium to 12/07. The rec-

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[1] National Research Council (1997) Chimpanzees in research: strategies for their ethical care, management and use. National Academies Press: Washington, D.C.
[2] Report of the Chimpanzee Management Plan Working Group to the National Advisory Research Resources Council; May 18, 2005.
[3] http://www.ncrr.nih.gov/compmed/cm__chimp.asp
[4] Ibid.
[5] National Research Council (1997) Chimpanzees in research: strategies for their ethical care, management and use. National Academies Press: Washington, D.C.

ommendation was accepted[6]—reasons included the high costs associated with care and the fact that chimpanzees are a poor model for human HIV research.[7] [8]

CIRCUMVENTING THE MORATORIUM

Despite the moratorium, NIH funds research projects requiring breeding. For example, the National Institute of Allergy and Infectious Diseases (NIAID) maintains a contract with the New Iberia Research Center (NIRC) to provide 10 to 12 infants annually for research. The 10 year contract entitled "Leasing of chimpanzees for the conduct of research" was allotted over $22 million (some $3.9 million plus has been spent since 2002).[9]

NIRC has also received $5.47 million from 09/00 to 08/05 for a grant from NCRR to maintain 138 chimpanzees for breeding. NIH/NCRR spends more than $1 million annually to maintain the NIRC breeding colony.[10] These grants result in $9 million going to breeding-related activities at NIRC alone since 2000.

Such expenditures circumvent the intent of the breeding moratorium, compelling the need to prevent the growing financial burden of increasing numbers of chimpanzees, particularly since, by the government's own admission, a "surplus" already exists.

COSTS FOR CHIMPANZEE MAINTENANCE

The cost of care for chimpanzees is a major concern, particularly with NIH's tightening budget. In 1995, the Institute for Laboratory Animal Research (ILAR) published a study that projected the future costs of maintaining chimpanzees in U.S. research.[11] ILAR, a division of the National Academies of Science, functions as "an advisor to the Federal Government, the biomedical research community, and the public."[12]

The ILAR study examined the per diem costs of the existing population of chimpanzees at six facilities. Taking into account a variety of factors such as longevity, distribution of sex, and complexity of care, it projected costs of maintaining the present colony over the next 60 years. To account for inflation, an annual 4 percent increase was incorporated, corresponding approximately to the Biomedical Research and Development Price Index.

The results of the study indicated that the lifetime cost of maintaining chimpanzees over the next 60 years—the approximate lifespan of chimpanzees in captivity—will exceed $3.14 billion. The 1995 projection, however, was based on a population of 1,447 chimpanzees. The present population of federally owned or supported chimpanzees in 2007, due to factors such as the implementation of the partial breeding moratorium in 1995, the end of the Air Force's use of chimpanzees and the close of the Coulston Foundation in 2002 (to which the majority of Air Force chimpanzees were sent), stands closer to 850. This represents approximately 59 percent of the 1,447 number used in ILAR's projection. Thus we can estimate the Federal cost of the existing colony to be $1.85 billion. The remainder of the original estimated $3.14 billion figure will now be carried by the U.S. public which contributes to the private sanctuaries caring for formerly federally owned or supported chimpanzees (minus a slight decrease in this estimate due to mortality). Thus, the caring American public has been burdened with the ethical obligation of some estimated $1.29 billion to care for chimpanzees from laboratories, without any further obligation for this care placed on the laboratories themselves and with none of these privately funded sanctuaries having, at this time, access to Federal dollars for their chimpanzee care. Given the American public's deep and growing concern over the use of chimpanzees in research, the NIH's history of breeding has created a hidden, even if self-assumed, "tax" for that faction of the public concerned about the humane and ethical treatment of chimpanzees from research for which NIH no longer assumes any financial responsibility.

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[6] http://www.ncrr.nih.gov/compmed/cm__chimp.asp

[7] Muchmore, E., (2001) Chimpanzee models for human disease and immunobiology, Immunological Reviews, 183, 86–93.

[8] Reynolds, V., (1995) Moral issues in relation to chimpanzee field studies and experiments, Alternatives to Laboratory Animals, 23, 621–625.

[9] Source: http://dcis.hhs.gov/nih/nih__daily__active__web.html (See contract No. 272022754)

[10] http://nirc.louisiana.edu/divisions/nihgrants.html

[11] Dyke, B., Williams-Blangero, S. et al, 1995 "Future costs of chimpanzees in U.S. research institutions," ILAR Journal V37(4) http://dels.nas.edu/ilar__n/ilarjournal/37__4/37__4Future.shtml

[12] Institute for Laboratory Animal Research, website at http://dels.nas.edu/ilar__n/ilarhome/about.shtml

The ILAR projection also concluded that the 2006 annual costs would be approximately $18.8 million. Adjusting this number by 59 percent results in $11 million spent in 2006 alone to maintain chimpanzees for research.

It is important to note that $11 million represents only a partial estimate of the entire Federal expenditure for chimpanzee research. The total population of U.S. chimpanzees available for research is estimated at 1,300. Approximately 500 of these chimpanzees are privately owned. Privately owned chimpanzees are also partially funded by Federal research dollars. Therefore, the 2006 estimate of annual expenditure actually exceeds $11 million by an undetermined amount.

DELIVERY OF CARE

USDA inspection reports indicate that facilities housing chimpanzees for research are not adequately meeting basic housing needs. Inspection reports for the NIRC 2004 showed some chimpanzees being housed in less than the minimal space requirements. The facility was given 1 year to correct the non-compliance, which needed to be further extended as construction of new housing facilities was still not completed. NIRC was also cited 7 times during its 12/04 inspection for improperly sanitizing cages and living quarters, as well as for failing to provide adequate environment enhancement.

Inspection reports filed on the Southwest Foundation for Biomedical Research and the Yerkes Primate Facility, both National Primate Research Centers, also demonstrate multiple non-compliant items for failing to keep chimpanzee areas in well-maintained condition, and failing to maintain safe facilities free of dangers due to disrepair.

A POOR MODEL

It is widely agreed within the scientific community that chimpanzees are a poor model for HIV. Years of research demonstrated that HIV-infected chimpanzees do not develop AIDS. Similarly, while chimpanzees are used in current hepatitis C research, they do not model the course of the human disease. The decoding of the chimpanzee genome pointed out similarities as well as differences between humans and chimpanzees. Some of those greatest differences relate to the immune system.[13] Such differences question the validity of using chimpanzees in infectious disease research, further arguing the need to curb populations and costs.

ETHICAL CONCERNS

The U.S. public is concerned about the use of chimpanzees in research because of their intellectual, emotional and social similarities to humans. A 2005 poll conducted by the Humane Research Council revealed that 4 out of 5 (83 percent) of the U.S. public recognize chimpanzees as highly intelligent, social individuals who have an extensive capacity to communicate. A full 71 percent of Americans support the release of chimpanzees if they have been used in research for more than 10 years.[14] A 2001 poll conducted by Zogby International showed that 90 percent of Americans believe it is unacceptable to confine chimpanzees in government-approved cages.[15]

CONCLUSION

We respectfully request that the following language appear in the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee Report for fiscal year 2008:

"None of these funds shall be used for the breeding of chimpanzees or research projects that require the breeding of chimpanzees."

We hope the committee will accommodate this modest request that will save the government substantial money, benefit chimpanzees, and allay some concerns and financial responsibilities of the public at large. Thank you for your consideration.

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[13] The Chimpanzee Sequencing and Analysis Consortium/Mikkelsen, TS, et al., (1 September 2005) Initial sequence of the chimpanzee genome and comparison with the human genome, Nature 437, 69–87.

[14] U.S. Public Opinion of Chimpanzee Research, Support for a Ban, and Related Issues, Prepared for the New England Anti-Vivisection Society, by the Humane Research Council, 2005.

[15] Public Opinion Poll, Prepared for the Chimpanzee Collaboratory, by Zogby International, 2001.

PREPARED STATEMENT OF THE PULMONARY HYPERTENSION ASSOCIATION

Mr. Chairman, thank you for the opportunity to submit testimony on behalf of the Pulmonary Hypertension Association (PHA).

I am honored today to represent the hundreds of thousands of Americans who are fighting a courageous battle against a devastating disease. Pulmonary hypertension (PH) is a serious and often fatal condition where the blood pressure in the lungs rises to dangerously high levels. In PH patients, the walls of the arteries that take blood from the right side of the heart to the lungs thicken and constrict. As a result, the right side of the heart has to pump harder to move blood into the lungs, causing it to enlarge and ultimately fail.

PH can occur without a known cause or be secondary to other conditions such as: collagen vascular diseases (i.e., scleroderma and lupus), blood clots, HIV, sickle cell, or liver disease. PH does not discriminate based on race, gender, or age. Patients develop symptoms that include shortness of breath, fatigue, chest pain, dizziness, and fainting. Unfortunately, these symptoms are frequently misdiagnosed, leaving patients with the false impression that they have a minor pulmonary or cardiovascular condition. By the time many patients receive an accurate diagnosis, the disease has progressed to a late stage, making it impossible to receive a necessary heart or lung transplant.

PH is chronic and incurable with a poor survival rate. Fortunately, new treatments are providing a significantly improved quality of life for patients. Recent data indicates that the length of survival is continuing to improve, with some patients managing the disorder for 20 years or longer.

Seventeen years ago, when three patients who were searching to end their own isolation founded the Pulmonary Hypertension Association, there were less than 200 diagnosed cases of this disease. It was virtually unknown among the general population and not well known in the medical community. They soon realized that this was unacceptable, and formally established PHA, which is headquartered in Silver Spring, Maryland.

Today, PHA includes:

—Over 7,000 patients, family members, and medical professionals as members and an additional 28,000 supporters and friends.
—A network of over 140 patient support groups.
—An active and growing patient-to-patient telephone helpline.
—Three research programs that, through partnerships with the National Heart, Lung and Blood Institute and the American Thoracic Society, will have directed more than $6 million toward PH research as of December, 2007.
—Numerous electronic and print publications, including the first medical journal devoted to pulmonary hypertension—published quarterly and distributed to all cardiologists, pulmonologists, and rheumatologists in the United States.
—A website dedicated to providing educational and support resources to patients, medical professionals, and the public that, over the past 9 years, has grown from receiving 600 visitors a month to 220,000 visitors a month.

THE PULMONARY HYPERTENSION COMMUNITY

Mr. Chairman, I am privileged to serve as the president of the Pulmonary Hypertension Association and to interact daily with the patients and family members who are seeking to live their lives to the fullest in the face of this deadly, incurable disease. I would like to share with you the stories of two remarkable PH patients, Emily Stibbs and Charity Tillemann-Dick. Emily's and Charity's stories illustrate the impact of pulmonary hypertension not only on PH patients, but also on everyone who care about them.

When their daughter Emily was 5, Jack and Marcia Stibbs noticed that she could not keep up with the other children in the neighborhood. She seemed to lack the energy and strength to run and play. This condition worsened to the point where she would have to stop and rest after coming down the steps in the morning. Jack and Marcia noticed that when she was sitting on the bottom step in the morning, Emily's lips appeared to have a bluish color.

Jack and Marcia pressed for an answer to these problems for several months, and Emily was finally diagnosed with pulmonary hypertension. Doctors told the Stibbs family that Emily's probable remaining lifespan was 3 years.

Charity Tillemann-Dick's diagnosis with pulmonary hypertension took not months, but years. When Charity was in her late-teens, she had the opportunity to travel abroad and share her considerable talents as a budding opera singer at her grandfather's 75th birthday party in Budapest. Just before the performance, Charity collapsed, but the episode was explained away as a case of nerves.

Over the next few years, Charity continued to have occasional fainting spells as well as a progressive loss in energy. She was diagnosed as being everything from out of shape to anemic. When Charity finally received an accurate diagnosis, her PH had progressed further, and was therefore more difficult to treat, than it would have been if she had been diagnosed while the disease was in its early stages.

I am happy to report that, with treatment, Charity has continued to live a full and accomplished life, including performances at several world capitals. Emily, too, has outlived her 3-year prognosis by 7 years and continues to thrive. There is, however, no cure for pulmonary hypertension. Each day, courageous patients of every age lose their battle with PH.

Thanks to congressional action, and to advances in medical research largely supported by the NHLBI and other government agencies, Emily and Charity have an increased chance of living with their pulmonary hypertension for many more years. However, additional support is needed for research and related activities to continue to develop treatments that will extend the life expectancy of PH patients beyond the NIH estimate of 2.8 years after diagnosis.

FISCAL YEAR 2008 APPROPRIATIONS RECOMMENDATIONS

National Heart, Lung and Blood Institute

Mr. Chairman, PHA commends the National Heart, Lung and Blood Institute for its strong support of PH research, particularly through the creation of the Specialized Centers of Clinically Oriented Research in PH. We are very excited about the promise these Centers hold for the development of new treatments and for progress on the road to a cure. In addition, we applaud the NHLBI and the National Institutes of Health Office of Rare Diseases for their co-sponsorship a two-day scientific conference on pulmonary hypertension in December 2006. This important event provided an opportunity for leading PH researchers from the United States and abroad to discuss the State of the science in pulmonary hypertension and future research directions.

According to these leading researchers, we are on the verge of significant breakthroughs in our understanding of PH and the development of new and advanced treatments. Twelve years ago, a diagnosis of PH was essentially a death sentence, with only one approved treatment for the disease. Thanks to advancements made through the public and private sector, patients today are living longer and better lives with a choice of five FDA approved therapies. Recognizing that we have made tremendous progress, we are also mindful that we are a long way from where we want to be in (1) the management of PH as a treatable chronic disease, and (2) a cure.

One crucial step in continuing the progress we have made in the treatment of PH is the creation of a pulmonary hypertension research network. Such a network would link leading researchers around the United States, providing them with access to a wider pool of shared patient data. In addition, the network would provide researchers with the opportunities to collaborate on studies and to strengthen the interconnections between basic and clinical science in the field of pulmonary hypertension research. Such a network is in the tradition of the NHLBI, which, to its credit and to the benefit of the American public, has supported numerous similar networks including the Acute Respiratory Distress Syndrome Network and the Idiopathic Pulmonary Fibrosis Clinical Research Network.

In order to maintain the important momentum in pulmonary hypertension research that has developed over the past few years, and to create a much needed pulmonary hypertension research network, the Pulmonary Hypertension Association encourages the subcommittee to provide the National Institutes of Health, particularly the NHLBI, with a 6.7 percent increase in funding in fiscal year 2008.

Centers for Disease Control and Prevention

PHA applauds the subcommittee for its leadership over the years in encouraging the Centers for Disease Control and Prevention to initiate a Pulmonary Hypertension Education and Awareness Program. We know for a fact that Americans are dying due to a lack of awareness of PH, and a lack of understanding about the many new treatment options. This unfortunate reality is particularly true among minority and underserved populations. However Mr. Chairman, you don't have to rely solely on our word regarding the need for additional education and awareness activities. On November 11, 2005 the CDC released a long-awaited Morbidity and Mortality Report on pulmonary hypertension. In that report, the CDC states:

(1) "More research is needed concerning the cause, prevention, and treatment of pulmonary hypertension. Public health initiatives should include increasing physician awareness that early detection is needed to initiate prompt, effective disease

management. Additional epidemiologic initiatives also are needed to ascertain prevalence and incidence of various pulmonary hypertension disease entities." (Page 1, MMWR Surveillance Summary—Vol. 54 No. SS–5)

(2) "Prevention efforts, including broad based public health efforts to increase awareness of pulmonary hypertension and to foster appropriate diagnostic evaluation and timely treatment from health care providers, should be considered. The science base for the etiology, pathogenesis, and complications of pulmonary hypertension disease entities must be further investigated to improve prevention, treatment, and case management. Additional epidemiologic activities also are needed to ascertain the prevalence and incidence of various disease entities." (Page 7, MMWR Surveillance Summary—Vol. 54 No. SS–5)

Mr. Chairman, we are grateful to the CDC for their recent support of a DVD highlighting the proper diagnosis of PH. However, despite repeated encouragement from the subcommittee over the past 5 years, CDC has not taken any steps to establish an education and awareness program on PH. Therefore, we respectfully request that you provide $250,000 in fiscal year 2008 for the establishment of a PH awareness initiative through the Pulmonary Hypertension Association.

"Gift of Life" Donation Initiative at HRSA

Mr. Chairman, PHA applauds the success of the Health Resources and Services Administration's "Gift of Life" Donation Initiative. This important program is working to increase organ donation rates across the country. Unfortunately, the only "treatment" option available to many late-stage PH patients is a lung, or heart and lung, transplantation. This grim reality is why PHA established "Bonnie's Gift Project."

"Bonnie's Gift" was started in memory of Bonnie Dukart, one of PHA's most active and respected leaders. Bonnie battled with PH for almost 20 years until her death in 2001 following a double lung transplant. Prior to her death, Bonnie expressed an interest in the development of a program within PHA related to transplant information and awareness. PHA will use "Bonnie's Gift" as a way to disseminate information about PH, transplantation, and the importance of organ donation, as well as organ donation cards, to our community.

PHA has had a very successful partnership with HRSA's "Gift of Life" Donation Program in recent years. Collectively, we have worked to increase organ donation rates and raise awareness about the need for PH patients to "early list" on transplantation waiting lists. For fiscal year 2008, PHA recommends an appropriation of $25 million (an increase of $2 million) for this important program.

Mr. Chairman, once again thank you for the opportunity to present the views of the Pulmonary Hypertension Association. We look forward to continuing to work with you and the subcommittee to improve the lives of pulmonary hypertension patients.

PREPARED STATEMENT OF THE RYAN WHITE TITLE III MEDICAL PROVIDERS COALITION

The members of the Ryan White Title III Medical Providers Coalition are pleased to submit this statement for the record in strong support of a $35 million increase to Title III (Part C) of the Ryan White Program for the fiscal year 2008 appropriations cycle. The Title III Coalition was founded to ensure that the voices of the HIV clinicians working on the frontlines of the AIDS epidemic in rural and urban communities across the Nation are represented in policy and program discussions that affect their ability to meet the medical needs of their patients with HIV/AIDS, including the national debate over the appropriate funding levels for the Ryan White CARE Act programs.

We formed our coalition in part to garner attention to the daily challenges we face in finding the necessary resources to ensure that our patients receive the comprehensive and complex medical care and services needed to sustain their health.

Title III of the Ryan White CARE Act provides grants to support outpatient medical services to HIV-positive individuals in underserved communities with no other source of care and treatment. Many Title III grants are in communities in which they are the only service providers accessible to un- and under-insured individuals. Our clinics use Title III funds to provide the range of services required to effectively manage and treat HIV disease, including physician care, medications, adherence counseling, laboratory testing, nutrition counseling and in some cases, mental health and substance abuse treatment.

Our clinical programs are seeing increasing numbers of patients with HIV/AIDS, with many of them presenting with serious, complex conditions in addition to HIV

disease, such as hepatitis C. We expect this trend to increase as States implement the Centers for Disease Control and Prevention's (CDC) recommendations for making HIV testing a more routine component of medical care. Additional resources for medical care, drug treatments and critical enabling services are essential if we are to continue providing state-of-the-art HIV care to our current patients and those newly identified with HIV disease.

As you finalize the funding recommendations for fiscal year 2008, we urge you to provide an urgently needed increase in funding for Title III (Part C) medical programs. After years of flat funding or decreases in grant awards, we estimate that the true need for these programs is an increase of at least $83.3 million over fiscal year 2007. This amount is based on the estimated annual cost of delivering HIV-related outpatient care ($2,414) multiplied by the current Title III caseload (191,229) plus the number of new patients that the Health Resources and Services Administration (HRSA) estimates will enter Title III programs in 2008 (36,333).

We appreciate the funding constraints that the committee is facing in determining fiscal year 2008 funding levels for a whole range of critical health programs. Therefore, at a minimum, we urge you to include a nominal $35 million increase for Title III housed under the Ryan White Program, with a prioritization of increases within that $35 million to current programs with the highest increases of patient burden. This proposed $35 million increase, albeit inadequate to respond to the flat funding and growing caseloads that have characterized our programs for a number of years, will help us to continue to provide our patients with the essential medical care necessary to preserve health and prevent disease progression.

While Title III (Part C) funds are critical to our ability to meet the medical needs of low-income people with HIV/AIDS in our communities, the other Titles now referred to as Parts of the Ryan White CARE Act also are vital to supporting our HIV care systems. Many of us receive funding from multiple parts of the Ryan White CARE Act and use these resources to patch together a comprehensive system of care for our patients. We strongly support the Ryan White funding requests put forward by organizations representing other members of the HIVAIDS community.

The HIV Medicine Association (HIVMA) and the American Academy of HIV Medicine (AAHIVM)—together representing most HIV clinical providers in the country—have joined forces to help assemble the Title III Coalition. Leadership of the Coalition includes providers from a wide range of settings, from New York City to New Orleans to Oakland, California.

If you have questions about the coalition, please contact Andrea Weddle at 703–299–1215 or Greg Smiley at 202–659–0699.

PREPARED STATEMENT OF THE SOCIETY FOR INVESTIGATIVE DERMATOLOGY

SUMMARY OF THE SOCIETY FOR INVESTIGATIVE DERMATOLOGY'S FISCAL YEAR 2008 RECOMMENDATIONS

A 6.7 percent increase for all of the National Institutes of Health (NIH) and for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

Establish a skin disease clinical trials network that will collect baseline data for specific orphan diseases and facilitate the exchange of scientific data across disciplines and institutes.

Encourage NIAMS to develop collaborative funding mechanisms with other NIH institutes and private foundations that leverage skin biology studies as a developmental model that will serve for the advancement of research across a multitude of diseases and specialties.

Encourage NIAMS to sponsor studies that capture general and skin-disease specific measures in order to generate incidence, prevalence and quality of life data attributable to skin diseases.

Increase the number of training awards through the NIH designed to facilitate the entry of more individuals into careers in skin disease research.

BACKGROUND

The Society for Investigative Dermatology (SID) was founded in 1938. Its 2,000 members represent over 40 countries worldwide, including scientists and physician researchers working in universities, hospitals and industry.

Along with our colleagues from the American Academy of Dermatology Association (AADA), members of the SID are dedicated to the advancement and promotion of the sciences relevant to skin health and disease through education, advocacy and the scholarly exchange of scientific information.

This collective commitment to research is evidenced in the scientific journal published by the SID, the Journal of Investigative Dermatology (JID). The JID is a catalyst for the exchange of scientific information pertaining to the 3,000 skin diseases that afflict nearly 80 million Americans annually.

The purpose of submitting testimony is to increase awareness of the need for more skin research, based on the burden attributable to skin disease. It will also highlight some of the advancements that past support has enabled.

We join with the Ad Hoc Group for Medical Research Funding in asking for a 6.7 percent increase for the National Institutes of Health (NIH) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

BURDEN OF SKIN DISEASE

Prior bill report language directed NIAMS to "consider supporting the development of new tools to measure the burden of skin diseases, and the training of researchers in this important area". There are only a handful of researchers working on NIH-sponsored research that will provide such measures.

Skin disease impacts our citizens more than previously estimated. A report released in 2004 by the SID and the AADA, "The Burden of Skin Disease", compiled data from only 21 of the known 3,000 skin diseases and disorders. The estimated economic costs to society each year from those 21 diseases totaled nearly $39 billion.

The true impact extends far beyond mere economics. These patients encounter discomfort and pain, physical disfigurement, disability, dependency and death. Skin conditions affect an individual's ability to interact with others and compromise the self-confidence of those inflicted.

One of the most striking findings in the study was the lack of general and skin-disease specific measures that are needed to generate data surrounding the incidence, prevalence, economic burden, quality of life and handicaps attributable to these diseases.

We ask the committee to devote the resources needed to develop components of national health surveys that capture dermatological data above and beyond skin cancer incidence and prevalence.

RESEARCH ADVANCES

Skin is the body's largest organ and serves as the primary barrier to external pathogens and toxins. Researchers at the NIH campus and institutions around the country are working diligently to define how the skin functions to protect us, how this fails in disease, and how compromised functions in disease can be restored.

Cell biology allows scientists to understand the life cycle of skin and hair-producing cells and identify the causes of disease, leading to better treatments and preventative measures. Advances in wound healing and skin ulcers are helping the elderly, veterans and patients with diabetes and burns. Lasers continue to provide less invasive options for patients requiring surgery.

Fundamental discoveries resulting from skin biology and translational research have yielded advances that are broadly applicable to human development and disease. Continued investment is required to fully capitalize on these ground-breaking advances.

Important new research findings include the following:

—The genes responsible for skin cancer and inherited skin diseases have been identified, making targeted therapy possible.

—The molecular mechanisms of auto-immune and inflammatory skin diseases are better understood, allowing for the use of focused, selective immunosuppressive therapy with greater safety and efficacy.

—Oral medications to treat and prevent viral and fungal diseases have become available.

—Lasers have made possible the removal of disfiguring skin malformations.

—Modern phototherapy and photochemotherapy allow for more effective treatment of inflammatory skin disease, lymphoma, depigmenting disorders and auto-immune diseases.

—Retinoids and sunscreens have reduced the risk of skin cancer in the elderly, in transplant patients, and in other populations.

—Painless transdermal drug delivery has become available.

Recent developments in the areas of clinical epidemiology, biostatistics, economics and the quantitative social sciences have begun to provide objective evaluation measures, although additional and improved measures are still desperately needed. These measures will help to identify effective interventions and allow us to better quantify contributions to the quality of life and health of Americans.

We ask the NIH to work to identify additional biomarkers in order to better understand skin disease pathways and interaction with other diseases and environmental factors.

TRANSLATING DISCOVERY TO TREATMENTS FOR AMERICANS

The goal of skin disease research is to improve the quality of life for the one in three Americans that suffer from skin disease. That goal is embedded in the collective missions of the SID and the intramural and extramural scientists funded through the skin portfolios of many of the 27 institutes and centers of the NIH.

Medical research organizations such as the SID are the direct recipients of the awards made possible through the rigorous peer-reviewed grant system in place at the NIH. The ultimate beneficiaries are the nearly 80 million Americans that stand to benefit from the discoveries resulting from research grants.

Inadequate levels of Federal funding have forced the institute administrators to reduce certain types of the available funding mechanisms currently in place at the NIH, to decrease success rates, to increase administrative cost reductions, to consider decreasing the number of awards and to cut award levels in existing programs.

Unfortunately, this reality impairs the ability of hypothesis-driven research to drive the research system. Adequate funding levels will allow the peer-review system to work at full potential, leading to findings that translate into better care for those suffering from debilitating diseases. Without sufficient funding provided specifically for skin research, nearly one third of the Nation would be denied any hope for a better quality of life.

We are grateful for the past support that has been given to the NIH and ask you to look for innovative ways to avoid flat or decreased funding levels for the institutes that are charged with improving the health of all Americans.

PREPARED STATEMENT OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE

Mr. Chairman and members of the committee: The Society for Maternal-Fetal Medicine is pleased to have the opportunity to testify on behalf of the fiscal year 2008 budget for the National Institute of Child Health and Human Development and to extend to the committee our appreciation for the support you have provided over the years to the National Institutes of Health, and in particular the National Institute of Child Health and Human Development.

Established in 1977, the Society for Maternal-Fetal Medicine (SMFM) is a not-for-profit organization of over 2,000 members that are dedicated to improving perinatal care through research and education. Maternal-fetal medicine doctors have advanced knowledge of the obstetrical, medical, genetic and surgical complications of pregnancy and their effects on both the mother and fetus. The many advances in research have allowed the maternal-fetal medicine physician to provide the direct care needed to treat the special problems that high risk mothers and fetuses face.

Having a high-risk pregnancy means that a woman has a greater chance of complications because of conditions in her pregnancy, her own medical status or lifestyle, or due to external factors. Many times, complications are unexpected and may occur without warning. Other times, there are certain risk factors that make problems more likely. For example:

—*Preterm Birth*.—Preterm birth is defined as births occurring before 37 weeks of gestation. Prematurity is the leading cause of newborn death and an estimated 20 percent of infants who survive suffer long term consequences, including cerebral palsy, mental retardation, and developmental delays that affect the child's ability to do well in school. The rate of preterm births has increased 30 percent since 1981 and in 2004, 508,000 babies were born prematurely.

Due to the growing problem of preterm birth, expanded research is needed on the underlying causes of preterm delivery and the development of treatments for the prevention of premature birth. SMFM recommends that the NIH Common Fund be utilized as a mechanism to fund research on preterm birth. As reported in the 2006 Institute of Medicine report, "Preterm Birth: Causes, Consequences, and Prevention," a multidisciplinary research approach is needed to better understand premature birth.

—*Adverse Pregnancy Outcome in Nulliparous Women*.—A recent national study showed that the rate of preterm births among first pregnancies has increased over 50 percent over the past decade and comprise about 40 percent of pregnant women in the United States. The rate of adverse pregnancy outcomes is unpredictable and substantial. For example, at least 12 percent of these women will have a preterm delivery, with associated high rate of neonatal mortality and long term morbidity. The data also revealed that women in their first pregnancy

are at highest risk for developing pre-eclampsia, which puts them at risk for devastating maternal complications, fetal death, and preterm delivery. Once one of these adverse outcomes has occurred, these women are considered at increased risk in their next pregnancy. In addition, the study also showed a racial disparity with Black women at a two-fold higher risk than white women. The prediction and prevention of the first adverse outcome is problematic and there is a paucity of research on the etiology, mechanism, and potential preventive interventions for poor pregnancy outcomes in this population.

SMFM recommends that NICHD launch an intensive research study of first pregnancy women in order to fill the major gap in our knowledge for the prevention of these complications.

—*Outcomes of Assisted Reproductive Technology*.—The increasing use of assisted reproductive technology (ART) over the past two decades has allowed thousands of infertile couples to have children, currently accounting for 1.1 percent of the total U.S. births and 17.1 percent of U.S. multiple births (CDC, 2002). ART includes all fertility treatments in which both eggs and sperm are handled in vitro such as in vitro fertilization with transcervical embryo transfer, gamete and zygote intrafallopian transfer, frozen-embryo transfer, and donor embryo transfer. Between 1996 and 2002, the number of births after ART treatment in the United States increased by 120 percent. ART is a significant contributor to preterm delivery and associated risks of prematurity. There is recent evidence of higher rates of adverse pregnancy outcomes even in singleton pregnancies associated with ART including increased preterm and term low birth weight, very low birth weight, preterm delivery, fetal growth restriction, genetic disorders, and congenital anomalies. The risks of birth defects are two times higher in ART babies as compared with naturally conceived singleton babies.

There is a lack of research on the mechanism for this increase in the adverse pregnancy outcomes. There is also insufficient research to date concerning the prevalence of adult chronic conditions, learning and behavioral disorders, and other reproductive effects in ART babies. Given the data for more proximal outcomes, these long-term outcomes should also receive further study. Preliminary results indicate that there may be an increase incidence of autism in ART offspring.

SMFM recommends a multi-center observational prospective cohort study on ART be conducted that would emphasize pregnancy outcomes—short- and long-term effects on children—to determine if the increase in adverse pregnancy outcomes are specifically related to the ART procedures versus underlying factors within the couple, such as coexisting maternal disease, the causes of infertility, or differences in behavioral risk and examine each step in the ART process to understand the mechanism for increased adverse pregnancy outcomes.

The National Institute of Child Health and Human Development is to be congratulated for its efforts to advance our understanding of the magnitude of complications related to pregnancy and for its efforts to sustain the investment in research during this time of tight budget constraints.

—A recent study found that molecules in blood can foretell the development of preeclampsia, a life-threatening complication of pregnancy. This finding appears to be an important step in developing a cure for preeclampsia.

—Researchers have developed an experimental vaccine that reduces stillbirths among rodents born to mothers infected with cytomegalovirus (CMV)—a common virus that can also cause mental retardation and hearing loss in newborn children who were infected in early fetal life.

According to NIH Director Elias Zerhouni, "medical science has dramatically improved our ability to help very small and premature babies survive. But as the rate of premature births continue to rise, it is even more critical that we develop ways to prevent many of the complications related to prematurity so that these children can lead healthy, robust lives."

RECOMMENDATIONS

SMFM urges this committee to continue to provide NICHD with sufficient funds so that the Institute can continue to make momentous advances in research that will result in improved health of mothers and children. We recommend:

—Fund NIH at the amount authorized for fiscal year 2008 in the NIH Reform Act of 2006.

—Provide $1,448,544,000 for NICHD in fiscal year 2008.

—Full funding for the—

  —Maternal Fetal Medicine Units Network so that it can continue to address issues pertaining to preterm births and low birth-weight deliveries.

—Genomics and Proteomics Network for Premature Birth, which will hasten a better understanding behind the pathophysiology of premature birth, discover novel diagnostic biomarkers and ultimately aid in formulating more effective interventional strategies to prevent premature birth.

—Stillbirth Collaborative Research Network which is addressing stillbirth, a major public health issue with morbidity equality to that of all infant deaths.

Thank you for allowing SMFM the opportunity to present our views to the committee.

PREPARED STATEMENT OF THE SOCIETY FOR NEUROSCIENCE

INTRODUCTION

Mr. Chairman and members of the subcommittee, I am David Van Essen, PhD, president of the Society for Neuroscience (SfN) and the Edison Professor of Neurobiology and Head of the Department of Anatomy and Neurobiology at Washington University in St. Louis, MO. I also currently serve on the Advisory Council of the National Institute of Neurological Disorders and Stroke.

I am writing in my capacity as SfN president to request your support for biomedical research funding at the National Institutes of Health (NIH). During the past several decades, NIH funding has allowed the neuroscience community to improve health outcomes and the quality of life for millions of Americans.

WHAT IS THE SOCIETY FOR NEUROSCIENCE?

SfN is a nonprofit membership organization made up of more than 36,500 basic scientists and physicians who study the brain and nervous system. Recognizing the tremendous potential for the study of the brain and nervous system as a separate field, the Society was formed in 1969. Since then, SfN has grown from 500 members to the world's largest organization of scientists devoted to the study of the brain. Today, there are more than 300 training programs in neuroscience in the United States alone.

Neuroscience includes the study of how the brain senses and perceives our world, how it learns and remembers, how it controls our movements and our emotions, how it regulates sleep and responds to stress, how it develops and ages, and how it malfunctions in countless neurological and psychological disorders. Neuroscience also involves studies of the molecules, cells and genes responsible for proper nervous system functioning.

SfN's primary goal is to advance the understanding of the brain and the nervous system in health and disease. As such, each fall, some 30,000 scientists from around the world gather to exchange ideas about cutting-edge research on the brain, spinal cord, and nervous system at the Society's annual meeting.

THANK YOU FOR PAST SUPPORT

SfN would like to thank the members of this subcommittee for their past support, which resulted in the doubling of NIH budget between 1998 and 2003. In particular, we are extremely grateful that the fiscal year 2007 Joint Resolution included an additional $620 million for NIH above the fiscal year 2006 funding level. This additional money will allow NIH to award an extra 500 research grants. It will also create a new $40 million program to support innovative, outside-the-box research, as well as $91 million for grants to first-time investigators.

MY RESEARCH

Currently, my research focuses on the structure and function of the cerebral cortex in humans and nonhuman primates. The cerebral cortex is the dominant structure of the human brain. It plays a key role in mediating our perceptions of the world around us, our cognitive capabilities, our emotions, and the control of our movements. It is highly variable from one individual to the next and is largely responsible for our unique personalities. Many neurological and psychiatric disorders arise from abnormalities of the cerebral cortex that are caused by hereditary or developmental factors or by injuries to cortical gray matter or to the underlying white matter.

My laboratory has developed novel methods of computerized brain mapping that allow accurate mapping of the complex convolutions of the cerebral cortex and accurate comparisons between individuals. Using these methods, we have worked with many collaborators to characterize patterns of cortical development in prematurely born human infants and abnormalities of cortical folding in specific disorders, in-

cluding William's Syndrome, autism, and schizophrenia. We have compared humans and in macaque monkeys (an intensively studied nonhuman primate), in order to better understand the differences that reflect the dramatic evolution of the human brain as well as the similarities that reflect common principles of cortical structure and function. In addition, my laboratory is active in the newly emerging field of neuroinformatics; we have developed a database and related tools to help neuroscientists communicate their discoveries and share their experimental data more effectively, thereby accelerating the pace of discovery and the efficiency of the neuroscience research enterprise.

NIH-FUNDED RESEARCH SUCCESSES

Today, scientists have a greatly improved understanding of how the brain functions thanks to NIH-funded research. To illustrate this progress SfN has created a 36-part series, called Brain Research Success Stories, which discuss some of the progress that has resulted from Federal funding for biomedical research. The following are just a few areas where our research efforts have helped the American public:

(1) *Down Syndrome*.—About one out of every 800 babies is born with Down Syndrome (DS) a disorder that includes a combination of birth defects such as mental retardation, certain physical distinctions, and an increased risk of several medical conditions, including heart problems, intestinal malformations, and visual or hearing impairments.

DS often results in high medical and non-medical costs, such as special education, rehabilitation, and other services. Data from 1992 suggests that each new case of DS costs over $450,000 each year.

NIH-funded research has led to the development of several medical tests that help identify whether a pregnant woman is carrying a baby with DS. These tests allow parents to prepare themselves mentally and financially, and give them time to secure intervention programs that can aid in their child's development.

Once a child is born, research shows that early intervention programs can benefit those with DS. For example, adolescents with DS who received intervention programs early in life had significantly higher scores on measures of intellectual functioning than a comparison group. Such improvements might help those with DS live more independently and maintain a job later in life.

(2) *Schizophrenia*.—This disease affects nearly 2 million Americans, and costs the United States over $32 billion a year in lost productivity and treatment. This devastating brain disorder torments sufferers with hallucinations, delusions, disordered thinking patterns, and memory deficits.

In the past, many individuals with schizophrenia became permanently lost to the social withdrawal and other behavioral problems characteristic of this disease, which is rooted in abnormal biology of the brain. However, thanks to NIH-funded research, new treatments, such as clozapine, have been developed.

Today's medications have fewer side effects and are more effective than older treatments. They help to quell the psychotic symptoms of schizophrenia, allowing patients to function more effectively in society. The medications also appear to cut the financial burden of the disease, decreasing hospital stays and treatment costs.

(3) *Amyotrophic Lateral Sclerosis*.—Each year, 5,000 Americans are diagnosed with the progressive neurological disease, called amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. The cost of treating these people is $300 million annually. ALS takes a quick toll on sufferers. Affected individuals may first notice muscle weakness, twitching, or cramping. The disease then progressively disables a person's ability to walk, talk, or swallow and, ultimately, to breathe. Many spend their last days completely unable to move, while their minds remain alert. ALS usually occurs in midlife and kills patients within 3 to 5 years of occurrence.

Government-funded ALS research produced a number of important findings in the early 1990s. First, researchers were able to start pinning down how the disease progresses by identifying the role of the potentially toxic amino acid glutamate. ALS sufferers tend to have higher levels of this chemical messenger in certain parts of their body, and scientists have noted that nerve cells exposed to high concentrations of glutamate over a long time start to die.

Researchers were able to use this basic research discovery to develop riuzole, an anti-glutamate drug that extends the lives of ALS patients. The first drug shown to change the course of ALS, it was approved by the Food and Drug Administration in 1995. In 1993, researchers supported by NIH identified a genetic component of the hereditary form of ALS and subsequently developed an animal model for ALS. This has allowed researchers to advance their study of the disease and to test dozens of potential treatments.

RESEARCH IMPROVES HEALTH AND FUELS THE ECONOMY

Diseases of the nervous system pose an enormous public health and economic challenge, as they directly affect nearly one in three Americans at some point in life, and indirectly affect nearly everyone by the adverse impact on family and friends. Understanding how the brain and nervous system develops, works, and ages—in health and disease—is the goal of neuroscientists. Improved health outcomes and positive economic data support the assertion that biomedical research is needed today to improve public health and save money tomorrow. Research drives innovation and productivity, creates jobs, and fuels local and regional economies.

Not only does research save lives and fuel today's economy, it is also a wise investment in the future. For example, 5 million Americans suffer from Alzheimer's disease today, and the cost of caring for these people is staggering. Medicare expenditures are $91 billion each year, and the cost to American businesses exceeds $60 billion annually, including lost productivity of employees who are caregivers. As the baby boom generation ages and the cost of medical services increases, these figures will only grow. Treatments that could delay the onset and progression of the disease by 5 years could save $50 billion in healthcare costs each year. Research funded by the NIH is critical for the development of such treatments. The cost of investing in NIH today is minor compared to both current and future healthcare costs.

PRESIDENT'S BUDGET NEGATIVELY IMPACTS RESEARCH

SfN is disappointed that the Bush administration's fiscal year 2008 budget proposes to cut funding for the National Institutes of Health by more than a half billion dollars in fiscal year 2008.

Mr. Chairman, inflation has eaten into the NIH budget. The NIH now projects the Biomedical Research and Development Price Index (BRDPI) may increase by 3.7 percent for both fiscal year 2007 and fiscal year 2008; 3.6 percent for fiscal year 2009 and 2010; and 3.5 percent for fiscal year 2011 and fiscal year 2012. Unfortunately, the President's budget for NIH did not factor in the increases in biomedical research inflation.

Several years of funding for NIH that are well below inflation rates has made efficient research planning difficult, led to a slower rate of research progress, and delayed the payoffs from recent scientific advances. As you know, basic research projects take years from conception to completion. Many excellent research projects have been curtailed in recent years because of the low percent age of grants receiving funding. In order to have maximum impact in our search to understand and treat disorders, we need a consistent, adequate level of funding. Without such a strategy, the Federal Government runs the great risk of spending many more dollars later on in medical costs and time lost from work. In recent months, we have been speaking with leaders in the biotechnology and pharmaceutical industries, who depend on NIH-funded discoveries a vital prelude to and driver of their product development efforts. They agree that rather than considering funding for NIH an expense, it should be considered an investment to address problems our country will face tomorrow.

We need a funding stream that keeps pace with the potential for advances that will help people lead healthier, more productive lives. NIH became the premier biomedical research institution it is today only through sustained support from congressional leaders, like you, to invest in the best facilities, research, and projects selected through a non-political, rigorous, and competitive peer review system that is envied and is now being emulated around the world.

FISCAL YEAR 2008 BUDGET REQUEST

NIH funded research saves lives and fuels the U.S. economy. Further, sustained investment in the NIH will lead to more effective treatments that will lessen future healthcare costs for the baby boom generation. Unfortunately, inflation and relatively flat funding have eaten into the NIH budget.

The Society for Neuroscience supports a 6.7 percent increase in funding for NIH per year for each of the next 3 fiscal years. This increase translates to an additional $1.9 billion for NIH in fiscal years 2008, 2009, and 2010.

This sustained increase is necessary to make-up for lost purchasing power that has occurred in the past 3 years. In addition, increased funding will help NIH to achieve future research goals by, among other things, helping to ensure that our best and brightest young people will enter the field and continue to make neuroscience research advances that are so vital to achieving a healthier Nation and a robust economy.

Mr. Chairman, thank you for the opportunity to submit testimony before this subcommittee.

PREPARED STATEMENT OF THE SOCIETY OF TEACHERS OF FAMILY MEDICINE; ASSOCIATION OF DEPARTMENTS OF FAMILY MEDICINE; ASSOCIATION OF FAMILY MEDICINE RESIDENCY DIRECTORS; AND NORTH AMERICAN PRIMARY CARE RESEARCH GROUP

HEALTH PROFESSIONS: PRIMARY CARE MEDICINE AND DENTISTRY (TITLE VII, SECTION 747)

We request that this committee fund the Primary Care Medicine and Dentistry Cluster (section 747 of Title VII) at no less than the fiscal year 2005 level of $88.8 million. This cluster received $48.9 million in the final fiscal year 2007 spending resolution, but the President's budget for fiscal year 2008 eliminates Title VII Health Professions Grants, except for $10 million in Scholarships for Disadvantaged Students.

In fiscal year 2006, funding for the health professions programs was cut dramatically. The primary care medicine and dentistry cluster was cut by 54 percent. The effect was to prevent any new competitive grant applications for that year and to cut the funding of those grants that were continuing in their second or third year. This year, instead of providing the committee with national studies regarding the effectiveness of these programs, we would like to put a human face to the impact of the cuts in fiscal year 2006. Below are anecdotes received from across the country showing, in their own words, how the institutions that apply for and receive these grants were affected by the loss of almost $50 million of Federal funding.

University of Iowa, Department of Family Medicine.—At Iowa, we furloughed 5 individuals (that means let them go) related to our educational and academic mission. We have had to shift funding from other core areas and reduce or eliminate programs that focused mostly on primary care fellowship training, academic development, preceptor education development and travel support to rural Iowa communities. Our department had consistently received about $800,000 to $1,000,000 a year over the last 30 years and now we have none of that support. Paul James, MD, Chair, Department of Family Medicine

University of Buffalo, Department of Family Medicine.—Here at the University at Buffalo we have laid off a PhD Clinical Psychologist who had been with the Department for 9 years. He participated actively in our clerkship training and in our residency training. He taught both students and residents about helping patients change behaviors (quit smoking, etc) and trained residents in dealing with difficult or non-compliant patients as well as the more difficult and time consuming issues of long term family therapy. We also laid off a master degree medical education specialist. We are the only medical school department to have had a person like this on our staff but she assured that our exams measured the goals of our training and our curriculum taught to these goals. Tom Rosenthal, MD, Chair, Department of Family Medicine

Tufts University, Division of Family Medicine.—At Tufts, we hired three minority faculty to increase the diversity of our faculty and now we will have to let go of one of them and reduce the time significantly of the other two because of our loss of funding. We also have an educational program that teaches students how to interview patients who do not speak English through a medical interpreter. We will have to cut that program as well. Wayne Altman, MD FAAFP

Montana Family Medicine Residency.—Many of our successes, including the integration of a top notch primary care mental illness management and collaborative program and a Northern Plains Indian cultural education program, have been possible only through Title VII funding. Our growth as a rather isolated residency—the only one in the State in any specialty, and remote from our affiliated University—is dependent on grant programs that are specifically designed for family medicine resident training . . . Geographically isolated programs like ours in Montana and also Alaska, and Wyoming also need to develop their own infrastructure . . . Roxanne Fahrenwald MD, Director, Montana Family Medicine Residency.

University of North Carolina, Department of Family Practice.—We cut one of our objectives [in our continuation grant] because there was not enough money to pay for it. It was a session on health disparities that we intended to introduce to all of our clerkship students, and then have them look at the issue during their clinical experience in a practice. The money we had intended to pay for the faculty involved was eliminated and she had to make it up from patient care time. Bob Gwyther, MD

Thomas Jefferson University, Department of Family and Community Medicine.—. . . . Predoctoral—Unable to expand our rural Physician Shortage Area Program (which has successfully increased the rural physician supply in Pennsylvania) to the State of Delaware; and unable to develop and implement new curricula focusing on vulnerable populations in the areas of health literacy, oral health, domestic violence, and medical professionalism. Howard Rabinowitz, MD [This entry was extracted from a longer list of six program areas that were deeply affected by these cuts]

WWAMI (a Partnership Between the University of Washington School of Medicine and the States of Wyoming, Alaska, Montana, and Idaho).—We have had some programmatic impacts on the faculty development fellowship program across the five WWAMI States. For us the impact of the funding cut was having to eliminate the support for a second year of training that would have exported fellows' projects to other programs and nationally. This was the opportunity to make use of what they had gained in the fellowship year in a way that solidified their learning and spread that learning to others. These changes meant the discipline, the region, and BHP [Bureau of Health Professions] didn't get to reap the benefit of these physicians' activities. *In a sense they lost the public good beyond the training of the individual faculty.* [emphasis added] Finally we lost the chance to see if that new model worked. Ardis Davis, MSW

THE AGENCY FOR HEALTH CARE RESEARCH AND QUALITY (AHRQ)

We request funding of $350 million for AHRQ in fiscal year 2008. This is an increase of $31 million over fiscal year 2007, and $20 million more than the President's fiscal year 2008 budget request. It should be noted however that a much larger investment should be made, as recommended by The Institute of Medicine's report, Crossing the Quality Chasm: A New Health System for the 21st Century (2001). It recommended $1 billion a year for AHRQ to "develop strategies, goals, and actions plans for achieving substantial improvements in quality in the next 5 years . . ." The report looked at redesigning health care delivery in the United States. AHRQ is a linchpin in retooling the American health care system.

For the last several years, funding for AHRQ has remained relatively stagnant, while it's portfolio of work has increased dramatically. Our researchers are finding that investigator-initiated grants are very difficult to obtain. In their own words, this is the status of AHRQ funding:

Brown University, Department of Family Medicine.—AHRQ funds so little new research we discourage people from applying to them. They could fund practice innovation; networks; new models of care; guideline research; doctor-patient communication research; electronic health record research. Jeffrey Borkan, MD, Chair

University of Connecticut, Department of Family Medicine.—A general plea for more "investigator initiated" research at AHRQ is very important. Most of their funds recently have been targeted to special initiatives and the new or experienced health services researcher is getting discouraged because there is no money to fund good ideas that develop a line of research. When I was on the study section I saw a lot of good, fundable research go unfunded because of pay lines. This will dry up the pipeline of HSR researchers. The agency's funding level needs to be re-expanded . . . to enable the REAL health services research and quality-of-care/outcomes research to proceed (especially as there is, more than ever, a huge need to restructure the delivery of healthcare, and a need to measure the outcomes of those changes) Rob Cushman, MD Chair, and Judith Fifield, PhD

Oregon Health and Sciences University, Department of Family Medicine.—Lately, I know AHRQ has had a difficult time funding K-award for junior researchers. Last year, they went three cycles without funding anyone. This lack of funding will have a grave affect on building the research infrastructure for primary care and health services research. Specific to R03 and R01 awards, they have been unable to fund countless worthy projects. In Oregon, we've had a lot of State policy experiments that desperately need further study, but applications to AHRQ have been rejected. Jennifer E. DeVoe, MD, DPhil

NATIONAL INSTITUTES OF HEALTH (NIH)

This is the first time that our organizations have made a request for funding for the NIH. Historically, much of the work that has been done at NIH hasn't been open to the kinds of questions that family medicine researchers have been concerned about. We are encouraged by the development of the NIH Roadmap and the Clinical and Translational Science Awards (CTSA), along with the establishment, in statute, of a funding stream for the common fund that NIH is moving to becoming a more fertile arena for family medicine and other primary care research. Hence, we support the Ad Hoc Group for Medical Research and others' call for an increase in NIH

funding by 6.7 percent in each of the next 3 years. However, there are major strides we believe NIH needs to make to ensure that the promise of bench to bedside research truly becomes bench to bedside to community—and back. What do we mean by that? In their own words:

University of Connecticut, Department of Family Medicine.—Adding more "action research", in which the community (including, but not exclusively, the community clinicians) participates more in the definition of the problem, the design of the solution, and the dissemination and management of the results as they evolve, could augment the impactfulness of the eventual findings. Rob Cushman, MD, Chair

University of Buffalo, Department of Family Medicine.—I think Family Medicine would like to see more opportunities for PBRN and community based participatory research approaches to further the translation of research from bedside to patient. In parallel, current study sections are heavily weighted with bench and clinical trial researchers. Having more family medicine researchers participate on review boards will help get more of these types of grants funded. Tom Rosenthal, MD, Chair

University of Massachusetts, Department of Family Medicine and Community Health.—As for NIH, trying to sell real-world interventions that may not be scientifically pure but answer relevant questions for improving care to study sections remains a challenge. Many editorials have been written about the lack of applicability of much RCT evidence to real-world practice situations because the populations have been so carefully selected that they are not remotely representative of primary care patients. Furthermore, for primary care researchers, the need to choose a disease or organ and focus narrowly to succeed at NIH is quite problematic—research affecting primary care needs to focus on patients, providers, and processes . . . Barry Saver, MD, MPH

CONCLUSION

We hope that the committee will be able, with the more generous figures included in the fiscal year 2008 House and Senate Budget Resolutions this year, to fund increases in these three important programs: health professions primary care medicine and dentistry training, AHRQ, and NIH. Certainly, at a minimum, we request that funding cuts to the health professions primary care medicine and dentistry training program be restored to at least fiscal year 2005 levels of $88.8 million. As a reminder however, these programs were funded at a historic high of $93 million in fiscal year 2002, and we support a return to that figure.

PREPARED STATEMENT OF THE SOCIETY FOR WOMEN'S HEALTH RESEARCH AND WOMEN'S HEALTH RESEARCH COALITION

On the behalf of the Society for Women's Health Research and the Women's Health Research Coalition, we are pleased to submit the following testimony in support of Federal funding of biomedical research at NIH and, more specifically, an investment into women's health research.

The Society for Women's Health Research is the only national non-profit women's health organization whose mission is to improve the health of women through research, education, and advocacy. Founded in 1990, the Society brought to national attention the need for the appropriate inclusion of women in major medical research studies and the need for more information about conditions affecting women disproportionately, predominately, or differently than men. In 1999, the Women's Health Research Coalition was created by the Society as a grassroots advocacy effort consisting of scientists, researchers, and clinicians from across the country that are concerned and committed to improving women's health research.

The Society and Coalition are committed to advancing the health of women through the discovery of new and useful scientific knowledge. We believe that sustained funding for biomedical and women's health research programs conducted and supported across the Federal agencies is absolutely essential if we are to meet the health needs of the population and advance the Nation's research capability.

NATIONAL INSTITUTES OF HEALTH

From decoding the human genome to elucidating the scientific components of human physiology, behavior, and disease, scientists are unearthing exciting new discoveries which have the potential to make our lives and the lives of our families longer and healthier. The National Institutes of Health (NIH) has facilitated these advances by conducting and supporting our Nation's biomedical research. Congressional investment and support for NIH has made the United States the world leader

in medical research and has provided a direct and significant impact on women's health research and the careers of women scientists over the last decade.

Great strides and advancements have been made since the doubling of the NIH budget from $13.7 billion in 1998 to $27 billion in 2003. However, we are concerned that the momentum driving new research has been eroded under the current budgetary constraints. Medical research must be considered an essential investment—an investment in thousands of newly trained and aspiring scientists; an investment to remain competitive in the global marketplace; and an investment in our Nation's health. A large majority of Americans believe they are receiving the highest quality and latest advancements in health care and they depend upon Congress to make a strong investment in biomedical research at NIH to continue that expectation.

Unfortunately, the administration's fiscal year 2008 budget request of $28.6 billion for NIH is unraveling the successes gained from the doubling of NIH's budget. NIH only truly receives $28.3 billion in the proposed budget due to the transfer of $300 million to the Global Fund to Fight HIV/AIDS. Further, the proposed budget actually represents a decrease of $511 million when compared to the amount provided for NIH research activities in the fiscal year 2007 continuing resolution. Not only does the proposed decrease not keep pace with the inflation rate, but it is lower than that of the Biomedical Research and Development Price Index.

Without a robust budget, NIH will be forced to reduce the number of grants it is able to fund. In this current fiscal year, 500 fewer grants would have been funded by NIH had it not received additional funding under the fiscal year 2007 continuing resolution. The number of new grants funded by NIH has already been dropping steadily since fiscal year 2003 and this trend must stop. This shrinking pool of available grants has a significant impact on scientists who depend upon NIH support to cover their salaries and laboratory expenses to conduct high quality biomedical research. Failure to obtain a grant results in reduced likelihood of achieving tenure. This means that new and less established researchers will be forced to consider other careers, with the end result being the loss of the critical workforce so desperately needed to sustain America's cutting edge in biomedical research.

In order to continue the momentum of scientific advancement and expedite the translation of research from the laboratory to the patient, the Society calls for a 6.7 percent increase over fiscal year 2007 actual budget for the NIH for fiscal year 2008. In addition, we request that Congress strongly encourage the NIH to assure that women's health research receives resources sufficient to meet the health needs of all women.

Scientists have long known of the anatomical differences between men and women, but only within the past decade have they begun to uncover significant biological and physiological differences. Sex-based biology, the study of biological and physiological differences between men and women, has revolutionized the way that the scientific community views the sexes. Sex differences play an important role in disease susceptibility, prevalence, time of onset and severity and are evident in cancer, obesity, coronary heart disease, immune dysfunction, mental health disorders, and other illnesses. Congress recognizes the importance of this research and should support NIH at an appropriate level of funding and direct NIH to continue expanding research into sex-based biology.

OFFICE OF RESEARCH ON WOMEN'S HEALTH

The NIH Office of Research on Women's Health (ORWH) has a fundamental role in coordinating women's health research at NIH, advising the NIH Director on matters relating to research on women's health; strengthening and enhancing research related to diseases, disorders, and conditions that affect women; working to ensure that women are appropriately represented in research studies supported by NIH; and developing opportunities for and support of recruitment, retention, re-entry and advancement of women in biomedical careers. ORWH has a pivotal role within the NIH structure and beyond to maintain and advance not only biomedical research in women's health but also careers of women in science and medicine. ORWH co-chaired a task force with the Director of NIH examining a report by the National Academies of Science regarding women in medicine and science. It is through ORWH that many initiatives can be achieved to strengthen the position of women scientists. Further, ORWH strives to address sex and gender perspectives of women's health and women's health research, as well as differences among special populations of women across the entire life span, from birth through adolescence, reproductive years, menopausal years and elderly years.

Two highly successful programs supported by ORWH that are critical to furthering the advancement of women's health research are Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and Specialized Centers of Re-

search on Sex and Gender Factors Affecting Women's Health (SCOR). These programs benefit the health of both women and men through sex and gender research, interdisciplinary scientific collaboration, and provide tremendously important support for young investigators in a mentored environment.

The BIRCWH program is an innovative, trans-NIH career development program that provides protected research time for junior faculty by pairing them with senior investigators in an interdisciplinary mentored environment. What makes BIRCWH so unique is that it bridges advanced training with research independence across scientific disciplines. It is expected that each scholar's BIRCWH experience will culminate in the development of an established independent researcher in women's health. The BIRCWH has released four RFAs (1999, 2001, 2004, and 2006). Since 2000, 287 scholars have been trained (76 percent women) in the 24 centers resulting in over 882 publications, 750 abstracts, 83 NIH grants and 85 awards from industry and institutional sources. Each BIRCWH receives approximately $500,000 a year, most of which comes from the ORWH budget.

The SCOR program, administered by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, was developed by ORWH in 2000 through an initial RFA that resulted in 11 SCOR Centers out of 36 applications. SCORs are designed to increase the transfer of basic research findings into clinical practice by housing laboratory and clinical studies under one roof. The program was designed to complement other federally supported programs addressing women's health issues such as BIRCWH. The eleven SCOR programs are conducting interdisciplinary research focused on major medical problems affecting women and comparing gender difference to health and disease. Each SCOR works hard to transfer their basic research findings into the clinical practice setting. A second RFA is due to be funded in 2007 with virtually no hope of expanding or matching the number of current SCOR programs, due to anticipated budget shortfalls. Each program costs approximately $1 million per year.

Despite the advancement of women's health research and ORWH's innovative programs to advance women scientists, it received a $15,000 decrease for fiscal year 2007 after having also received a cut of $249,000 for fiscal year 2006 from the Office of the Director. It is unconscionable to cut the funds from this critical program at NIH. This research is vital to women and men and we implore Congress to direct NIH to continue its support of ORWH and its programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Department of Health and Human Services (HHS) has several offices that enhance the focus of the government on women's health research. Agencies with offices, advisors or coordinators for women's health or women's health research are the Department of HHS, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Healthcare Quality and Research, the Indian Health Service, the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, and the Centers for Medicare and Medicaid Services. These agencies need to be funded at levels adequate for them to perform their assigned missions. We ask that the committee report clarify that Congress supports the permanent existence of these various offices and would like to see them appropriately funded to insure that their programs can continue and be strengthened in the coming fiscal year.

HHS OFFICE OF WOMEN'S HEALTH

The HHS Office of Women's Health (OWH) is the Government's champion and focal point for women's health issues. It works to redress inequities in research, health care services, and education that have historically placed the health of women at risk. The OWH coordinates women's health efforts in HHS to eliminate disparities in health status and supports culturally sensitive educational programs that encourage women to take personal responsibility for their own health and wellness. An extraordinary program initiated by the OWH is the National Centers of Excellence in Women's Health (CoEs).

Developed in 1996, the CoE's offer a new model for university-based women's health care. Selected on a competitive basis, the current twenty CoEs throughout the country seek to improve the health of all women across the lifespan through the integration of comprehensive clinical health care, research, medical training, community outreach and public education, and medical school faculty leadership development. The CoEs are able to reach a more diverse population of women, including more women of color and women beyond their reproductive years. However, CoEs are vulnerable to pressures of obtaining adequate funding and having to compete for scarce resources. A CoE designation by the OWH is critical not only to patients

and surrounding communities but also to establishing foundation and other non-government funding. The CoEs must continue to exist and must have their funding assured if women are to be able to continue to access quality care through the life cycle. It is our understanding that the funding for CoEs is being cut in fiscal year 2007 and 2008. This must not happen.

In fiscal year 2006, OWH received a $1 million decrease in its budget, bringing it to $28 million, and in fiscal year 2007 under the continuing resolution it was flat funded at the fiscal year 2006 level. The President's proposed fiscal year 2008 budget decreases OWH funding by $1 million again, bringing the budget down to $27 million. We urge Congress to provide an increase of $2 million for the HHS OWH, to bring funding back up to the fiscal year 2005 level. This will allow OWH to continue and to sustain and expand the National Centers of Excellence in Women's Health.

AGENCY FOR HEALTHCARE AND RESEARCH QUALITY

The Agency for Healthcare Research and Quality (AHRQ) is the lead Public Health Service Agency focused on health care quality, including coordination of all Federal quality improvement efforts and health services research. AHRQ's work serves as a catalyst for change by promoting the results of research findings and incorporating those findings into improvements in the delivery and financing of health care. This important information provided by AHRQ is brought to the attention of policymakers, health care providers, and consumers who can make a difference in the quality of health care that women receive.

AHRQ has a valuable role in improving health care for women. Through AHRQ's research projects and findings, lives have been saved and underserved populations have been treated. For example, women treated in emergency rooms are less likely to receive life-saving medication for a heart attack. AHRQ funded the development of two software tools, now standard features on hospital electrocardiograph machines that have improved diagnostic accuracy and dramatically increased the timely use of "clot-dissolving" medications in women having heart attacks.

While AHRQ has made great strides in women's health research, the administration's budget for fiscal year 2008 could threaten such life-saving research. Even with the administration's proposed budget for fiscal year 2008, which includes an $11 million increase, this does not address the major shortfall which this Agency has been operating under for years. Furthermore, this budget increase is targeted for a specific program and does not help to address the lack of funding that the women's health office has experienced for years. If instead a budget of $319 million were enacted, AHRQ would be virtually flat funded for the fifth year in a row at fiscal year 2007 levels. Flat funding seriously jeopardizes the research and quality improvement programs that Congress demands or mandates from AHRQ.

We encourage Congress to fund AHRQ at $443 million for fiscal year 2008. This will ensure that adequate resources are available for high priority research, including women's health care, gender-based analyses, Medicare, and health disparities.

In conclusion, Mr. Chairman, we thank you and this committee for its strong record of support for medical and health services research and its unwavering commitment to the health of the Nation through its support of peer-reviewed research. We look forward to continuing to work with you to build a healthier future for all Americans.

PREPARED STATEMENT OF THE SPINA BIFIDA ASSOCIATION

SUMMARY

On behalf of the more than 70,000 individuals and their families who are affected by Spina Bifida—the Nation's most common, permanently disabling birth defect—the Spina Bifida Association (SBA) appreciates the opportunity to submit written testimony for the record regarding fiscal year 2008 funding for the National Spina Bifida Program and other related Spina Bifida initiatives.

SBA respectfully requests that the subcommittee provide the following allocations in fiscal year 2008 to help improve quality-of-life for people with Spina Bifida:

(1) $7 million to the National Spina Bifida Program at the National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention (CDC) to support existing program initiatives and allow for the further development of the National Spina Bifida Patient Registry; and

(2) $200,000 to the Agency for Healthcare and Quality to support its validation of quality patient treatment data measures for the National Spina Bifida Patient Registry.

As you may know, these funding requests are supported by a broad bipartisan group of Members of Congress, including congressional Spina Bifida caucus leaders, Representatives Bart Stupak, Chris Smith, Ileana Ros-Lehtinen, and Dan Burton, among many others.

COST OF SPINA BIFIDA

It is important to note that the lifetime costs associated with a typical case of Spina Bifida—including medical care, special education, therapy services, and loss of earnings—are as much as $1 million. The total societal cost of Spina Bifida is estimated to exceed $750 million per year, with just the Social Security Administration payments to individuals with Spina Bifida exceeding $82 million per year. Moreover, tens of millions of dollars are spent on medical care paid for by the Medicaid and Medicare Programs. Our Nation must do more to help reduce the emotional, financial, and physical toll of Spina Bifida on the individuals and families affected. Efforts to reduce and prevent suffering from Spina Bifida help to save money and save lives.

IMPROVING QUALITY-OF-LIFE THROUGH THE NATIONAL SPINA BIFIDA PROGRAM

SBA has worked with Members of Congress to ensure that our Nation is taking all the steps possible to prevent Spina Bifida and diminish suffering for those currently living with this condition. With appropriate, affordable, and high-quality medical, physical, and emotional care, most people born with Spina Bifida likely will have a normal or near normal life expectancy. The National Spina Bifida Program at the CDC works on two critical levels—to reduce and prevent Spina Bifida incidence and morbidity and to improve quality-of-life for those living with Spina Bifida. The program seeks to ensure that what is known by scientists is practiced and experienced by the 70,000 individuals and families affected by Spina Bifida. Moreover, the National Spina Bifida Program works to improve the outlook for a life challenged by this complicated birth defect—principally identifying valuable therapies from in-utero throughout the lifespan and making them available and accessible to those in need.

The National Spina Bifida Program serves as a national center for information and support to help ensure that individuals, families, and other caregivers, such as health professionals, have the most up-to-date information about effective interventions for the myriad primary and secondary conditions associated with Spina Bifida. Among many other activities, the program helps individuals with Spina Bifida and their families learn how to treat and prevent secondary health problems, such as bladder and bowel control difficulties, learning disabilities, depression, latex allergy, obesity, skin breakdown and social and sexual issues. Children with Spina Bifida often have learning disabilities and may have difficulty with paying attention, expressing or understanding language, and grasping reading and math. All of these problems can be treated or prevented, but only if those affected by Spina Bifida—and their caregivers—are properly educated and taught what they need to know to maintain the highest level of health and well-being possible. The National Spina Bifida Program's secondary prevention activities represent a tangible quality-of-life difference to the 70,000 individuals living with Spina Bifida with the goal being living well with Spina Bifida.

One way to increase research in Spina Bifida, improve quality and save precious resources is to establish a patient registry for Spina Bifida. Plans are underway to create the National Spina Bifida Patient Registry intended to determine both the best practices clinically and the cost effectiveness of treatment of Spina Bifida and the support the creation of quality measures to improve care overall. It is only through research towards improved care that we can truly save lives while realizing a significant cost savings.

In fiscal year 2007, SBA requested $6 million be allocated to the National Spina Bifida Program to support and expand the National Spina Bifida Program. Although the House version o the fiscal year 2007 LHHS appropriations bill provided the $6 million request; the fiscal year 2007 Continuing Appropriations Resolution provided $5.025 million (level funding) for this program. SBA understands and appreciates that the Congress and the Nation face difficult budgetary challenges. However, the progress being made by the National Spina Bifida Program must be sustained and expanded to ensure that people with Spina Bifida—over the course of their lifespan—have the support and access to quality care they need and deserve. To that end, SBA advocates that Congress allocate $7 million in fiscal year 2008 to the National Spina Bifida Program it can continue its current scope of the work and increase its folic acid awareness and Spina Bifida prevention efforts, further develop the National Spina Bifida Patient Registry, and sustain the National Spina Bifida

Clearinghouse and Resource Center. Increasing funding for the National Spina Bifida Program will help ensure that our Nation continues to mount a comprehensive effort to prevent and reduce suffering from Spina Bifida.

PREVENTING SPINA BIFIDA

While the exact cause of Spina Bifida is unknown, over the last decade, medical research has confirmed a link between a woman's folate level before pregnancy and the occurrence of Spina Bifida. Sixty-five million women are at-risk of having a child born with Spina Bifida and each year approximately 3,000 pregnancies in this country are affected by Spina Bifida, resulting in 1,500 births. The consumption of 400 micrograms of folic acid daily prior to becoming pregnant and throughout the first trimester of pregnancy can help reduce incidence of Spina Bifida up to 75 percent. There are few public health challenges that our Nation can tackle and conquer by three-fourths in such a straightforward fashion. However, we must still be concerned with addressing the 25 percent of Spina Bifida cases that cannot be prevented by folic acid consumption, as well as ensuring that all women of childbearing age—particularly those most at-risk for a Spina Bifida pregnancy—consume adequate amounts of folic acid prior to becoming pregnant.

The good news is that progress has been made in convincing women of the importance of folic acid consumption and the need to maintain diet rich in folic acid. Since 1968, the CDC has led the Nation in monitoring birth defects and developmental disabilities, linking these health outcomes with maternal and/or environmental factors that increase risk, and identifying effective means of reducing such risks. This public health success should be celebrated, but it is only half of the equation as approximately 3,000 pregnancies still are affected by this devastating birth defect. The Nation's public education campaign around folic acid consumption must be enhanced and broadened to reach segments of the population that have yet to heed this call—such an investment will help ensure that as many cases of Spina Bifida can be prevented as possible.

SBA works collaboratively with CDC, the March of Dimes and the National Council on Folic Acid to increase awareness of the benefits of folic acid, particular for those at elevated risk of having a baby with neural tube defects (those who have Spina Bifida themselves or those who have already conceived a baby with Spina Bifida). With additional funding in fiscal year 2008 these activities could be expanded to reach the broader population in need of these public health education, health promotion, and disease prevention messages. SBA advocates that Congress provide additional funding to CDC to allow for a particular public health education and awareness focus on at-risk populations (e.g. Hispanic-Latino communities) and health professionals who can help disseminate information about the importance of folic acid consumption among women of childbearing age.

In addition to a $7 million fiscal year 2008 allocation for the National Spina Bifida Program, SBA supports a fiscal year 2008 allocation of $137.6 million for the NCBDDD so the agency can enhance its programs and initiatives to prevent birth defects and developmental disabilities and promote health and wellness among people with disabilities.

IMPROVING HEALTH CARE FOR INDIVIDUALS WITH SPINA BIFIDA

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to improve the outcomes and quality of health care; reduce its costs; improve patient safety; decrease medical errors; and broaden access to essential health services. The work conducted by the agency is vital to the evaluation of new treatments in order to ensure that individuals and their families living with Spina Bifida continue to receive the high quality health care that they need and deserve—SBA urges the subcommittee to allocate $200,000 in fiscal year 2008 to AHRQ so the agency can continue to support and expand the development of a National Spina Bifida Patient Registry. This funding will allow AHRQ to direct and lead the effort to validate quality patient treatment data measures for the National Spina Bifida Patient Registry, which will help improve the quality of care provided throughout the Nation's system of Spina Bifida Clinics. In addition, SBA recommends that AHRQ receive an overall funding allocation of $350 million in fiscal year 2008 so that it can continue to conduct follow-up efforts to evaluate Spina Bifida treatments and sustain and expand its myriad initiatives to improve quality of health care throughout the Nation.

SUSTAIN AND SEIZE SPINA BIFIDA RESEARCH OPPORTUNITIES

Our Nation has benefited immensely from our past Federal investment in biomedical research at the National Institutes of Health (NIH). SBA joins with the rest of the public health and research community in advocating that NIH receive a 6.7

percent increase ($30.869 billion) in fiscal year 2008. This funding will support applied and basic biomedical, psychosocial, educational, and rehabilitative research to improve the understanding of the etiology, prevention, cure and treatment of Spina Bifida and its related conditions. In addition, SBA requests that the subcommittee include language in the report accompanying the fiscal year 2008 LHHS measure to:

—Urge the National Institute of Child Health and Human Development (NICHD)—expansion of its role—and support of—a more comprehensive Spina Bifida research portfolio;

—Commend the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for its interest in exploring issues related to the neurogenic bladder and to encourage the institute to forge ahead with its work in this important topic area; and

—Encourage the National Institute of Neurological Diseases and Stroke (NINDS) to continue and expand its research related to the treatment and management of hydrocephalus.

CONCLUSION

SBA stands ready to work with the subcommittee and other Members of Congress to advance policies that will reduce and prevent suffering from Spina Bifida. Again, we thank you for the opportunity to present our views on funding for programs that will improve the quality-of-life for the 70,000 Americans and their families living with Spina Bifida and stand ready to answer any questions you may have.

PREPARED STATEMENT OF THE AIDS INSTITUTE

The AIDS Institute, a national public policy research, advocacy, and education organization, is pleased to comment in support of critical HIV/AIDS and Hepatitis programs as part of the fiscal year 2008 Labor, Health, and Education and Related Services appropriation measure. We thank you for your consistent support of these programs over the years, and trust you will do your best to adequately fund them in the future in order to provide for, and protect the health of many Americans.

HIV/AIDS

HIV/AIDS remains one of the world's worst health pandemics in history. In the United States, according to the CDC, an estimated 1.2 million people have been infected, 40,000 new infections each occur each year, and 531,000 people have died.

Persons of minority races and ethnicities are disproportionately affected by HIV/AIDS. African Americans, who make up approximately 13 percent of the United States population, account for half of the HIV/AIDS cases. HIV/AIDS also disproportionately affects the poor, and about 70 percent of those infected rely on public health care financing.

The U.S. Government has played a leading role in fighting AIDS, both here and abroad. The vast majority of the discretionary programs supporting HIV/AIDS efforts domestically and a portion of our Nation's contribution to the global AIDS effort are funded through your subcommittee. The AIDS Institute, working in coalition with other AIDS organizations, have developed funding request numbers for each of these domestic and global AIDS programs. The AIDS Institute asks that you do your best to adequately fund these programs at the requested level.

We are keenly aware of budget constraints and competing interests for limited dollars. Unfortunately, despite the growing need, almost all domestic HIV/AIDS programs in recent years have experienced funding decreases, and in fiscal year 2007 all programs except one part of the Ryan White program were flat funded by the Joint Resolution.

This year, the President has proposed increases to three new domestic HIV/AIDS programs: $25 million for the AIDS Drug Assistance Program (ADAP); $6.3 million for early treatment Ryan White programs; and $63 million for HIV testing. The AIDS Institute applauds this and encourages the committee to fund them. The President has proposed a $6 million decrease for Ryan White AIDS Education and Treatment Centers (AETCs) and $30 million to implement the Early Diagnosis Grant Program. The AIDS Institute opposes these proposals and asks you to as well.

RYAN WHITE CARE ACT

[In millions of dollars]

	Amount
Fiscal year:	
2007	2,112
2008 President's Request	2,133
2008 Community Request	2,794

The centerpiece of the government's response to caring and treating low-income individuals with HIV/AIDS are those programs funded under the Ryan White CARE Act. CARE Act programs currently reach over 571,000 low-income, uninsured, and underinsured people each year. Providing care and treatment for those who have HIV/AIDS is not only compassionate, but is cost-effective in the long run, and serves as a tool in prevention of HIV/AIDS.

In fiscal year 2007, all programs except Part B base funding, were flat funded. This is on top of many years of funding decreases, except for minor increases for ADAP. It is now time to reverse these funding decreases and provide these vitally important programs with the community requested level of funding. Consider the following:

(1) Caseload levels are increasing. People are living longer due to lifesaving medications; there are 40,000 new infections each year; and the CDC has recommended routine voluntary HIV testing in all healthcare settings for everyone from the ages of 13 to 64. CDC estimates its proposed $63 million testing initiative will result in 31,000 new infections being diagnosed. All of this will necessitate the need for more CARE Act services and medications.

(2) The price of healthcare, including medications, is increasing and Medicaid benefits are being scaled-back at both the State and Federal levels.

(3) Funding under the recently reauthorized CARE Act is being distributed through a different formula which, without additional funding, will result in many cities and States losing funding. While some jurisdictions are experiencing increases, others are receiving decreases. Congress can help limit the drastic funding losses caused by formula changes by increasing the overall funding levels.

(4) ADAP funding shortfalls are causing States to place clients on waiting lists, limiting drug formularies, and increasing eligibility requirements. In January 2007, four States reported having waiting lists, totaling 558 people. In the State of South Carolina there are 540 people on its waiting list. Six other ADAPs reported other cost containment measures, including three with capped enrollment and others with formulary reductions, eligibility restrictions and limiting annual client expenditures. Since ADAP received no increase last year and a mere $2.2 million the year before, severe restrictions are anticipated in many States across the country.

(5) Two reports conclude there are a staggering number of people in the United States who are not receiving life-saving AIDS medications. The Institute of Medicine report "Public Financing and Delivery of HIV/AIDS Care, Securing the Legacy of Ryan White" concluded that 233,069 people in the United States who know their HIV status do not have continuous access to antiretrovirals. A study by the CDC titled, "Estimated number of HIV-infected persons eligible for and receiving antiretroviral therapy, 2003 United States", reached similar conclusions. According to the CDC, 212,000, or 44 percent of eligible people living with HIV/AIDS, aged 15–49 in the United States, are not receiving antiretroviral therapy.

Fiscal Year 2007 Administration Proposals.—While we appreciate the $25 million increase for ADAP proposed by the administration, it is far from the $233 million that is truly needed. As we seek to provide lifesaving medications to those abroad, we must ensure we are providing medications to our own in the United States. The administration has also proposed to increase funding for Part C (Title III) early treatment programs by $6.3 million. Again, while this increase is appreciated, it is far short of the increased need of $88 million for funding over 360 community-based primary health clinics and public health providers.

The President has proposed an unprecedented decrease of $6 million for AIDS Education and Treatment Centers (AETCs), which train more than 100,000 people per year. The new CARE Act now requires them to add trainings on Hepatitis B and C and culturally competent training for Native American and Alaska Native populations. To meet current needs, AETCs require a $15.3 million increase.

Funding increases for other Ryan White CARE Act programs are also urgently needed. While patient caseloads increase, over the past 5 years, Part A (Title I) has been cut by $15 million, over the past 4 years Part C (Title III) has been cut by $5 million, and Part D (Title IV) by $2 million.

Part A, which used to cover 51 urban areas most affected by HIV/AIDS, now includes 56 areas, but received no increased funds, meaning there will be less money to go around. They are requesting an increase of $236 million. Part B Base, which provides funds to the States received an increase of $70 million in fiscal year 2007, but still lacks the adequate levels and is requesting an increase of $57 million.

Title IV, which funds HIV care, psychosocial and other essential services to women, infants, children and youth, is requesting an increase of $46 million. The AIDS Institute also supports an increase of $6 million to Dental Reimbursement and Partnerships Programs.

The AIDS Institute supports continued and increased funding for the Minority AIDS Initiative (MAI). MAI funds services nationwide that address the disproportionate impact that HIV has on communities of color.

CENTERS FOR DISEASE CONTROL AND PREVENTION—HIV PREVENTION AND SURVEILLANCE

[In millions of dollars]

	Amount
Fiscal year:	
2007	652
2008 President's Request	745
2008 Community Request	1,049

While the number of new HIV infections in the United States has greatly decreased since the 1980's, there are still an estimated 40,000 new infections each year. As with other domestic AIDS programs, prevention funding is severely lagging and CDC's AIDS funding has declined in the last 5 years. It is not surprising given the budget decreases, the goal of reducing the infection rate in half by 2005 was not reached.

Fiscal Year 2008 Administration Proposals.—The AIDS Institute is in strong support of the President's proposed increase of $63 million to support HIV testing of more than 2 million people, mostly African-Americans, in 10 jurisdictions with the highest rates of new infections, as well as the incarcerated and injecting drug users. Knowledge of one's HIV status, particularly for high risk individuals, is an effective prevention tool. Approximately one-quarter of the over 1 million people living with HIV in the United States (252,000 to 312,000 persons) are unaware of their HIV status. This initiative should help prevent future infections and bring more people into lifesaving treatment and care. The AIDS Institute urges the committee to fund this extremely worthy program.

The administration is also proposing $30 million to implement the Early Diagnosis Grant Program, as called for by the new CARE Act. No State currently meets the grant conditions, which go beyond current CDC testing recommendations. We recommend that this funding be spent on other CDC HIV/AIDS prevention programs.

While The AIDS Institute supports increased testing programs, we do not support funding these efforts at the expense of prevention intervention programs, which are already under funded.

Efforts to improve prevention methods and weed out non-effective programs should be a constant undertaking and be guided by science and fact based decision-making. It is for these reasons The AIDS Institute opposes abstinence-only until marriage programs, for which the President requested a $28 million increase. While we support abstinence-based prevention programs as part of a comprehensive prevention message, there is no scientific proof that abstinence-only programs are effective. On the contrary, they reject proven prevention tools, such as condoms, and fail to address the needs of homosexuals, who can not marry, and who remain greatly impacted by HIV/AIDS.

NATIONAL INSTITUTES OF HEALTH—AIDS RESEARCH

[In millions of dollars]

	Amount
Fiscal year:	
2007	2,903
2008 President's Request	2,905
2008 Community Request	3,200

Through the NIH, research is conducted to understand the AIDS virus and its complicated mutations; discover new drug treatments; develop a vaccine and other prevention programs such as microbicides; and ultimately, a cure. Much of this work at the NIH is done in cooperation with private funding. The critically important work performed by the NIH not only benefits those in the United States, but the entire world.

This research has already helped in the development of many highly effective new drug treatments, prolonging the lives of millions of people. As neither a cure nor a vaccine exists, and patients continue to build resistance to existing medications, additional research must continue. We ask the committee to fund critical AIDS research at the community requested level of $3.2 billion.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Many persons infected with HIV also experience drug abuse and/or mental health problems, and require the programs funded by SAMHSA. Given the growing need for services, we are disappointed by proposed funding cuts at SAMHSA, including $47 million for the Center for Substance Abuse Treatment, $36 million for the Center for Substance Abuse Prevention, and $76 million for the Center for Mental Health Services. We ask the committee to reject these cuts, and adequately fund these programs

VIRAL HEPATITIS

Viral Hepatitis, whether A, B, or C, is an infectious disease that also deserve increased attention by the Federal Government. According to the CDC, there are an estimated 1.25 million Americans chronically infected with Hepatitis B, and 60,000 new infections each year. Although there is no cure, a vaccine is available, and a few treatment options are available. An estimated 4.1 million (1.6 percent) Americans have been infected with Hepatitis C, of whom 3.2 million are chronically infected. Currently, there is no vaccine and very few treatment options. It is believed that one-third of those infected with HIV are co-infected with Hepatitis C.

Given these numbers, we are disappointed the administration is calling for continued level funding of $17.5 million for Viral Hepatitis at the CDC. This amount is less than what was funded in fiscal year 2003 and falls short of the $50 million that is needed. These funds are needed to establish a program to lower the incidence of Hepatitis through education, outreach, and surveillance, and to support such initiatives as the CDC National Hepatitis C Prevention Strategy and the 2002 NIH Consensus Statement on the Management of Hepatitis C and accompanying recommendations.

The administration is proposing to cut the 317 Immunization Grant Program funds that serve as the major source in the public sector for at-risk adult immunizations. Instead of facing cuts, this cost-effective program should be significantly enhanced in order to protect people from Hepatitis A and B. We recommend funding the 317 Program at $802 million for fiscal year 2008 in order to fully realize the public health benefits of immunization.

The AIDS Institute asks that you give great weight to our testimony and remember it as you deliberate over the fiscal year 2008 appropriation bill. Should you have any questions or comments, feel free to contact Carl Schmid, Director of Federal Affairs, The AIDS Institute, 1705 DeSales Street, NW, Washington, DC 20036; (202) 462–3042; cschmid@theaidsinstitute.org. Thank you very much.

PREPARED STATEMENT OF THE HUMANE SOCIETY LEGISLATIVE FUND

The Humane Society Legislative Fund (HSLF) supports a strong commitment by the Federal Government to research, development, standardization, validation and acceptance of non-animal and other alternative test methods. We are also submitting our testimony on behalf of The Humane Society of the United States and The Procter & Gamble Company. Thank you for the opportunity to present testimony relevant for the fiscal year 2008 budget request for the National Institute of Environmental Health Sciences (NIEHS) for the fiscal year 2008 activities of the National Toxicology Program Center for the Evaluation of Alternative Toxicological Test Methods (NICEATM), the support center for the Interagency Coordinating Committee for the Validation of Alternative Test Methods (ICCVAM).

In 2000, the passage of the ICCVAM Authorization Act into Public Law 106–545, created a new paradigm for the field of toxicology. It requires Federal regulatory agencies to ensure that new and revised animal and alternative test methods be scientifically validated prior to recommending or requiring use by industry. An inter-

nationally agreed upon definition of validation is supported by the 15 Federal regulatory and research agencies that compose the ICCVAM, including the EPA. The definition is: "the process by which the reliability and relevance of a procedure are established for a specific use."

FUNCTION OF THE ICCVAM

The ICCVAM performs an invaluable function for regulatory agencies, industry, public health and animal protection organizations by assessing the validation of new, revised and alternative toxicological test methods that have interagency application. After appropriate independent peer review of the test method, the ICCVAM recommends the test to the Federal regulatory agencies that regulate the particular endpoint the test measures. In turn, the Federal agencies maintain their authority to incorporate the validated test methods as appropriate for the agencies' regulatory mandates. This streamlined approach to assessment of validation of new, revised and alternative test methods has reduced the regulator burden of individual agencies, provided a "one-stop shop" for industry, animal protection, public health and environmental advocates for consideration of methods and set uniform criteria for what constitutes a validated test methods. In addition, from the perspective of animal protection advocates, ICCVAM can serve to appropriately assess test methods that can refine, reduce and replace the use of animals in toxicological testing. This function will provide credibility to the argument that scientifically validated alternative test methods, which refine, reduce or replace animals, should be expeditiously integrated into Federal toxicological regulations, requirements and recommendations.

HISTORY OF THE ICCVAM

The ICCVAM is currently composed of representatives from the relevant Federal regulatory and research agencies. It was created from an initial mandate in the NIH Revitalization Act of 1993 for NIEHS to "(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use." In 1994, NIEHS established the ad hoc ICCVAM to write a report that would recommend criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to Federal agencies and the scientific community. Through a series of public meetings, interested stakeholders and agency representatives from all 14 regulatory and research agencies, developed the NIH Publication No. 97–3981, "Validation and Regulatory Acceptance of Toxicological Test Methods." This report, and subsequent revisions, has become the sound science guide for consideration of new, revised and alternative test methods by the Federal agencies and interested stakeholders.

After publication of the report, the ad hoc ICCVAM moved to standing status under the NIEHS' NICEATM. Representatives from Federal regulatory and research agencies and their programs have continued to meet, with advice from the NICEATM's Advisory Committee and independent peer review committees, to assess the validation of new, revised and alternative toxicological methods. Since then, several methods have undergone rigorous assessment and are deemed scientifically valid and acceptable. In addition, the ICCVAM is working to streamline assessment of methods from the European Union (EU) that have already been validated for use within the EU. The open public comment process, input by interested stakeholders and the continued commitment by the Federal agencies has led to ICCVAM's success. It has resulted in a more coordinated review process for rigorous scientific assessment of the validation of new, revised and alternative test methods.

REQUEST FOR COMMITTEE REPORT LANGUAGE

In 2006, the NICEATM/ICCVAM at the request of the U.S. Congress began a process of developing a 5-year roadmap for assertively setting goals to prioritize ending the use of antiquated animal tests for specific endpoints. The HSLF and other national animal protection organizations provided extensive comments on the process and priorities for the roadmap.

While the stream of methods forwarded to the ICCVAM for assessment has remained relatively steady, it is imperative that the ICCVAM take a more proactive role in isolating areas where new methods development is on the verge of replacing animal tests. These areas should form a collective call by the Federal agencies that compose ICCVAM to fund any necessary additional research, development, validation and validation assessment that is required to eliminate the animal methods. We also strongly urge the NICEATM/ICCVAM to closely coordinate research, development and validation efforts with its European counterpart, the European Centre

for the Validation of Alternative Methods (ECVAM) to ensure the best use of available funds and sound science. This coordination should also reflect a willingness by the Federal agencies comprising ICCVAM to more readily accept validated test methods proposed by the ECVAM to ensure industry has a uniform approach to worldwide chemical safety evaluation.

We respectfully request the subcommittee consider the following report language for the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations bill to ensure that the 5-year roadmap is completed in a timely manner:

"The committee commends the National Interagency Center for the Evaluation of Alternative Methods/Interagency Coordinating Committee on the Validation of Alternative Methods (NICEATM/ICCVAM) for commencing a process for developing a 5-year plan to research, develop, translate and validate new and revised non-animal and other alternative assays for integration of relevant and reliable methods into the Federal agency testing programs. The 5-year plan shall be used to prioritize areas, including tiered testing and evaluation frameworks, which have the potential to most significantly and rapidly reduce, refine or replace laboratory animal methods. The committee directs a transparent, public process for developing this plan and recommends the plan be presented to the committee by November 15, 2007. Funding for completing the 5-year plan shall not reduce the NICEATM/ICCVAM appropriation."

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

On behalf of The Humane Society of the United States (SUS) and our more than 10 million supporters nationwide, we appreciate the opportunity to provide testimony on our top funding priority for the Labor, Health and Human Services, Education and Related Agencies Subcommittee in fiscal year 2008. We are also submitting our testimony on behalf of The Humane Society Legislative Fund (HSLF). Thank you for the opportunity to present testimony relevant for the fiscal year 2008 budget request.

BREEDING OF CHIMPANZEES FOR RESEARCH

The HSUS requests that no Federal funding be appropriated for breeding of chimpanzees for research, or for research that requires breeding of chimpanzees, for the following reasons:

—The National Center for Research Resources has a publicly-declared moratorium (extended until December 2007) on breeding chimpanzees which prohibits breeding of federally owned or supported chimpanzees or NIH funding of projects that require chimpanzee breeding (NCRR written communication, February 28, 2006).

—The United States currently has a surplus of chimpanzees available for use in research due to overzealous breeding for HIV research and subsequent findings that they are a poor HIV model.[1]

—The cost of maintaining chimpanzees in laboratories is exorbitant, totaling between $4.7 and $9.3 million each year for the current population of approximately 800 federally owned or supported chimpanzees ($15–39 per day per chimpanzee; $500,000 per chimpanzee's 50-year lifetime). Breeding of additional chimpanzees into laboratories will only perpetuate a number of burdens on the government—up to 60 years per chimpanzee born into the system.

—Expansion of the chimpanzee population in laboratories only creates more concerns than presently exist about their quality of care.

—Use of chimpanzees in research raises strong public concerns.

BACKGROUND AND HISTORY

Beginning in 1995, the National Research Council (NRC) confirmed a chimpanzee surplus and recommended a moratorium on breeding of federally owned or supported chimpanzees,[1] who now number approximately 800 of the 1,300 total chimpanzees available for research in the United States. According to a National Research Resources Advisory Council September 15, 2005 meeting, the National Center for Research Resources (NCRR) of NIH extended the moratorium until December 2007 because of high costs of chimpanzee care, lack of existing colony information, and failure of chimpanzees as a model, such as for HIV. Further, it has also been

[1] NRC (National Research Council) (1997) Chimpanzees in research: strategies for their ethical care, management and use. National Academies Press: Washington, D.C.

noted that "a huge number" of chimpanzees were not being used in active research protocols and were therefore "just sitting there."[2] NCRR will be making a decision this year as to whether the breeding moratorium should continue. There is no justification for breeding of additional chimpanzees for research; therefore The HSUS hopes that NCRR will continue the moratorium into the future. Importantly, however, lack of Federal funding for breeding will ensure that no breeding of federally owned or supported chimpanzees for research will occur in fiscal year 2008.

Furthermore, despite the moratorium on breeding, there are cases in which the moratorium is not being obeyed, further prompting the need for congressional action.

DEVIATIONS FROM THE MORATORIUM

Despite the NCRR breeding moratorium, which prohibits breeding of federally owned or supported chimpanzees or NIH funding of projects that require chimpanzee breeding (NCRR written communication, February 28, 2006), chimpanzee breeding is still being funded by NIH. For example, the National Institute of Allergy and Infectious Diseases maintains a contract with New Iberia Research Center in Louisiana to provide 10 to 12 infant chimpanzees annually for research projects. The 10-year contract entitled "Leasing of chimpanzees for the conduct of research" has been allotted over $22 million, with $3.9 million awarded since its inception in September 2002.

CONCERNS REGARDING CHIMPANZEE CARE IN LABORATORIES

Inspections conducted by the U.S. Department of Agriculture demonstrate that basic chimpanzee housing requirements are often not being met. Inspection reports for three federally funded chimpanzee facilities reported housing of chimpanzees in less than minimal space requirements, inadequate environmental enhancement for primates, and/or general disrepair of facilities. Problems at three major chimpanzee research facilities add further argument against the breeding of even more chimpanzees.

CHIMPANZEES HAVE OFTEN BEEN A POOR MODEL FOR HUMAN HEALTH RESEARCH

The scientific community recognizes that chimpanzees are poor models for HIV because chimpanzees do not develop AIDS. Similarly, though chimpanzees do not model the course of the human Hepatitis C virus, they continue to be widely used for this research. According to the chimpanzee genome, some of the greatest differences between chimpanzees and humans relate to the immune system,[3] calling into question the validity of infectious disease research using chimpanzees.

ETHICAL AND PUBLIC CONCERNS ABOUT CHIMPANZEE RESEARCH

Chimpanzee research raises serious ethical issues, particularly because of their extremely close similarities to humans in terms of intelligence and emotions. Americans are clearly concerned about these issues: 90 percent believe it is unacceptable to confine chimpanzees individually in government-approved cages; 71 percent believe that chimpanzees who have been in the laboratory for over 10 years should be sent to sanctuary for retirement (chimpanzees can live to be 60 years old);[4] and 54 percent believe that it is unacceptable for chimpanzees to "undergo research which causes them to suffer for human benefit."[5]

We respectfully request the following committee bill or report language: "The committee directs that no funds provided in this act be used to support the breeding of chimpanzees for research or to support research that requires breeding of chimpanzees."

We appreciate the opportunity to share our views for the Labor, Health and Human Services, Education and Related Agencies Appropriations Act for fiscal year 2008. We hope the committee will be able to accommodate this modest request that will save the government a substantial sum of money, benefit chimpanzees, and allay some concerns of the public at large. Thank you for your consideration.

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[2] Cohen, J. (2007) Biomedical Research: The Endangered Lab Chimp. Science. 315:450–452.

[3] The Chimpanzee Sequencing and Analysis Consortium/Mikkelsen, TS, et al., (1 September 2005) Initial sequence of the chimpanzee genome and comparison with the human genome, Nature 437, 69–87.

[4] 2006 poll conducted by the Humane Research Council for Project Release & Restitution for Chimpanzees in laboratories.

[5] 2001 poll conducted by Zogby International for the Chimpanzee Collaboratory.

PREPARED STATEMENT OF THE TRUST FOR AMERICA'S HEALTH

Trust for America's Health (TFAH), a national non-profit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority, is pleased to provide the subcommittee with the following testimony. In order to provide the resources to build a 21st century public health system that gives all communities a strong defense against today's health threats, TFAH identifies a number of programs essential to achieving this goal.

BOLSTERING THE NATION'S ABILITY TO DETECT AND CONTROL INFECTIOUS DISEASES SUCH AS PANDEMIC INFLUENZA

Pandemic Preparedness ($1.542 billion, $350 million over the President's request).—In November 2005, the President requested a total of $7.1 billion to respond to an influenza pandemic. To date, Congress has appropriated just over $6 billion of that request. We were pleased that the fiscal year 2008 budget proposal would honor that commitment with an additional $1.2 billion for pandemic preparedness activities, including making improvements in vaccine technology and manufacturing; stockpiling antivirals, diagnostics and medical supplies; developing contingency planning; enhancing risk communication; and enhancing global and domestic health surveillance.

The emergency supplemental passed by the House and Senate contains $625 million of the $870 in one-time pandemic flu funding recommended in the President's fiscal year 2008 budget proposal, primarily for purchasing antiviral medications and medical supplies. In addition, there is a need for an ongoing annual investment, particularly at the CDC, to ensure that preparedness efforts are sustained and effective. These activities require funding beyond the life cycle of the supplemental appropriations vehicles. TFAH supports the remaining $245 million in one-time pandemic flu funding not included in the emergency supplemental; and $322 million for ongoing pandemic preparedness activities in the Department of Health and Human Services, which includes $158 million at the CDC.

Further, we support $350 million in annual recurring funding for State and local pandemic preparedness activities. States would use this funding to exercise response plans, make revisions and updates to plans, and build medical surge capacity. In the midst of a pandemic, it could be difficult to shift resources from one part of the country to another, so every jurisdiction must be prepared. In fiscal year 2006, Congress provided $600 million in one-time funding for State and local pandemic preparedness, but this funding will expire at the end of fiscal year 2007, and no such funds have been requested for fiscal year 2008.

GLOBAL DISEASE DETECTION

Global surveillance for infectious disease outbreaks is also critical. The CDC's Global Disease Detection initiative aims to recognize infectious disease outbreaks faster, improve the ability to control and prevent outbreaks, and detect emerging microbial threats. In fiscal year 2006, Global Disease Detection centers across the globe help countries investigate numerous outbreaks, including avian influenza, hemorrhagic fever, meningitis, cholera and unexplained sudden death. TFAH recommends funding the Global Disease Detection initiative at $45 million, which is an increase of $12.5 million over the President's requested level.

UPGRADING STATE AND LOCAL BIOTERRORISM PREPAREDNESS

The terrorism events of 2001 and the subsequent anthrax and ricin attacks illustrated the need for a responsive public health system and demonstrated that the existing structure has enormous gaps. The Federal Government took unprecedented first steps towards improved preparedness by providing funding to State and local public health departments to better respond to terrorism. These funds have allowed States and localities to conduct needs assessments, develop terrorism response plans and training activities, strengthen epidemiology and surveillance capabilities, and upgrade lab capacity and communications systems. Yet a great deal of work remains to be done.

The December 2006 TFAH Report, Ready or Not?—Protecting the Public's Health from Diseases, Disasters and Bioterrorism, examined 10 key indicators to assess areas of both improvement and ongoing vulnerability in our Nation's effort to protect against bioterrorism. The report found that 5 years after the September 11th and anthrax tragedies, emergency health preparedness is still inadequate in America. To address these shortcomings, we recommend the following:

—*State and Local Capacity ($919 million, $221 million over the President's request)*.—CDC distributes grants to 50 States and four metropolitan areas for public health infrastructure upgrades to respond to acts of terrorism or infectious disease outbreaks. In fiscal year 2008, the President proposes to cut funding for this program by $125.4 million, a nearly 25 percent cut since fiscal year 2005. This would force health departments to cut staff dedicated to preparedness; laboratories would lose trained personnel and the ability to purchase new technology; and disease surveillance and response efforts would be hindered.

—*Hospital Preparedness Grants ($650 million, $236 million over the President's request)*.—The primary focus of the National Bioterrorism Hospital Preparedness Program is to improve the capacity of the Nation's hospitals and other supporting healthcare entities to respond to bioterrorist attacks, infectious disease epidemics, and other large-scale emergencies by enabling hospitals, EMS, and health centers to plan a coordinated response. The President proposes to cut funding for hospital preparedness grants by $60 million in fiscal year 2008.

CHRONIC DISEASES CONTINUE TO TAKE A TOLL

Chronic diseases account for 70 percent of all deaths in the United States and untold disability and suffering. In fact, five of our top six causes of death—heart disease, cancer, stroke, chronic obstructive pulmonary disease, and diabetes—are chronic diseases. The treatment of chronic diseases consumes three-quarters of the $1.7 trillion the United States spends annually on health care.

Smoking, for example, is the single most preventable cause of death and disease in the United States, causing 440,000 premature deaths annually. And increasingly, obesity is a significant risk factor in such major chronic disease killers as heart disease, stroke and diabetes.

FIGHTING THE EMERGING OBESITY EPIDEMIC

The number of overweight and obese individuals has reached epidemic proportions in the United States with 64.5 percent of the adult population being diagnosed as obese (119 million). In the United States, the percentage of young people who are overweight has tripled in the last 20 years. Despite this troubling trend, the President's proposed fiscal year 2008 budget provides no increases for existing obesity-related programs.

—*Division of Nutrition and Physical Activity (DNPA) ($65 million, $23.6 million over the President's request)*.—CDC's grant funding allows State health departments to develop a nutrition and physical activity infrastructure; develop a primary prevention plan for nutrition and physical activity to coordinate and link partners in and out of State government; identify and assess data sources to monitor the burden of obesity; and evaluate the progress and impact of the State plans and intervention projects. Currently, only 28 States receive DNPA grants, 7 at basic implementation, and 21 at capacity-building levels. An increase to $65 million would fund all 50 States and provide $5 million for the National Fresh Fruit and Vegetable Nutrition Program.

—*School Health Programs ($75.8 million, $20 million over the President's request)*.—CDC's grant funding assists States in improving the health of children through a school level program that engages families and communities and develops health education, physical education, school meals, health services, healthy school environments, and staff health promotion. Currently, school health programs are funded in only 23 States. The recommended increase of $20 million would expand the number of States to 40.

—*STEPS to a Healthier United States ($43.6 million, $17.3 million over the President's request)*.—STEPS grants support communities, cities and tribal entities to implement health promotion programs and community initiatives. STEPS works with health care and insurance systems to combat obesity in over 40 communities, cities, and tribal entities. The President's budget proposes to cut funding for STEPS by $17.2 million.

—*Adolescent Health Promotion Initiative ($17.3 million, equal to the President's request)*.—This new initiative aims to help schools encourage regular physical activity, healthy eating, and injury prevention. Schools will have access to the Department of Health and Human Services' (HHS) School Health Index, which they can use to make self-assessments and develop action plans. Schools can apply for one of CDC's approximately 3,600 School Culture of Wellness Grants to help implement their action plans.

IMMUNIZATION

Immunization through vaccination of children and adults is proven effective as a means to prevent some of the most important infectious diseases. Immunization should remain a high public health priority, and, to ensure that its benefits are fully realized, the Federal Government should increase its commitment to these life saving public health interventions.

National Immunization Program ($802.5 million, $257.5 million over the President's request).—This program provides for childhood and adult operations/infrastructure grants, the purchase of childhood and adult vaccines, and related prevention activities. Each day, 11,000 babies are born in the United States who will need up to 28 vaccinations before they are 2 years old. Even so, nearly 1 million 2-year-olds do not receive all the recommended doses. Every dollar spent on vaccines saves an extraordinary amount downstream: $27 with DTaP (Diphtheria, Tetanus and Pertussis), $26 with MMR (Measles, Mumps and Rubella), and $15 with Hepatitis B. However, the vaccine cost to fully immunize one child has risen in the past 6 years alone from $186 to $570.

Currently, the CDC provides grants to all 50 States, six cities and eight current or former territories to carry out immunization activities. TFAH recommends providing $802.5 million for the National Immunization Program at CDC. This includes $720 million for the 317 Immunization Program ($245 million for State operations/infrastructure grants, and $475 million for the purchase of childhood vaccines); and $82.543 million for program operations ($4.887 million for vaccine tracking and $77.656 million for prevention activities).

SUPPORTING OTHER PUBLIC HEALTH TOOLS

TFAH supports additional funding for disease detection and surveillance activities which are vital to stemming an infectious disease outbreak, tracking rises in chronic diseases, or responding to a bioterror event.

Federal and State public health laboratory capabilities ($47 million, $20 million over the President's request).—Additional funds are needed to upgrade facilities and equipment and to bolster the workforce. This funding is essential if scientists are to have the capability to conduct clinical testing for potentially dangerous chemicals, such as ricin, cyanide, nerve agents, and pesticide exposure or test for novel strains of influenza. Of the suggested $20 million increase, TFAH recommends that $10 million be used to enhance State public health laboratory biomonitoring capabilities, with $10 million used to bolster the intramural CDC lab program.

Environment and Health Outcome Tracking ($50 million, $26 million over the President's request).—The program links environmental and health data in order to identify problems and effective solutions to reduce the burden of chronic disease. Additional funds would enable the program to fund additional States and local health departments, or order to systematically and comprehensively track respiratory diseases, developmental disorders, birth defects, cancers and environmental exposures to help scientists find answers about causes and cures of these diseases. Further, the program plans to issue a major national report on the environment and health in 2008, and expects to make operational its Web-based environmental tracking system and roll out a report reflecting data from funded States within 2 years.

Mr. Chairman, thank you again for the opportunity to submit testimony on the urgent need to enhance Federal funding for core public health programs.

PREPARED STATEMENT OF THE UNITED TRIBES TECHNICAL COLLEGE

For 38 years, United Tribes Technical College (UTTC) has been providing postsecondary vocational education, job training and family services to Indian students from throughout the Nation. We are governed by the five tribes located wholly or in part in North Dakota. We are an educational institution that consistently has excellent results, placing Indian people in good jobs and reducing welfare rolls. The Perkins funds constitute about half of our operating budget. We do not have a tax base or State appropriated funds on which to rely.

The request of the United Tribes Technical College Board for the section 117 of the Perkins Act, Tribally Controlled Postsecondary Career and Technical Institutions Program is:

—$8.5 million or $1.1 million above the administration's request and the fiscal year 2007 enacted level. Funding under section 117 of the Perkins Act has in recent years it has been distributed on a formula basis.

UTTC Performance Indicators. UTTC has:

—An 87 percent retention rate,

—A placement rate of 95 percent (job placement and going on to 4-year institutions),

—A projected return on Federal investment of 1 to 20 (2005 study comparing the projected earnings generated over a 28-year period of UTTC Associate of Applied Science and Bachelor degree graduates of June 2005 with the cost of educating them.), and

—The highest level of accreditation. The North Central Association of Colleges and Schools has accredited UTTC again in 2001 for the longest period of time allowable—10 years or until 2011—and with no stipulations. We are also the only tribal college accredited to offer on-line associate degrees.

The Demand for our Services is Growing and we are Serving More Students.—For the 2006–2007 school year we enrolled 1,018 students (an unduplicated count). The majority of our students are from the Great Plains States, an area that, according to the 2003 BIA Labor Force Report, has an Indian reservation jobless rate of 76 percent. UTTC is proud that we have an annual placement rate of 95 percent.

In addition, we have served 254 students during school year 2005–2006 in our Theodore Jamerson Elementary school, and 350 children, birth to 5, were served in the child developments centers for 2005–2006.

UTTC Course Offerings and Partnerships With Other Educational Institutions.—We offer 15 vocational/technical programs and award a total of 24 2-year degree and 1-year certificates. We are accredited by the North Central Association of Colleges and Schools.

Licensed Practical Nursing.—This is our program with the highest number of students. We have an agreement with the University of North Dakota system that allows our students to transfer their credits to these 4-year nursing programs.

Medical Transcription and Coding Certificate Program.—Our newest academic endeavor is our Medical Transcription and Coding Certificate Program which is offered through the college's Exact Med Training program and supported by Department of Labor funds.

Tribal Environmental Science.—Our Tribal Environmental Science program is being offered through a National Science Foundation Tribal College and Universities Program grant. The 5-year project supports UTTC in implementing a program that leads to a 2-year Associate of Applied Science degree in Tribal Environmental Science.

Injury Prevention.—Through our Injury Prevention Program we are addressing the injury death rate among Indians, which is 2.8 times that of the U.S. population We received assistance through Indian Health Service to offer the only degree-granting Injury Prevention program in the Nation. Injuries are the number one cause of mortality among Native people for ages 1–44 and the third for overall death rates.

Online Education.—We are working to bridge the "digital divide" by providing web-based education and Interactive Video Network courses from our North Dakota campus to American Indians residing at other remote sites and as well as to students on our campus. This spring semester 2007, we have 61 students registered in online courses, of which 48 students are studying exclusively online (approximately 34 FTE) and 13 are campus-based students. These online students come from the following States: Colorado, Georgia, Hawaii, Idaho, Kentucky, Nebraska, North Dakota, Oklahoma, Oregon, South Dakota, West Virginia, and Wisconsin.

Online courses provide the scheduling flexibility students need, especially those students with young children. We offer online full degree programs in the areas of Early Childhood Education, Injury Prevention, Health Information Technology, Nutrition and Food Service and Elementary Education. All totaled, 156 online course seats are filled by students this semester. Over 50 courses are currently offered online, including those in the Medical Transcription and Coding program and those offered through an MOU with Owens Valley Career Development Center.

Our newest online course is suicidology—the study of suicide, its causes, and its prevention and of the behavior of those to threaten or attempt suicide—and we expect that with additional outreach that there will be a significant demand for this course. We also offer a training program through the Environmental Protection Agency to train environmental professionals in Indian Country. The Indian Country Environmental Hazard Assessment Program is a training course designed to help mitigate environmental hazards in reservation communities.

United Tribes Technical College is accredited by the Higher Learning Commission of the North Central Association of Colleges and Schools to provide associate degrees online. This approval is required in order for us to offer Federal financial aid to students enrolled in these online courses. We are the only tribal college accredited to offer associate degrees online.

Computer Information and Technology.—The Computer Support Technician program is at maximum student capacity because of limitations on learning resources

for computer instruction. In order to keep up with student demand and the latest technology, we will need more classrooms, equipment and instructors. Our program includes all of the Microsoft Systems certifications that translate into higher income earning potential for graduates.

Nutrition and Food Services.—UTTC will meet the challenge of fighting diabetes in Indian Country through education. Indians and Alaska Natives have a disproportionately high rate of type 2 diabetes, and have a diabetes mortality rate that is three times higher than the general U.S. population. The increase in diabetes among Indians and Alaska Natives is most prevalent among young adults aged 25–34, with a 160 percent increase from 1990–2004. Diabetes mortality is 3.1 times higher in the Indian/Alaska Native population than in the general U.S. population (Source: fiscal year 2008 Indian Health Service Budget Justification).

As a 1994 Tribal Land Grant institution, we offer a Nutrition and Food Services Associate of Applied Science degree in an effort to increase the number of Indians with expertise in nutrition and dietetics. Currently, there are only a handful of Indian professionals in the country with training in these areas. Among our offerings is a Nutrition and Food Services degree with a strong emphasis on diabetes education, traditional food preparation, and food safety.

We have also established the United Tribes Diabetes Education Center to assist local tribal communities and our students and staff in decreasing the prevalence of diabetes by providing diabetes educational programs, materials and training. We publish and make available tribal food guides to our on-campus community and to tribes.

Business Management/Tribal Management.—Another of our newer programs is business and tribal management designed to help tribal leaders be more effective administrators. We continue to refine our curricula for this program.

Job Training and Economic Development.—UTTC is a designated Minority Business Development Center serving Montana, South Dakota and North Dakota. We also administer a Workforce Investment Act program and an internship program with private employers in the region.

Economic Development Administration funding was made available to open a "University Center." The Center is used to help create economic development opportunities in tribal communities. While most States have such centers, this center is the first-ever tribal center.

Upcoming Endeavors.—We continue to seek a Memorandum of Understanding with the BIA's Police Academy in New Mexico that would allow our criminal justice program to be recognized for the purpose of BIA and Tribal police certification, so that Tribal members from the BIA regions in the Northern Plains, Northwest, Rocky Mountain, and Midwest areas would not have to travel so far from their families to receive training. Our criminal justice program is accredited and recognized as meeting the requirements of most police departments in our region. We also anticipate providing similar training for correctional officers, a vital need in Indian country.

Additionally, we are interested in developing training programs that would assist the BIA in the area of provision of trust services. We have several technology disciplines and instructors that are capable of providing those kinds of services with minimum of additional training.

Department of Education Study Documents our Facility/Housing Needs.—The 1998 Carl Perkins Vocational Education and Applied Technology Act required the Department of Education to study the facilities, housing and training needs of our institution. That report was published in November 2000 ("Assessment of Training and Housing Needs within Tribally Controlled Postsecondary Vocational Institutions, November 2000, American Institute of Research"). The report identified the need for $17 million for the renovation of existing housing and instructional buildings and $30 million for the construction of housing and instructional facilities. These figures do not take into account the costs of inflation since the study was completed in 2000.

We continue to identify housing as our greatest need. Some families must wait from 1 to 3 years for admittance due to lack of available housing. Since 2005 we have assisted 311 families with off campus housing, a very expensive proposition. In order to accommodate the enrollment increase, UTTC partners with local renters and two county housing authorities (Burleigh, Morton).

UTTC has worked hard to combine sources of funding for desperately needed new facilities—within the past few years we have built a 86-bed single-student dormitory on campus, a family student apartment complex, and a Wellness Center. Sources of funds included the U.S. Department of Education, the U.S. Department of Agriculture, the American Indian College Fund, the Shakopee-Mdewakanton Sioux Tribe, among others. We still have a critical housing shortage and more housing

must be built to accommodate those on the waiting list and to meet expected increased enrollment. We also have housing which needs renovation to meet safety codes.

UTTC has acquired an additional 132 acres of land. We have also developed a master facility plan. This plan includes the development of a new campus on which would be single-student and family housing, classrooms, recreational facilities, offices and related infrastructure. A new campus will address our need for expanded facilities to accommodate our growing student population. It will also enable us to effectively address safety code requirements, Americans with Disabilities Act requirements, and to become more efficient in facility management.

Thank you for your consideration of our request. We cannot survive without the basic core vocational/technical education funds that come through the Department of Education. They are essential to the operation of our campus and to the welfare of Indian people throughout the Great Plains region and beyond.

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