

CANCER RESEARCH AND PREVENTION

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TUESDAY, JUNE 4, 2002

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:35 a.m., in room SH-216, Hart Senate Office Building, Hon. Tom Harkin (chairman) presiding.
Present: Senators Harkin, Murray, Specter, and Cochran.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Good morning everyone. The Subcommittee of Labor, Health and Human Services, and Education of the Appropriations Committee will come to order.

Thirty years ago, in 1971 President Nixon declared war on cancer. Today we are going to take a progress report on our Nation's battle against this killer disease.

We have good news. We have made great strides since then. Childhood leukemia is no longer the dreadful killer it once was, and many of the side effects of chemotherapy are less devastating than they used to be.

In 1998, we had a march on cancer here in Washington. I assume many of you in this room were at that march. It was a very inspiring event. I said then that we were not putting anywhere near the funds needed into cancer research. That day we set out to correct a problem. Today, 5 years later, I am proud to report that with this year's appropriation and with the support of Secretary Thompson and the administration, we will have doubled funding for cancer research in 5 years. That is an accomplishment you can all be proud of.

But now is not the time to take a victory lap. So far, we have taken the beach, we have gathered troops, and set the stage for the next part of this battle, for it is only through a three-pronged offensive—research, treatment, and prevention—that we will win this.

Cancer claims the lives of over 500,000 Americans each year, and another 1.2 million are diagnosed annually. That is 1.2 million of our brothers and sisters, our mothers, fathers, sons, and daughters, 1.2 million who this year will hear the three scariest words in the English language: "You have cancer."

All of us in this room today have had our lives touched by this killer. I lost my only two sisters and two of my three brothers to cancer. So, it has hit the Harkin family pretty darned hard.

Today, as I said, we will take a progress report on how we are doing in preventing other families from being hit so hard. We are fortunate to have a truly distinguished panel of witnesses to help us do that. We will hear from a panel of people on the front lines of science, prevention, and patient experience. I look forward to each of their statements.

I want to particularly welcome Michael Bruene from West Des Moines. Mr. Bruene, I have heard a lot about the work you are doing to raise awareness about cancer and I certainly thank you for making the trip with your wife here this morning.

I also want to thank you in the audience. We have a great crowd here this morning who have come from great distances to be here. You are the ones who have put a human face to this effort. You are the ones who deal with cancer every day and you are the ones who will march to victory against cancer. It is your hard work on the front lines and your dedication to stopping this epidemic that will lead us to victory.

And we will win. We will come back next year and the next year and the next year until cancer is a disease of only historical relevance.

I also want to thank a long-time friend and trusted advisor and fellow Iowan Dan Smith. As the founder and Chair of the One Voice Against Cancer Coalition, he is making a tremendous contribution to this great cause.

Senator Specter is unavoidably detained at the White House for a meeting, and he will be here shortly.

STATEMENT OF HON. TOMMY THOMPSON, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator HARKIN. It is my great honor and distinct pleasure to welcome once again to this subcommittee a great friend, a good neighbor.

Secretary Thompson is the 19th Secretary of Health and Human Services. He has had a long and distinguished career as a public servant, starting first in 1966 as a representative in Wisconsin's State Assembly. Of course, from 1987 to 2000, he was the Governor of the State of Wisconsin and is now our great Secretary of Health and Human Services.

Secretary Thompson, again, I thank you for your leadership, especially in this effort on cancer. And I know how deeply you feel about it, and I know that you have been working very closely with those at NIH to again make sure that we stayed focused and do everything that we possibly can. So, I welcome you again to the subcommittee. Your statement will be made a part of the record in its entirety. I know you have to leave right after you make your statement, so please proceed as you so desire.

Secretary THOMPSON. Thank you very much, Chairman Harkin. I just would like to say thank you. Thank you, Senator, for what you are doing, your leadership, your passion on this subject. It comes through loud and clear, and I just want to say publicly thank you for your leadership and that of Senator Arlen Specter. The two of you make a dynamic duo in this fight that we are waging, and I am confident with your leadership, we are going to win and we are going to overcome this insidious disease.

I want to thank you first for inviting me to come before you today to discuss the progress that we are making in our fight against cancer, as well as President Bush's bold proposals to make sure that we win this battle so essential to the health of our country.

I also want to thank Steve Case of AOL Time Warner. I understand Steve's brother is waging his own battle against brain cancer, and I want to thank them for their courage, as well as their leadership in forming with Dan the Accelerate Brain Cancer Cure Foundation. It is a wonderful effort, like many other efforts of many wonderful people in this room who are making the tremendous effort to fight this wonderful fight against this insidious disease.

Mr. Chairman, in recent years, we have made stunning progress in the war against cancer, some of which I will detail in a moment. But the challenges remain real, as well as very painful. Today I am here to report that the President and I join with you and Senator Specter and all the members of this committee in rededicating ourselves to meeting those challenges head on. This year, as you have said, 1.2 million new cases of cancer are expected in the United States, and about 550,000 Americans are expected to die of cancer. That means more than 1,500 individuals a day and a quarter of all deaths in our country annually are caused by cancer.

The National Institutes of Health estimates the overall monetary cost for cancer was \$156 billion in the year 2001. That is an astonishing figure, larger than the gross domestic products of all but a few nations on earth.

But the greater cost, Mr. Chairman, is in the immeasurable suffering, as you said, of cancer patients, their families and friends as they struggle to survive and cope, and in the lost contributions of those who are taken from us so soon.

I am personally passionate about this issue because of the high toll it takes on our Nation, but like you, Senator Harkin, because of cancer's effect on my own family. My grandfather died of brain cancer. My mother died of melanoma. My mother-in-law died of breast cancer and my wife, Sue Ann, is a breast cancer survivor. Our family knows firsthand, like you do, Senator Harkin, the stress of cancer treatments, the worrying and the wondering that turns your world upside down. And now I have two daughters and a granddaughter, and as Secretary of Health and Human Services, I am absolutely passionate, committing myself to doing everything, like you, I can to spare them the pain and the anguish of this devastating, insidious disease.

That is one reason we have already approved in less than a year 41 State plan amendments that permit States to provide treatment to women with breast and cervical cancer under Medicaid. These are women who are screened through programs funded by the Centers for Disease Control and Prevention and who are not otherwise eligible for Medicaid. This optional benefit was authorized in the Breast and Cervical Cancer Prevention and Treatment Act of 2000. We had our first application less than a year ago. 41 States have already been approved, and I will be approving two more within the week. So, we are moving forward to arrest cancer at every level.

The President's budget is a major step in achieving that goal for my family, for your family, Mr. Chairman, as well as for every American family in America. Within the fiscal year 2003 budget, we are requesting approximately \$5.6 billion for research on cancer throughout the National Institutes of Health. This is an increase of almost \$630 million, or nearly 13 percent over the current year.

We want to and must continue ample funding of the war on cancer because we have begun to make some significant breakthroughs. It is not an exaggeration to say that the tide in the battle might well be turning.

In recent years, we have begun to think about cancer in a different way. Now we know that cancer is really a collection of up to 200 related but distinct diseases with different properties. And we are no longer resigned to thinking of cancer as a death sentence today. We can successfully treat or increase life expectancy for more than half of all cancer patients. That is a sign of the dramatic progress we have made and will continue to make.

We are, Mr. Chairman, at the threshold of a new understanding of cancer at the genetic and the molecular level. Now more than ever before, we are bringing together researchers with seemingly disparate scientific expertise into interdisciplinary ventures. For example, last spring we announced a new drug called Gleevec. It has been approved for use in the cases of people with chronic myeloid leukemia, and from the time it came out of NIH, we worked with FDA and got it approved within 2 months, the fastest ever for a cancer drug in the history of this country.

Gleevec marks the wave of the future because it is the first cancer drug that is the product of molecular targeting, the groundbreaking ability to deliver a drug directly to the diseased cells, leaving the healthy cells alone. Gleevec targets a single cancer-causing protein, and like a light switch is able to turn off its signal to produce leukemia cells.

Earlier this year, scientists from the FDA and the National Cancer Institute reported a new way to find ovarian cancer through a simple blood screening. The test can be completed in as little as 30 minutes from blood obtained from a stick in your finger. Using a sophisticated artificial intelligent computer program, scientists were able to train the computer to tell the difference between patterns of small proteins found in the blood of cancer patients versus the control samples.

We made a similar breakthrough last year when artificial intelligence combined with gene-expressed microarrays to develop a method of genetic fingerprinting that can tell the difference between several closely related types of childhood cancer.

Gene-related research offers great promise. In February, researchers at the National Genome Research Institute, in tandem with scientists at Johns Hopkins and the Cleveland Clinic said they found a gene associated with an inherited form of prostate cancer.

As a final example, recently the FDA approved a capsule that you can swallow that contains a tiny camera. This camera snaps pictures twice a second as it moves through the small intestine. The device enables the physicians to see areas that are not reach-

able by endoscope, potentially facilitating early detection of cancer of the small intestine.

We are working hard to get new interventions out to the people who need them as quickly as possible. There are two new NCI programs that are especially relevant to this effort. The Rapid Access to Intervention Development and the Rapid Access to Preventive Intervention Development expedite new agent development by making NCI's preclinical drug development resources and expertise available for clinical trials. That is what we used, Mr. Chairman and Senator, in regards to Gleevec, and that is why we were able to get it to market within 2 months.

In addition, since 1996, the FDA has approved about 80 cancer-related medications or new uses of already available drugs. 35 of these products have been reviewed and marketed within 6 months of their submission to the agency.

HRSA supports also a network of more than 3,300 community health centers that now serve 11 million people annually, and nearly 90 percent of these low-income uninsured, under-insured women seen at our health centers are current with their PAP smears and more than 60 percent are up to date with mammograms, a higher percentage than the overall national average.

I would be remiss, however, not to note that tobacco use remains the single most preventable cause of death in the United States, with cigarette smoking accounting for nearly one-third of all cancer deaths each year. So, we are actively engaged in public education campaigns to help decrease incidence of smoking among young people especially.

President Bush and all of us in the Department of Health and Human Services are unrelenting in our dedication to win the battle against cancer. We look forward to continuing to work with this committee to that end.

PREPARED STATEMENT

I thank you very much, Mr. Chairman, Senator Specter, Senator Cochran, for giving me this opportunity to speak with you today about our efforts in this fight against cancer.

I now would be pleased to answer any questions that you may have.

[The statement follows:]

PREPARED STATEMENT OF HON. TOMMY G. THOMPSON

Thank you for your invitation to appear before the Subcommittee today to talk about cancer, a disease that affects every one of us. The President has said that while we are engaged today in a war against terrorism to defend our way of life, we've been engaged in a war against cancer for decades to defend our quality of life. In recent years, we have begun to think about cancer in a different way. We are no longer limited to thinking of cancer as one disease that may attack any part of the body and spread. Now we know that cancer is really a collection of related, but different diseases with different properties. We are no longer resigned to thinking of cancer as a death sentence. Today, we can successfully treat or increase life expectancy for more than half of all cancer patients. There is real hope for a future where all cancers are uncommon and easily treated, and where everyone can benefit from the breathtaking progress that grows from each new discovery.

The National Cancer Institute continues to press forward with an ambitious agenda, featuring a large number of new and expanded initiatives across a wide range of research areas identified by members of the cancer research and advocacy community. The President's Budget for fiscal year 2003 requests \$4.7 billion for NCI,

an increase of \$515 million over the fiscal year 2002 level. Across all of the Institutes, we estimate total spending on cancer to be about \$5.6 billion in fiscal year 2003.

We are at the threshold of a new understanding of cancer at the fundamental genetic and molecular level, and now more than ever before, we are bringing together researchers from a broad array of scientific disciplines. We are leveraging this new interdisciplinary approach to find cancer sooner and treat it more effectively and with less ill effect than ever before. Let me relate to you some examples of the impact this is having for each one of us.

Ovarian cancer is one of the deadliest cancers for women, due in part to lack of effective screening methods. There is new hope that comes to us from a multidisciplinary team of investigators who recently demonstrated that a sophisticated new computer-based screening tool can recognize protein profiles. The tool was used successfully to distinguish between blood samples of women who had ovarian cancer and women who did not. This tool could potentially use the same technique to detect new cancer cases in women who have no symptoms at an early stage of disease. This new approach, which takes advantage of the molecular signatures of cancer cells, may deliver powerful new tools for detecting many types of cancer and its recurrence.

In the last decade, there has been an enormous investment in developing molecularly targeted agents in cancer chemotherapy. As a direct result, we have seen recently some inspiring success stories. A few years ago, one of the first oncogene-targeted drugs, STI571 or Gleevec, was developed based upon the identification of a defective protein that is expressed in about 95 percent of chronic myeloid leukemia (CML) patients, and in some patients with other types of cancers. Gleevec, which was recently approved by the Food and Drug Administration (FDA) in a record time of 2.4 months, has shown remarkable promise in the treatment of chronic-phase CML—it was recently demonstrated that Gleevec is superior to standard therapy in the treatment of this disease—and the National Cancer Institute (NCI) is partnering with Novartis, the drug manufacturer, to expand clinical trials evaluating Gleevec for other cancers. Researchers have identified over one hundred potential targets in the cancer process that may present similar drug development opportunities.

Recently, FDA approved a swallowable capsule containing a tiny camera that snaps pictures twice a second as it is moved by natural muscular waves of the digestive track through the small intestine. The device enables the physician to see areas that are not reachable by endoscope, potentially facilitating early detection of cancer of the small intestine.

These developments are only the most recent in a long string of successes in cancer research that are changing the way cancer affects us. Five years ago, we began publishing an annual report about the burden of cancer in our Nation. The report is a collaboration among HHS agencies including NCI, the Centers for Disease Control and Prevention (CDC) and its National Center for Health Statistics, along with our partners at the American Cancer Society (ACS), and the North American Association of Central Cancer Registries. It draws upon statistical information from all of these sources to present a numerical picture of how cancer affects our communities. This year, we are continuing to see encouraging overall trends, including continued decline in the rate of new cancer cases and cancer deaths. Adult smoking is down dramatically from the 1960s for men and the increase in smoking among women has finally reached a plateau. However, youth smoking continues to rise except in states with vigorous tobacco control programs. While breast cancer incidence continues to rise (due to increase in early stage disease), overall breast cancer deaths continue to decline. And for the first time ever, we are seeing a small, but significant decline in breast cancer mortality among African-American women.

In spite of the stunning advances we have made against cancer in recent years, we look around us and still see the persistent burden cancer places on our communities. Cancer is still a common and ruthless disease. This year over 1.2 million new cases are expected in the United States, and about 550,000 Americans are expected to die of cancer—more than 1,500 people a day. The number of new cancer cases is still rising for some cancers such as esophageal, liver, melanoma, and non-Hodgkin's lymphoma. And there remains a disparate burden of cancer experienced by America's underserved populations.

The National Institutes of Health (NIH) estimates the overall monetary cost for cancer was \$156.7 billion in the year 2001. And while the significance of that figure is not lost on any of us here today, I think we can agree that the real cost is even more dear. The immeasurable elements of the real cost can be seen in the suffering of cancer patients and their families and friends as they struggle to survive and cope, and in the lost contributions of those who are taken from us too soon.

We have an obligation to continue to pursue promising research leads, and HHS is committed to doing that. At the same time, we must focus on increasing our ability to translate new advances in cancer research into clinical practice at the community level. We are employing a cross-institutional effort that mobilizes resources and takes advantage of the expertise throughout HHS, as well as outside HHS, to make progress in the fight against cancer.

The overall cancer research effort in the United States is collectively referred to as the National Cancer Program, and is led by NCI. When Congress formalized the National Cancer Program as part of the National Cancer Act of 1971, the NCI Director was charged to “plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of NCI, related programs of the other research institutes and other Federal and non-Federal programs.” Today, we have a unique partnership, the National Dialogue on Cancer, that is giving new life to the National Cancer Program that was envisioned over 30 years ago. In December of last year, Dr. Andy von Eschenbach was named by the President to be the Director of the NCI. At that time, the President highlighted how we as a Nation stand on the brink of an era of amazing research breakthroughs and new opportunities in cancer therapies and cures. He set out the goals to move the fight against cancer forward and I would now like to describe how the NCI and other HHS agencies are actively pursuing these goals.

We will expand our nationwide infrastructure of cancer centers, centers of research excellence, networks, and consortia in ways that promote and facilitate complex scientific interactions and the sharing of information and resources. Our Specialized Programs of Research Excellence (SPORes) exemplify our commitment to translational research—that is, research that focuses on cancer biology specifically as a driver for the development of new treatments. NCI will expand the use of SPORes in the coming year.

We will continue our efforts to ensure that the clinical trials program addresses the most important medical and scientific questions in cancer treatment and prevention quickly and effectively through state-of-the-art clinical trials that are broadly accessible to cancer patients, populations at risk for cancer, and the physicians who care for them. Despite major advances in our understanding of tumor biology and potential molecular targets for cancer prevention and treatment, our capacity to apply and test these findings in clinical settings has not kept pace. The NCI will invest more resources in developing and testing new therapies and increasing access to and participation in clinical trials.

To sustain the generation of new ideas, we will continue to nurture and develop new scientists. To deliver new biology-based interventions, we must educate and train capable physicians. That’s why NCI will continue to expand its efforts to design and implement opportunities for scientists at all career levels to meet the challenge of building a stable, diverse cadre of basic, clinical, behavioral, and population scientists trained to work together effectively and use the most advanced technologies.

An important collaborative activity is the mapping and tracking of cancer patterns in populations. To accomplish this, a national cancer surveillance system is in place that includes the National Program of Cancer Registries at the CDC and the Surveillance, Epidemiology and End Results (SEER) program at the NCI. CDC’s NPCR complements the SEER registry program, with SEER gathering in-depth data on cancer cases diagnosed in five states and six metropolitan areas and submitting their data to the NPCR state registries. Data collection efforts are coordinated with other federal agencies, such as the Department of Veterans Affairs, the Department of Defense, and American Indian/Alaska Native organizations. The overall surveillance system enables public health professionals to monitor cancer statistics to assess progress, identify population subgroups and geographic areas where cancer control efforts need to be concentrated, and to identify when and where cancer screening efforts should be enhanced.

The components of HHS are working collectively and collaboratively to expand access to quality systems of care developed around evidence-based medical practices. We are building programs and creating outreach efforts to reduce cancer as a public health problem.

We are working hard to get new interventions out to the people who need them as quickly as possible. The NCI has two important programs, Rapid Access to Intervention Development (RAID) and Rapid Access to Preventive Intervention Development (RAPID) to address this concern. These programs expedite new agent development on the part of independent investigators in universities or biotechnology companies by making NCI’s preclinical drug development resources and expertise available for moving novel molecules toward clinical trials.

The FDA has made great strides in making effective new drugs speedily available to patients. Since 1996, the FDA has approved approximately 80 new cancer-related medications or new uses of already-available drugs. Some of these products treat the disease, some alleviate its pain and other symptoms, some help to diagnose it, and one reduces the risk of cancer in people who are considered at high risk. Thirty-five of these products have been reviewed and marketed within six months of their submission to the agency.

Within the DHHS, the Agency for Healthcare Research and Quality (AHRQ) is the lead agency on the quality of health care. Once biomedical research identifies new options for improving the prevention, diagnosis, and treatment of cancer, health services research done by AHRQ provides information so that Americans can make wise cancer care decisions. AHRQ research helps to identify which groups of patients are most likely to benefit from specific interventions, ways to improve the accuracy and quality of specific services, and ways to overcome the barriers physicians face in providing quality cancer care. NCI and AHRQ are working together to develop a core set of quality cancer care measures. This work is critical for informed decision-making both by physicians in making recommendations to patients and by the patients who must decide on treatment options.

The Quality of Cancer Care Initiative is a collaborative activity involving organizations across DHHS, as well as private entities. The goal of the initiative is to enhance the state of the science for defining, monitoring, and improving the quality of cancer care and inform Federal-level decision making on cancer care delivery, coverage, and regulation. NCI, Health Resources Services Administration (HRSA), Center for Medicare and Medicaid Services (CMS) and the Department of Veterans Affairs (VA) will be considering demonstration projects on quality measurement and assessment, and will share new knowledge on ways to translate research into practice at the Federal level with private partners through the National Dialogue on Cancer, the National Cancer Policy Board, private associations, and health care systems.

The Centers for Disease Control and Prevention (CDC) serves as a leader for translation of knowledge gained through research into public health practices. CDC conducts and funds studies to identify problems, needs, and opportunities related to modifiable behavioral and other risk factors for cancer and to identify the feasibility and effectiveness of cancer prevention and control strategies. Results are used to plan or improve cancer prevention and control activities, such as the National Comprehensive Cancer Control Program and the National Breast and Cervical Cancer Early Detection Program in the communities where they are needed.

Health Resources and Services Administration (HRSA) programs reach into every corner of America, providing a solid safety net of health care services relied upon by millions of our fellow citizens. HRSA supports a network of more than 3,300 community health center sites that provide free and low-cost preventive and primary health care services to 11 million people each year now. A Presidential initiative will increase and expand this network in 1,200 communities over five years, eventually doubling the number of patients served. HRSA-funded community health centers provide a broad spectrum of cancer care for patients, including prevention, screening, diagnosis, referral, and follow-up. More than 88 percent of adult women seen at these centers are up-to-date with their Pap smears and more than 63 percent are up-to-date with mammograms, outpacing the national average for these services. In 2000, 1 million women received Pap smears and 170,000 received mammograms through our efforts.

I support the President's commitment to expand beneficiary access to preventive health services, and we are working on ways to improve health quality for America's most vulnerable citizens. As you may know, simply offering coverage for preventive health care services, like cancer screening, is not always enough to guarantee that Medicare beneficiaries take advantage of the benefits. We have to actually get beneficiaries to come into the physician's office and be screened. That is why we strive to use efficient and cost effective approaches by partnering with other agencies and organizations, utilizing Medicare contractors to educate people with Medicare about covered preventive services and encouraging beneficiaries to use these services. To this end, we include health promotion information as a part of many education campaigns that address different aspects of the Medicare program or Medicare + Choice options. We have partnerships among many HHS agencies, including CMS, NCI, and CDC, to carry out health promotion initiatives, distribute outreach kits, and produce multi-media, multi-year campaigns involving numerous partners at the local and national level.

Tobacco use remains the single most preventable cause of death in the United States, with cigarette smoking accounting for nearly one-third of all cancer deaths each year. CDC provides national leadership working with federal, state, and local

government agencies, professional and voluntary organizations, and academic institutions to develop and implement a comprehensive, broad-based approach to reducing tobacco use. Activities in surveillance, prevention, treatment, and research conducted across HHS contribute to this effort. CDC works to build the capacity of states to prevent and control tobacco use, providing technical assistance to help states plan, establish, and evaluate tobacco control programs. AHRQ issues smoking cessation guidelines and other materials for physicians, health care professionals, and the general public. At the National Institutes of Health, NCI conducts research on smoking cessation and promotes programs to reduce the rate of illness and death associated with smoking, and the National Institute on Drug Abuse supports research on addiction, including the effects of cigarettes and other nicotine products. The Substance Abuse and Mental Health Services Administration (SAMHSA) conducts the National Household Survey that provides annual estimates of the prevalence of tobacco use and monitors the trends in use over time. CMS is testing ways to help older Americans stop smoking. The demonstration cessation project will test specific strategies for helping older people quit smoking, using counseling by health care providers or counselors, and FDA-approved drugs such as nicotine replacement therapy or prescription drugs in a variety of combinations.

In the Department of Health and Human Services, we see our responsibility to chart a course and develop a plan that will allow us to maintain the high quality of our research and service delivery programs while facing the challenges that come with new approaches, technologies and knowledge. If the 20th century will be remembered for its breakthroughs in basic cancer science and improved treatments, the next century should be remembered for its progress in translating discoveries and applying them to all populations.

Thank you very much for giving me the opportunity to speak with you today about HHS efforts in the fight against cancer. I would be pleased to answer any questions you may have.

Senator HARKIN. Mr. Secretary, thank you.

I am going to tell you all here there is no stronger voice in this administration against smoking than Secretary Thompson, and you deserve our thanks and our applause for your leadership.

I mean that, Mr. Secretary. You have just been great. And you all know that. He has just been wonderful on this.

Before if I get to question you, I would recognize Senator Specter for an opening statement.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you very much, Mr. Chairman. Welcome again, Mr. Secretary. I regret being a little late here, but the First Lady, Laura Bush, was having a special program on libraries and I had wanted to be there for at least part of it.

I thank you, Mr. Chairman, for convening this hearing and I thank you, Mr. Secretary, for your leadership on cancer.

When I take a look at the funding that has been provided by the Federal Government for cancer, it is really very gratifying to see that last year we had in excess of \$5 billion, and this year we will be approaching \$6 billion. That has resulted, I think fairly stated, from the advocacy of this subcommittee. Senator Harkin and I took on the funding challenge a few years back when it was \$12 billion, and it is now \$23 billion. And the President, with the Secretary's advice, is asking for \$3,400,000,000 more this year. So, we will have more than doubled the funding.

Now the question arises as to what happens next, and I am frequently asked by scientist doctors around the country, what are you going to do next? I have a very short answer. It is triple it.

I did not get quite as much applause as you did, Mr. Secretary, but pretty close.

We are a very wealthy country. We have a gross national product of \$10 trillion and a Federal budget of \$2.1 trillion. To be spending \$26 billion for the National Institutes of Health is not too much, and it is a matter of priorities. And nothing is more important than health.

I do want to make one brief comment, controversial as it may be. This subcommittee has never shied away from controversy. We are facing a very difficult vote in the next several weeks on the issue of nuclear transplantation which is an aspect of using stem cells. And stem cells are controversial because they come from embryos, and embryos can produce life. And if all of the embryos created for in vitro fertilization could produce life, I would be for it. That would be the highest calling, but when you have 100,000 frozen not to be used, I think that the wise course is to use them to save lives.

Then we have the issue of reproductive cloning, which we all disagree with. Then there is nuclear transplantation. Without going in any detail, it is a procedure so that if someone, for example, has cancer and you want to get a stem cell, you have it with the DNA of the patient so the stem cell is not rejected.

I know there are differences of opinion in this room and on this dais on that subject, but we are going to be coming to a vote, and every opportunity I have, especially when I am talking to an assembly like this, to urge those of you who agree that we ought to leave medical science able to do the research they need to do to contact your Senators because it is going to be a big, big vote. My own instinct is that when so many people in America are touched by cancer or heart disease or Parkinson's or Alzheimer's or other maladies, that if it is really understood, America would insist on having science able to move ahead with nuclear transplantation.

Thank you very much, Mr. Chairman, for letting me speak on my somewhat tardy arrival.

Senator HARKIN. Thank you very much, Senator Specter, and thank you for your leadership on all issues of health care and biomedical research. I appreciate that.

I would recognize Senator Cochran.

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, I am glad to have an opportunity to welcome the Secretary to our hearing and to thank him for his cooperation and his leadership which is now well known.

I am hopeful that these hearings can lead us into a better understanding of how we can allocate our research funds. We need to increase funding, of course, through our Federal agencies and through research centers that are doing outstanding work trying to identify the causes that we can find out about and reducing and eliminating those causes of cancer, detecting better methods of screening so that we can detect cancer at an earlier date. It was very encouraging to hear the Secretary talk about some of these advances that are being made. Treatments and therapies are very important too, but if we can get into the process of discovering ways to detect and to prevent cancer to start with, that would really be a wonderful thing for our society. So, I hope our research dollars can be allocated in that way, as well as the other ways that we already know about and talk about.

Education and outreach is so important, developing ways to communicate effectively with the general public about what can be done by each individual to lessen the likelihood of cancer in their lives or in their families is of enormous importance and cannot be overstated.

Access to care and treatment. Those are challenges. I just made notes of things that to me are important in my State.

We appreciate, incidentally, your coming to the University of Mississippi Medical Center and delivering the commencement address there. You were a big hit. We appreciate that so much. You have gone all over the country talking to people about what the Department is trying to do to be helpful in this area, and we appreciate your attention to our concerns and interests in my State as well.

Thank you very much, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran.

Welcome, Senator Murray. We have already heard from Secretary Thompson. Do you have an opening statement?

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Thank you, Mr. Chairman. I will submit my opening statement for the record. I just want to thank you for having this very important hearing on cancer today. I think we have made a lot of strides. I think we have a lot work left to go, particularly in prevention and access to treatment. So, I want to go ahead and let us move to questions at this time, but again I really appreciate your focusing on this today.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Mr. Chairman, I want to thank you for scheduling this hearing and for all your work on cancer research and prevention.

I know you've lived through the personal nightmare of cancer, and you've used your experience to increase our commitment to cancer research and prevention.

I look forward to hearing from today's witnesses on some of the latest developments.

One of the most promising avenues in our war on cancer has been the rapid development of biomedical technology.

In just five short years, I think we have all seen the rewards of investing in NIH research and reforming the FDA to expedite the review of life saving drugs and therapies.

Survival rates are increasing, and people are living longer with cancer.

Today's treatments—including alternative and complimentary medicine—have brought us to this point.

Unfortunately, I'm not sure our health care system has adapted to this remarkable change.

While we have come so far, we still have a long way to go to reaching the ultimate goal of curing cancer.

As we pursue that goal, we must continue to focus on prevention and access to screening and treatment.

Senator HARKIN. Thank you very much, Senator Murray.

Secretary Thompson, I do not really have so much of a question as just an observation to discuss with you a little bit about what we might be doing in the next few months in your Department and with this committee.

One of the real concerns I hear from this community of people who are involved with supporting more money for cancer research

and who are involved in a lot of clinical trials, and the American Cancer Society is that we are doing more and more basic research, but what is happening with translational? How are we getting this to the bedside? How are we getting more people in clinical trials? I just heard the figure from a group that I was with before I came in here that only 3 percent of adults with cancer are in clinical trials. And that does seem to me to be low. I am not an expert in this area, but it does seem to be low. Over the last few years, I keep hearing more and more about this, that we are just not getting enough translational research, clinical research, clinical trials out there.

I do not know the answer, but what I would like to propose is that perhaps sometime during the summer or sometime this committee might want to get Dr. von Eschenbach down here because he is the head of the NCI, CDC, HRSA, the Agency for Healthcare Research and Quality, AHRQ, and get them together at the table at one time to discuss about this aspect of more clinical trials. I have not set a date for that, but it just seems to me that we need to get everyone together and enlighten us perhaps, enlighten me a little bit more as to what they are doing to increase the number of clinical trials. Again, it is not a question. It is just discussion. If you have any observation on that, I would be glad to hear it.

Secretary THOMPSON. I certainly do. And I thank you. I think we should be looking at all of these particular matters, Senator, to find out how we can improve. I am one of those people that abhor the status quo. I always believe there are ways to improve it. If there are some complaints from the cancer community, we should be looking at that.

We have set up a website for all questions and information. Anybody can dovetail into website and get up-to-date information.

In regards to clinical trials, it takes money away from basic research. That is basically the decision that has to be made by NCI and NIH. But I think it should be something that should be reviewed, and I think your hearing would be very apropos and would be very informative, not only for you but for the cancer community.

In regards to a couple of things we have already done in translating research into practice, the best one is Gleevec. Gleevec, of course, is where the 9th and 22nd chromosome collapses emitting a protein. It is called the Philadelphia chromosome, Senator Specter. It emits a protein causing a cancer, and Gleevec targets that and is able to turn off the protein emissions, therefore starving the cancer. And Gleevec went through the basic research at NIH and they collaborated with FDA and were able to bring it to market within 2 months.

Herceptin is another one of those gene-targeting drugs. We think we are on the cusp of having a lot of breakthroughs that are going to be able to look at genes that cause cancer and different forms of cancer, and that is the basic research that is going on.

Then the question is, how do you get that to the market as fast as possible like we did in Gleevec. But one-half of the cancer drugs in the last 3 years were able to get to market within 6 months. So, that is a positive thing of translating from basic research into the cancer community, into those individuals that are hurting. We can

continue to work on that. We can continue to improve and I am confident that we can, Senator.

Senator HARKIN. Thank you very much, Mr. Secretary.

I forgot to mention CDC is a part of that component also in terms of prevention.

Secretary THOMPSON. CDC is putting out the information to all the States for this cervical and breast cancer new procedure, and we have 41 States now that have signed up that have been approved. We have two more that are pending that I will be granting their approval sometime this week. So, we will have 43 out of the 50 States that now grant a Medicaid review and Medicaid treatment for women who come in who are under-insured or uninsured and are able to get treatment. It is a wonderful program and I compliment the Congress and I compliment the States for doing it.

Senator HARKIN. Thank you, Mr. Secretary.

Do you have any questions, Senator Specter?

Senator SPECTER. Yes, thank you, Mr. Chairman.

Mr. Secretary, from time to time, this subcommittee has explored the issue of success on curing a variety of maladies. We had testimony not too long ago that the experts thought we were within 5 years of curing Parkinson's. That is just a speculative estimate. But it is very helpful when we seek funding, as we move to the full committee and then to the full Senate and in conference, as we have advocated these increases for NIH, to the extent possible, to get judgments as to what the progress has been, what the funding has accomplished, what an additional number of dollars would do so that we can tell our colleagues, in as practical of terms as possible, what the money is used to accomplish. Obviously, you cannot be precise on it.

I noted in a publication that success stories included a majority of patients with Hodgkin's lymphoma and nearly all patients with testicular cancer could be saved. I think it would be very useful if you, Mr. Secretary, NIH, CDC, et cetera—you have all the experts at your disposal—could give us a breakdown of the various kinds of cancers, because there are so many different categories, and a specification as to where the funding is going for the various kinds and what the progress has been.

Of course, a big part of it turns on early detection. We would like to see on this subcommittee, as a matter of our oversight, how much of the funding goes to early detection and prevention and the relationship between early detection and cure.

But when we talk to our colleagues about all this money, the more specific we can be, the better off we are.

Secretary THOMPSON. Fine. Thank you very much, Senator. Why do I not just make a compilation of all of the preventive programs that we are doing, make it very short, concise, but very complete, and also what we are doing as far as diagnosis, as far as coming up with therapies and treatment and get that to the members of the committee. I will send it to your attention, Senator Specter. Hopefully we can get it done within a week.

We have also got tobacco programs set up in every State now through CDC. We are trying to integrate the departments so we are all working as one body trying to make sure we get the information out.

I also would quickly like to add that I know your passion for embryonic stem cells. There has just been a breakthrough, Senator Specter, at the Weisman Center where they have been able to put an embryonic stem cell in a mouse's brain. It has been able to emit dopamine, and it is just real exciting. I went out to look at it. It is just fascinating and exciting. So, there are a lot breakthroughs there. I think we are on the cusp of really some wonderful new innovations and some new therapies that are going to be very helpful in this particular area.

Senator SPECTER. Well, Mr. Secretary, when you talk about my passion, you are right. It reminds me of the title of my book, *Passion for Truth*. It is in paperback.

On stem cells, I have been talking to some of my colleagues who disagree with me about the issue of nuclear transplantation, erroneously referred to as therapeutic cloning. We are searching for a way where we might have some sort of an accommodation. It is possible that neither side will have 60 votes to cut off debate on Senator Brownback's bill, the Brownback-Landrieu bill, or the legislation with Senator Harkin and Senator Kennedy, Senator Feinstein, Senator Hatch, and I have sponsored.

What my colleague and I were talking about was perhaps moving ahead on reproductive cloning, to ban it. The thought was on his idea of a regulatory group of some sort which could oversee what is being done by research scientists on the ethical side which would perhaps assuage some people as to what is going on if the 60 votes are not there for either of the bills to pass.

I would appreciate it if you and your experts at HHS, NIH, and CDC would give some thought to that as well because when the debate is over, we are still going to have the responsibility for coming up with something constructive which works. It is highly likely that the vote will not be definitive. So, we really need to address the issue as to how we look out for all the competing interests and, in the spirit of accommodation, try to work something out which suits as many people as possible. You will never satisfy everybody.

Secretary THOMPSON. No, that is true.

Senator SPECTER. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Senator Cochran.

Senator COCHRAN. Thank you, Mr. Chairman.

I notice in the statement that you had prepared and we were furnished before the hearing, you mention the presidential initiative through the Health Resources and Services Administration. That caught my attention because I think in my State we are qualified for some of the benefits of this program particularly in research and how to translate the findings of causes and treatments into information and outreach and education so that people who are in areas that are under-served, in terms of medical treatment centers and the like, will have an opportunity to share in the benefits of the research investments that are being made through our committee and through NIH's activities.

I ask you what, if anything, we should be aware of in terms of emphasis on that part of our funding. This is an appropriations committee and we are trying to identify cost effective ways to use

Federal dollars, leverage against networks like the community health center sites around the country and other facilities. I just wanted to emphasize my interest in that and encourage you to continue to explore ways to make sure that every area of the country and every population benefits from what we are trying to do in cancer research and therapies and treatment.

Secretary THOMPSON. Senator, you are absolutely correct, and that is what we are trying to do. We are trying to really have a tremendous outreach program. NIH has got a great website, NCI does, HRSA does, and CDC does. So, we have plenty of information out.

We are also going beyond that. We are trying to go through the State health departments to get information out through CDC, through HRSA, and so on. Today we are announcing in all the States that we are giving out \$30 million worth of grant dollars to improve nursing in America, another shortage. In cancer, we are trying to get the information out about herceptin and also Gleevec and the other gene-targeting drugs that are coming through. FDA has got a great website to do that.

We are trying to make sure that States like Mississippi and other rural States and southern States that have not maybe had the same access as before get as much access as they possibly can have. And we are going to do that and we are going to reach to every State we possibly can. If you have any ideas or any suggestions how we can do a better job, please tell me. I will be more than happy to implement them, Senator.

Senator COCHRAN. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran.

Senator MURRAY. Well, thank you very much, Mr. Chairman, and thank you, Mr. Secretary, for clearly a passion for improving cancer research, prevention, early diagnosis. We all appreciate your focus on this.

I want to follow up on some of the questions regarding access to early screening and prevention and care. One of my concerns is that in reaching out to people, we often miss the minority communities. Native Americans and Asian Pacific Islanders, in particular, I note have less access. Their survival rates are increasing, not decreasing. I was just curious what this administration was doing to improve survival rates for all populations, including minorities.

Secretary THOMPSON. Thank you very much, Senator Murray. I mentioned in my opening testimony that 90 percent of the women that are coming into our community health clinics across America, which were 11 million last year, are receiving their PAP screens. 60 percent are receiving cervical and breast cancer examinations and mammograms. That is a much higher percentage than the population at large.

We also, through NCI's Center to Reduce Cancer Health Disparities, are doing research on how social, economic, and cultural health care providers and factors contribute to health disparities. We have got an ongoing program on that.

We have got special population networks identifying barriers to screening, follow-up and treatment and developing sensitive health curriculum and education curriculum. We have got a breast and

ovarian cancer family registry which identifies genetic factors that contribute to breast cancer risks and interactions with environmental factors. And by 2005, the registry will have enrolled over 700 African American women with breast cancer and their families.

We also have got a program called SEER which expands coverage to include 24 percent of the U.S. African Americans to enhance their capability to track cancer trends. That is up and running. We are expanding that.

I also would like to point out that because of a program that was passed by you and other members of the Congress called the Cervical and Breast Cancer Law, we now have had an outreach program, and we now have 41 States that have enrolled and I have granted waivers to them, so that this program not only can give under-insured and uninsured women all over America to come in and get their breast and cervical examinations and their mammograms, but if they detect cancer, Medicaid in those 41 States will treat them. It is a carve-out from the Medicaid, and it is a wonderful program. There are two more States that have just applied within the last week. I will be approving them. That will get us up to 43. I have got an outreach going out to the other 7 States encouraging them as well so that we can get all the States into this wonderful program. It will be tremendously helpful not only to African Americans and Hispanics, but to all low income, uninsured and under-insured women in America.

Senator MURRAY. Are you coordinating efforts with IHS too? I have a real concern about Native Americans who are not getting access.

Secretary THOMPSON. We are doing that through our Indian Health Service, Senator, and we have got a wonderful outreach program.

Senator MURRAY. So, you coordinate with IHS on that.

Secretary THOMPSON. Yes, we do.

Senator MURRAY. Okay, good. I would just note that the Hutch in my State in Seattle is just hiring a new person to do external affairs in minority communities to do outreach, to determine what some of the barriers are to early access and prevention. I would encourage this administration to look at something similar. I think it is really important. Sometimes we do not understand the cultural differences.

I also wanted to talk about children and childhood cancer. I think we have made some really great strides there. We have got a lot of really great, committed pediatric oncologists and some wonderful children's hospitals who have contributed a lot to that. It is wonderful that leukemia—there are a lot of kids who are celebrating birthdays today that would not have even a decade ago.

But I am really concerned that we keep our commitment to GME for children's hospitals to ensure that pediatric cancer specialists receive the support and the training that is so important to their work. I really wanted to urge you today to encourage the administration to do full funding for GME children's hospitals and work with us to restore the proposed 30 percent reduction in the administration's budget.

Secretary THOMPSON. Thank you.

Senator MURRAY. I also, in working with children, just want to mention pediatric testing and labeling for drugs was an issue I know the administration was looking at, rolling back some of the FDA requirements on pediatric testing. I am glad that that did not occur.

Secretary THOMPSON. Could I just explain?

Senator MURRAY. Sure.

Secretary THOMPSON. That was a mistake. There was a lawsuit. Some lawyer in FDA made a decision that did not go up to the acting FDA Director, never got to my office. They made a decision that was a wrong decision. We corrected it. I was out of the District and I was out of the country. When I got back, we corrected it immediately. I said this is not true.

The acting Director of FDA was absolutely appalled when he read about it in the paper. Some things happen. I have got a huge Department. Sometimes some people make decisions. We rolled it back, and that I can assure you is not the policy of the FDA, of me or the President.

Senator MURRAY. Well, I really appreciate that, and I am glad to hear your strong convictions on that. Can you just tell me what the administration is going to do in order to deal with the court challenge on this?

Secretary THOMPSON. We are fighting it.

Senator MURRAY. Would you support, I think it is, 2394, Senator Clinton and others working on codifying the FDA regulation?

Secretary THOMPSON. We do not think it is necessary because of our strong position, but that is a decision that you will have to make, Senator.

Senator MURRAY. My time is out. I just want to mention really quickly, Mr. Chairman, that I am very concerned about asbestos, work place safety. I held a hearing on what happened in Libby, Montana where thousands of innocent people unknowingly have been exposed to asbestos from the vermiculite mine there, and we have thousands of homes around the Nation that have asbestos contaminated vermiculite in their homes.

I am going to be introducing legislation shortly to finally ban asbestos, which we should have done many years ago and did not. I really want to work with you as we try and move that legislation forward. I think it is extremely important.

Secretary THOMPSON. I want to work with you. I want to work with all of you. In fact, I have got to get out to Libby, Montana. My Deputy Secretary took 1 day out of his vacation last summer and spent it at Libby, Montana. So, it is high on our agenda.

Senator MURRAY. Well, thank you. I appreciate that. I think Senator Baucus from Montana and I would be happy to work with you to facilitate any kind of visit out there.

Secretary THOMPSON. Thank you very much.

Senator HARKIN. Well, thank you very much, Mr. Secretary. I look forward to working with you.

Secretary THOMPSON. It is always a privilege.

Senator HARKIN. Thank you, Mr. Secretary.

Next we will call our panel to the table. Dr. Elmer Huerta, of Cancer Preventorium at the Washington Hospital Center; Dr. Ronald Herberman, director of the University of Pittsburgh Cancer In-

stitute; Susie Novis, president of the International Myeloma Foundation; Michael Bruene, Iowa cancer patient; Mr. Steve Case, chairman of AOL Time Warner.

STATEMENT OF ELMER E. HUERTA, M.D., M.P.H., DIRECTOR, CANCER PREVENTORIUM, WASHINGTON HOSPITAL CENTER

Senator HARKIN. We will proceed in the order in which the witnesses were called. I would start first with Dr. Huerta. Dr. Huerta is the Founder and Director of the Cancer Preventorium of the Cancer Institute at the Washington Hospital Center. He is internationally known through his radio and TV shows and for his health promotion and disease prevention efforts in the Hispanic community.

I would say to you, Dr. Huerta, and to all of you that your statements will be made a part of the record in their entirety. If you could just sum them up briefly for us, we would be very appreciative so we could get into more of a discussion perhaps. Dr. Huerta.

Dr. HUERTA. Thank you, Mr. Chairman. Good morning. My name is Elmer Huerta. I am the founder and director of the Cancer Preventorium at the Cancer Institute of the Washington Hospital Center in Washington, D.C. I am pleased to appear before you today on behalf of One Voice Against Cancer.

Most of my work as a physician has focused on providing care to those in greatest need. Early in my medical career, I was a practicing medical oncologist where I have spent significant time, medical resources, and money on people diagnosed in the late stages of cancer who had very poor prognosis. My observation, however, was that almost all of those patients had tumors that could have been prevented or detected earlier had people known how to do it. People know more about soap operas, the life of their entertainment than about health. That was very sad. And that was especially sad because we know that 75 percent of cancers that kill people in this country are either preventable or detectable. So, for me as a medical oncologist, it did not make any more sense to give chemotherapy to patients with advanced cancers that could have been prevented or detected earlier had people known how to do it.

That is why we started a center here in Washington, D.C. at the Washington Hospital Center that has a sign that says, if you think that you're healthy and you want to learn how to prevent cancer and you want to have a complete cancer screening, please come in. If you have a symptom, please visit your primary care physician.

We started that center in 1994 here in Washington, D.C., and we have been very successful. We have attracted over 10,000 people to the center, 85 percent of them without any symptoms. The reason why these people have shown up to my center is because I use media, but the media used with four basic principles.

First is that the media needs to be used every single day like weather and like sports.

Second, media health education programs need to be comprehensive. There is no point in talking only about cancer when there are other needs in the community. What about diabetes, hypertension? What about maternal and child health problems? What about many other needs that the community has?

The third principle in using media is that we need to be full-time media. Mr. Case here on the panel knows that very well. We need to have programs, radio 1 hour, television, Internet. We need to write articles for newspapers. In other words, Mr. Chairman, we need to involve the community with health education programs.

Fourth is creating trust in the community, and creating trust in the community means you have to kind pull apart your business from your educational messages.

Well, the center has been very successful. We have attracted 10,500 people to the center, 85 percent of them without any health problem just for cancer screening and cancer prevention.

So, the point maybe this morning is that we can double the NIH budget, and I think we should. Science needs to work. We are on the verge of discovering but also we need to communicate to the public all the discoveries.

We know that only 3 to 5 percent of adults in this country get into clinical trials. We know that. But we do not know how much those people know about clinical trials. Do they think they are guinea pigs? Do they have many misconceptions about clinical trials? I think we are doing more efforts in selling cars, sodas, beer, things like that, than educating our public in health issues.

Ninty percent of my clinic patients here at the Cancer Preventorium are listeners of my radio program. Ninty-six percent are Latinos. Eighty percent have no health insurance, and as I said, 80 percent of them have no symptoms.

Mr. Chairman, my time is up. I just want to say that in the 1940's, there were 754 sanitoriums in the United States. A sanitorium is defined as a place where sick people used to go, tuberculosis, mental health—754 sanitoriums. It was the industry of illness in the United States in 1940's.

My dream would be to have 754 preventoriums, places where people are attracted healthy to have education, to have screening, and to involve them in community activism. So, if we were able to have 754 sanitoriums once, I think we should have preventoriums in such a way that we can change the paradigm in which we take care of people in the United States. My 10,000 patients that have found early hypertension, early diabetes, early cancer—primary care doctors would be extremely happy to have them because they can manage a less burdened population with disease.

So, the CDC plays an extremely important role. The NIH is the machine of creating knowledge. I think the CDC should be the machine of delivering this knowledge to the public.

But again, in this time, 2002, yesterday or last week the World Cup started in Korea and Japan, 1.3 billion people watched that inauguration. 1.3 billion people. So, we are living in a world where media is extremely important. I think we have failed as a country to take advantage of using media in public education, in health education for our communities.

So, I am here to really support the efforts of the One Voice Against Cancer Coalition to increase funding not only for cancer research but also prevention and education programs at the CDC.

If some of the members of the committee want to visit here right here at the Washington Hospital Center, you are welcome. You can

see how prevention and health promotion really work. Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF ELMER E. HUERTA

Good morning. My name is Elmer Huerta, M.D. I am the founder and director of the Cancer Preventorium of the Cancer Institute at the Washington Hospital Center in Washington, D.C. I am pleased to appear before you today on behalf of One Voice Against Cancer.

Most of my work as a physician has focused on providing care to those in greatest need. Early in my medical career, I was a practicing medical oncologist where I spent significant time, medical resources, and money on people diagnosed in late stages of cancer who had very poor prognosis. My observation, however, was that almost all of those patients had tumors that could have been prevented or detected early, had people known how to do it. Knowing that 75 percent of cancers that kill people in the United States can be either prevented or detected early. Because of this, I decided to pioneer a new concept in fighting cancer starting before patients are sick, before they are even diagnosed with cancer. My Preventorium has the goal of keeping healthy people healthy through a multi-pronged approach to prevention and early detection.

I am here to tell you more about this new theory of prevention and treatment of cancer and how the federal government can put this new concept to work in order to reduce the mortality of cancer. As a nation, we have made tremendous scientific progress in the battle against cancer. The federal government has made funding for cancer research a top priority. I am here as a clinician who has experience on the other end of the spectrum—the application of that science. The knowledge gleaned from research concerning the nature of cancer is providing us critical insights into how we can prevent, detect and treat cancer more effectively. What better way to treat cancer than by preventing it—or at least detecting it in healthy individuals rather than in the late stages when most people with cancer enter care.

My center does just that. We educate the public—in this case a minority population who would most likely be considered one of the hardest to reach—through the use of radio, television and other media outlets. Then we work with them to keep them healthy. In fact, we only accept patients who are healthy (that is to say symptom-free) and willing to invest in their health. Many of the patients at my Center have origins outside of our borders. Many face linguistic barriers, lack of health insurance, lack of access to culturally appropriate medical facilities; lack of understanding of the medical system. In real terms, what this means is that these individuals, in general, are less likely to have a regular source of medical care, less likely to have had a recent physician visit, more likely to delay seeking medical care, more likely to report they have not received needed care, and less likely to use preventive or early detection services.

Many of my patients did not have primary health physicians before coming to my clinic. Many did not understand what preventive or early-detection measures were. In my clinic, these individuals learn about cancer risks and prevention/early-detection. They receive comprehensive screenings for colorectal, prostate, cervical, breast cancers. They learn about nutrition and eliminating behaviors that increase their risk of cancer. And, if needed, they are referred to a specialist for the early treatment of cancer. Otherwise, they agree to return each year for an exam. My clinic sees approximately 1,500 individuals each year and approximately 50 percent are returning patients.

What I have shown in my work, is that prevention and health promotion does work. Given the knowledge and opportunity, even the most disadvantaged populations will respond to this concept. My clinic population has been at near capacity for 7 years.

What we have shown, is that if our investments in research and prevention are increased and efforts are targeted to make the biggest impact at the community level—particularly in medically underserved communities—we can reduce death and suffering by preventing cancer from occurring in the first place or, if cancer occurs, detecting it at its earliest, most treatable stage.

We can double the NIH budget—and I think we should. But we must also translate those research advances into meaningful prevention and early detection practices to succeed in achieving our goal of eradicating cancer at the earliest possible time.

Opportunities to reach all American citizens, in my opinion, lies with linking sustained media-based educational campaigns to affordable and accessible cancer pre-

vention/detection/treatment programs. This link is vital if we want to reverse the bleak panorama of underserved communities. I tested this theory by creating a health education radio program in the Washington, D.C. metropolitan area. The program has been on the air daily, uninterrupted, since its inception in 1989. Different surveys have shown that this program is listened to or watched by approximately 60 percent of Latinos living in the Washington, D.C. metro area. This interest demonstrates that, when offered quality programs, the community is responsive to learning about health issues through the media. A great percentage of these individuals are encouraged to enter primary medical care to receive early detection for cancer.

Ninety percent of my patients at the clinic are listeners of this radio program. Ninety six percent of the patients at the Center are Latinos, 80 percent have no health insurance and 85 percent have no symptoms. Access to education led them to preventive care.

The Centers for Disease Control and Prevention (CDC) is critical in the promoting and funding programs for the education and early-detection of cancer. For example, the CDC's National Breast and Cervical Cancer Early Detection Program is making an enormous difference in the lives of poor, underserved women who are at greater risk of breast and cervical cancer. This proven CDC program provides important breast and cervical cancer screenings, outreach, and post screening diagnostic and treatment services in all 50 states to women who do not have health insurance coverage and who do not qualify for either Medicaid or Medicare. Now in its eleventh year, the program builds on the existing public health infrastructure and involves all sectors of the community in outreach and delivery of services.

Through this program, more than 2.7 million screening examinations have been performed. Over 8,600 breast cancers and 39,400 pre-malignant cervical lesions have been diagnosed; and nearly half of all screenings have been for minority women. Like many other CDC cancer programs, this program suffers from inadequate funding. And while increased funding is not the solution to every problem, we know that not much will happen in its absence.

Another example is the National Hispanic Colorectal Cancer Outreach and Education Project developed by the National Alliance for Hispanic Health as a direct response to observed colorectal cancer morbidity and mortality trends within the Hispanic community. The CDC identified colorectal cancer as a priority area for prevention and early detection activities, particularly in the Hispanic community where it is the third most common cancer in Hispanic men and women. The Project's primary purpose is to increase awareness about colorectal cancer prevention and early detection in the Hispanic community through education and outreach.

Similarly, the CDC leads programs focused on prevention and early detection of skin and prostate cancers. The Comprehensive Cancer Control Program provides an integrated approach to reducing cancer's impact through prevention, early-detection, rehabilitation and end-of-life care. This initiative provides support and technical assistance to states and tribal entities so they can develop and implement a comprehensive cancer control plan targeted towards the needs of their state. Finally, complementing and partnering with the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program, CDC's National Registries Program supports cancer monitoring in 45 states, the District of Columbia and three territories.

By extending the reach of public education/awareness efforts geared to prevention and early detection, including the few examples I have provided today, we will sooner achieve our goal of reducing incidence and mortality from all types of cancer, and improving the quality of life for people living with cancer. In other words, Mr. Chairman, we should not focus only in studying Mrs. Smith's tumor, as we have been so far, but in Mrs. Smith herself.

The CDC plays an absolutely vital role in meeting these goals. CDC's programs apply the advances gained as a result of our past and continued federal investments in cancer research. We must not lose sight of the fact that we invest dollars in cancer research ultimately to save lives through better treatment, earlier diagnoses and more targeted preventive strategies. From my experience at my clinic, I know first-hand the value of cancer prevention and early detection and I strongly support the efforts of the One Voice Against Cancer Coalition to increase funding not only for cancer research but also prevention and education programs at the Centers for Disease Control. Thank you.

STATEMENT OF RONALD B. HERBERMAN, M.D., DIRECTOR, UNIVERSITY OF PITTSBURGH CANCER INSTITUTE

Senator SPECTER. Mr. Chairman, thank you for according me the opportunity to introduce Dr. Ronald Herberman, a distinguished science administrator from the University of Pittsburgh, Associate Vice Chancellor for Research and Health Studies. Dr. Herberman has had an extraordinary record starting in 1968 with the National Institutes of Health, moving into a specialized position in 1975 and in 1981 on biological therapeutics. He left the National Cancer Institute in 1985 to establish the University of Pittsburgh Cancer Institute and has done remarkable work there. It is a good example of how the National Cancer Institute has produced experts who have moved on to distinguished educational institutions like the University of Pittsburgh where he is now an administrator as well as a scientist.

Thank you for all that you have done, Dr. Herberman, and thank you for joining us here today.

Dr. HERBERMAN. Thank you, Mr. Chairman and members of the subcommittee. Good morning. I am Dr. Ronald Herberman and the director of the University of Pittsburgh Cancer Institute. The UPCI for short is an NCI-designated comprehensive cancer center, and one of the particular areas of emphasis that our center has is to hasten the translation from the basic laboratory discoveries into clinical application to benefit patients with cancer.

In order to do that we, as well as like centers around the country, are extensively involved in clinical trials research. Our own initiated clinical research has garnered national recognition for advances in the treatment of melanoma and a variety of other cancers, including brain tumors, head and neck cancer, prostate cancer.

We are particularly appreciative of this subcommittee's leadership in doubling the NIH budget. This is certainly capitalizing on the recent dramatic progress in molecular biology and genetics and immunology. As a cancer researcher for my entire career, I am really in awe of the almost explosive increase in our understanding of the causes of cancer, and equally so in what goes on to lead to progression of cancer and the metastasis which is really the heart of the problem that we have to face. We now are increasingly able to identify molecular changes in the cells that make them malignant or allows them to progress. It is now possible to detect in a very sensitive and specific way new drugs that can specifically target the molecular changes and to arrest them.

But for all of these areas of progress, as you, Mr. Chairman, alluded to before in your comments to Secretary Thompson, all of these laboratory steps need to be evaluated in patients through clinical trials. It is the requisite path for our advances to apply them to patients with cancer.

The clinical trials mechanism in the United States has been really very impressive. As Senator Specter alluded to, I finished my medical training in the mid-1960's. At that time, if one did not have the ability to find a cancer early and to cure it by either surgery or radiation therapy, there was uniform fatality from cancer. As the chairman has already alluded to, the situation for several types of cancer is much better than that. There are now cures of

certain types of cancer even when they are diagnosed at advanced stages. All of this has come from effective clinical research.

There, unfortunately, are a number of problems with the current clinical research mechanisms in the United States. The problems are multiple. They include an insufficient number of well-trained investigators. We are overly burdened with inefficient regulatory mechanisms. There also are not enough specific resources to make the clinical trials mechanism function as effectively as possible. And unfortunately, there are infrequent, but in some cases serious lapses in protection of human subjects.

How can we do better than that? Well, first of all, I think it is important to promote more effective partnering between the Federal Government, academic medical centers like ours, and the pharmaceutical industry.

A second issue is education and credentialing. I think we need to provide more resources to increase the pool of physician scientists. We need to train physicians and other health professionals to more properly carry out clinical research. I think credentialing is also worthy of more attention. I believe that both institutions to perform clinical research and individual investigators need to be credentialed.

The process for approving and implementing clinical trials is a very cumbersome one, and to do the very large scale clinical trials, to prove that something is really effective requires participation of multiple institutions across the United States. Right now that process requires repeated reviews at various institutions which are often even divergent with each other. I and a number of my colleagues believe that this could be done much more efficiently by having a centralized institutional review board that could review these right once and get things approved and into clinical trials more effectively. This centralized process could also more effectively oversee the occurrence of serious adverse events.

One final point that I would like to touch on is that once one collects the necessary data from clinical trials research, one does have to get approval by the FDA. Although we are very pleased the Gleevec came through the approval process in record time, unfortunately most of the cancer drugs take considerably longer than that. I believe that it would be better to have an integrated oncology approval mechanism at the FDA that could deal with this more efficiently and to put more reliance on what we know about the molecular targets, use biomarkers and other surrogate endpoints to help accelerate the approval process.

I see my time is up, and in closing I would like to reiterate the enormous opportunities that lie before us. As has already been alluded to, we are at the cusp of some of the greatest advances imaginable. There is a tremendous opportunity to translate the burgeoning biologic knowledge and our technical capabilities and apply them for either prevention or treatment of cancer. But I feel strongly that we need to restructure our clinical trials mechanism to make it more efficient so that we can more rapidly get these promising preventive or therapeutic agents into the hands of health care professionals to actually deal with the problems of patients.

PREPARED STATEMENT

Thank you for the opportunity to testify. I look forward to working with you to improve this critically important system and would be happy to answer any questions you might have.

[The statement follows:]

PREPARED STATEMENT OF DR. RONALD B. HERBERMAN

Mr. Chairman and members of the Subcommittee: Good Morning, I am Dr. Ronald Herberman and I serve as director of the University of Pittsburgh Cancer Institute (UPCI). Today, I am here on behalf of the Academic Health Centers Clinical Research Forum, an organization comprised of more than 20 of this nation's leading academic institutions.

As a National Cancer Institute-designated Comprehensive Cancer Center, UPCI's missions are to provide specialized cancer prevention, diagnosis, and treatment services and to conduct cutting-edge research to better understand the causes of cancer and its progression, and to develop more effective ways to relieve the burden of cancer. UPCI's particular emphasis is to hasten the translation of new insights in the laboratory into new approaches for the prevention and treatment of cancer in patients. To that end, UPCI is extensively involved in clinical trials research. UPCI-initiated clinical research has garnered national recognition for advances in the treatment of melanoma, and brain, lung, head and neck, prostate and ovarian cancers.

We are very appreciative of this Subcommittee's leadership in doubling the NIH's budget, to capitalize on the recent dramatic progress in molecular biology, genetics and immunology. As a cancer researcher, I am in awe of the almost explosive increase in our understanding of the causes of cancer and the opening of entirely new avenues for cancer treatment and prevention. The identification of molecular changes that cause a normal cell to become cancerous or cause a locally growing cancer cell to spread to other parts of the body is leading to new anti-cancer agents that specifically target these changes. Potential new drugs can be screened against hundreds if not thousands of new molecularly targets and those that appear to be promising in the laboratory must then be evaluated in patients through clinical trials. This is the requisite path for developing innovative and more effective treatments for patients with cancer.

Across the country, clinical trials have enhanced our armamentarium to combat cancer by providing solid evidence of the safety and effectiveness of new modalities for cancer treatment and diagnosis. When I completed my medical training in the mid-1960's, most cancers that were not detected early and cured by surgery or radiotherapy were uniformly fatal. Now, as a direct result of clinical research, a variety of malignancies including children's cancers, Hodgkin's disease and testicular cancer are usually curable even in advanced stages. Just in the past few years, clinical trials have continued to contribute to improvements in survival and quality of life for patients with many types of cancer.

For example, last year, STI-571 (Gleevec™) received FDA approval for the treatment of chronic myeloid leukemia following demonstration of effectiveness by clinical trials. Gleevec is an excellent example of the rapidly expanding array of molecularly targeted cancer drugs that, in contrast to typical chemotherapy drugs, can selectively eliminate cancer cells without damaging normal cells.

Unfortunately, at the same time we have such unprecedented opportunities to make major advances in the treatment or prevention of cancer and other life-threatening diseases, the clinical trials process in the United States has become endangered by a combination of:

- an insufficient number of well-trained investigators,
- inefficient and overly burdensome regulatory mechanisms,
- insufficient or inefficiently deployed resources, and
- infrequent but serious lapses in protection of human subjects.

The Academic Health Centers Clinical Research Forum and also the Clinical Trials Team of the National Dialogue on Cancer have been considering these issues in depth. To effectively and rapidly avail ourselves of the great opportunities to improve the care of patients with cancer and other life-threatening diseases, we must develop a new paradigm for the initiation and successful completion of clinical trials. The American clinical trials system must be streamlined and well supported, while also maximizing the safety of patients who participate in clinical trials.

To accomplish these objectives, we propose the following:

- Promotion of more effective partnering among academic research centers, the pharmaceutical industry, and the federal government, to accelerate the pace of translation of promising laboratory insights into clinical applications.
- Increase in the number of physician scientists, who can provide the needed leadership for implementation of well-designed clinical trials. To keep pace with new basic science discoveries, the NIH should expand its training support for junior investigators (K23 awards) and career support for established clinical investigators (K24 awards). Increased support by NIH for the recently launched loan repayment program for extramural clinical researchers would also facilitate this goal.
- Development of an effective program for education of health professionals in the importance of clinical research and training in good clinical research practices. Physician investigators, clinical research coordinators, and members of Institutional Review Boards (IRBs) need to be well trained in the conduct of clinical trials and protection of human subjects. This can be readily accomplished by internet-based education and certification, as has been recently implemented and made mandatory for all involved in clinical research at the University of Pittsburgh.
- Development of an effective process for credentialing and oversight of institutions to perform high quality clinical research. Promising national initiatives in this important direction have recently been undertaken.
- Credentialing and oversight of investigators performing clinical research. This function should probably be assumed by each institution performing clinical trials, e.g. by the local IRBs.
- Streamline the review and oversight of multi-institutional clinical trials. For demonstration of efficacy and safety of a new treatment, large numbers of subjects need to be entered at multiple institutions. Currently, before approval for implementation, such trials undergo redundant and often divergent reviews by a variety of private and governmental entities, which slow the process, consume many resources but do not increase the quality of the studies or better promote the protection of the research subjects. Rather, we propose that for such multi-institutional trials, a well-constituted central IRB perform the reviews and receive reports of any serious adverse reactions.
- Provide sufficient resources and better utilize existing resources for the performance of high quality clinical trials. For example, to better enable physicians to participate in clinical research and accrue patients onto clinical trials, the NCI recommends increasing reimbursement to \$3,500 per patient, from the current level of about \$2,000 per patient. Such steps seem warranted to substantially improve the current unacceptable statistics of only about 3 percent of cancer patients participating in clinical trials and large-scale trials taking an average of 5 years to complete.
- Promote more streamlined and efficient analysis of the data needed for approval of new drugs by the FDA. For example, with oncology treatments, we recommend an integrated office for review of all oncology treatments, whether drugs or biologics, and greater emphasis on the use of surrogate biomarkers and the improvement in the clinical course of disease, rather than the current predominant focus on significant increase in survival.

In closing, I would like to reiterate the enormous opportunities that lie before us. Medicine and science are on the cusp of some of their greatest advances yet. There has never been a greater opportunity to translate biological knowledge and technical capability into powerful tools for preventing and treating cancer. But we need to restructure our current clinical trials system to more efficiently transform these discoveries in the lab into beneficial clinical applications for the patient.

Thank you for this opportunity to testify. I look forward to working with you to improve this critically important system.

Thank you for this opportunity to testify. I would be glad to answer any questions you may have.

Senator HARKIN. Thank you, Dr. Herberman.

STATEMENT OF SUSIE NOVIS, PRESIDENT, INTERNATIONAL MYELOMA FOUNDATION

Senator HARKIN. Now we will turn to Ms. Susie Novis. Ms. Novis is the president of the International Myeloma Foundation, which she founded in 1990. Over the past 12 years, the foundation has been active in over 64 countries, establishing a myeloma registry with over 90,000 members, and has raised over \$13 million for pro-

gram support. Quite a remarkable achievement. Welcome to the committee.

Ms. NOVIS. Thank you. I am very pleased to be here on behalf of the International Myeloma Foundation and One Voice Against Cancer.

Multiple myeloma is an incurable cancer of the bone marrow plasma cells. Myeloma patients represent 1 percent of all cancers diagnosed and 2 percent of all cancer mortality in the United States. Myeloma patients experience painful bone fractures, particularly in the vertebrae, ribs, and hips. Additional complications include kidney failure, anemia, and infection that ultimately lead to death.

As I said, I am here representing not just the multiple myeloma community, but all cancers represented by One Voice Against Cancer. One Voice Against Cancer is a coalition of more than 40 national and community-based organizations that represents tens of millions of Americans. One Voice was formed to unify the public health community on the need for a comprehensive, targeted Federal approach to develop cures for the spectrum of cancers affecting our Nation.

On behalf of One Voice, I would like to ask this committee to fulfill the following appropriations requests for fiscal year 2003. \$27.3 billion for the National Institutes of Health to fulfill the 5-year doubling pledge. \$5.69 billion for the National Cancer Institute to fulfill the NCI Director's bypass budget recommendation. \$199.6 million for the National Center for Minority Health and Health Disparities to lower the disproportionate rate of cancer incidence and mortality among under-served communities, and \$348 million for the Centers for Disease Control and Prevention for its cancer programs to enhance education, outreach, prevention, and screening.

We are particularly supportive of the idea that Congress fully fund the NCI Director's bypass budget. Fully funding the bypass budget will provide hope to those Americans who will be diagnosed with rare, deadly forms of cancer. Patients diagnosed with the deadliest cancers, which include myeloma, kidney, and pancreatic cancer, face the bleakest choices. The 5-year survival rates range from 4 percent for pancreatic cancer to 28 percent for myeloma. So, without dramatic increases in research funding, the outlook for these patients will remain bleak.

Fulfilling the bypass budget will provide resources for new research for cancers that have been traditionally underfunded by NCI and allowing NCI Director Andrew von Eschenbach to implement the new paradigm for cancer research. This approach will lead to targeted therapies that treat cancer at the molecular level. This molecular level is, indeed, the ultimate expression of a rising tide lifting all boats.

Today is a very emotional day for me. It is my anniversary. Thirteen years ago today, June 4, Brian Novis and I were married. Brian was diagnosed with multiple myeloma when he went in for a simple blood test in preparation for our marriage. He was only 33 years old. His doctor told him he had 3 to 5 years to live. We prayed that the doctors were wrong and that we would be able to

raise a family and have a long and happy life together. But Brian died in 1992, just 4 years after his diagnosis.

But even though we never had children, we did create a family. With the help of Dr. Brian Durie, the International Myeloma Foundation was created, a family comprised of patients, caregivers, and professionals.

I would like to take a moment and introduce you to some members of our family. Mary Goodwin is a nurse from Cedar Rapids, Iowa. Mary was diagnosed with myeloma in 1996 after injuring her back while lifting a patient preparing for surgery. Mary's husband of 20 years runs a family-owned restaurant, and her 14-year-old daughter Lanessa sitting next to her has spent almost half her life knowing that her mother is fighting a rare and debilitating cancer. But Mary said to me the other day, Susie, I just need to keep on going. The other choices are not so good.

Brad High of Haverford, Pennsylvania believed strongly in One Voice Against Cancer. He understood the need for cancer advocates to work together and to avoid the inclination to say one cancer is more important than another. Now, Brad had planned to be here today, but he lost his 7-year battle with myeloma on May 22.

Everyone in this room has been touched by cancer. I lost my husband to myeloma, my mother to colon cancer, and I have lost many dear friends to all forms of cancer. Mr. Chairman, you know as well as anyone that cancer destroys not just the person. It destroys the family. It destroys the community. It breaks hearts and it crushes dreams.

When Brian Novis decided to start the International Myeloma Foundation, I was skeptical, but he looked at me and he said, Susie, one person can make a difference, but two people can make a miracle. As I look around this room today, I see many people who can make miracles happen. Cancer can be cured. It is going to take money and commitment to get the job done, especially for cancers like myeloma.

Some of you may be thinking how can we afford to increase the funding for cancer research, but I say, how can we afford not to. We are one voice against cancer. Our voices must be heard. We are your voice too.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF SUSIE NOVIS

Mr. Chairman, my name is Susie Novis and I serve as the president of the International Myeloma Foundation, the world's oldest and largest nonprofit organization supporting the needs of the multiple myeloma community. I want to thank you for the opportunity to present the views of the IMF in support of the One Voice Against Cancer coalition agenda. I am here representing not just the multiple myeloma community I serve, but all cancers.

MULTIPLE MYELOMA: AN INCURABLE CANCER

Multiple myeloma is an incurable cancer of the plasma cells of the bone marrow. The myeloma patient population represents one percent of all cancer diagnoses and two percent of the cancer mortality rate. Approximately 15,000 Americans will be diagnosed with myeloma this year and about 12,000 will die. Myeloma patients experience bone fractures, particularly in the vertebrae and hips, and continuous, degenerative symptoms of bone loss that ultimately leads to death. Additional complications include kidney failure, severe anemia, pneumonia, shingles, and, in advanced cases, physical disability.

Patients live an average of three to five years after diagnosis, although some survive significantly longer. The five-year survival rate for myeloma patients between 1974 and 1993 increased from 24 to 28 percent, suggesting that little progress has been achieved. The one thing that has improved, thanks to drugs like bisphosphonates—a bone strengthening drug—and thalidomide, is the general quality of life of most patients.

No categorical causes of myeloma are known. Myeloma incidence may be linked to prolonged or excessive environmental exposures to toxins or other agents. These suspected linkages cause patients to live in tragic uncertainties that something related to their careers or choice of home may have had something to do with their illness. They wonder if by serving their country in foreign wars they may have exposed themselves to the things that cause myeloma. They wonder if that good job at the refinery may have raised their short-term income at the cost of their long-term health. They wonder if those afternoons spent planting the crops may have sown the seeds of an incurable disease. They wonder, with research suggesting a possible linkage between myeloma and viruses, if they could possibly infect a loved one. They search in vain for definitive answers because the current state of research is too inconclusive to answer their questions.

Research has found that myeloma is more prevalent in western industrialized countries. Within those countries, higher rates of occurrence have been observed in coastal, industrial zones, agricultural belts, and in areas with high concentrations of population. In other words, it is cancer associated with modern living. As the world becomes more industrialized, it is not illogical to assume that rates of myeloma incidence will rise accordingly.

THE INTERNATIONAL MYELOMA FOUNDATION: PUTTING PATIENTS FIRST

Today is a very special and emotional day—it is an anniversary for me. Thirteen years ago today, my late husband Brian Novis and I were married. Brian was diagnosed with multiple myeloma in 1988 at the age of 33. He found out he had the disease after taking a life insurance physical examination prior to our wedding. Like virtually all myeloma patients, the first time he heard about the disease was when he was diagnosed. Among his greatest frustrations was a lack of access to knowledge about the disease and specialists.

So he responded by founding the IMF in 1990 with the help of other patients, doctors, and researchers who were interested in the field. The first, and in many ways, still the most important, project of the IMF was the establishment of a toll-free hotline that provided information to patients and family members when they most needed it. The IMF has grown to become the foremost resource about the disease for patients and doctors alike. In 1992, the IMF hosted the first worldwide clinical conference ever held for MM specialists. The results of that conference led to the initial publication of *Myeloma Today*, which, at the time, was the only periodical focused exclusively on MM research and patient issues.

Now in its twelfth year, the IMF has a membership of more than 90,000 individuals worldwide. We have conducted more than 41 Patient/Family Seminars to provide individuals access to the latest knowledge and the foremost experts. That, in turn, points out the value of the most important service the IMF provides. Through use of the hotline and mail requests, the IMF sends out—at no charge—more than 1,000 patient information packets per month. In fact, if you are affected by myeloma, you know about the IMF—because it is likely the first source of comprehensive information you ever received about the disease. And since 1994, the IMF has funded 42 Brian D. Novis Research Grants totaling \$2.7 million.

Brian's doctor said he had three to five years to live. Our family and friends hoped and prayed that he was wrong, that we would be able to raise a family and have a long and happy life together. We were wrong—the doctor was right. Brian died in 1992, just four years after his diagnosis at the age of 37. Our life together, however brief, was happy. And even though we never had children we did create a family. Our family became the International Myeloma Foundation; a family comprised of patients, family members, caregivers, scientists, health care professionals, and friends. I would like to introduce you to two members of our family.

Mary Goodwin, who is here with me today, is from Cedar Rapids, Iowa. Mary's story is typical, unfortunately, of so many myeloma patients. Mary, who works as a nurse, was diagnosed with myeloma in 1996 after injuring her back while lifting a patient preparing for surgery. Although she is a nurse, Mary had to go back to her college text to find out what myeloma was after being told she had it. The old text informed her that the disease was terminal and had a life expectancy of one year. Mary's husband of 20 years runs a family-owned restaurant. Her 14 year-old daughter has spent almost half her life knowing that her mother is fighting a rare,

debilitating cancer. And Mary must continue to work in order to keep her life insurance, for which the annual deductible has been paid by February of each year. But, as she said to me, she would “just like to keep on going. The other choices aren’t so good.”

Brad High of Haverford, Pennsylvania lost his seven-year battle with myeloma on May 22. Brad attended the first two annual One Voice Advocacy Days and had made plans to be here today. Brad was the leader of our Philadelphia Multiple Myeloma Networking Group, arguably the most active myeloma support group in the nation. He had had two stem cell transplants and went back to the University, of Pennsylvania hospital in late April to receive a third. Brad had his own business making wedding cakes. He loved to be with people and make them happy. He was an inspirational leader of the networking group who believed in advocacy to raise awareness and federal research funding; although he realized that he would likely not benefit him. Brad believed in One Voice Against Cancer because he understood the need for all cancer advocates to work together and avoid the inclination to say that his cancer was any more or less important than anyone else’s.

ONE VOICE AGAINST CANCER

The IMF became involved in public policy advocacy in September 1998, during The March for Cancer Research on the Mall here in Washington, DC. Our initial focus, working in large part with this Committee was to include report language on myeloma in the annual appropriations bills. But since then, we have learned that this committee does not appropriate funds according to specific disease categories. And for our constituency to be effective, we would have to reach out to join forces with other groups fighting cancer. That is why we have become so supportive and active in One Voice Against Cancer.

One Voice Against Cancer is a coalition of more than 40 national and community-based organizations and collectively represent tens of millions of Americans. One Voice Against Cancer focuses its advocacy on the funding of cancer research and application programs at the National Institutes of Health (NIH), the National Cancer Institute (NCI), the National Center for Minority Health and Health Disparities (NCMHHD), and the Centers for Disease Control and Prevention (CDC).

One Voice Against Cancer was formed more than two years ago to unify the public health community on a clear and consistent message regarding the need for a comprehensive, targeted federal approach to cures for the spectrum of cancers affecting our nation. In our view, this would lead to the discoveries needed to make available better prevention and early detection strategies, treatments, and therapies that will ultimately lead to cures for the various cancers.

One Voice supports the following appropriations priorities for fiscal year 2003:

- \$27.3 billion for the NIH to fulfill the commitment to double NIH funding by fiscal year 2003.
- \$5.69 billion for the NCI, the full amount recommended in the NCI Director’s Bypass Budget.
- \$199.6 million for the NIH Center for Minority Health and Health Disparities to enable the Center to fulfill its important mission, particularly as it concerns the disproportionate incidence, morbidity, and mortality that cancer has in many racial and ethnic minority populations.
- \$348 million for the CDC cancer education, outreach, prevention and screening efforts that apply the important research done at NIH to those affected by or at risk for cancer. Specifically, OVAC recommends the following funding levels for CDC cancer-related programs:
 - \$10 million for the Comprehensive Cancer Control Initiative;
 - \$55 million for the National Cancer Registries Program;
 - \$25 million for the Colorectal Cancer Prevention and Control Initiative;
 - \$20 million for the Prostate Cancer Control Initiative;
 - \$220 million for the National Breast and Cervical Cancer Early Detection Program;
 - \$8 million for the Ovarian Cancer Control Initiative; and
 - \$10 million for the National Skin Cancer Prevention Education Program.

Funding for all of these critical agencies and programs must be efficiently and effectively utilized so that the American people reap clear and rapid benefits from research and its application. To that end, we look forward to working with you to ensure that these federal agencies responsibly meet their obligations.

THE BYPASS BUDGET

We would like to highlight in our testimony the importance of funding at the level recommended by its Director in the Bypass Budget. Under the National Cancer Act

of 1971, NCI's Director is required to submit directly to the President an annual budget estimate to provide the national cancer research program with the technology and investment it needs. This Bypass Budget is prepared and submitted prior to the submission of the annual budget to Congress, and is unique among all federal medical research institutes. At current funding levels, which have fallen short of the requested amount each year, NCI is able to fund only about 28 percent of its peer-reviewed and approved grants.

In the view of the IMF, fully funding the Bypass Budget would offer hope to those Americans who will be diagnosed with rarer, deadly forms of cancer that still lack early detection tools or treatment options. We feel this is especially true since Congress does not appropriate funds for specific medical research programs, projects, specific diseases, or cancers. It does not take much of a stretch to understand what achieving the Bypass Budget could potentially do to find better treatments and cures.

Fulfilling the Bypass Budget would provide resources for new research initiatives for the cancers that have been traditionally neglected by NCI. Patients diagnosed with one of the seven deadliest cancers—esophageal, kidney, liver, lung, multiple myeloma, pancreatic, and stomach—generally face the bleakest choices of all those diagnosed with cancer. The five-year relative survival rates for these cancers range from a low of 4 percent for pancreatic cancer to 28 percent for multiple myeloma. Without dramatic increases in research on each of the deadly cancers, the outlook for diagnosed patients will remain gloomy.

THE NEW PARADIGM

We strongly believe in NCI Director Andrew von Eschenbach's emphasis on the New Paradigm for cancer research. The New Paradigm focuses on expanding and translational research—applying discoveries in the lab toward more immediate and direct applications for patients. The New Paradigm also puts more emphasis on the most promising, state-of-the-art research of genomics—drugs and therapies that target and treat cancer at the molecular level.

The New Paradigm, which replaces the “search and destroy” mindset with “command and control,” demonstrated with drugs like Gleevec for chronic myelogenous leukemia, Iressa for lung cancer, or Herceptin for breast cancer, targets the molecular mechanisms that trigger growth of cancers without debilitating or destroying healthy cells, organs, or systems. The new genomic drugs have proven to be successful in diminishing—or eliminating—many side effects of treatment. Moreover, they have the potential for increasing long-term survival and enhancing quality of life for people living with cancer.

When we look at cancer through the genomic lenses of the New Paradigm, molecular targets will not be conveniently categorized by body parts or tumor types. The key is to identify, through research, the targets that trigger the malignant growth of cancer cells. For cancers like myeloma, there may be dozens, if not hundreds, of targets to be identified. And some of the targets for certain cancer types, at the molecular level, may look more like other cancer types. For example, hematological cancers like myeloma or leukemia may actually have some targets in common with targets in cancers of the lung, colon, kidney, or pancreas rather than other hematological cancers.

In our view, fulfillment of the One Voice Against Cancer recommendations would provide resources for a New Paradigm linking federal support to the translational research needed to produce the drugs and therapies for all cancer patients. Most importantly, however, the future of the cancer research would not be dictated by trying to carve out turf for particular cancer disease categories.

It would, instead, ensure that all cancer types are represented in the new research and create a logical, transparent system of cancer research leading down a path from incurable condition to chronic, manageable disease to, ultimately, cures for all cancer types. It would provide the framework to encourage cancer researchers to focus more on molecularly targeted therapies. It would allow NCI to engage in programs to explore research initiatives in the smaller, deadlier cancers that have few market incentives to develop new drugs and therapies. And it would do so based on scientific opportunity, not political popularity contests. This molecular approach is indeed the ultimate expression of “a rising tide lifting all boats.”

Mr. Chairman, we at the IMF applaud the recent advances in cancer research. But our patients and family members become more impatient for results about their disease the more they hear about advances in other fields. Everyone in this room has been touched by cancer. Everyone in this room knows someone who has cancer. I lost my husband to myeloma, my mother died of colon cancer, and I have lost innumerable friends to every form cancer chooses to take. As you know as well as any-

one, Mr. Chaimian, cancer destroys not just the person; it destroys the family, the community. It breaks hearts and it crushes dreams.

When Brian Novis first decided to start the International Myeloma Foundation I was somewhat skeptical—but he looked at me and said “Susie, one person can make a difference two people can make a miracle.” As I look around this room I see lots of people—you have the ability to make miracles happen. We can cure cancer. But it is going to take money and sustained commitment, especially for cancers like myeloma. Some of you may be thinking how can we afford to increase the funding for cancer research—but I say—how can we afford not to?

We are One Voice Against Cancer—and our voices must be heard. We’re your voice too.

Senator HARKIN. Thank you, Ms. Novis.

Thank you for a very, very powerful statement.

STATEMENT OF MICHAEL BRUENE, CANCER SURVIVOR

Senator HARKIN. Next we turn to Mr. Michael Bruene. Michael was born and raised in Iowa and now resides in West Des Moines with his wife Nicole, who is here with him today. On March 30, 2000, Michael was diagnosed with brain cancer and is currently participating in a clinical trial that compares the reoccurrence of tumors between patients treated with radiation versus those treated with chemotherapy. Michael, thank you and your wife so much for being here and thank you for being a brave example for all of us in confronting this and being on the cutting edge of these clinical trials. Please proceed.

Mr. BRUENE. Thank you, Mr. Chairman and members of this committee, for giving me the opportunity today to share my story.

As Mr. Harkin said, on Thursday, March 30 at the age of 29, I heard the three words that changed my life forever: “You have cancer.” In my case, it is a cancerous brain tumor. Before this date, I was relatively symptom-free. Like everyone, I had occasional headaches, but I never gave them much thought as they occurred at very stressful times in either my job or my life. An over-the-counter pain medication always relieved them.

Then on March 29 something changed. I had what I thought were two muscle spasms while I was at work. My left arm sort of tightened up. I did not think too much of them because I was a relatively healthy man at the time. Then on my drive home from work at a very busy intersection, the entire left side of my body locked up and my car swerved into the oncoming lane of traffic. If it was not for the fact that there were no cars coming at that time, my story may have ended right there. Luckily for me I was able to steer my car to the side of the road where I sat paralyzed and feeling helpless until the paralysis wore off. It was at that point I realized something was dreadfully wrong.

When I arrived home, I told my wife Nicole that she needed to call an ambulance. She was lying on the couch and could not see me, and she thought I was just pulling one of my numerous jokes and she responded with her usual response of “whatever.”

Then she saw the look on my face and immediately called 911. While waiting for the ambulance to arrive and on the ride to the hospital, the episodes—what I now know were seizures—became more frequent and more severe.

At the hospital, the doctors were able to give me medication to stop the seizures and I continue taking that today to prevent them from reoccurring.

For me that marked the end of one life and the start of another. Once in the emergency room, a CAT scan revealed a tumor about the size of a small rock growing in the right frontal portion of my brain. I was immediately admitted for surgery. The next morning further tests indicated that the tumor was, in fact, more the size of an egg or a lime. In medical terms, I have a grade 2 astrocytoma. Most astrocytomas cannot be cured because they spread widely throughout the surrounding normal brain tissue.

If there is one silver lining in my diagnosis, it is that my tumor is considered very slow growing. Still, the average survival time for these types of tumors is only 6 to 8 years. With other faster growing tumors of the same type, the survival time can drop to as low as 12 to 18 months.

After my surgery, the neurosurgeon informed my wife that he was able to remove 90 to 95 percent of the tumor, but he stopped when it became impossible to distinguish between cancer and healthy brain cells. What that means for me is a life expectancy of 3 to 8 years, of which 2 years have already passed.

Two days after surgery I was discharged from the hospital. This was a scary time for both me and my wife, as we knew very little about cancer and even less about brain tumors. I have since found out that brain tumors are very rare. They only account for 1.4 percent of all cancers and 2.4 percent of all deaths. I have also found out that the majority of brain cancers are not associated with any risk factors. They just simply happen. There are no blood tests or other screening examinations currently available to detect brain tumors at an early stage. In most cases, survival of the patient with a brain tumor depends on the type of tumor and its location, not how early it is detected.

The standard treatment for brain tumors is radiation, but there have been some great advances in combining radiation with chemotherapy. Because I did not want to face cancer with a negative attitude and because I understand the value that research holds, I decided to enter a phase III study that is comparing the reoccurrence of tumors with radiation only versus reoccurrence with combined radiation and chemotherapy. As a member of the control group, I receive 30 doses of high intense radiation over the course of 6 weeks. The radiation had tremendous effects on myself and my family. All of my hair fell out. I was emotionally and physically exhausted to the point that I could not work.

As for my prognosis, it is reevaluated every 6 months on a sliding scale. I will never truly be in remission as a portion of the tumor remains lodged in my brain. That is why I consider the diagnosis the start of a new life. Right now the tumor is currently stable; that is to say, it is not growing or spreading.

Senator HARKIN. Take your time, Michael. Take your time.

Mr. BRUENE. This Friday will mark the fifth wedding anniversary for my wife and myself. We have tried to live our lives as though the tumor is not there, but in the back of my mind, I know that there is a clock ticking and that one day the clock will expire and the tumor will start to grow back.

As a person living with cancer, I am here to tell you that we should not become complacent. We should remember that this is still one of the most deadliest causes of death in this country. We

should remember that rarer, deadlier, and more difficult to detect and treat cancers like brain cancer require more research dollars in order to find more effective treatments, earlier detection, and to gain a better understanding of the disease.

In short, I am here not only to tell you my story, but the story of the more than 1 million people who will be diagnosed with and the half a million people who will die this year of cancer. We ask you to please support additional funding for cancer research and prevention programs. They hold the promise for all of us.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF MICHAEL BRUENE

Mr. Chairman and Members of this Committee, thank you for the opportunity to share my story this morning. On Thursday, March 30, 2000, at the age of 29, I heard three words that changed my life forever—You have cancer. In my case it is a cancerous brain tumor.

I was relatively symptom-free before the diagnosis. Like everyone else, I had occasional headaches but never gave them much thought because they occurred at stressful moments in my job or life and over-the-counter pain relievers always got rid of them.

Then, on March 29, while at work, I had what I thought were muscle spasms in my left arm. I had two of them. They were mild and spread apart by several hours. For a relatively healthy man of my age, I didn't think too much of them. However, on my way home that evening—at a busy intersection—the entire left side of my body became immobile. My car swerved into the oncoming lane of traffic. If it weren't for the fact that there were no oncoming cars, perhaps my story would have ended there. Yet, I managed to steer my car safely to the side of the road where I sat for what seemed like an eternity waiting for the paralysis on the left side of my body to end. As I waited, the frightening realization that this was not a simple muscle spasm began to sink in.

When I arrived home, I told my wife Nicole to call an ambulance. She thought I was pulling one of my numerous jokes—and came back with the usual response of “whatever”—until the seriousness of the situation became apparent on my face.

While waiting for the ambulance to arrive and throughout the ride to the hospital, the “episodes”—what I now know were seizures—became more frequent and severe. At the hospital, the doctors were able to stop the terrifying seizures through the use of medication.

For me, that day marked the end of one life and the beginning of another.

Once in the emergency room, a CAT scan revealed a growth about the size of a small rock in the frontal portion of my brain. I was immediately admitted for surgery. Additional tests the next day revealed that the tumor was, in fact, the size of an egg or a lime. In medical terms, I had a grade two astrocytoma. Most astrocytomas cannot be cured because they spread widely throughout the surrounding normal brain tissue or along the cerebrospinal fluid pathways.

My tumor was considered a slow growing tumor. Still, the average survival time for these types of tumors is only 6 to 8 years. With other, faster growing, tumors of the same type the average survival time drops to as low as 12 to 18 months.

After my surgery, the neurosurgeon informed my wife that he was able to remove 90–95 percent of the tumor but stopped when it became impossible to distinguish cancer from health brain cells. What this means to me is a life expectancy of between 3 and 8 years.

Two days after the surgery, I was discharged from the hospital. This was a very scary time for me and my family. We knew little about cancer and even less about brain tumors. I have since found out that approximately 17,000 malignant tumors of the brain and spinal cord (cancers of the central nervous system) will be diagnosed in the United States this year and approximately 13,100 people will die from these malignant tumors.

Brain and spinal cord tumors are rare—accounting for approximately 1.4 percent of all cancers and 2.4 percent of all cancer-related deaths. I found out that the majority of brain cancers are not associated with any definite risk factors—they simply happen for (what I am told is) no apparent reason. There are no blood tests or other screening examinations currently available to detect brain tumors at an early stage.

In most cases, survival of the patient with a brain tumor depends on the type of tumor and its location, not how early it is detected.

The standard treatment for brain tumors is radiation, but there have been some great advances in combining radiation with chemotherapy—improving survival time somewhat. Because I didn't want to face cancer with a defeatist attitude, and because I understand the value that research holds, I decided to enter a Phase III study that is comparing the reoccurrence of tumors with radiation versus reoccurrence with combined radiation and chemotherapy treatment. As a member of the control group, I receive 30 doses of targeted radiation over the course of 30 days. As for the prognosis of my condition—it is re-evaluated every six months on a sliding scale. That is why I consider the diagnosis the start of a new life. "Certainty" has new meaning for me. Right now, the tumor is considered stable—that is to say not growing or spreading. For me, in my new consciousness, that is the only certainty I can count on.

As a person living with cancer, I am here to tell you that we should not become complacent. We should remember that it is still one of the leading causes of death in this country. We should remember that rarer, deadlier and more difficult to detect and treat cancers (like brain cancer) require more research dollars in order to find more effective treatments, earlier detection mechanisms and to gain a better understanding of the epidemiology of the disease.

So, in short, I am here not only to tell my story, but the story of the 1.2 million diagnosed with and 500,000 that die of cancer a year. We ask you to please support additional funding for cancer research and prevention programs at the National Institutes of Health and the Centers for Disease Control and Prevention. They hold the promise for all of us.

MICHAEL BRUENE

Michael Bruene was diagnosed with brain cancer on March 30, 2000. After several years of headaches and immediately following the onset of seizures, doctors diagnosed Michael with a Grade II Astrocytoma, a slow growing malignant tumor, in the right frontal portion of his brain.

Initially the doctors thought the tumor was the size of a small rock, but it ended up being closer to the size of an egg or lime. The neurosurgeon was able to remove 90–95 percent of tumor.

Although told the normal life expectancy is 3 to 8 years, Michael is hopeful that through positive thinking and continued research, there will be a cure or a treatment found soon. He entered a Phase III clinical study that is comparing the reoccurrence of tumors with radiation only to those patients that also receive chemotherapy. He is in the control group and receives 30 doses of targeted radiation over the course of 30 days. Michael's condition is evaluated every six months and to date the tumor is stable and he remains healthy.

Born and raised Iowa, Michael worked as a TV news producer for five years in California. He now resides with his wife Nicole in Des Moines and works as a marketing strategist for Fortune 500 companies. Both are actively involved in the American Cancer Society's Relay For Life and are serving as volunteer chairs for this year's Greater Des Moines event in July.

Senator HARKIN. Thank you, Michael.

Senator SPECTER. Mr. Bruene, I have asked Senator Harkin to allow me to make a comment at this time in light of your very moving testimony where it is apparent the impact when you are given a death sentence. It is pretty hard to take.

But I want to tell you that I had similar advice and it was wrong. I had tightening of my shirt collar and light pains running down my head, and the doctors could not find out what was wrong. And finally I asked for an MRI and they said, it will not do any good. And I said, well, it is not invasive. I want one. And I had an MRI and it showed a golf ball right in the front of my head. And the doctor who looked at the films was very pessimistic. He said you have got 3 to 6 weeks to live and that was on June 11th of 1993.

It so happened that on that weekend, my wife was joining me here in Washington to take a trip down to Little Washington to a fancy restaurant. So, I sort of said involuntarily, well, gee, my wife

is coming down to go to Little Washington for the weekend. As strange as this may sound, the doctor said to me, go and have a good time. And I said, give me my films. I am going to Philadelphia.

I went to Philadelphia, and some other people looked at the films and were not quite so sure. But you never now. That was a Friday afternoon, and Monday morning I had an operation, a resection. They took it out, and then they even had to slice it down to see whether it was benign or malignant.

I then studied the issue and found out that these characterizations are very tenuous. They depend upon an analysis of how many particles are moving. That does not qualify for a scientific opinion, but that was my interpretation. But it was uncertain.

At any rate, like you, they did not get it all, and it started to grow back. Then I investigated the advances in medical science and found out there was a thing called a gamma knife. Are you familiar with it?

Mr. BRUENE. Yes.

Senator SPECTER. Have you explored whether it would work for you?

Mr. BRUENE. I have not at this point.

Senator SPECTER. You ought to do that because with the stereotactic gamma knife, they put a helmet on you and they send beams, 200 of them, which concentrate on that spot, so that unlike your surgeon who stopped the operation when he got to what he considered healthy brain, it just zeroes in right on the spot.

Dr. Herberman can take you to the University of Pittsburgh to Dr. Dade Lunsford. He is the fellow who did it.

I had this procedure done in 1996 and it has regressed. So, sometimes the predictions are not correct, and I tell you that not only for yourself but for other people who are listening. This is on C-SPAN. Maybe they will play it some day. Who knows.

Some insomniac may see it at 3:00 a.m.

That is the time they feature hearings for Senator Harkin and me.

But listen carefully to the doctors and their pessimism and take it very seriously, but inquire yourself. My recounting to you is just one of many, many who have defied the odds.

Your hair is growing back. You look pretty good.

Mr. BRUENE. Thank you.

Senator SPECTER. Good luck to you, Mr. Bruene. If you want some more details, I would be glad to provide them to you.

Mr. BRUENE. Thank you.

Senator HARKIN. Thank you very much, Arlen. That was great.

Now we turn to one of the great entrepreneurial giants and entrepreneurial geniuses of our time.

STATEMENT OF STEVE CASE, CHAIRMAN, AOL TIME WARNER

Senator HARKIN. Mr. Case is I think another great example of what one person with vision and drive can do in a free society to profoundly change the way we live and work and communicate. Mr. Case is now applying those abilities and his leadership to his fight on cancer. And, Mr. Case, we are honored by our presence here today. Please proceed.

Mr. CASE. Well, thank you, Chairman Harkin for this opportunity to be here, and Senator Specter, for your very constructive and moving remarks, and Senator Murray, for being here. I know it is a busy day here in the Senate, so the fact that you are taking the time to be here this morning is appreciated.

Obviously, I am impressed, as you all were, I am sure, by this panel. I am a little daunted to be the clean-up hitter because people have been so impressive.

But as you said, my name is Steve Case. I am the chairman of AOL Time Warner, and in that role, I have testified many times before many Senate subcommittees, but never about a matter so close to my heart. I am here today not as a chairman of a company, but as the brother of a brave man who is fighting a terrible illness and as a concerned citizen who is determined to help accelerate a cure for brain cancer.

My older brother Dan was diagnosed with brain cancer, stage 4, glioblastoma, in March of 2001, and our lives have never been the same. As Dan has struggled to overcome his illness, our family has struggled to learn as much as we can about brain cancer to educate ourselves about the most effective forms of treatment and promising new therapies and, of course, to come to terms the enormous emotional toll cancer takes, as you have heard, on an entire family.

In this, we are like the millions of Americans whose lives are profoundly affected by cancer when a loved one becomes seriously ill. And like so many others, including so many dedicated people in this room today, we did not want to just wait passively for a cure. We wanted to try to take some action.

As a business person who believes strongly in entrepreneurial models of active engagement, innovation, and partnership, I felt—I hoped—we could apply some of those lessons to the challenge of accelerating a cure for brain cancer. So, together with my brother and the Case Foundation and leading scientists and entrepreneurs from across the country, we formed ABC2, a foundation designed to assess the state of brain cancer research, treatment, and prevention and to try to find new ways to improve our progress using an entrepreneurial model.

It has been a long and interesting journey, but there is still a long way to go. I would like to take a moment to tell you about what we have learned so far, what we think is working, and what we think we could be doing better.

Let us start with what is working. At one end of the spectrum, we have learned—and you heard this this morning also from Secretary Thompson—that basic research is well handled by large Government institutions and academic centers, although I do hasten to add and reinforce what you heard earlier that we really must increase the funding for cancer research at both the National Cancer Institute and the National Institutes of Health.

At the other end of the spectrum, we have seen how patient advocacy and support groups are doing a great job of providing information, resources, and comfort to cancer patients and their friends and families.

We have also seen a real lack in what is known to you all as translational research, the translation of great basic science into practical clinical realities for patients.

We have also seen a tremendous need for commercial sponsorship, without which no drug can really be successfully developed or marketed. This is particularly critical when it comes to a disease like brain cancer since the relatively small number of patients discourages pharmaceutical companies from committing the funds to develop products to treat the disease.

We have also seen that even as promising new treatments are envisioned, the implementation and aggregation of good ideas is lagging somewhat behind.

So, this is a very basic background. I want to tell you what ABC is doing to try to change the equation for a brain cancer patient such as Michael and my brother Dan.

As I mentioned a moment ago, ABC2 is founded on the idea of entrepreneurialism, which depends on innovation and rapid response and partnership and results-driven strategies that can actually leverage existing developments and accelerate therapies that could help cure brain cancer.

So, what does that really mean?

First in the year since we launched ABC2, we have awarded grants to 21 investigators at nine leading academic institutions to accelerate therapies from the lab into the clinic. Just as important, we actively track these researchers' progress to ensure accountability, help them overcome obstacles, and improve the outcomes of the projects we support.

Second, ABC2 has created a preclinical evaluation center at Duke University, a leader in brain cancer work, to test promising cancer therapies in preclinical models of the disease. This we think is a cost effective way of seeing what is working and then if the early results are favorable, working together to move these therapies more rapidly into clinical trials.

Third, ABC2 created its first collaboration with a for-profit entity Genentech. This unique collaborative effort helps Genentech to improve its risk/reward ratio so it can develop new therapies specifically for brain cancer. The way it works is Genentech does the basic research and presents its results to ABC2. If the results are favorable, ABC2 then steps up to share development costs through phase I and II clinical trials and share the great relationships we are building with leading academic centers. If these early trials are positive, then Genentech itself takes the next step funding the phase III trials and marketing of the product, and ABC2 receives a small royalty on product sales which it can then reinvest back into the research process.

We think this is a good example of how an entrepreneurial model can work in this new arena, developing and accelerating a new therapy to treat brain cancer by reducing the business risk and fast-tracking the testing cycle.

I am pleased to tell you that ABC2 has already received inquiries from other companies to pursue similar arrangements, and I really think this is a promising step on this road, this journey to a cure.

But let me be clear. I am by no means suggesting that the market alone can find a cure for brain cancer or that someone like me or our family can singlehandedly fund a new treatment for cancer. In fact, I am suggesting the opposite.

No single entity will find a cure for brain cancer by working alone. The only way we can find a cure for brain cancer is by working together.

Many of you may not know that my brother Dan is a somewhat legendary venture capitalist in Silicon Valley, someone who seeks out great ideas and transforms them into profitable action. And because of his life's work and passion, many, many businesses have thrived. So, I think it is fitting that that same spirit of entrepreneurialism that Dan has always supported may in the end help to cure my brother and so many others like him.

PREPARED STATEMENT

In closing I want to say this. We came together as a family to support my brother Dan and to seek the best possible treatment for him. But to find a cure for brain cancer, we all need to come together like a family, a family of health care professionals, researchers, lawmakers, community leaders and family members themselves. That is how we will find a cure for brain cancer and so many other cancers, and I am confident that, working together, we some day will.

Thank you again for this opportunity to be with your committee. Senator HARKIN. Thank you, Mr. Case.
[The statement follows:]

PREPARED STATEMENT OF STEVE CASE

Thank you, Chairman Harkin, for this opportunity to share my thoughts here today before this subcommittee.

My name is Steve Case and I am the Chairman of AOL Time Warner. In that role, I have often testified before Senate Subcommittees—but never before about a matter so close to my heart.

I am here today not as the chairman of a company, but as the brother of a brave man who is fighting a terrible illness—and as a concerned citizen who is determined to help accelerate a cure for brain cancer.

My older brother Dan was diagnosed with brain cancer in March of 2001—and our lives have never been the same.

As Dan has struggled to overcome his illness, our family has struggled to learn as much as we can about brain cancer . . . to educate ourselves about the most effective forms of treatment and promising new therapies . . . and, of course, to come to terms with the enormous emotional toll cancer takes on an entire family.

In this, we are like the millions of Americans whose lives are profoundly affected by cancer when a loved one becomes seriously ill.

And, like so many others, we didn't want to wait passively for a cure—we wanted to take action.

As a business person who believes strongly in the entrepreneurial model of active engagement, innovation and partnership, I felt we could apply some of those lessons to the challenge of accelerating a cure for brain cancer.

So, together with the Case Foundation and leading scientists and entrepreneurs from around the country, we formed ABC2—a foundation designed to assess the state of brain cancer research, treatment and prevention and find new ways to improve our progress, using an entrepreneurial model.

It has been a long journey—and there is still far to go. So I'd like to take a moment to tell you about what we have learned, what we think is working and what we think we could be doing better.

Let's start with what's working.

At one end of the spectrum, we have learned that basic research is well handled by large governmental institutions and academic centers—although I hasten to add that we must increase funding for brain cancer research at both the National Cancer Institute and the National Institute of Health.

At the other end of the spectrum, we've seen how patient advocacy and support groups are doing a great job providing information, resources and comfort to cancer patients and their friends and families.

But, we have also seen a real lack in what is known as “translational research”—the translation of great basic science into practical clinical realities for patients.

We have also seen a tremendous need for commercial sponsorship—without which no drug can be successfully developed or marketed.

This is particularly critical when it comes to brain cancer, since the relatively small number of patients discourages pharmaceutical companies from committing the funds to develop products to treat this disease.

And, we have also seen that even as promising new treatments are envisioned, the implementation and aggregation of good ideas is lagging behind.

So, with this as a very basic background, I want to tell you about what ABC2 is doing to change the equations for brain cancer patients.

As I mentioned a moment ago, ABC2 is founded on the idea that entrepreneurialism—which depends on innovation, rapid response, partnership and results-driven strategies—can actually leverage existing developments and accelerate therapies to cure brain cancer.

How does that translate in real terms?

First, in the year since we launched ABC2, we have awarded grants awards to 21 investigators at 9 leading academic institutions to accelerate therapies from the lab into the clinic.

Just as important—and what makes this unique—is that we track these researchers’ progress, to ensure accountability, help them overcome obstacles and improve the outcomes of projects we support.

Second, ABC2 has also created a preclinical evaluation center at Duke University—a leading academic institution—to test promising cancer therapies in pre-clinical models of the disease.

This is a cost-effective way of seeing what’s working—and then, if results are favorable, working together to move these therapies more rapidly into clinical trials.

Third, ABC2 created our first collaboration with a for-profit entity, Genentech, consistent with our charitable mission. This unique collaborative effort helps Genentech to improve its risk/reward ratio so it can develop new therapies specifically for brain cancer.

Let me sketch out how this works.

Genentech does basic research and presents its results to ABC2. If results are favorable, ABC2 will share development costs through Phase I and II clinical trials—and share our great relationships with leading academic centers. If early trials are positive, Genentech funds Phase III and markets the product, and ABC2 receives a royalty on product sales.

It’s a perfect example of how the entrepreneurial model can work in this new arena—developing and accelerating a new therapy to treat brain cancer.

I’m proud to tell you that ABC2 has already received inquiries from other companies to pursue similar agreements—and I really think this is a very promising step on the road to a cure.

But let me be clear. I am by no means suggesting that the market alone can find a cure for brain cancer, or that someone like me can singlehandedly fund a new treatment. In fact, I am suggesting the opposite.

No single entity will find a cure for brain cancer by working alone.

The only way we will find a cure for brain cancer is by working together. And that is the most important lesson we have learned.

Many of you may not know that my brother Dan is a legendary venture capitalist—someone who seeks out great ideas and transforms them into profitable action. Because of his life’s work and passion, many new businesses have thrived.

So I think it’s fitting that the same spirit of entrepreneurialism that Dan has always supported may, in the end, help to cure my brother and so many others like him.

In closing, I want to say this: We came together as a family to support my brother Dan and to seek the best possible treatment for him. To find a cure for brain cancer, we all need to come together like a family—a family of health care professionals, researchers, law makers and community leaders, and family members themselves.

That’s how we’ll find a cure for brain cancer—and I am confident that, working together, we will.

Thank you again for this opportunity.

Senator HARKIN. Mr. Case, the development of how ABC2 is working. Sounds like a great model. Can you tell me, have you reached out to other foundations? Are they also looking at doing something like this too, other than just the Case Foundation?

Mr. CASE. Oh, absolutely. It is not really directly related to the Case Foundation. It is a new foundation that was created called Accelerate Brain Cancer Cure, and the first step is trying to partner with as many organizations as possible.

One thing that we found as we started looking into this—I am sure people in this room and people like yourselves who have been looking at this for many years have known this for some time, but it was relatively new to me—was how fragmented, how silo-ized the developments are within the cancer field, how some people focus on prostate cancer and some people focus on brain cancer, and the work tends to be fairly fragmented. So, trying to figure out where you can connect the dots—indeed, probably some of the most promising therapies for a specific cancer like brain cancer may be coming from other cancers that have been studied for a longer period of time. But right now, there is not enough focus on trying to translate that to apply to brain cancer. So, we are trying to partner with as many different organizations as we can to identify those promising therapies, partner with institutions like a Duke to accelerate their research, partner with companies like a Genentech so they can accelerate the process of moving that from trials into the field. It is something that really does require a “connecting the dots” mentality and a real spirit of partnership.

Senator HARKIN. So, you feel that this is definitely working and can work even more to bridge that gap, to fill in that translational research that we mentioned earlier about getting more than just 3 percent of adults with cancer into clinical trials.

Mr. CASE. Absolutely. I think we all know that there is no silver bullet here. There needs to be continued and accelerated funding and basic research. I actually think one of the things we are starting to see is it would be helpful to have more of a platform approach to cancer, more of an integrated model, whether it be informatics or other things that might accelerate the exchange of knowledge and insight between different fields. There needs to be more effort on the translational side and more investment in clinical trials, more people aware of the different options and so forth, and then better models to accelerate, particularly for the more specialized cancers like brain cancer.

What is difficult about brain cancer is not just the number of people who get it is relatively small, but unfortunately, as Senator Specter says, it is a little bit of a death sentence. The life span is relatively short. So, from a business standpoint, it is not going to hit the radar screen of pharmaceutical companies. So, we need to figure out new models that reduce the risk from an investment standpoint and also reduce the burden from a regulatory standpoint.

One thing we have heard from many companies is even though they think some of their drugs may be applicable to brain cancer, they are reluctant to begin that journey because if they are unsuccessful in their efforts, it may taint their review by the FDA or others as it relates to other cancers. So, they believe they have something that might be helpful, but they believe the risk, from a business standpoint and a regulatory standpoint, is too great. So, trying to look at ways to reduce that risk through public-private partnerships like ABC2 and I am sure the things you are looking at

in terms of regulatory reform I think could be very helpful particularly for these more specialized cancers.

Senator HARKIN. You have hit on one thing that—I forgot the name for it, but where drugs are developed for one thing, but they believe through certain bench kinds of experiments that it may be applicable somewhere else. But we really have a tough time in moving in that direction. I am not certain why. I do not know the answer to that, but obviously you are again focused on that too with this foundation. In other words, how do you get FDA to be more supportive of allowing some of these experimental drugs to overlap into other areas where it looks like they might be applicable. We have had a problem with that and I do not know the answer.

Mr. CASE. Others here probably have a better answer, but I would say from a company standpoint, regulatory reform there is necessary so it can reduce the risk. One thought would be, to the extent they do, to take the risk of taking a particular therapy and applying it to a particular cancer with a belief that it might work but not certainly the certainty that it might work, if in that particular area it does not work, it does not strike me as if that should taint the results related to some other cancer. If it is developed for prostate cancer, it is working for prostate cancer, you say, you know, given the nature of this therapy, the nature of this particular disease, and particularly as you get better molecular—we think this actually could apply to brain cancer or some other cancer, if they are willing to give it a shot, they are willing to put some money behind that, it does not seem fair to penalize them if it does not work. That it seems to me what the regulatory process right now does.

I understand the concern about patient safety, but frankly, when you have a situation like you heard with Michael or my brother and Senator Specter had 10 years ago and somebody says you have 6 weeks or 6 months or 2 years or what have you to live, it is not particularly comforting to hear about the regulatory process that has been put in place with lots of safeguards when you are willing to roll the dice because the risk/reward clearly is in favor of taking a risk.

Senator HARKIN. Well, I have a bill that I have introduced, and I have been trying to get it through for some time now. It is called the Access to Medical Treatment Act. Basically what it says is simply this, Mr. Case. It says that if you are a licensed practitioner in a State, licensed by the State, and you want to apply a certain therapy to a patient and that patient gives informed consent and furthermore, that therapy has not proven in the past to be harmful—there is no indication it has ever been harmful—you give informed consent. It is done by a licensed practitioner in a State, an oncologist and others. You ought to be able to have it. But we cannot even do that. And sometimes we have people who are facing short sentences.

I remember when one of my brothers passed away with cancer and trying to get some experimental drugs. My brother said, what have I got to lose. He said you might as well. He was like you. He was a businessman, and he said, of course, let me try whatever is

out there. As long as it has not proven to be harmful, why should I not try it?

So, this is another one of those hurdles that we just confront all the time with FDA and others. So, any insight and suggestions you can give—and you have given us some on how to get over that.

Dr. Huerta, I just want to say again to Mr. Case here that next year, not this committee, another committee I chair, will be having hearings and reauthorizing the child nutrition programs, school lunch, school breakfast, and the others. We know that what you eat later in life probably started early. You talk about nutrition and diets and things like that. I may call you back at that time to testify.

But you are talking about getting information out to people. Well, there is no one who knows more about getting information out to people than Mr. Case here. This seems to me again something that we have got to know more about. How do we get information out to groups of people on the risks they face, what they need to do to cut down on smoking, and how they can do it, or their diets, what nutrition they need to have?

Dr. HUERTA. Thank you, Mr. Chairman. Very briefly. What I do, for example, is I write a radio show every single day. Every single day it broadcasts three times a day and that show is distributed among 90 radio stations across the United States, Puerto Rico, and Latin America. Then every day I have a 1-hour talk show on health on radio because they built a radio studio in my office. So, I see patients during the morning. I take a break. I am connected live with the public. I talk to them on health issues, encouraging them to do health promotion, health prevention, and then I say, see you tomorrow, lunch, and next patient 2:30 in the afternoon. Saturday we have a television show. So, the idea is that we need to be consistent.

I ask you and I ask the members of the panel and the public, do you conceive of your 11 o'clock news without a sports guy?

Probably not. What happens if he sports guy if he does not show up? Why can we not have health information every single day? Every night at 8:03 p.m. on National Public Radio here in Washington, D.C. there is a wonderful show about the stars, Stars Watch. I am learning a lot, where Venus is, Mars is.

Senator HARKIN. When I am driving home, I hear it.

Dr. HUERTA. Exactly. Where is the health show every single day on National Public Radio to educate us about health? It is lacking.

At NIH, they have a wonderful infrastructure. They have so many institutes, so many offices. They would have an enormous amount of material to put out for the public. We are lacking that.

Senator HARKIN. One last thing. I just want to say to all of you who are here thank you for being here. You have been a great audience. But more than that, use your time on the Hill to—I will not say lobby, but educate Members of the House and the Senate. Senator Specter knows full well we will try to do our job here, but we do not run everything around here. We have our committee, but we need help in making sure that we get the allocation of funds that we need in order to be able to meet these obligations. So, we need your help in going around and talking to others about the need for the necessary funds to fight cancer. So, I hope that you will meet

as many Senators and Congresspeople as you can while you are here.

I know time is running out, but I want to recognize Senator Specter.

Senator SPECTER. Well, thank you, Mr. Chairman.

Just a few questions. Mr. Case, thank you for what ABC2 is doing. It is great to have the entrepreneurs in the field to make an independent analysis. You have a little different view than the NIH, the National Institutes of Health. Senator Harkin and I for years have been trying to push clinical trials again and again and again. There is a lot of skepticism or there is a lot of concern about taking any money away from research. But if you do not know how to apply it, all the research in the world cannot give you the ultimate answers.

Your ways of trying to get companies to research and develop drugs, cures for ailments like brain tumors is really commendable because it does just hit a small percentage. But if you are that percentage, Mr. Bruene and I can tell you we need the help on that.

Dr. Herberman, you testified that there are cures for certain types of cancers. Could you amplify that? Which ones do you include in that category?

Dr. HERBERMAN. Well, the ones that I was particularly alluding to which I think are most impressive are childhood leukemias, Hodgkin's disease, and testicular cancer. With these, quite remarkably, even when they are diagnosed at advanced stages, chemotherapy or some other treatment can cause a complete cure.

Senator SPECTER. Well, I think that is very important to emphasize, that when you talk about cures, most of the time in popular parlance, there is a view that there is no cure for cancer. So, when you identify some forms of cancer which can be cured, I think that gives heart to a lot of people.

Then the issue is to find cures for the other forms of cancer. I am convinced that there are cures out there, that if we open enough doors on scientific research, that we can find cures for all these problems. Medical science has wonders just to no end to what can be done. So, I think that identifying some cures is very important.

You then said that there are tremendous opportunities. Are you referring to research opportunities with even more funding?

Dr. HERBERMAN. Yes, very much so. I think we now understand in great detail that essentially any type of cancer represents a molecular abnormality in the genes of the cancer cell. By understanding what those particular genes that are malfunctioning are, we are able to molecularly target these genes and correct the abnormalities. These are the extraordinary opportunities that are referred to.

Senator SPECTER. So, you think if we look hard enough, we can find answers, cures for all these molecular abnormalities?

Dr. HERBERMAN. I am very optimistic. If not find cures for all of them, to at least convert what is a rapidly fatal situation to one where we could at least stabilize and have prolonged quality of life for people with cancer. It is not so bad to live with cancer for a long time as long as one has good quality of life during that period.

Senator SPECTER. Well, prolonged quality of life is second best. The best is a cure.

Dr. HERBERMAN. Absolutely.

Senator SPECTER. Senator Harkin and I are going to press you to find cures if we are going to give you all this money.

Dr. HERBERMAN. We are working very hard at this, Senator.

Senator SPECTER. Okay. Keep working.

Last question. You talked about restructuring the clinical mechanisms. We would like you to give us a writing on that. Give us your ideas as to how to restructure the clinical mechanisms. We cannot take it up in the course of an abbreviated hearing, but when Senator Ellen and Senator Betty Lou write the appropriation report, they have great powers in their pens to give direction to NIH and CDC and everybody else. But we need to know what to say. I know it will shock you, but we do not have all the answers. So, when we have you high-powered experts, we like you to tell us what you would suggest on restructuring the clinical mechanism, and we will try to help you make it happen.

Dr. HERBERMAN. Well, thank you very much, Senator. I very much welcome that opportunity and I will forward you detailed thoughts about doing exactly that.

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

Senator HARKIN. Thank you, Senator Specter.

Again, I want to thank all of you. I want to thank especially the Iowans who came here. I want to thank you, of course, Michael, for your bravery and Nicole, your wife.

Senator SPECTER. I want to thank the Iowans too. Now, will you thank the Pennsylvanians?

Senator HARKIN. Well, you can thank them.

Thank you very much, Mary and Lanessa, for being here, Serge, Threase. Thank you all for being here today.

Just one last thing. I bring this up not every hearing we have on cancer, but almost every one. I have in my office a book. It is called a Compendium of Spontaneous Remissions. It was given to me by Senator Claiborne Pell before he left. It is a book of known cases, diagnosed cases of cancer, in which after certain treatments or maybe not some treatments, there was spontaneous remission. They just went away. I happen to have a friend of mine in Sioux City who came to NIH some 30 years ago with a rare form of cancer. They did a few things. She went home and never had cancer again.

I have often wondered why has the research community not taken all of these and put them in some kind of a matrix. Who are these people? How did they live? What did they eat? What did they do? Is there some connective thing there on why these people had spontaneous remissions and others do not? I have never yet been able to get an answer to that question. So, I just leave it at that and I hope that you will maybe ponder it and think about it, and if you have some suggestions for me, please let me know.

But you have been a great panel. We thank you all very, very much for being here. We will do what we can.

Do you have any last statements that anybody wanted to make before I close down? Steve or Michael, Susie, Dr. Herberman, Dr. Huerta?

Dr. HERBERMAN. Maybe I will just respond to the spontaneous remission issue, which has also fascinated me for many years. I am actually an immunologist and focus particularly on how the body can fight against cancer. I think this provides a very important clue. The body has a remarkable ability to recognize in some cases cancer and fight against it. I think by understanding those cases, that really is an important clue to broaden this and make it more frequent.

Senator HARKIN. I hope we do more research.

Susie.

Ms. NOVIS. My closing comment would just be that again I urge you to fully fund the bypass budget. Information we received from the NCI says that 72 percent of all approved grants do not get funded, and it is apparent that we need research. They have been approved, but there just is not the funding to make them happen.

Senator HARKIN. Excuse me. I thought it was higher than 28 percent.

Ms. NOVIS. No. The information that we have received from the National Cancer Institute was that figure.

Senator HARKIN. How far does that data go back? Because we have doubled the funding in the last 5 years in order to get that rate up to in the 40 to 50 percent.

Ms. NOVIS. I am told that that information is 2 years old. But still we have a long way to go, so again I urge you fully fund the bypass budget.

Senator HARKIN. Well, I urge you to please get a hold of your Congressmen and Senators and others and tell them that we need the allocation for it in our budget in order to do it. Once we get our allocation, that is all we have got to fight hard to get the requisite money.

Let me close on this. We talk and people say, well, my gosh, we put how much money into research? Where is that figure that we put into cancer research this last year? You had all those figures, Susie. NIH was \$5 billion. We have doubled the funding to \$27 billion. And people say, my gosh, that is a lot of money. If you cannot find a cure for cancer with that, I mean, you are not going to find it. That is a lot of money.

I keep pointing out that we started this doubling in 1998. In the 2 years previous to that, 1996 and 1997, we spent more money as a Nation on military research and development than we have on—are you ready for this—all medical research since the turn of the century. I will repeat that. We spent more on military research and development in 2 years than we as a country spent on all medical research since the turn of the 20th century. That means everything from polio to smallpox to everything else.

Now, I do not bemoan the fact that we spent that much on the military. Obviously it has made us the most powerful nation on earth. It is preserving our freedom. But you put it in context, you think, my gosh, we have not even scratched the surface in the amount of money that we can put out for biomedical research.

This basic research is, as I have often said, like you have got 10 doors. You do not know what is behind them. If you open one door, what are your odds against finding the answer? If you open two doors, what are your odds? If you open three doors? That is where we are now, as you pointed out, about 28 percent. What if we opened five or six or seven doors? Then the odds are much greater.

Ms. NOVIS. Exactly. And now with targeted research, this opened a huge door. We need to have the money to go through that door.

Senator HARKIN. That is right, exactly.

Dr. HUERTA. Mr. Chairman, we need to also focus on that research. It is not only the biology of the tumor. It is not only the antibodies. It is not only the marker. It is also the person, as you said. So, in addition to focusing on the tumor of the person, we need to focus on the person himself or herself. It is extremely important.

Senator HARKIN. I agree.

PREPARED STATEMENTS

We have received the prepared statements of Senator Mary L. Landrieu and Senator Ernest F. Hollings. They will be made part of the record.

[The statements follow:]

PREPARED STATEMENT OF SENATOR MARY L. LANDRIEU

Thank you Mr. Chairman. To understand the huge impact Cancer has had on the lives of most Americans, one need only ask themselves the question: How many people do I know or have I known who have this disease? For most of us, the answer is easily in the double digits. In 2002, roughly 21,900 people in Louisiana will be diagnosed with cancer. What's more, 9,500 Louisianians will die from this debilitating disease this year alone. This number is growing with each year. It is predicted that the number of people diagnosed annually with cancer will double over the next fifty years, from 1.3 million to 2.6. By 2050, more than 1.1 million people seventy five years or older will be diagnosed with cancer each year.

The human toll of this disease is incomparable. 1,500 Americans lose their lives to this disease daily. 1,400 children under the age of 14 will lose their battle each year. Yet, what is almost as staggering is the fiscal cost of cancer nationwide. In 2001, the overall cost of cancer was estimated to be \$156.7 billion dollars, \$56.4 billion for direct medical costs, \$15.6 billion for lost productivity due to illness, and \$84.7 billion for lost productivity due to premature death.

Like with many diseases, the fight against cancer is two fold; the race for a cure and working towards preventing and treating the disease. The American Cancer Society reports that one third of all cancer deaths in 2002 will be related to nutrition, physical inactivity, obesity and other lifestyle factors that might have been prevented. Smoking is responsible for 87 percent of lung cancers and at least 30 percent of all cancer deaths. We need to be doing more to educate people about how they can take charge of their lives and protect themselves against this horrible fate. I encourage the NIH and the CDC to continue to work together, through efforts such as the CDC Cancer Prevention and Control programs, to improve the public education in this area, especially to our young people. Rates of obesity and teenage smoking among girls are on the rise. Changing this mind set early will reduce the number of people who fall victim to diseases such as cancer.

Another key area is early detection. In most every form of cancer, the patient's survival rates are greatly increased if the disease is caught and treated early. Right now, the CDC's Breast and Cervical Cancer Early Detection Program is only reaching 18 percent of those eligible to receive these services. With more funding, this program would be able to serve and protect all women and thereby reduce the both the human toll and the financial cost of this deadly disease. In addition, we must work to ensure that the promise of prevention, early detection and treatment are available to all Americans. When compared with the general population, significant disparities are found among racial and ethnic groups and the medically underserved. Under current law, the National Center for Minority Health and Health Dis-

parities is charged with the mission of ensuring that these populations receive the attention they need and deserve. Increasing the funding for within the NIH for cancer research, treatment and prevention will mean nothing if we do not also remove the barriers to quality medical care that exist today.

Like the majority of my colleagues on the committee, I fully support the goal of doubling the NIH budget in five years. If we meet the President's request of \$27.3 billion we will have met that commitment. Right now, the NIH is using these dollars to support over 36,000 research projects. Each of these projects holds the promise of a cure or a more effective treatment for an American who is suffering. For those suffering from Cancer, it is the hope of these answers that keeps them going. While I understand that our budget is limited this year, I hope we can find the resources necessary to meet the National Cancer Institute's needs.

Again, thank you Mr. Chairman for holding this important hearing and I look forward to hearing from the Secretary and the other witnesses here this morning.

PREPARED STATEMENT OF SENATOR ERNEST F. HOLLINGS

I would like to thank the Chairman for bringing such a distinguished panel before the Subcommittee today. Cancer is a disease that affects families of all backgrounds in all parts of the country. However, cancer affects more families in my state than most others. We hold the unfortunate distinction of ranking among the top five in the nation in rates of multiple myeloma and oral, prostate, pancreatic, and esophageal cancer. We are also not far behind in regard to cervical and larynx cancer.

Through the significant investment this Subcommittee has made in cancer research, we have enabled scientists across the country to expand our basic understanding of cell growth and death and to develop effective forms of treatment and prevention. Much of this work was accomplished in NCI-designated comprehensive cancer centers. I am troubled that these centers tend to cluster in the Northeast and along the Pacific Coast, and bear little correlation to cancer incidence or mortality rates. In fact, only three of the fifteen states with the highest cancer mortality rates have a comprehensive cancer center. While we should continue to fund the best and brightest in their efforts to find cures for cancer, I believe the current concentration of comprehensive cancer centers deprives us of gaining valuable knowledge in the parts of the country where cancer is most prevalent. I would hope that as the National Institutes of Health designates new comprehensive center centers, they will make awards to institutions in states with the highest cancer rates, those truly on the front lines of the war against cancer.

Secretary Thompson, I look forward to hearing your testimony and look forward to working with the distinguished Chairman and Ranking Member of this Subcommittee to provide you with the resources necessary to bring more comprehensive cancer centers to states and communities across the country.

I thank the chair.

CONCLUSION OF HEARING

Senator HARKIN. Thank you all very much for being here, that concludes our hearing.

[Whereupon, at 11:25 a.m., Tuesday, June 4, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]