PRIORITIES OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES REFLECTED IN THE FISCAL YEAR 2002 BUDGET

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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PRIORITIES OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES REFLECTED IN THE FISCAL YEAR 2002 BUDGET

THURSDAY, APRIL 26, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Greenwood, Burr, Whitfield, Ganske, Norwood, Shadegg, Bryant, Buyer, Pitts, Brown, Waxman, Strickland, Barrett, Towns, Pallone, Engel, Wynn, and Green.

Staff present: Marc Wheat, majority counsel; Kristi Gillis, legislative clerk; John Ford, minority counsel; and Bridgett Taylor, minority professional staff member.

Mr. BILIRAKIS. The hearing will come to order.

I am extremely pleased to welcome the Honorable Tommy Thompson, Secretary of the U.S. Department of Health and Human Services and, as we all know, the former Governor of Wisconsin to testify before the subcommittee.

This, sir, is your first appearance before the Energy and Commerce Committee as part of the new administration, and I know all of us are delighted that you are able to take the time out of your busy schedule to be here.

The purpose of today's hearing is to discuss the priorities of the Department as they are reflected in the administration's fiscal year 2002 budget request.

In addition, many members are interested in learning more about a number of regulatory issues. To facilitate a dialog with the Secretary, which Ranking Member Brown and I are both anxious to do, I request unanimous consent that the opening statements of all members, other than the chairman and ranking member, be limited to 1 minute, with full statements submitted for the record, of course.

The fiscal year 2002 budget delivers on President Bush's vision for a responsible approach to improving the health and well-being of all Americans. This budget includes $468.8 billion in total outlays, an 8.9 percent increase over fiscal year 2001 spending. In particular, I am very pleased to see for the first time in a long time

an increase in the Health Care Financing Administration's administrative budget.

The committee has communicated extensively with Secretary Thompson about our Patients First project, which is intended to help HCFA operate more efficiently and improve the quality of care for parents; and I think we all agree that increased administrative funding is a necessary step. We have all seen that to be the case in our hearings, but it is only part of the solution. I appreciate the Secretary's active input in our Patients First initiative, and I know that we will benefit greatly from his practical experience as a former Governor.

Finally, I would like to commend President Bush and Secretary Thompson for recognizing Medicare reform and the inclusion of a prescription drug benefit in the Medicare program as a top priority. In addition to streamlining burdensome and inflexible bureaucratic controls, we must act now to protect and strengthen this vital program.

Mr. Secretary, the members of this committee and I look forward to working closely with you and with President Bush to enact broader reforms to preserve Medicare for the future while improving the program by establishing a prescription drug benefit.

I now yield to my good friend, Mr. Brown of Ohio.

Mr. BROWN. Thank you, Mr. Chairman.

Welcome, Secretary Thompson. Your appointment to HHS was a good one, and we are very glad that you are here with us and look forward to working with you in the next few years.

You and I have spoken previously about a number of issues, including the privacy rule and the importance of full funding for Children's Hospital GME. Since that conversation, the President has decided to move forward with the privacy rule and the budget has been released with substantial but not full funding for Children's Graduate Medical Education. These outcomes are positive, even if we have some distance to go on both issues.

The guidance that will be issued to clarify the privacy rule is as important as the rule itself. I look forward to working with you to make sure this guidance clears up any confusion about the intent of the regulations, without compromising the hard-fought protections established by the rule.

Mr. Secretary, the Children's Hospital GME program should be fully funded. We do not expect other teaching hospitals to squeeze blood from a stone and self-fund graduate medical education. We shouldn't expect children's hospitals, most of which survive on far-from-generous Medicaid funding, to self-finance the training of our pediatricians and pediatric specialists.

Let me turn to Medicare. The President's budget diverts $150 plus billion from the Medicare Trust Fund into prescription drug assistance and Medicare reform. Prescription drug assistance would take the form of block grants the States do not want and stand-alone prescription drug plans the insurance industry tells us they won't sell.

The Medicare reform proposal, although not specified in any level of detail, appears to want to reform the program by introducing more choice, also known as HMOs, into the program while minimizing the role of traditional Medicare. The President plans to de-

plete the Part A trust fund, even though we know that the demands on that trust fund will increase at a substantially greater rate than the fund itself, provide nowhere near the funding necessary. Both parties agree to establish meaningful prescription drug coverage for seniors, and plans to overhaul traditional Medicare by making it one big plus choice program, when our constituents tell us that it is actually the plus choice part, not the traditional fee-for-service part, that is not working.

I can see how the Medicare proposals accommodate the President's tax cut and I can see how the Medicare proposals benefit the insurance industry and the prescription drug industry, but I can't for the life of me see how those proposals protect Medicare, improve Medicare, or address a single concern raised by beneficiaries and their families.

Again, these concerns overwhelmingly relate to the Medicare managed care program, not to traditional Medicare, which is working very well.

I want to switch gears for a moment and talk about HHS-funded programs on food safety. Five thousand Americans die each year from food-borne illnesses. Hundreds of thousands of others are hospitalized. In addition to the well-known and documented instances of food-borne illnesses, Americans need to be concerned about antibiotic-resistant bacteria in food, genetically modified organisms of unknown risk, and lethal contaminants such as mad cow disease. Yet we inspect at our borders only .7 of 1 percent of our food.

The modest increases in the President's budget barely skim the surface of the problem, and even those dollars could easily be diverted toward FDA's core drug approval activities. It has unfortunately happened before. We need to do better with food safety, with inspections. We can't do that, Mr. Secretary, without your active participation and leadership; and we look forward to that.

Thank you.

Mr. BILIRAKIS. I thank the gentleman. Now the Chair recognizes the vice chairman of the subcommittee, Dr. Norwood.

Mr. NORWOOD. Thank you very much, Mr. Chairman.

Mr. Secretary, we welcome you today. I think I congratulate you on your appointment. I believe that you perhaps have one of the most difficult agencies out there to deal with, and I also believe that you are the man for the job that can straighten it out.

I am one of those people that happen to believe that the President, the CEO of our country, is very correct in trying to make certain that we limit the amount of increase in spending every year; and I am one of those people who believes that, even though many problems and many things need to be changed—for example, in Medicare, in managed care, at HCFA, et cetera—not always the solution is throwing dollars at it. Sometimes we may just want to try to do things right and be a little more efficient, and I believe that you are the man for that job.

I am pleased about your passions that you bring to Washington and bring to HHS, for example, in your deep interest in organ transplants and in other areas. That is the kind of Secretary I would like for us to have, not someone who just pushes numbers around but one that really believes in this issue. So I very much

look forward to working with you, and I know we are going to do some great things in many areas, and I thank you, sir.

I yield back.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Pallone, for a brief opening statement.

Mr. PALLONE. Thank you, Mr. Chairman, for holding this hearing.

The President, Mr. Chairman, in my opinion should be fighting for health priorities that protect Medicare, provide a meaningful Medicare prescription drug benefit and ensure funding for public health programs that provide care to those who cannot afford it. After reviewing the HHS budget priorities, it is clear to me that just the opposite will be accomplished. That is, the budget will spend the Medicare surplus on other priorities, the budget will fail to provide a meaningful prescription drug benefit, and the budget will cut important safety net programs and public health programs that provide care to the underserved population.

It is particularly alarming that President Bush's tax cut forces him to use the Medicare surplus to fund other spending initiatives. The budget includes the Medicare surplus in an $842 billion contingency fund that will be used for defense, education, agriculture and debt reduction. It is estimated that the contingency fund will be quickly depleted, therefore leaving the Medicare trust fund surplus vulnerable to being used for other priorities. From my understanding, even Secretary Thompson agrees that the budget fails to protect the Medicare trust fund.

The government is in a unique financial position to make necessary changes to Medicare and to add necessary health services to those who lack resources. This is not the time to funnel Federal dollars that can be used for health priorities to instead fund a tax cut plan that costs over $2 trillion ultimately.

I want to thank you again, Mr. Chairman, for holding this hearing; and I am interested in hearing from the Secretary on the budget and look forward to opportunities to ask questions.

Mr. BILIRAKIS. I thank the gentleman.

The Chair now recognizes Dr. Ganske and would also report that a vote is being expected in the next 3 or 4 minutes downstairs on the telecom bill, so some of us will be getting up and jumping down for that.

Mr. GANSKE. Thank you, Mr. Chairman. I thought you were saying a vote on the floor was going to occur and giving me a hint to be brief. I will be brief.

Welcome, Mr. Secretary, a fellow Midwesterner, somebody who has been intimately involved with Department of Health and Human Services issues for a long, long time, very knowledgeable on these issues and I think a great appointment by President Bush for this slot. And thank you for your public service throughout the years and particularly now in this difficult job.

There are so many things to talk about. I don't know how much time you will have with us today. We could talk about implementation of patient rights as they relate to Medicare. There are important public health issues like tobacco and the role of the FDA, which you have spoken about to some extent. Prescription drug benefit will, I am sure, come up. I would like at some time to talk

to you about how we can improve the reimportation of prescription drugs which Congress worked on.

The big issue is the solvency of Medicare in the long term. But as it relates to Medicare there is one issue that you, as a former Midwestern Governor, and I, as a representative of Iowa, think a lot about and that is that rural States have not received a fair reimbursement proportion. Nationally, Iowa ranks about 25th in terms of overhead expenses and yet we are dead last, right at the bottom, 50th in terms of Medicare reimbursement. That is not fair, and I think we need to do something about it. I know that you have taken an interest in that, and I look forward to your testimony.

Mr. BILIRAKIS. Mr. Towns, for an opening statement. We have had unanimous consent to limit our opening statements to 1 minute. But obviously if we can stay as close to it as possible, that would be appreciated.

Mr. TOWNS. Fifty-five seconds, Mr. Chairman.

Mr. Secretary, let me congratulate you again. I was pleased to see in your testimony that you will attempt to streamline antiquated systems at HCFA. I hope that under your watch you will also reduce some of the burdensome and unnecessary regulations from HCFA.

Let me briefly describe one such unnecessary regulation that is affecting the seniors in my district.

On January 10, 2001, HCFA issued approval of the Home Health Advance Beneficiary Notice and required all home health agencies to give this form to all of their duly eligible patients by March 1 of this year. This form is on the top of multiple other written notices home health agencies are required to provide to patients under their care.

While this form is an improvement over earlier versions, it still does not allow HHA to inform duly eligible patients that, if Medicare will not cover their services, Medicaid has covered them in the past and is likely to continue to cover them in the future. Instead, the form provides only three options, all of them informing the patient that Medicare will either reduce, limit, or deny coverage for the relevant home health service. This frightens the patients and family members often to the point where they will refuse the home health care they desperately need in order to avoid getting stuck paying for a bill that the home health agency knows is covered.

Mr. Secretary, if we can put a man or a woman on the moon, surely this country can devise a home health care form which will permit low-income seniors to receive the care they desperately need. I urge you, Mr. Secretary, as part of the planned HCFA reforms, to simply add a third option in this form which will permit Medicaid to be properly billed for home health service.

I look forward to working with you in the days and months ahead. Thank you very much.

Mr. NORWOOD [presiding]. Ladies and gentlemen, the committee chairman has asked that we hold to 1 minute in order to give the Secretary as much time as possible; and though I am uncomfortable interrupting you, I am going to at 1 minute. So please limit your remarks to 1 minute.

Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman.

I, too, want to add my welcome to you and tell you that I am personally very pleased that you are in the position that you are in. In the interest of saving time, I will adopt the statements of my colleagues on this side of the aisle and would yield back the balance of my time.

Mr. NORWOOD. Thank you, sir.

Now we will hear from Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I know we are eager to hear from Secretary Thompson, so I will keep my remarks short. I have a much longer statement that I will submit for the record.

Welcome, Mr. Secretary. Mr. Chairman, the services provided by HHS have a direct benefit and touch the lives of more Americans than any other agency. From the life-saving research performed at the NIH to the vital assistance provided by the LIHEAP program, this agency has vast and critical responsibilities. It is essential that we provide HHS with the resources it needs to perform those duties.

While the President has made investments in some programs such as NIH and community health centers, he eliminates or cuts or provides insufficient funds for others. I am especially concerned about elimination of the Community Access Program, cuts to the Pediatric Graduate Medical Education Program, and also reductions in the CDC's Chronic Disease Program. These programs are critical to our fight to provide health care to the Nation's 43 million uninsured and our battles against chronic disease and the training of pediatricians and pediatric specialists. I look forward, Mr. Secretary, to hearing you today and look forward to working with you and also to discuss some of these particular programs that we have.

I yield back my time. How long was that, Mr. Chairman?

Mr. NORWOOD. One minute and 5 seconds.

Mr. GREEN. I thought I was going to do it in 59 seconds.

Mr. NORWOOD. You did pretty good.

Mr. Buyer for 1 minute.

Mr. BUYER. Mr. Secretary, I also welcome you here today and let you know that I come from a rural district in Indiana, and I want to make sure that the American rural areas, their medical needs and health needs are also met so we will make sure that we have equity in our systems. Out there in those rural areas reimbursement for ambulance rates are very important to make sure that we can get these patients to those health centers.

The other thing I would just throw out on the table to you, as you hear Mediscare, and that is what we have heard from some statements here today, I would like to remind you that it was back in 1995, when Republicans took control of Congress, in the face of bankruptcy, we worked with President Clinton. We did not get support from those who were the advocates of universal health care or government controlled health care. But when we moved forward to save Medicare from bankruptcy, that didn't mean that we got it all right. So we have to be very attentive in that process, and we want to work with you and especially on the Medicare prescription drug program.

Mr. NORWOOD. Mr. Strickland, I know that 1 minute is not enough, but you are recognized for 1 minute.

Mr. STRICKLAND. Thank you, my friend.

Thank you, Mr. Secretary, for being here.

I note that the Community Access Program—which is a program that helps rural areas in particular because it helps community providers provide greater services for the uninsured—has been eliminated to the tune of $125 million. The Health Resources Service Administration facilities program eliminated, some $251 million. The Bureau of Health Professions has been cut by $213 million, and this program helps train professionals to serve in medically underserved communities. Rural health and telehealth cut by $58 million, and SAMSHA's mental health programs cut by $16 million.

I just point these out because I am from an Appalachian area, a very poor area, and I think these programs are very vital to a region like mine and many others across the country. So I am glad you are here today. I look forward to your testimony, and I hope you can speak to some of these issues.

How did I do?

Mr. NORWOOD. You did absolutely great. You gave Mr. Waxman an extra 10 seconds.

I now recognize the vice chairman of the full Commerce Committee, Mr. Burr, for 49 seconds.

Mr. BURR. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. There still are some people in this Congress that believe that if you just pump more money at something you get a different result. If we have learned anything over the last 6 years, it is that there are many areas of your responsibility that require structural and cultural change, the type of change that can only happen with a bipartisan effort of Congress with the commitment from HHS.

I want to commend you as you have begun to assemble a staff to work under you. You not only have chosen capable but you have chosen experienced individuals to head up many of the issues that we are going to deal with between this committee and your agency. I know today that we can reach solutions to these problems if the commitment is as strong on our side as I am sure it will be from you. I thank you once again.

Mr. NORWOOD. I thank the vice chairman for being exactly perfect on time.

Mr. Waxman, I am delighted to give you 1 minute, sir.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Secretary, I welcome to you our committee. Your Department has jurisdiction over health care for Americans, whether it is Medicare or Medicaid, the CHIP program, and all of the activities of the FDA and prevention programs and family planning and on and on and on. Those are within the jurisdiction of our committee, and we want to work with you in these efforts. We want to be cooperative to assure your Department has the resources it needs to do the job that people are depending on you to do.

But, in that vein, I want us to not give away in tax cuts for the wealthy the financial resources we must have to meet the needs of those who depend on Medicare or Medicaid, or on the Ryan White programs for persons with AIDS, or on training funds for nurses and medical personnel; on a strong and effective FDA, or on serv-

ices for severely disabled children or legal immigrant children, to name only a few. Because the fact is when we endanger the surplus and take away available resources with massive tax cuts, particularly for the wealthy who do not need it, it is at the expense of those people who depend on the programs in your Department; and they are the ones who will suffer.

I look forward to your testimony today and working with you in the future. Thank you.

Mr. NORWOOD. Now, we would like to recognize the Pennsylvania delegation. First, Mr. Greenwood for 1 minute.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Mr. Secretary, it was good to meet with you in my office yesterday. I am very excited about your stewardship of the Department. I think your notion of going from agency to agency, actually running your office out of those agencies and running those agencies yourself is spectacular.

In 1 minute, I could list a few of the things that I looked forward to working with you on: Title 10, medical records, privacy, HCFA reform, FDA reform, organ transplants, computer security, clinical research, chimpanzee retirement, average wholesale price of drugs, AIDS, NIH, and cloning and a few other things. I look forward to your comments.

I yield back the balance of my time.

Mr. NORWOOD. Mr. Pitts of Pennsylvania, you are allowed 1 minute.

Mr. PITTS. Thank you, Mr. Chairman. I am pleased that you are holding this important hearing today. And, Mr. Secretary, thank you for taking time to be with us to discuss the budget of one of the Nation's most important domestic spending programs.

I look forward to working with you on a number of issues, as we face even some issues of controversy as well as importance. Some of these would include funding for community health centers; the CDC practice of blind HIV testing; abstinence funding; the abortion drug, RU 486, making sure that it does not endanger the health of women; alternatives to embryonic stem cell research; oversight of the Title 10 program and others.

I look forward to hearing your testimony, and I thank you for coming.

Mr. NORWOOD. I remind all of my colleagues that all of us had a lot more that we would like to say than 1 minute and you are more than welcome to submit for the record your written testimony. But the purpose of this hearing is to hear from the Secretary.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. ELIOT L. ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. Chairman, first let me say that I am pleased to be here today and I welcome you Mr. Secretary and look forward to your testimony and the opportunity to discuss some of the specific provisions of the Department of Health and Human Services' (HHS) budget.

When the President proposed tax cuts totaling over $2 trillion I was extremely concerned about what programs would be cut or eliminated in order to pay for such a large proposal and how the cuts would affect American families. It seems that for health care especially, the cuts are deep and will have a terrible impact on our country's health care safety net. The budget talks about replacing the State Children's

Health Insurance Program (S-CHIP) with private health insurance through the use of tax credits. In addition, the Community Access Program is eliminated, while Ryan White and Healthy Start funding levels are frozen. Many of the cuts are in programs that assist families in New York and across the country in obtaining basic health services and should not suffer at the hand of a huge tax cut that for the most part will go to a very few wealthy people at the top of the income ladder.

These are only a few examples of the types of programs that this budget hits hard. Also, the President's effort to provide seniors with a Medicare prescription drug benefit appears vastly inadequate. In fact, the budget only sets aside $153 billion over ten years for a prescription drug benefit and Medicare reform and siphons money out of the Medicare Part A trust fund, thus bringing Medicare closer to insolvency. Congress must act to provide a real benefit for seniors and must pay for it with resources outside of Medicare to ensure the solvency of the program.

Mr. Chairman, I hope that we can examine some of these provisions and realize that we in Congress cannot go along with this budget. I look forward to working with my colleagues to bring about substantial changes so that we can continue the work we have done in Congress on behalf of American families.

Mr. NORWOOD. With that, Secretary Thompson, you have the floor.

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

Mr. THOMPSON. Thank you very much, Acting Chairman Norwood. It is a privilege for me to be in front of this wonderful committee, and I want to thank Chairman Bilirakis for scheduling it and also Congressman Brown and all the other members.

Let me just start out by saying that, like all of you, I believe very passionately in the Department of Health and Human Services, our mission and what we can do together on a bipartisan basis. I am looking forward for your advice and your criticisms—constructive criticisms and your support to accomplish the objectives set out by the mandates that you have set in statute, and I am looking forward to working with you.

I am honored to appear before you today to discuss the President's fiscal year 2002 budget for the Department of Health and Human Services. Much has been written and said about selective portions of our budget and some unfair and some inaccurate charges have been leveled against it. That is why I am very pleased today to have this opportunity to appear in front of you to discuss our detailed budget proposal. I am very confident that a review of the full details of our budget will demonstrate that we are proposing a very balanced, responsible approach to building a strong and healthy America.

The budget before you today keeps the promises that the President of the United States has made and proposes new and innovative solutions for meeting the challenges that face our Nation. Our proposal begins the modernization and the strengthening of Medicare. It expands access to health care, reforms the way the Department operations are managed.

Mr. Chairman and members, the total HHS request for fiscal year 2002 is $468 billion. The discretionary component totals $55.5 billion, or a 5.1 percent increase.

I would like to begin today by talking about Medicare, the cornerstone of our health care system. It provides coverage to 40 million Americans, and it is the largest health insurer in the Nation. All of us, you on the committee and me at the Department and all the other residents of America, are paying our taxes into this sys-

tem; and they are supporting it not only for today's beneficiaries but in the full faith and expectation that this program will be there when we need it and when our children need it, delivering health care at a price that we all can afford.

Costs for all of Medicare will quadruple, growing from 2.2 percent of the gross domestic product today to 8.5 percent. At the same time, revenues only grow from 2.4 percent of GDP today to 5.3 percent. That is a big gap.

What does that mean for America? Precisely why we must act now to modernize, strengthen and protect this popular and vital program and, yes, add a prescription drug benefit.

Modernizing Medicare is just one part of President Bush's initiatives to strengthen the health care safety net for those most in need, notably, the 43 million Americans who do not have health insurance.

Among the President's top priorities is to increase funding for community health centers, which provide high-quality, community-based care to approximately 11 million patients, 4.4 million of whom are uninsured, through a network of more than 3,000 centers in rural and urban areas. The President has proposed to expand and increase the number of health centers by 1,200 by 2006 and increase the number of patients being seen by 11 million to 20 million.

As a first installment of this multiyear initiative, we propose to increase the funding for community health centers by $124 million. We also will be looking at ways to reform the National Health Service Corps so as to better target placement of providers in areas that experience the greatest shortage of health care professionals, a lot of those in rural areas.

We are also acting to address the nursing shortage in America by increasing fundings for nursing professional programs to $82 million for fiscal year 2002, which is a 7 percent increase.

And you cannot talk about health care in America without talking about improving women's health. This administration recognizes the vital role that women play in the health of their families. Therefore, we are increasing funding for the Office of Women's Health by $10 million to $27 million because we recognize that healthy women mean healthy families.

This administration also is committed to giving States greater flexibility in managing their health programs. Our budget proposes to give States expanding authority to transfer funds among public health grants, thereby enabling them to make more efficient and inventive use of Federal resources and to target and reallocate funds to public health priorities, identified at the State and local levels.

To that end, we are investing in modernizing and increasing the efficiency of the Health Care Financing Administration. I know that this committee is keenly interested in HCFA, and many of you recently visited and visited its office. I commend the members of this committee for taking such a very active interest, and I want to work with you to improve it.

I have also been up to visit HCFA, and I saw an agency strapped with excess regulations and responsibilities without actually receiving the resources necessary in order for it to do its job effectively.

It is clear that HCFA offices were filled with hundreds of dedicated employees but also with outdated computers and a bookkeeping system that is absolutely arcane and demands that have spread the agency too thin for too long. HCFA needs our help now so it will be able to help, Congressman Towns, your people and other people across America.

To help HCFA begin to meet these challenges, the budget proposed an increase of $192 million, or 9 percent, to be able to manage HCFA in its programs and modernize so it can do the job properly. We are going to dedicate $36 million to update antiquated information technology systems; and we are working to ensures HCFA is more responsive, efficient, pleasant, and flexible in dealing with States and health care providers in daily operations.

We are also going the Department a step further. Next week, on Monday morning, I will be moving the Secretary's office from the Humphrey Building to Baltimore to run HCFA for a week personally to see how it truly operates, what it does well and what can be done better. This firsthand experience undoubtedly will help me learn how we can operate HCFA better so that it is more responsive to your constituents that HCFA was set up to serve.

I know some of you have experienced concerns in your speeches this morning about various decisions in the Department's budget: child care, AIDS, and providing care for the uninsured. I am here today to assure you that these are top priorities for this administration and for me and the total Department of Health and Human Services.

I would also urge to you look at the budget as a whole and not just individual lines and individual agencies. Look at issues as a whole and you will see that we will have better collaboration among agencies within the Department to make a concerted effort on an array of issues that can better serve all Americans.

President Bush recognizes the importance of investing in our children, and the HHS budget reflects that commitment. The budget includes increases for both existing programs as well as new investments in a number of new programs designed to fulfill President Bush's commitment to making sure that no child is left behind. One of the most important things that we as a government can do is to help working families, especially those trying to move from dependency to the workforce, is to assist them in obtaining child care. The President requested a total of $2.2 billion for the child care and development block grant, which is a discretionary pot, a 10 percent increase, and coupled with an additional $150 million increase for the mandatory portion of child care. We will be increasing spending on child care, therefore, over last fiscal year by $350 million.

To further strengthen American families, President Bush has proposed ambitious initiatives to promote stable families and responsible fatherhood, paternity group homes, a compassionate capital fund and a proposal to establish a center for faith-based and community initiatives within the Department.

We also will be increasing funding for substance abuse through SAMHSA by $100 million.

This administration also, ladies and gentlemen, remains committed to fighting AIDS, both at home and, yes, abroad, which is

a serious problem. This budget includes $10.2 billion for the HIV/AIDS program, a 7.2 percent increase for research, treatment, and prevention. It also includes an additional 11 percent increase for international AIDS spending.

Along these same lines, the Department of Health and Human Services is joining with the State Department to develop a task force headed up by Colin Powell and myself at the request of the President to provide real leadership in the fight against HIV/AIDS, both domestically and internationally, and looking at trying to come up with a total plan, especially in the continent of Africa. The President, Secretary Powell, and I are committed to fight this disease on all fronts.

A top priority for this administration, of course, is ensuring that the National Institutes of Health continue to have the resources necessary to help turn these promises into a reality. The research that is conducted and supported by the NIH is absolutely phenomenal, from most basic research in biological systems to the effort to map the human genome, offers the promise of breakthroughs in prevention and treating diseases from cancer to Parkinson's to Alzheimer's.

The potential that lies in these projects is why President Bush's plan to double the resources for the NIH by 2003 is so vital. The $2.75 billion increase in this budget is the largest 1-year increase ever for NIH, and it will support 34,000 research grants, most of those in the States that you represent. This happens to be the most in the agency's history. The President has also included $208 million for asthma research at NIH, a 12 percent increase, and $768 million for diabetes research, a 11.3 percent increase. We are committed to fighting two of our most prevalent and chronic conditions in America.

Finally, Mr. Chairman, I would also like to commend you personally for your work that is particularly close and near to my heart, organ donation. Your Organ Donation Improvement Act is a strong step in the right direction in helping America increase the number of organs donated, and it will work hand in hand with the five-point organ donation initiative that we unveiled earlier this month at the Department of Health and Human Services.

The President also has proposed a 33 percent increase for organ transplantation programs at the Health Resources and Service Administration; and we must continue to fight to try to cut into the waiting list of 76,000 Americans who need an organ, an increase of 300 each and every month. It is time that it is brought to the forefront of our health care agenda, and I look forward to working with each of you in the future.

Mr. Chairman, I have talked about a few of the dozens and dozens of exciting initiatives in President Bush's budget for the Department of Health and Human Services. A more detailed list is included in the written testimony that I submitted earlier. The common thread, however, that binds all of our proposals together, and which binds together the bipartisanship of this committee, is the desire to build a strong and a healthy America and to improve the lives of all of our citizens.

I am prepared to work with each of you to ensure that we develop a budget for this Department that effectively serves the national interests.

Now I would be happy to address any questions that you may have.

[The prepared statement of Hon. Tommy G. Thompson follows:]

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

Good Morning, Chairman Bilirakis, Congressman Brown, and members of the Subcommittee. I am honored to appear before you today to discuss the President's FY 2002 budget for the Department of Health and Human Services. I am confident that a review of our budget for these programs will demonstrate that we are proposing a balanced, responsible approach to building a strong and healthy America.

Part of this approach means we must no longer be content to do things a certain way because "that's how we've always done it". It means we must be willing to reform our business practices and seek innovative ways to manage our programs. And, while we know that the federal government has an important role to play, we must also recognize that our State, local and tribal government partners, community and faith-based organizations, the private sector and academic institutions—all are indispensable sources of new and creative approaches to solving public problems. The President and I share this view, and I am proud to say it is manifested in the budget he has put forward.

The President's budget proposes innovative solutions for meeting the challenges that face the nation. Our proposal begins the modernization of Medicare; expands access to health care; enhances the groundbreaking research being sponsored by the National Institutes of Health; protects public health; and, invests in infrastructure and reforms the way the Department's operations are managed. The HHS budget also reflects the President's commitment to a balanced fiscal framework that puts discretionary spending on a more reasonable and sustainable growth path; protects Social Security, Medicare, and other priority programs; continues to pay down the national debt; and provides tax relief for all Americans. Let me now highlight some priorities in the HHS budget.

ENHANCING SCIENTIFIC AND HEALTH CARE QUALITY RESEARCH

Advances in scientific knowledge have provided the foundation for improvements in public health and have led to enhanced health and quality of life for all Americans. Our FY 2002 budget enhances support for scientific research as well as for research to improve the quality of the Nation's health care system.

Biomedical Research Sponsored by the National Institutes of Health

The National Institutes of Health (NIH) is the largest and most distinguished biomedical research organization in the world. The research that is conducted and supported by the NIH, from the most basic research on biological systems to the successful mapping of the human genome, offers the promise of breakthroughs in preventing and treating any number of diseases. A top priority for this Administration is ensuring that the NIH continues to have the resources necessary to help turn these promises into a reality.

This budget keeps the President's commitment to double NIH's FY 1998 funding level by FY 2003. For FY 2002, we are proposing an increase of $2.75 billion, which will be the largest dollar increase ever for NIH. This funding level will enable NIH to support over 34,000 research project grants, the highest level in the agency's history. NIH will expand its focus on four research areas that show the greatest potential for yielding new scientific breakthroughs: genetic medicine, clinical research, interdisciplinary research, and health disparities.

With any large increase in resources, there also comes the increased challenge of making sure that those resources are managed properly. I take this responsibility very seriously, and NIH will work to develop strategies to ensure that we are managing taxpayer dollars in the most effective way in setting research priorities.

IMPROVING MEDICARE

Of all the issues confronting this Department, none has a more direct effect on the well-being of our citizens than the quality of health care. Our budget proposes to improve the health of the American people by taking important steps to improve Medicare, including the addition of a prescription drug benefit, and by directing

funds to various initiatives aimed at directing funds to initiatives aimed at expanding access to health care.

Modernizing Medicare and Immediate Helping Hand

The Medicare program has been the center of our society's commitment for ensuring that all of our seniors enjoy a healthy and secure retirement. Honoring this commitment means making sure that the program is financially prepared for new beneficiaries, and ensuring that current beneficiaries have access to the highest quality care. One clear example of our need to renew Medicare's promise is the lack of adequate prescription drug coverage. When Medicare was created in 1965, prescription drugs were not an integral part of health care as they are today and coverage was not included as part of the Medicare benefit package. But what was acceptable thirty-five years ago is simply unacceptable today.

We have already waited too long to address this problem. The President has put forward our Immediate Helping Hand proposal as an interim measure to do so. Our proposal provides $46 billion over five years to help States so that they can provide prescription drug coverage to beneficiaries with limited incomes or high drug expenses; and it will provide immediate coverage for up to 9.5 million beneficiaries.

Almost half the states currently have prescription drug assistance programs of some kind, and most of the other states are considering such programs. With modifications, these programs would be eligible for IHH grants. The IHH would be fully funded by the Federal government and would provide States with the flexibility to choose how to establish coverage or enhance existing plans. Individuals with incomes up to $11,600 and married couples with incomes up to $15,700 who are not eligible for Medicaid or a comprehensive private retiree benefit would pay no premium and no more than a nominal charge for prescriptions. Individuals with incomes up to $15,000 and married couples with incomes up to $20,300 would receive subsidies for at least half the cost of the premium for high-quality drug coverage. The IHH plan also includes a catastrophic component that would cover any Medicare beneficiary with very high out-of-pocket drug costs.

The President's Immediate Helping Hand proposal is a temporary plan to help our Nation's seniors who are most in need of assistance with their prescription drug costs. The benefit will sunset in December 2004, or as legislation to strengthen Medicare including a prescription drug benefit is implemented. However, this plan is critical because it provides assistance to millions of Americans immediately. The President and I want to work closely with Congress in a bipartisan fashion to see this happen.

We also believe, along with many Members of Congress who have supported and continue to support bipartisan efforts to strengthen Medicare, that we must take steps to improve Medicare as soon as possible. Inadequate prescription drug coverage is only the most obvious gap in Medicare benefits. Today, Medicare covers 55 percent of the average senior's annual medical expenses, and the options available to seniors to help them limit these expenditures are declining. Moreover, the program faces a looming fiscal crisis. A full assessment of the health of both the Part A and Part B Trust Funds reveals that current spending exceeds the total of tax receipts and premiums dedicated to Medicare and that this financing gap is expected to widen dramatically. Even without a financing problem, Medicare modernization would be necessary to ensure that beneficiaries continue to get high quality health care. President Bush proposes to devote $156 billion (including funding for Immediate Helping Hand) over the next ten years to a set of improvements in Medicare that are urgently needed. These Medicare modernizations should include taking steps to make better coverage options available, to assure that all seniors have affordable access to prescription drugs, to provide better coverage for high out of pocket expenses, particularly low-income seniors, and to ensure that Medicare has greater overall financial security.

INVESTING IN INFRASTRUCTURE AND REFORMING MANAGEMENT

For any organization to succeed, it must never stop asking how it can do things better. I am committed to seeking new and innovative ways to improve the management of HCFA and all our programs at HHS. But we must also recognize that we do a disservice to all who rely on this Department if we do not provide the resources necessary to effectively administer our programs. In preparing our budget, we began the process of evaluating the programs and business practices of this Department and identifying the areas where we can do a better job of managing taxpayer resources, as well as those areas where new investments are required if we are to successfully administer our operations.

HCFA Management Reform

One of the most important management reforms we will pursue is the improvement of the Health Care Financing Administration (HCFA). We have all heard the complaints by patients, providers, and States about the scope and complexity of the regulations and paperwork that govern the Medicare, Medicaid, and State Children's Health Insurance programs. And, in many cases, these complaints are valid.. But in its defense, HCFA has been tasked with implementing several pieces of major legislation and its responsibilities have grown more complex with each new major health care law or budget reconciliation.

Concerns about HCFA's management capabilities have been raised in several General Accounting Office reports, including the *High Risk Series: An Update* (January 2001) and *Financial Management: Billion in Improper Payments Continue to Require Attention* (October 2000). HCFA management reform is an Administration priority. HCFA will undertake a major effort to modernize and streamline its operations to effectively manage current programs and implement new legislation. In particular, HCFA's role in a modernized Medicare program needs to be carefully considered. This may require substantial changes in HCFA's mission and structure. My goal is to assure that HCFA's resources are focused as effectively as possible on improving quality and limiting costs for Medicare beneficiaries, limiting burdens for providers, and increasing efficiency for taxpayers.

The budget proposes an increase of $109 million, or 5 percent, for HCFA program management. Included in this budget is a $53 million, increase of $36 million over this year, to support the development of the HCFA Integrated General Ledger Accounting System (HIGLAS). HCFA currently relies on several financial management systems to account for the hundreds of billions of dollars spent on Medicare benefits, and most contractors do not use double entry accounting methods or claims processing systems with general ledger capabilities. This system requires financial statements to be imputted manually, increasing the risk of administrative and operational errors and misstatements. The new system will provide a uniform Medicare accounting system that will help HCFA detect and collect money owed to the Medicare Trust Funds, retain a clean opinion on financial statements without more expensive, alternative efforts, and comply with financial management statutory requirements.

Contracting Reform

I am also committed to reforming HCFA's antiquated and inefficient contracting system. We are considering a number of options in this area including: allowing carriers who are not health insurance organizations to become Medicare contractors; allowing the Secretary (as opposed to the Part A provider) to contract for and assign fiscal intermediaries to perform claims processing, claims payment, communications, audit functions, renewing contracts, and transferring functions; and replacing current special provisions for terminating contracts with more standard terms and conditions embodied in the Federal Acquisition Regulation (FAR). In addition, I am including in the budget $115 million in new proposed user fees for duplicate and paper claims processing. We will work hard to enact these fees, which will help to improve the efficiency and lower the cost of processing Medicare claims.

Revitalizing Laboratories and Scientific Facilities

There are other investments that are just as important as HCFA reforms. For example, it is critical that we invest in the modernization of our laboratories and scientific facilities, for obsolete facilities affect our scientific readiness and compromise our ability to retain the top scientists. Our budget includes funds to continue the revitalization of key facilities at the Centers for Disease Control and Prevention and the National Institutes of Health. We are requesting $150 million for buildings and facilities at the Centers for Disease Control and Prevention, which will support construction of a laboratory facility dedicated to handling the most highly infectious pathogens, such as Ebola, and construction of an Environmental Toxicology Lab. The budget also requests $307 million for intramural buildings and facilities at the National Institutes of Health to support projects such as the construction of the John Edward Porter Neuroscience Research Center and a centralized, multi-level animal facility.

Enhancing Coordination and Reducing Duplication of Operating Systems

The only way that this Department can effectively serve its many clients is if we commit to making the necessary investments in our management and infrastructure. One of the challenges in a large, decentralized Department such as HHS is finding ways to bring together diverse activities and to develop coordinated systems for managing our programs. Our budget provides the resources necessary to begin

the process of streamlining our financial management and information technology systems so that we can enhance coordination across the Department and eliminate unnecessary and duplicate systems.

For financial management, we propose to invest $92.5 million, an increase of $50 million over this year, to move toward a unified financial accounting system, including funding for HCFA's accounting system. The Office of Inspector General has cited problems with the Department's current system structure, which involves five separate accounting systems operated by multiple agencies. We plan to replace these antiquated systems with unified financial management systems that will increase standardization, reduce security risks, allow HHS to produce timely and reliable financial information needed for management decision-making, and provide accountability to our external customers.

In the information technology arena, we are proposing $30 million for a new Information Technology Security and Innovation fund. Currently, the Department's information technology systems are highly decentralized, heterogeneous, and vulnerable to exploitation. Funds would be used to implement an Enterprise Infrastructure Management approach across the Department that would minimize our vulnerabilities and maximize our cost savings and ability to share information. With this approach, we will be able to reduce duplication of equipment and services and be better able to secure our systems against viruses and network intrusion.

As the largest grant-making agency in the Federal Government, this Department will also continue to play a lead role in the government-wide effort to streamline, simplify, and provide electronic options for the grants management processes. As part of the Federal Grant Streamlining Program, we will work with our colleagues across the government to identify unnecessary redundancies and duplication in the more than 600 Federal grant programs and to implement electronic options for all grant recipients who would prefer to apply for, receive, and close out their Federal grant electronically.

Redirecting Resources and Enhancing Flexibility

Being a wise steward of taxpayer resources means not only recognizing where you need to invest but also where resources can be redeployed to more effective uses. In preparing our budget, we carefully reviewed each agency, identified areas where funding could be redirected, and made targeted reductions in selected programs. The FY 2002 budget eliminates $475 million in earmarked projects and $155 million in funding for activities that were funded for the first time in FY 2001. The one-time nature of most of these projects did not necessitate their continuation in FY 2002 allowing the Department to redirect the associated funding to higher priority investments described in this testimony while moderating the overall growth of the HHS budget. In addition, the budget shifts $597 million from programs that are duplicative, or whose goals are better met through other avenues, to higher priority activities. And, to assist in financing other high priority activities, the budget expands the use of Public Health Service Evaluation funds. These decisions helped to meet our goal of moderating the large increases in discretionary spending that have occurred over the last few years and putting the budget on a more sustainable growth path for the future.

This Administration is also committed to giving States greater flexibility to manage public health grant programs. Our budget proposes to give States expanded authority to transfer funds among public health grants, thereby enabling them to make more efficient and effective use of Federal resources and to target and reallocate funds to public health priorities identified at the State and local levels.

In addition to giving the States greater flexibility, I am seeking to increase my transfer authority from one percent to six percent, and to eliminate the restriction that the transfer may not increase an appropriation by more than three percent, and to make it Department-wide. I believe this transfer authority is a valuable tool for managing the Department's resources and will allow me to respond to emergency needs or unforeseen events that would otherwise adversely effect a program or agency.

Continuously Evaluating and Improving Program Performance

The Government Performance and Results Act serves as an important tool for making sure that this Department is not only doing the right things but that we are doing them well. As in previous years, our budget request is accompanied by the annual performance plans and reports. The performance measures and targets in these reports touch nearly every aspect of the Department's multi-faceted mission and detail a number of notable achievements, including:

- HCFA met its FY 2000 target of reducing the Medicare error rate to 7 percent. Auditors estimated improper payments at $11.9 billion, compared with $13.5

billion in FY 1999. The error rate has fallen to roughly half of what its was in FY 1996, and HCFA is pursuing increasingly rigorous goals for FY 2001 and FY 2002.

- CDC reported a reduction of perinatal Group B streptococcal disease—the most common cause of severe infections in newborns—by 70 percent from 1995 to 1999, exceeding the goal.

GPRA has been and will continue to be an important part of our effort to improve the management and performance of our programs.

EXPANDING ACCESS TO QUALITY HEALTH CARE

Expanding Community Health Centers

Our budget also proposes steps to strengthen the health care safety net for those most in need. Community Health Centers provide high quality, community based care to approximately 11 million patients, 4.4 million of whom are uninsured, through a network of over 3,000 centers in rural and urban areas. The President has proposed to expand and increase the number of health center sites by 1,200 by FY 2006, and to double the number of individuals without alternative coverage who are served by the centers. As a first installment of this multi-year initiative, we propose to increase funding for Community Health Centers by $124 million. We will also be looking at ways to reform the National Health Service Corps so as to better target placement of providers in areas experiencing the greatest shortages of health professionals.

The Administration believes we should increase our investment in proven programs—like the Community Health Centers—and provide communities with increased flexibility through the President's Healthy Communities Innovation Fund, which allows communities to address health care access challenges in innovative ways using existing resources.

Increasing Access to Drug Treatment

The problems caused by substance abuse affect not only the physical and mental condition of the individual, but also the well-being of society as a whole. Nationwide, approximately 2.9 million people with serious substance abuse problems are not receiving the treatment they desperately need. To help close this treatment gap, we propose to increase funding for substance abuse treatment by $100 million. Of these funds, $60 million will be used to increase the Substance Abuse Block Grant, the primary vehicle for funding State substance abuse efforts, and $40 million will go to increase the number of Targeted Capacity Expansion grants, which seek to address the treatment gap by supporting strategic and rapid responses to emerging areas of need, including grants to organizations that provide residential treatment to teenagers.

Organ Donation

Our budget supports an initiative very close to my heart. Approximately 75,000 patients are awaiting organ transplants, far above the number of available donors. In fact, organ transplants in 2000 totaled 22,827, an increase of 1,172 over the 21,655 transplants that occurred in 1999. The number of living donors rose from 4,747 in 1999 to 5,532 in 2000, an increase of 16.5 percent, the largest one-year jump ever recorded. While I am encouraged by the progress that has been made in the last year, there is still a very long way to go. To tackle this problem, I launched a new national initiative, on April 17th, to encourage and enable Americans to "Donate the Gift of Life". I am beginning a national "Workplace Partnership for Life", in which employers, unions and other employee organizations can join in a nationwide network to promote donation. I released a model organ and tissue donor card, incorporating proven elements from today's donor cards and have ordered an immediate review of the potential of organ and tissue registries where donors' wishes could be recorded electronically and made available to families and hospitals when needed. I have also made a pledge to create a national medal to honor the families of organ donors and will create a model curriculum on donation for use in driver education courses, to be offered to states and counties nationwide. And, let me tell you, this is just the beginning. I intend to do everything I can to increase organ donation throughout America and to create the most comprehensive effort ever in our nation regarding donation and transplantation.

Patient Safety and Health Care Quality

The Agency for Healthcare Research and Quality (AHRQ) is the Federal agency with primary responsibility for research on the Nation's health care system and is HHS's lead agency for improving patient safety and the quality of everyday health

care. The FY 2002 budget provides a total program level of $306 million for AHRQ, an increase of $36 million or 13.5% over FY 2001.

AHRQ will devote a total of $53 million to identify ways to reduce the incidence of medical errors. These funds will support activities to research the causes of medical errors, develop and test new technologies to reduce medical errors, test reporting strategies, and improve training. Earlier this week, I announced the establishment of a new Patient Safety Task Force within the department in which AHRQ will collaborate with FDA, CDC, and HCFA to improve existing reporting systems on patient safety. AHRQ will lead this effort to identify the type of data health care providers, states and others need to improve the safety of health care services.

Our request includes a $26 million increase for research on health care quality and cost-effectiveness. Like you and many others, we are reviewing the recent recommendations by the Institute of Medicine for research to improve the quality of health care. Once that review is complete, I expect that an appropriate portion of these resources will be directed toward the recommendations that we conclude should be given the highest priority. I also expect the findings of this an other research on patient safety, which has emphasized the importance of encouraging and rewarding the development of health care systems that encourage safer and higher-quality care, to guide our efforts to improve Medicare, Medicaid, and other government health programs.

PATIENT PRIVACY PROTECTIONS

Knowing of this Committee's concern for patient privacy protections, I wanted to close by commenting on the recent decision two weeks ago by President Bush to immediately put into effect strong patient privacy protections. President Bush and I strongly believe that we must protect both vital health care services and the right of every American to have confidence that his or her personal medical records will remain private. In response, we allowed the patient privacy rule to take effect on April 14, 2001. As you know, under the HIPAA law, affected parties have two years to comply with the new regulation, until April 14, 2003. While I understand that some members of this committee continue to have concerns and differing opinions as to the best way to protect privacy, our citizens must not wait any longer for protection of the most personal of all information—their health records.

Over the past two months the Department of Health and Human Services received and reviewed more than 11,000 written comments, with 24,000 signatures, on the health information privacy rule. In addition, we met with a diverse group of lawmakers, interest groups and health care leaders to listen to their concerns regarding this regulation.

We will consider concerns expressed by all commenters as we move to develop guidelines to clarify certain points of confusion about the rule, and will issue our first guidance for affected organizations next month. Furthermore, we will work with consumer and industry groups to develop additional guidance in the future. We are also considering where modifications to the rule may be needed to ensure that quality of care does not suffer inadvertently from these new rules.

The focus of our guidance and modifications will be to clarify that doctors and other providers continue to have access to the medical information they need to provide timely, high-quality care to their patients. Patient care will not be unduly hampered by confusing requirements surrounding consent forms. And, parents will have access to information about the health and well-being of their children. We will ensure that this patient privacy rule delivers strong and long overdue protections for patient privacy while maintaining the high quality of care we expect in this great nation.

WORKING TOGETHER TO BUILD A STRONG AND HEALTHY AMERICA

Mr. Chairman, I want to thank you for the opportunity to testify before you today on the many different proposals that constitute the Department of Health and Human Services budget for FY 2002. The common thread that binds them all together is the desire to build a strong and healthy America and to improve the lives of the American people. Our proposals, from modernizing Medicare and expanding access to care to enhancing scientific research are presented with these simple goals in mind. I know we share these goals and I look forward to working with you on these important issues. I would be happy to address any questions you may have.

Mr. BILIRAKIS. Thank you very much, Mr. Secretary, and we, too, are thrilled with the many somewhat innovative ideas that your testimony speaks to. Over the years, certainly the last few years, we have held a number of hearings on HCFA regarding some of the

problems there and the terrible image of the organization. I am not saying it is all completely deserved, but it is a terrible image that HCFA has had over the years.

In terms of testimony from HCFA personnel, I can't say that there has ever been any emphasis on not enough dollars. It has been members up here who basically made those points for the most part, but not by HCFA.

And, in fact, I recall a particular hearing when one of the HCFA personnel—I can't recall whether he was a witness or whether he was just with a particular witness—came up to me and said to me that they had requested over a period of time additional dollars for HCFA, and OMB would shoot them down and, therefore, for that reason, they weren't coming into those requests.

I understand that your request for HCFA is $2.31 billion, which is higher than any request in the last few years; and I certainly commend you for that.

My question is—and certainly I won't say this is extra money; it sounds like certainly it is very needed money, but it is extra in the sense of that it hasn't been requested in prior years. What would you intend to do with that money?

Mr. THOMPSON. Thank you so very much, Mr. Chairman. This is a subject that it is very near and close to me, and I am delighted to be able to answer that question to the best of my ability.

HCFA is an agency that everybody loves to hate. I haven't found anybody that really likes HCFA. Democrats, Independents, Republicans, providers, people that write into my agency, everybody hates HCFA. And I am no exception. As a Governor, I was probably one of the biggest critics in America against HCFA.

So I went out and talked to people at HCFA. I first got up in front of several thousand of the employees, and I said, you know, it is difficult to love something called a HCFA. You know, I think the first thing we might want to do is just change our name.

The second thing I said, what is the problem? I mean, why are you having the problems out here? And I listened to a lot of wonderful employees. My attitude about HCFA has changed tremendously.

First off, Mr. Chairman and members, they have a computer program. They have a billion transactions a year, and they have a computer program that was installed in 1970. Do you know of any law office, any medical office, any hospital, any clinic, any insurance company, any business that still operates in America with an insurance—with a computer system that was installed in 1970? Granted, it has been updated, but it is still is a 1970 chassis.

Then, I looked at it and they came to me and they—the IG inspector said they had $11.8 billion in mistakes last year. And I called in the people from HCFA and I said, how can we have $11.8 billion in mistakes? And they said, Mr. Secretary, 5 years ago, it was $22 billion.

And I said, well, that may be true, but that is not good enough. We are going to get rid of it. And I said, what is the problem? He said, we have an antiquated bookkeeping system. And I said, what do you mean? He said, we still have a single-entry bookkeeping system which went out in 1911. They don't have a double-entry

bookkeeping system. I don't know of any business in America that can run on a single-entry bookkeeping system.

The third thing is, when Medicare was adopted in 1965, there was a compromise made, which there is in all legislation usually, a big compromise in which the hospitals and the health insurance industry at that time made a request, and Congress adopted to get Medicare through, that the hospitals would be able to designate or nominate the fiscal intermediaries to operate the contracts. And so we cannot put an RFP out and find the best person to be a fiscal intermediary. It has got to be nominated by the hospital industry.

This is contentious, and I put it out there. It is something this is going to have to be looked at.

The second thing is, it is on a cost-plus type of contract. Now, how can you have efficiencies when you have a cost contract? What is the reason? What is the motivation to saving costs?

So the money that I am requesting is to modernize and to change HCFA. I also asked the people at HCFA, you know, you have been beaten down by so many people that you have an attitude out here that you look for ways to say no. Why don't we try and change our attitude and try to find a way to say yes in the attitude of HCFA? And they said, you know, that is a good idea. And that is what we are going to do.

These are the kinds of changes that I want to bring to HCFA; but I need the dollars, and I want to tell you it was a tough sell at OMB. And I fought very hard to get this in, because if you want to change HCFA, we have to put the resources in there to get the job done.

And I am asking for this committee's support, because this committee is the one that is taking a real interest, Mr. Chairman. I know my answer has gone too long, but you can tell I am dedicated to changing it and I need your help to do it.

Mr. BILIRAKIS. I appreciate that answer, and we certainly appreciate your persistence and perseverance with OMB, because I guess they have been a fly in the ointment in that regard.

Very quickly, my time has expired. But the cost-plus nature of those contracts that you mentioned, is that something that HCFA can do——

Mr. THOMPSON. No.

Mr. BILIRAKIS. [continuing] on their own? It would take legislation on our part?

Mr. THOMPSON. You have to change that, Mr. Chairman.

Mr. BILIRAKIS. That goes to many of the questions we have asked over the years. Tell us how. What can we do legislatively to help you do your job better? I don't recall that there has ever been a request made to this committee over the years to give them the kind of leeway to change that.

Mr. THOMPSON. It is in the law, but we have to change it, so we can put it out. Times have changed since 1965, and also it is—we should reduce the number of fiscal intermediaries. You know, with the modern computer system, we can get by with 10, 15, but that is—I want to be up front with you, you are going to have a lot of opposition to changing this from the status quo.

And so I am telling you, it needs to be changed. I am asking you to change it, but I also want to alert you—I am very honest with you—it is going to be difficult, but it needs to be changed.

Mr. BILIRAKIS. Who was going to oppose it?

Mr. THOMPSON. Everybody has got a contract, sir.

Mr. BILIRAKIS. Yes.

Mr. THOMPSON. Every hospital in America.

Mr. BILIRAKIS. Yes.

Mr. Brown.

Thank you very much, Mr. Secretary.

Mr. THOMPSON. And every Congressman and Senator has a fiscal intermediary in their State.

Mr. BILIRAKIS. That is what I was getting at.

Mr. BROWN. Thank you. And I appreciate your comments about HCFA. I don't agree that HCFA is as universally unpopular as some here say.

Mr. THOMPSON. Thank you.

Mr. BROWN. I think it is certainly unpopular with this subcommittee, and we spend much time in this subcommittee criticizing HCFA and micromanaging HCFA, giving HCFA new regulations and rules to carry out and starving it as an agency.

Mr. THOMPSON. That is true.

Mr. BROWN. So I think there is—there oftentimes needs to be a mirror in front of us when we criticize HCFA. It is certainly deserving, as all institutions are deserving of some criticism.

I want to talk about prescription drugs, but not so much the coverage that you suggested and the President suggested with the $100 million. As you know, many of us in this institution and both parties think that is not enough to do a good prescription drug plan.

But let me talk more about the costs. Generic drug application review times average about 18 months for generics. In contrast, new drug applications' review times average about 12 months, and for those that are on the so-called "fast track," that is—apparently the average is 6 months.

Your budget provides no extra funds for generic drug approvals, but all of us know that generics will save billions of dollars. The faster generics are in the pipeline, in the marketplace, the more money that—the billions of dollars that consumers would save as a result.

Would you reconsider this matter in terms of your budget and work with us, one, to provide more money for speeding generic drug applications? And second, would you work with us, overall, to speed the approval with additional money and in other ways also?

Mr. THOMPSON. Congressman, let me just tell you, this is an area that is a big concern of mine. And I want to work with you. I don't know if it is just extra money that it needs. I want to work with you to speed up the process and make it more efficient and find ways that we can accelerate, when necessary, when safety allows us to do it, and make sure that we don't go too fast so that we in any way hamper the patient's safety.

I am not sure that I can say here that the only way that you will support me or that I can support you is by increasing the money. I don't know so. But the problem is, I have only been at the De-

partment for 75 days, and this was—the Food and Drug Administration is an area that I have not been able to devote as much attention to as yet, but it is something that is a prime concern of mine. But I want to work with you in a cooperative way.

Mr. BROWN. We have determined in the subcommittee in the past and in this Congress that more money did, in fact, accelerate approval time, reduce approval time, through the Prescription Drug User Fee Act, through PDUFA 1 and PDUFA 2l; and that was the purpose for it, in part. There were other reforms, but a big part of it was expending the money. And we can certainly guarantee a patient's safety—if we can do a new drug in 12 months, we can certainly—and a fast track in 6, we certainly can approve the generic drug——

Mr. THOMPSON. I can't defend——

Mr. BROWN. [continuing] and partly take money.

Mr. THOMPSON. There is an additional $37 million in this fiscal year budget——

Mr. BROWN. Okay.

Mr. THOMPSON. [continuing] a 5.6 percent increase.

Mr. BROWN. Let me talk about cost containment and a prescription drug benefit, whether it is the administration plan or another plan.

Estimates for prescription drug spending continued to go up at an alarming rate. CBO's new drug baseline this year increased significantly since everyone—if someone introduces a plan in 6 months, a year from now, it is clearly costing more.

Mr. THOMPSON. Sure.

Mr. BROWN. Some have suggested that we rely on competition from private plans through an HMO or through an insurance mechanism. That was tried in Nevada, they didn't even have anybody bid. Finally, when they bid, the cost was too high. Pretty clearly, that hasn't worked.

There are several other ideas that have been suggested. I would just like to ask you your opinion of them in terms of prescription drug cost containment. One is using a pharmacy benefit manager, which the private sector uses, which your predecessor, Secretary Shalala, suggested in her plan last year. That is estimated to save 10 or 15 percent. That is not a huge savings, but that could be a start.

Second, would you support the approach of the Allen bill to allow Medicare—as the Canadians do, for instance, to allow Medicare to negotiate on behalf of the 39 million beneficiaries to get lower prescription drug costs? Would you look at something that I worked on legislatively that was suggested most recently by Gail Wilensky, reducing the length of patents so generics could get into the pipeline sooner, would pay a significant royalty to the patent-holder, and be competition in the marketplace.

Which of any of those would you support—PBMs, the Allen proposal with the Medicare buying power, if you will?

Mr. THOMPSON. Congressman, I don't think any of those is mutually exclusive. I think we should look at all of them. I don't think there is anything that should not be under the table when we look at drug costs and drug containment. I think it only behooves as a

department and Congress to try to find ways to control pharmaceutical costs in America.

And I want to be—I am willing to work with you, but I would like to point out that it is the President's position, and my position very strongly, that in order for us to have prescription drugs included in Medicare, we have to reform Medicare.

I really strongly believe that we have the greatest opportunity ever to reform Medicare and include prescription drugs. But if we just do the prescription drugs, I don't know if we will ever get around to reform and strengthen Medicare, and I think that is just as vitally important as prescription drugs are.

Mr. BROWN. Will you suggest a mechanism for cost containment to this Congress when you recommend—will you at some point do that?

Mr. THOMPSON. I am in the process, Congressman, right now, of working with the White House on Medicare and prescription drugs, and absolutely it will be coming.

Mr. BROWN. I hope it goes beyond using private plans, which private insurance companies don't have because of adverse—don't have any real incentive to write policies when they cannot go beyond it.

Mr. THOMPSON. I can assure you, Congressman, that I am not an individual that likes the status quo and what is on the table. I like to look at all opportunities. And your options are just three, but I am not limited to those three. There are many others that I am looking at.

Mr. BROWN. We can give you more also. Thank you, Mr. Secretary.

Mr. BILIRAKIS. Dr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman.

Mr. Secretary, it is fairly clear to me and I think most members of the committee that we have a looming crisis in Medicare. We just simply cannot ignore it, and the longer we wait, the harder it is going to be to deal with it.

I agree with your remarks 100 percent that—I don't see how we can logically produce a prescription drug plan without looking at the big picture first or we are going to add to the future problems of Medicare.

Mr. THOMPSON. Yes, sir, accelerate it.

Mr. NORWOOD. My question is timing. Do you expect—I know you will work with Congress to enact Medicare reforms, but do we expect that this year, or will it be next year or the next year?

Mr. THOMPSON. I want it this year, Congressman. I am—I am very much in favor—I am an activist. I don't like to wait, as you probably have heard. I like to see a problem—I like to come up with a common-sense solution and move forward on it.

Mr. NORWOOD. You may have heard, I don't like to wait either, and I would like for you to do it this year.

Mr. THOMPSON. I figured I was talking to the choir when I said that, Congressman.

Mr. NORWOOD. Should we—does it make sense, for example, to not rush, though, to cure the problem in Medicare——

Mr. THOMPSON. True.

Mr. NORWOOD. [continuing] but in the interim do something about prescription drugs? Helping Hands comes to mind, something that immediately we can begin to help those people who simply cannot afford any type of medication right now; should we do that as an interim step to get to the final product?

Mr. THOMPSON. If, in fact, we can't get the finished product down, this other absolutely. And the President has put out Helping Hand because he was not sure that we could reach a bipartisan solution on Medicare reform with prescription drugs. That is why he put out an additional $12 billion this year for States to come up with their own individual program over the course of the next 4 years, $12 billion each and every year.

So it is a wonderful fallback plan, and it is one which we should take to the forefront, if in fact we had mired down in not being able to solve the major problem, which is Medicare reform, Congressman.

Mr. NORWOOD. We all have been rather caught off guard about the 33 percent increase from CBO in the costs of drugs. I don't think we should have been caught off guard, but perhaps we have.

Do your budgeteers feel that we have allocated enough funds to enact the reforms needed to change reform, strengthen Medicare programs?

Mr. THOMPSON. We feel that it is necessary to take a look at the overall reforms in Medicare and then cost it out. And at this point in time, we are not—not at liberty or not able to tell you if the $153 billion—we think $153 billion over 10 years can get the job done.

Just a lot of people out there, including CBO, that think it will cost more. But they do not put into their mix any cost savings in Medicare reform, and we would like to put the Medicare reform out there with the prescription drug and then have a cost analysis by CBO and other individuals, Mr. Congressman.

Mr. NORWOOD. Well, I would like to go on record just agreeing with that. I don't want to rush into the fix; I want to do it right when we do it, because this is very major for my grandchildren and yours.

Mr. THOMPSON. Absolutely.

Mr. NORWOOD. But in the interim, if you think just with your brain, not necessarily with your heart, for us to be preventive in the area of prescription drugs for those who can afford half their prescription or none of their prescription, probably there is a cost saver for the trust fund.

There are going to be—reap great benefits with being able to take those medications rather than spend 2 weeks in the hospital, because they didn't take those medications. So I am just saying, I agree with you, and would encourage us perhaps to think like that.

I am—very quickly, because my time is running out, I am one of those people who loves to bash HCFA. And I don't do that because I don't have anything else to do; I do that because every time I go home, I get jumped on, big time, by a lot of people who say their life is absolutely miserable dealing with HCFA. Though, I agree with Mr. Brown wholeheartedly, it isn't just HCFA; it is the Congress of the United States and some of the mess we do, micromanaging that particular agency.

One of the things I need to hear is, there is some way possible that we can do a better job from HCFA to the provider physician at home in terms of the rules and regulations that that physician has to live under. Now, some people say it is 130,000 pages of rules and regulations. Some people say it is 40,000—whatever, it is about 18 inches high. We need to be able to do something to help our doctors have more time with their patients and less time with government paperwork.

Any ideas?

Mr. THOMPSON. We have lots of ideas, but we haven't implemented anything yet. But we are talking to the people at HCFA. I had a meeting in my office at 7 o'clock on Monday evening on some new HCFA rules. And I looked at them and I said, I can't understand them. And, granted, I have only been here for 75 days, but I looked at it as a country lawyer, and I could not understand it, so I sent it back.

I am going to keep sending things back until they simplify it so I can understand it. If I can understand it, I am confident that a doctor can understand it.

Mr. NORWOOD. We have to simplify it, because it is so unfair.

And, just quickly, the House has passed——

Mr. BILIRAKIS. We will have a second round if the members prefer. I don't want to go too far afield here. Very quickly.

Mr. NORWOOD. I just want to mention the lockbox has been passed by the House, so that we don't tap into the Medicare Trust Fund which I am totally against, and the geriatric ward over there takes a little longer. They will get to it eventually, and perhaps we will make sure.

Mr. THOMPSON. I am not going to get into this fight, Congressman.

Mr. BILIRAKIS. Mr. Pallone, you may inquire.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. Secretary, I wanted to follow up on what Mr. Brown mentioned with regard to generic drugs, because I really am an advocate for promoting generics as a way of saving costs. I know you sort of deemphasized the money factor, if you will. But, you know, the fact of the matter is that there is a lot of manipulation that goes on with the Waxman-Hatch Act that I think contributes to the fact that there is so much delay with getting approval for generic drugs.

You know, you have this filing of frivolous patents with the FDA to trigger this mandatory 30-month hold on approving generic applications. You have these patent extension bills, you know, private bills, so to speak, that we hear about during the dark of the night or when we are at the end of the session, and you have also had the misuse of citizens' process.

These are a lot of, you know, procedural ways that are used.

Mr. THOMPSON. Sure.

Mr. PALLONE. And I just wondered if you would support some kind of statutory mechanism to try to address some of these manipulations and to try to bring the approval process more in line with the amount of time it takes for the brand industry to get approval.

Mr. THOMPSON. Congressman, I would like to have some time to—I am not delaying the answer—your direct answer to your question. I would just like to have some time to study FDA.

What I intend to do is, I intend to go to every one of the operating divisions and spend a week, actually operating the division and being there to find out exactly how things go.

I would like to be able to come back to you sometime later on this summer and talk to you about it and about some of my suggestions, how we can improve it.

Mr. PALLONE. That is fine. I don't want to spend a lot of time.

Mr. THOMPSON. I want to point out, we are putting a 5.6 percent increase into this area.

Mr. PALLONE. I appreciate that. I don't want to delay it. You know, I appreciate the fact that you will get back to us. But I just want to point—I think there are a lot of things that can be done other than the money as well. I agree with the fact that the money is an important factor.

Mr. THOMPSON. The suggestions you have are probably very good ones. I would like to be able to take those suggestions; and I solicit and—I am the type of person who loves ideas. If you have got ideas, I would like to take a look at them and work on them and come back to each of you, Democrats and Republicans alike, to see if we can come together, because my feeling is, if we work together, we can come up with a better product.

Mr. PALLONE. All right. I appreciate that.

Let me ask you about the patient protection provisions that we would like to see in the Medicaid program. You know that in the last, you know, few days or the last couple months of the Clinton administration, we put in place, or he put in place a regulation that would allow the patient protection, something like the Patients' Bill of Rights to be applied to Medicare—to Medicaid, I should say. We already have it for Medicare.

I understand that the Bush administration has delayed that. It was supposed to go into effect, I think, sometime earlier in April. They have now delayed that and said they are not going to make a final decision on whether to lift the hold on that until sometime in June.

That concerns me, because I have to be honest with you and say we had a hearing on HMO reform in the subcommittee a month or so ago. At that time, I was very critical of the Bush administration because I think during the campaign the President suggested that he was going to address Patients' Bill of Rights and would support something like the Texas law.

Yet, Mr. Ganske, Mr. Dingell, others have introduced on a bipartisan basis a bill, a Patients' Bill of Rights bill that I think is exactly like the Texas law, and so far all we have seen from this administration is the delay in this regulation with regard to Medicaid—the Medicaid program and criticism, if you will, of the Ganske-Dingell bill saying that it is not, you know, what we want.

I just don't see any effort really on the part of the administration to address the issue of HMO reform. I think it is something that was talked about in the campaign, but in terms of the actions in the first 100 days, the only action is to say we don't like Ganske's

bill, and we don't—we are not sure if we are going to put these regulations into effect.

Can you assure us that we will see these regulations go into effect so that Medicaid has the same patient protections as Medicare? What is going to be done? What is the administration proposing on the Patients' Bill of Rights?

Mr. THOMPSON. Very valid question. As you know, all rules and regulations were put on a 60-day hold. But you also know that the privacy rule was published on time last—2 weeks ago on Friday. It is a pretty strong indication that this President is very—very definite on protecting patients' rights and is very passionate about it, as you are, as members are, as I am.

In regards to the Medicaid one, we are looking at it and reviewing it, and it will be—we will be making a final decision in the course of the next several weeks. And I will get back to you if I have any problems with it, but right now, I haven't discovered any.

Mr. PALLONE. You know, I have to say, Mr. Secretary, I believe strongly if the President got up and said, I want to meet on a bipartisan basis with the members who are playing a key role on this, and I want to resolve this and have a Patients'——

Mr. THOMPSON. Are you talking about the Patients' Bill of Rights?

Mr. PALLONE. I am talking in a larger sense. I want to have this done by June 1, I have no doubt that it can be done. I really don't think the differences are great—are that great, and I don't see the President moving in that direction.

Mr. THOMPSON. I think the President is doing a very good job in moving that direction. He set out his bill of particulars, what he needs and what he would like to see in it. We all know, you know, every member on this committee and every person in the House and the Senate knows that there are really two big issues, liability and scope. And we have to work on those two, and we have to work on them on a bipartisan basis.

I am confident that we are going to have a Patients' Bill of Rights sometime this summer, and we are going to be able to resolve our differences on those two subject matters.

Mr. PALLONE. I hope so. And I appreciate the fact that you are willing at least to talk about the summer as a deadline, because I am just afraid it is going to continue.

Mr. THOMPSON. That is my suggestion, but I am finding out that I am no longer a Governor; I am a secretary, so. . .

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Thank you.

Dr. Ganske.

Mr. GANSKE. Once again, Mr. Secretary, thank you for coming. Mr. Secretary, since I came to Congress in 1995, when the Republicans took the majority, we have been universally opposed to user fees. President Clinton in his budgets repeatedly, across various agencies, proposed user fees.

I can specifically remember a lot of Republican comments on the floor of the House of Representatives and in the Senate against user fees as being basically tax increases. In addition, as I mentioned earlier, in my home State, we were dead last in terms of provider reimbursement. My rural hospitals are really hurting.

I am concerned about a user fee on submission of claims to Medicare. I personally consider that to be a tax increase, and I can tell you that my providers back in Iowa, considering their low reimbursement, already believe that adds insult to injury.

And so my question to you, Mr. Secretary, is, is this administration proposing user fees on data transmission or claim transmission to Medicare?

Mr. THOMPSON. First, let me tell you that it is not the President. It is not this administration. It is Tommy Thompson who is pushing this. So you have nobody to get mad at me except me, Congressman, because I am the one who fought very hard to get this in, and I will tell you why.

First off, I have the same problems, or did have the same problems in Wisconsin as far as reimbursement. I didn't know Iowa was dead last, I thought Wisconsin was dead last, so I understand your concern. But I also understand full well that HCFA needs a lot of assistance, and when 80 percent of our claims are being sent in via the computer, it is much easier to process. And if somebody else wants to send in paper, which costs more to process, slows down the system, delays it so your doctors and hospitals don't get reimbursed as quickly as they would have if everything was on the computer system, I thought it was only fair and equitable if a doctor and hospital want to continue to use paper, they should pay an additional dollar for it.

I would then take that money and use it to upgrade and improve the computer system at HCFA. It was one way I found to improve the resources necessary to make HCFA more responsive. And so don't blame the President, don't blame OMB; blame me. And tell your doctors and hospitals, when they complain to you, to call me; and I will tell them they don't have do pay that user fee, all they have to do is convert over to a computer system like 80 percent of the other providers do in America.

It would speed up the process, and it would make it more efficient, and you would learn to love a HCFA just a little bit more, Congressman.

Mr. GANSKE. Mr. Secretary, let me ask you to reconsider your position on this——

Mr. THOMPSON. Okay.

Mr. GANSKE. [continuing] and here's why. I think it is fine to have electronic transmission, and the benefit, if it really is there, is in the quicker return on your reimbursement.

Mr. THOMPSON. Right.

Mr. GANSKE. Okay. So that is a carrot, but I don't think that you should basically create a tax increase on those who, for particular reasons, may be submitting paper.

I can give you a lot of reasons why those claims are submitted on paper. From my own medical practice, for instance, we submitted paper because we provided documentation on a large number of procedures that HCFA was going to require paper documentation anyway.

And so if we didn't do that in the first place, then we were looking at a 2-, 3-, 4-, 6-month delay because we would send in our electronic claim first, and then we would months later get a request for paper. There are a large number of procedures that par-

ticular providers need to do that HCFA requires the paper documentation on.

We can't, for instance, submit the pathology report or the operative report by electronic methods. Those are things we receive via paper from the hospital.

I am totally in favor of providing the necessary funding for HCFA to do its job. For years, I have been a supporter on that, Mr. Secretary. But to leave the carrot for those who want to submit by electronic, but don't provide a hammer for those who, for various reasons, have to submit paper; there are a lot of reasons.

And that gets me to the second thing about——

Mr. BILIRAKIS. Please do this very quickly, the time is up.

Mr. GANSKE. For at least 10 years, 8 years, HCFA has refused to give prior authorization for procedures, and they basically, in my opinion, have tried to scare Medicare patients from getting needed treatment.

For instance, perhaps a patient needs a procedure on their eyelids because they can't see laterally when they drive, okay, so today HCFA will say, well, maybe we will pay for it and maybe we won't. And if we don't, then you, the Medicare recipient, are responsible.

In the past, it used to be, you would send in your documentation, visual fields, whatever, and you would ask for a prior authorization from HCFA, and they would say yes or no. Then at least the Medicare beneficiary knew where they were at.

I think the procedure that is currently followed by HCFA is designed to scare Medicare recipients from getting needed treatment. I would sincerely ask that you revise this policy so that on particular types of procedures we can return to a prior authorization method, so that you can put at ease the mind of the Medicare recipient, knowing in advance whether in fact this will be a covered service.

Mr. BILIRAKIS. The gentleman's time has expired. If you have a very brief comment, Mr. Secretary, you will have the opportunity obviously in writing to respond to a number of questions.

Mr. THOMPSON. Thirty seconds?

Mr. BILIRAKIS. Thirty seconds.

Mr. THOMPSON. Thirty seconds.

Mr. BILIRAKIS. Without objection.

Mr. THOMPSON. I will consider it. But I would like you in response to give me a list of all of those problem areas.

Let us change the rules. Let us make it easier. And I also have the provision to waive any problems under the user fee. So in your case, if there was a problem, we could waive it.

Mr. BILIRAKIS. Mr. Green to inquire.

Mr. GREEN. Thank you, Mr. Chairman.

And again, welcome, Mr. Secretary.

In my opening statement, I talked about a number of issues, but first I would like to talk about the CAP program, Community Access Program. In your testimony you emphasized the importance of utilizing our State and local community partners, and I agree we must improve funding for the Community Health Centers. But I question the elimination of the CAP program.

The CAP has helped fill the gaps in our health care safety net by improving infrastructure, communications among agencies, par-

ticularly in our urban areas like Houston which I represent; and with better information, the agencies can provide preventive primary and even emergency clinical services in an integrated and coordinated manner.

The funding under CAP has been used to support a variety of projects, to improve access for all levels of care for the uninsured, and each community designs a program that best addresses the needs of the underinsured and uninsured and the providers of our community.

Again, I understand the flexibility that the CAP program gives districts like I have in Houston. In fact, the vice president of Community Outreach at the University of Texas Medical Branch, Ben Raimer, said in a letter to the President, "the Community Access Program is one of the programs that works at the community base level and one that I feel fits nicely with the President's own personal philosophy regarding local community."

Mr. Chairman, I would like to submit that letter from Ben Raimer for the record.

Mr. BILIRAKIS. Without objection.

Mr. GREEN. Mr. Secretary, can you address the administration eliminating the Community Access Program?

Mr. THOMPSON. Absolutely, Congressman Green. Let me just say that we looked at it. And I am not saying that the program is not good, but we felt that we could use the money more effectively by putting it into Community Health Centers, we could serve a lot more people; and that was a decision.

And in your business and in my business, you know, we have to balance it off. And the Community Access Program is a relatively new program. It has been in existence 1 year. I know Texas has benefited. I know that Louisiana has benefited.

We felt the Community Health Centers is much more dispersed throughout America, and that we would be able to help a lot more underserved and uninsured families by putting the money there. And that was the reason for it. Not to say anything against the CAP program; we just made the decision that Community Health Centers was a better buy for the money that we had, and we invested it there.

Mr. GREEN. And I guess if you have that, those limits, but again you really need both, the Community Health Services, but also the coordination of benefits. So we do get the most out of our dollars.

Let me go on to the CDC. Our chronic diseases like diabetes, heart disease, cancer and arthritis are leading causes of death in America. In fact, they kill 7 out of 10 Americans. The costs of chronic diseases are staggering. More than 70 percent of health care expenditures in the United States are for chronic diseases, and by 2020, $1 trillion, or 80 percent of the health care expenditures, will be spent on chronic diseases.

Now, we have learned that chronic disease prevention and control programs save lives and money. For example, the diabetes programs resulted in a significant decline in complications of the disease in New York. When CDC funded a comprehensive diabetes control program, the hospital rates decreased 35 percent in 2 years; and lower extremity amputations have gone down by about 39 percent.

Can you explain the rationale behind cutting $175 million from the CDC's chronic disease program?

Mr. THOMPSON. Because we took the money and put it into NIH. We put in $639 million, which is a huge increase, in infectious diseases in NIH. We felt, Congressman Green, that we could do a better job trying to find the research necessary for chronic diseases and put the money there, so we put a huge increase in NIH to do that.

So there is a reduction in CDC of some $100 million, but there is an increase of $639 million for the same type of programs, more for treatment, more for research in NIH. And the reason—and the reason we did that, Congressman, is that we have an epidemic problem coming in diabetes, and the two things that will prevent diabetes—enhance diabetes is changing the life-style and exercise. We feel that research—and how we might be able to do that.

And I intend to try to make the Department a focal point for preventive health in America. I am asking you for your assistance in this, because if we don't, the epidemic of diabetes is going to continue to grow and get worse in your State and in all the States in America.

Mr. GREEN. Mr. Secretary, I agree, but the concern I have is, we have—we want the research.

Thank you again for plussing up NIH. It is an effort in Congress we have tried to do, but we have to go from research to prevention.

The concern we have, we have to move that science from the bench to the trench where we can actually see it happen.

Mr. THOMPSON. I understand.

Mr. GREEN. And that is what CDC does. So if you would look at it and say, we want to plus up NIH—and believe me, I think you have unanimous support on this subcommittee. But also we need to see that research being placed out there, like CDC does, like we see the success in New York. I would like to have the same success in Houston and in every city in our country with diabetes control.

So that is the concern we have. We need to plus up the research, but also make sure that information gets out on the street.

Mr. THOMPSON. Thank you.

Mr. BILIRAKIS. Mr. Bryant to inquire.

Mr. BRYANT. Thank you, Mr. Chairman.

Mr. Secretary, I would like to talk about two subjects, and at the conclusion, I invite your comments on both of those.

The first has to do with Community Health Centers. This is a program, I think, that has proven very efficient and cost effective. It is one that is important to my district, which is both rural and urban.

But we are looking at reauthorizing the health centers program this year, and I certainly want to strengthen that program as much as possible in order to serve more of the uninsured in the future.

I am pleased that the President's budget has placed these health centers—has called for doubling the number of patients that they serve over the next 5 years, and also his budget calls for an additional $124 million increase for these health centers.

And, again, I will ask you to comment about that and your view of these health centers.

But the second point I would like to make has to do with medical records, privacy regulation. And your testimony has indicated that you still have problems with the regulation that would have been fixed through guidelines and additional modifications.

I want to ask you about some of those general problems or changes that you would recommend, but before I do that, I would like to mention two specific problems I see. And this first one is, as a former lawyer, recovering lawyer, I might add——

Mr. THOMPSON. Me too.

Mr. BRYANT. [continuing] I would say that the American Psychiatric Association points out a very good point in a letter to you where they talk about the ability of attorneys involved in litigation to acquire medical records.

It generally has been done over the years where you have a medical consent authorization from the litigant, the patient or at least they know about it, but under this new regulation, the lawyer can simply write a letter and make a statement that this is needed in litigation, and he is involved in it.

It is a little more sophisticated then that, but yet, the patient whose record we are talking about is kind of taken out of that loop. And you generally rely, I guess, on the integrity of the attorneys. And I have a concern with that.

Second, it has to do with, I guess, the administration also seeking additional funding for research on health quality; and included in the health quality is the issue of medical errors, this minimum standard that we are talking about with records being——

Mr. THOMPSON. Minimum necessary.

Mr. BRYANT. Yes. And how, if we are concerned about health care in general, that we are going to limit in effect the ability of doctors to acquire the records they might need from other sources. It just seems to me that sort of works in the other way, and it might cause more medical errors if the doctor has not enough in the records to look at.

Those two examples and anything else you might mention, as well as just a comment maybe on the Community Health Centers program, I would appreciate it.

Mr. THOMPSON. Well, thank you for raising both issues with me, Congressman.

First off, on the Community Health Centers, I happen to be a very strong advocate. We have—back when I was Governor, I put a lot of money into the Community Health Centers myself from the State, and I am delighted that the President has seen fit to try and increase the number of Community Health Centers in rural America, as well as urban areas to underserved people. Approximately a third of those are completely uninsured families.

We are going to hope to go from 3,200 by—increase it by 1,200 and increase the number of patients being seen from 11 million to 20 million, almost a 100 percent increase. And what a laudable goal, and I compliment the President on doing that.

I think you know we can really do a great job in covering and getting a lot of uninsured and underserved people in to get good health care, and that is what we want. That is what we want in our country and that is what you want in this Department—in this

committee. So I think it is it is the right decision and the right investment of our dollars.

And in regard to privacy, it is a very complex rule. There is no question about it. But the basic thing is that we want to protect patients' rights, as you do and as does every member on this committee, and we are going to do that.

There are certain things—I didn't know about the psychiatric letter we received—I think, 12,000 letters; I haven't read them all, I am up to 3,300—no, not really. But we are looking at them and trying to comprehend and put in some sort of usable form how we might be able to make some meaningful changes, but not get at the basic premise of protecting patients' rights, which every one of us is concerned about, especially the President.

And in regards to the minimum necessary standard, that has to have some clarification, because we want to make sure that the patient that goes in to see his or her doctor is going to be able to get the necessary reports and the necessary collaboration between the doctors to be able to give that patient the best treatment possible. There has to be some guidance in regards to that, some guidance in the purchase of drugs, which is another problem.

I agree with you that the patient needs to be involved in any litigation and should have to sign some sort of consent form before that information is made available. So we will be looking at it. I did not know that problem existed, and I am very appreciative that you brought it to my attention.

Mr. BRYANT. Thank you.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Strickland to inquire.

Mr. STRICKLAND. Mr. Secretary, thank you for being here, and let me say that on a personal level, your responses to us today have encouraged me.

Mr. THOMPSON. Thank you.

Mr. STRICKLAND. I have a young constituent in my district in southern Ohio. She is 31 years of age. She has been diagnosed with chronic leukemia. Her physician says she needs a bone marrow transplant. She has a brother who is a perfect match.

The insurance company is saying they will not pay for it, that it is experimental. I have talked to her physician; he says it is the standard of treatment. I have gone to the James Cancer Center in Columbus, Ohio, and talked to transplant specialists there myself about her condition. They say that the standard of care is for her to receive this transplant, and that her chance of living and being cured is very good, given her brother's willingness to assist her.

We need a Patient's Bill of Rights. We need a strong one. We need it quickly. I think it is a matter of life and death. And I just encourage you, for the sake of this woman and many others like her, this mother, 31-year-old mother of two children, that this administration and this Congress needs to take these matters seriously.

I have two questions for you.

Mr. THOMPSON. Could I comment on those——

Mr. STRICKLAND. Absolutely.

Mr. THOMPSON. [continuing] on those two things, Congressman?

First off, I would like to—if it is at all possible, for you to have this patient give me the information.

Mr. STRICKLAND. I would be most happy if you would receive that.

Mr. THOMPSON. I would like to have some of our doctors at the Cancer Institute take a look at it. We are doing some wonderful things up there. And I would like to be able to help you. So if you could give me that information as quickly as possible, I would like to get some doctors from our place and see if there is a way that we can solve this problem.

Mr. STRICKLAND. Thank you, Mr. Secretary. I deeply appreciate your response.

Mr. THOMPSON. I appreciate that.

Second, on the Patients' Bill of Rights, you have got to realize that this President passed a very comprehensive Patients' Bill of Rights in Texas. He is in favor of it. I passed one in Wisconsin. I am in favor of it. We need bipartisan support.

There are two issues, scope and liability. It doesn't seem to me to be that difficult if we are really willing on a bipartisan basis to make some compromises to get the job done. I am looking for you. You know, it can't only be compromised from my side; you have got to have some compromise from your side. And if we work together—and I am not saying that you are not willing to compromise. I am just saying this as a example.

Let us see if we can't compromise and get a plan that all of us can be very happy with. I agree with you. We need a Patients' Bill of Rights, and let us get it done. Let us compromise and do the job right.

Mr. STRICKLAND. Thank you, Mr. Secretary.

If I can give you one other example of a constituent, and I applaud you for your concern about organ transplant——

Mr. THOMPSON. Thank you.

Mr. STRICKLAND. [continuing] concerns.

A constituent came to me. She is 64 years of age, she is on a waiting list to receive a lung. She is covered by her husband's Teamsters insurance. If she receives that lung transplant prior to her 65th birthday, which is November 24, when she goes on Medicare at age 65, Medicare will not assist her with paying for the antirejection medications.

If she does not receive that lung transplant until November 25 when she is 65, Medicare will not only pay for the transplant, but provide for the antirejection medication, which is incredibly expensive.

I know this is a can of worms. I know this is a terribly expensive thing to bring to you, but it seems so unreasonable that a birthdate would have that kind of impact on whether or not this woman would receive the assistance she needs.

Mr. THOMPSON. It doesn't make sense.

Mr. STRICKLAND. And if we could—if we could just talk about that and——

Mr. THOMPSON. I would appreciate that.

Mr. STRICKLAND. [continuing] and work on that, I deeply—I would deeply appreciate it, sir.

Mr. THOMPSON. And maybe we can work on it in the context of reforming Medicare and prescription drug provisions. And I would like to do that, straightening these things out.

I am looking for ideas like this in order to improve the system. So don't be bashful about sending me these problems. We will see if we can help you out on all of them. I mean, that is what we are there for, to serve you.

Mr. STRICKLAND. Do I have a minute left, sir?

Mr. THOMPSON. Can I just tell you on organ transplant? We have 76,000 Americans, including your constituent, waiting to get an organ, and only 22,000 are going to be taken care of.

Can you understand the angst and the anxiety that a person must have, waiting to see if they are going to beat the clock and get an organ? We need to redouble our efforts. I would appreciate, you know, your help in developing a Congressional Medal in which we could bring in five families from every Congressman's district to Washington, give them a Gift of Life Medal and highlight the need for organ donors in America.

This is too much of a great country. We are too compassionate people to allow this problem to continue, to worsen each and every month.

Mr. STRICKLAND. I look forward to working with you, sir. Thank you so much.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. And I am hoping for a second round, Ted. I don't know if you know that.

Mr. Buyer.

Mr. BUYER. Thank you.

Mr. Secretary, earlier in the remarks, I brought up the issue about quality access of health care in the rural areas, and I want to associate myself with the question and your answer with regard to Mr. Bryant on the Community Health Centers.

Part of the problem of getting adequate health to underserved areas is also a lack of health care providers, and you mentioned your concern about nursing care. If 50 percent are going to retire in the next 15 years, we are in deep trouble, because we don't even have—even if you packed them all into all of those universities out there, it is still not going to be enough. So I want to compliment you in your oversight and what you are doing.

I would like to ask this question: Don't you agree that we should make sure that there are no barriers to faith-based charities serving as Community Health Centers? And how will $3 million of HHS centers for faith-based and community initiatives work with the Community Health Center program?

Then I have a second question for you, so hold that thought.

Mr. THOMPSON. Okay.

Mr. BUYER. With regard to the Nursing Home Oversight Improvement program—this will be my second question for you—the President's budget recommends over $67 million for nursing home oversight.

My concern is that there is an overregulation of that nursing home operator having Federal regulators and State regulators. What can we do to provide relief to the overregulation with regard

to these nursing home operators and let us really go after the bad actors?

Those are my two questions.

Mr. THOMPSON. First off, let me tell you that the nursing crisis is very severe, and I am so appreciative that you raised that question. I am very appreciative of the fact that this Congress is concerned about it.

At the present time, we have 90,000 shortages in RNs and 250,000 CNAs that are badly needed, especially in the nursing home industry.

And going into your last question, first, if we don't solve the CNA problem and the RN problems, we are going to have a severe nursing home problem in America. And whether it would be too much regulation or too little regulation, without nursing, you are going to have a crisis; and so we have to address that.

In regards to regulation in the nursing home industry, I think we have to spend more time going after the bad nursing homes and putting more investigations, more—and more sporadic, so they are not timed; and be able to try and improve and use the best practices of the good nursing homes and inculcate those kinds of best practices into the whole industry.

And so that is what I intend to do and attempt to do in the nursing home regulations.

In regards to faith-based, it still is in the embryonic stages. We are putting $3 million in the Department of Health and Human Services to set up the office; then we are going to be looking at all the programs and see where the faith-based programs could be utilized to the best. We haven't really got a plan as of yet, because it is just getting started.

We don't have the $3 million, as you know, but I would appreciate once the plan is further along to come over to your office and talk to you about it.

Mr. BUYER. Would you be open to the idea or the concept of a—if you have a particular religious organization that is also involved in providing a health service on a community health basis that you would include those in a community health center funding?

Mr. THOMPSON. That question has not been asked. I would like to.

Mr. BUYER. I just invite you to be open to the idea as you are developing—you said it is in an embryonic stage. Let us be creative and open.

Mr. THOMPSON. We certainly are, and we certainly will look at that.

Mr. BUYER. Very good.

I yield back my time.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Waxman to inquire.

Mr. WAXMAN. Yes, thank you very much.

Mr. Secretary, I am delighted you are here and we have this opportunity to exchange some views.

I wanted to talk to you about section 1115 waivers. That section of the Social Securiry Act gives the Secretary broad power for demonstration projects and to waive various parts of the Federal law.

It is often used in Medicaid and other areas. It has the purpose of trying to encourage innovation and experimentation.

Mr. THOMPSON. Right.

Mr. WAXMAN. On the other hand, we do have Federal requirements that assure us that patients, beneficiaries, get the services that they need. So it is a concern that we make sure that we don't waive all the Federal laws and find that we are not getting experimentation, but regression in the requirements. The President's budget has suggested $27 billion will be spent in Medicaid demonstration projects in fiscal year 2001.

Now, a number of us—Mr. Dingell, Mr. Brown and I—are sending you a letter today to request that HHS work with us on these waiver issues to provide us with quarterly updates on section 1115 waivers, as well as basic information on existing waivers and demonstrations, the criteria for waiver and demonstration approval and the assurances that beneficiaries are adequately protected under current and future programs.

I look forward to getting your response and working with you in this regard. I think it is important for us to be in communication with each other as you move forward on these waivers. You have the authority to do it, but we ought to be involved.

Mr. THOMPSON. Congressman, all you have to do is call me, and I will be more than happy to discuss anything with you and any other member of this committee concerning waivers or anything like this.

I want to point out that 1115 waivers, we have only issued one. There are only 20 in existence, and there are a couple of those I got when I was Governor, and one set up the Batcher care program, which is, I think, heralded by you and by other members of the committee as one of the SCHIP programs in America.

Mr. WAXMAN. I think the waivers can serve a very useful purpose. What I would like to ask of you, not just to talk to me personally, but if we could have a process to make the information on approved and pending waivers available to the public to get the terms and conditions and other information posted on the HCFA Web site, just like all the 50 States' Medicaid programs already put this information on their Web sites.

Mr. THOMPSON. I would have to consider that.

Mr. WAXMAN. You don't have to give me an answer now, but we are requesting it.

Mr. THOMPSON. Sure. I want to work with you.

You have got to realize, I believe in waivers. I come from a State that was very innovative in coming up and being able to develop programs. Most of the waivers, Congressman, have been used to expand programs to give more service to underserved people, to children and to minorities and those that need help.

I think that States have done an excellent job. We are not going to waive things that are going to be deleterious to the health care of America.

But I want to work with you, and I am willing to.

Mr. WAXMAN. I understand we may have differences, but I understand that you have good intentions. But what I think we need is transparency——

Mr. THOMPSON. Okay.

Mr. WAXMAN. [continuing] and cooperation and communication. And I would——

Mr. THOMPSON. I am very cooperative.

Mr. WAXMAN. And I would encourage that we have that.

I understand also the Bush administration is planning on revising the Department's policy on granting section 1115 waivers for demonstrations.

Previous administrations have articulated their policies in the various Federal Register notices, Medicaid operation manuals, review guides, approval letters and conditions of approval. Can you tell us whether and how you are planning on modifying the policies that have been in place during other administrations and whether you will solicit our views on those as well?

Mr. THOMPSON. I haven't made any major changes. I may accelerate it considerably; I don't like to delay. I like to examine waivers and make decisions one way or the other. I think it helps the system if you say no, to allow Governors and other individuals to know that it is not going to go. And if it is suitable and it is budget-neutral and we are going to say yes, why not get it out?

Mr. WAXMAN. None of that is inconsistent with what I am suggesting.

Mr. THOMPSON. So that is my overall philosophy. But changing—to having a writing and any other major change at this point in time, I haven't—I haven't made any.

Mr. WAXMAN. I appreciate that.

Before my time is up, I do want to commend you on going forward with the privacy rules. I thought that was a good step and an important one, because the American people have been waiting a long time for some privacy protections.

I also understand you have indicated you are going to make some modifications of those rules. The rule is designed to respect the approach that the States have taken, even though they may vary from one State to another.

I particularly want to know whether you are going to change the medical privacy rule to allow parents to access their children's health records, even in States where the policies are to allow a minor to obtain an abortion without parental consent.

Mr. THOMPSON. Truthfully, Congressman, we haven't even——

Mr. WAXMAN. You are not there.

Mr. THOMPSON. We are not there. We are not there, and it would be premature even to attempt to answer that, because we haven't—we haven't even published a rule. Right now, we are looking at the guidance, not the major changes that you are talking about.

This would be a major change. And we haven't even got to that.

We are looking at how we might be able to put out some guidance to solve some of the problems that Congressman Bryant was talking about, how to solve the problem about being able to pick up your wife's prescription drugs if she is too sick to do it and doesn't get a chance to sign a consent, guidance on going to a doctor, having some lab work done, being able to allow the doctor to talk to the lab technician and get the analysis without having to have a written consent.

Those—those directional kind of things for guidance are the things that we are working on. And the minor changes and the

major changes, we haven't gotten to yet, and you will certainly know when I get there.

Mr. WAXMAN. Thank you very much.

Mr. BILIRAKIS. Mr. Burr to inquire.

Mr. BURR. We look forward, Mr. Secretary, to any input we can offer you of our expertise and experience also, as you move through changes in the privacy.

Mr. THOMPSON. Thank you.

Mr. BURR. I want to as well inquire——

Mr. BILIRAKIS. Those mikes don't appear to be picking up.

Mr. BURR. Mr. Chairman, I think this mike is broken, but I will try and speak loudly. I also want to encourage you where it is appropriate to bring transparency under the waiver process to do it; and I am confident had that existed in the last administration you would not have inherited so many waivers that had not been acted on; and in a bipartisan way, we spent much of the last 2 years trying to find out the status of waivers.

I am glad that North Carolina received its waiver on SCHIP, because I think our program was just a little bit better than Wisconsin's.

Mr. THOMPSON. That is debatable, but I know also that I am the witness, and I am your—I will be quiet.

Mr. BURR. Ours was good enough that we still have individuals who should be on it.

Mr. THOMPSON. Right.

Mr. BURR. And the Federal estimates for North Carolina had grossly underestimated the population. And I look forward to working with you to figure out how we can cover those children.

Let me ask you on two different areas. In the memory of Dr. Coburn, who is no longer with us, were he to have been here, with your statement on HIV, he would have asked you this question: Will HHS consider on domestic AIDS policy a mandatory testing for pregnant women so that we can detect the possibility of transmission of HIV prior to delivery because we know that we have medicine that can lower the incidents of transmission?

Mr. THOMPSON. Let me first talk to you about the waiver situation in North Carolina. We have pushed very rapidly on waivers as everybody knows, and we are getting the backlog done very quickly. Most of the waivers that we have granted have expanded services and programs to people that need them.

And I think most of them have been widely disseminated and been favorably accepted by both political parties. We will continue to do that.

In regards to AIDS, we have not developed that plan and it is something that—all of the things that you have talked about in regards to mandatory testing are things that will have to be considered, but at this point in time have not been.

Mr. BURR. Great. As it relates to BIPA, it mandated that GAO study HCFA's reimbursement methodology and make those recommendations to ensure that the methodology reflects actual physician costs.

Even though the study is supposed to be finished, I think in July of this year, if the study calls for HCFA to make changes, I doubt

that those changes could be complete before January 1, 2002; and that is the implementation date of the reimbursement reductions.

Would you consider delaying those reductions from taking place if, in fact, that report comes back——

Mr. THOMPSON. Yes.

Mr. BURR. [continuing] and suggests it is flawed?

Mr. BURR. I thank you very much for your answers. I yield back the balance of my time.

Mr. NORWOOD [presiding]. Thank you, Mr. Burr.

Mr. Barrett, it is your turn.

Mr. BARRETT. Mr. Secretary, it is nice to see you in Washington.

Mr. THOMPSON. Congressman, how are you? It is good to see you.

Mr. BARRETT. It is a lot like Elroy, would you not say?

Mr. THOMPSON. Not quite. Elroy does not have a stop and go light. Elroy, if you call someone and get a wrong number, you can still talk for half an hour.

Mr. BARRETT. That is right. On this committee last year we have had some sharp debate over the issue of organs.

Mr. THOMPSON. Yes.

Mr. BARRETT. My sense was always that we were talking about a pie of one size and cutting up the pieces. And if there is anything that I have been encouraged by—and there have been many things that I have been encouraged by—but if there is anything in particular that jumps out with me what you have done since you had this position is your work on organ donations.

Because I honestly feel that you are in a position to use your bully pulpit to travel this country and talk about this. And I want to encourage you to do that. Because the success we had in Wisconsin that we are both familiar with, I think, can be replicated.

Just if you could elaborate on what you are planning on doing, because I think you can really do some good stuff there.

Mr. THOMPSON. Thank you so very much, Congressman. This is really a passion for me, and I really applaud your support and bipartisan support, Congressman Barrett and Congressman Strickland. This is something we need to do in America. 76,000 people are waiting for an organ; 22,000 transplants last year.

It does not look like it is going to get any better. And what we need to do is we need to highlight it; and I have developed a partnership with employers, like the welfare-to-work program, that was started a couple of years ago in which we got employers to go out and agree to hire welfare mothers.

What we are trying to do now is to get employers and with the labor unions to team up together and make this a cause for the workplace, to talk to employees about the importance and the need to the giving of organs.

I am very, very proud to announce that the big three, Chrysler, General Motors and Ford, and UAW have written in to their contracts that they are going to do this. That is a giant step forward.

The second thing is we are putting out a national organ card with two witnesses; and what we are encouraging people to do, not only sign their organ card, talk it over with your family. Because what we are finding is that 95 percent of the people when they are there, they will say, yes, they will support the husband or the

wife's views. But when it gets to the hospital, only 50 percent follow through.

The third thing, based upon a Wisconsin law, as you know, we passed the Knockrinder bill in which Kelly Knockrinder was 16 and she was very much advanced for her young age. She got killed in a very tragic incident. Her boyfriend was driving, she got killed; but she gave all of her organs up to help three families. Her family came and says we should do something in her memory, and we wrote in the Knockrinder bill in which every person before they reach 16 and gets a driver's license has to have a 30 minutes' study and course done on organ donation.

If we could sort off encourage other States to do that, if we can get a gift of life medal given out by this Congress, you know, a Congressional Gift of Life Medal, like an Olympic medal and have five families from every congressional district come out here with a recipient and have a day of organ donors on the National Capital, what a great way to highlight it. Those are the things that we need to do.

Finally, I tell people—and I am speaking all over the country, as you probably know—and I tell people, you know, if your organs had a vote, do you think your organs—do you not think your eyes would continue to vote to see the beauty of this great land? Do you not think your heart would continue to want to beat in somebody else's body? I know your kidney and livers would love to continue to drink Wisconsin beer and eat Wisconsin cheese. So I know that they would vote for that. And that is what we have to do.

Mr. BARRETT. I do not disagree with that.

Mr. THOMPSON. We have to get that story out. I thank you for the question.

Mr. BARRETT. I need your help on something else. Twice today you mentioned that the Patients' Bill of Rights has two legitimate issues, two real issues: scope and liability.

Mr. THOMPSON. Yes.

Mr. BARRETT. My concern is that there is a third, what I have often called bogeyman, issue out there, which is that we are somehow trying to nail employers. And we need your leadership on this issue, because I do not know anybody who is pushing this legislation who wants employers to be held liable.

And, again, twice you identified what I have said when I have businesspeople from Wisconsin come into my office. I say, there are two legitimate issues here, the scope and the liability. You have echoed that today.

So I think you could advance this debate much further if you sent the word out to the business community we are not talking about employer liability here.

Mr. THOMPSON. I am willing to do that.

Mr. BARRETT. Good. The third, I was in Marshfield last week at St. Joe's Hospital and they were talking about diabetes and the concerns there.

Just briefly if you could talk about what you are planning to do, because what you mentioned today about diabetes was something that was mentioned in Marshfield last year.

Mr. THOMPSON. I went down to CDC, Congressman, and the experts down there tell me that 75 to 80 percent of diabetes can be

controlled or eliminated by doing two things: eating properly, life-style change and exercising.

Now, if we were able to motivate America about smoking, what an impact we could have on the Medicare dollars, the Medicaid dollars, and the health care dollars in America, if we could somehow get the information out about life-style and about exercise.

And I think this Department, the Department of Health and all, should be leading the effort in that. We want to develop programs and preventive health, especially in diabetes.

I am looking for ideas. I do not have any. And I am looking for ideas from you, Congressman, to find ways in which we can do that. I do not know if the 75 to 80 percent figure is correct. But if it is only 50 percent, what a tremendous impact we could have on the health care of America if we just did that.

Mr. BARRETT. Thank you.

Mr. NORWOOD. Thank you, Mr. Barrett.

Mr. Whitfield, I believe it is your turn.

Mr. WHITFIELD. Thank you very much. Mr. Secretary, welcome to the committee. We are all delighted that you are in your new position of responsibility.

Mr. THOMPSON. Thank you.

Mr. WHITFIELD. Last month, Rose Crum-Johnson, who is the Region IV administrator for HCFA, was in my district and helped us arrange a forum for health care providers to express their frustrations with reimbursement issues; and we had over 120 providers there. There was about a 2- and a 3-hour—2- to 3-hour question and answer series, which I think went very well.

I hope as you address these issues of reform internally that you might at least consult with her, because she may have received some insights from that forum that could be helpful.

She did a great job, and I must say very frankly that we were not nearly as impressed with the contractor for that region as we were the HCFA personnel that were there.

The second thing, we have heard a lot of discussions today about Patients' Bill of Rights, and all of us obviously want a Patients' Bill of Rights. I, for one, am pleased that the administration is taking its time, particularly on the liability issue, because anytime you talk about preemption of ERISA, there is a problem with employer liability.

I know that—we know for a fact there is some reentrenchment on health care benefits from employers, and the last thing that we want to do is pass a bill that is going to create more uninsureds. So I am delighted that the administration is moving forward cautiously on Patients' Bill of Rights.

Mr. NORWOOD. The time is up.

Mr. WHITFIELD. I want to talk to you about the issue of a nursing shortage. There has been some legislation regarding that and Lois Capps and others are involved in that. And I think we would like to get our legislation over to you and let you all look at it and see if you have any suggestions and see if we can work together to try to move that legislation.

Mr. THOMPSON. I would like that very much, Congressman.

Mr. WHITFIELD. On the fourth issue, like everyone else, I am very much interested in this Community Health Centers. It is frus-

trating to see people who are just over the line, they are not eligible for Medicaid, and they are paying taxes for Medicare and Social Security and Medicaid for other people; but they are not receiving any benefit.

And as we look for ways to address this uninsured pool—obviously, Community Health Centers is one way to do it. Other ways are health marks, tax deductions, tax credits for health care premiums and so forth.

Do you all at HHS have any sort of task force that is looking at ways that we can address this uninsured problem at all at this time?

Mr. THOMPSON. We do not have a task force, but we certainly are looking at it. We are looking at Community Health Centers as you know. We are looking at the Presidential tax credit that he wants. But we are always—we do not have to have a task force to be looking at. We are looking at ways to improve it and make more people eligible.

The working poor that you are concerned about is something that, you know, I was very concerned about as a Governor; and I always felt, you know, that people on the Medicaid end of the spectrum were able to get very good medical care. People that were middle income to wealthy were able to get good medical care.

It was the poor working person that was just above the line that worked very hard that could not afford health insurance; and that is when we decided to work on Badger Care in Wisconsin. And I am sorry the gentleman from North Carolina is not here; I would like to tell him how much better tragic areas than his program in North Carolina is but——

Mr. WHITFIELD. I will tell him.

Mr. THOMPSON. You tell him that I said that, but I waited until he was out of the room. I want to be helpful, and this Department wants to be helpful. We would like to be able to reduce the number of uninsured and increase the number of people that get health coverage.

Mr. WHITFIELD. But you see the Community Health Centers as one of the primary ways to do that?

Mr. THOMPSON. I see it as an excellent way to do it.

Mr. WHITFIELD. And I am not sure on eligibility requirements for Community Health Centers, but is there some sort of sliding scale based on income to be eligible?

Mr. THOMPSON. There is. And usually in the Community Health Centers that you fill out a form, and the ones that I am most familiar with, you have to pay something. You have to pay something toward it, but it is based upon your income. It is affordable, but the concept has been that you should pay something to go in there.

Mr. WHITFIELD. And the $124 million that you are requesting——

Mr. THOMPSON. $124 million.

Mr. WHITFIELD. [continuing] how many centers do you anticipate with that?

Mr. THOMPSON. We want to be able to increase the number of centers by 1,200 over the next 5 years.

Mr. WHITFIELD. Okay.

Mr. THOMPSON. And this is the first installment, so it would be about 300.

Mr. WHITFIELD. Mr. Chairman, thank you for giving me the time.

Mr. NORWOOD. The last time, thank you Mr. Whitfield. Mr. Wynn it is your turn.

Mr. WYNN. Thank you very much, Mr. Chairman; and welcome, Mr. Secretary.

Mr. THOMPSON. Thank you, Congressman.

Mr. WYNN. One of the things I am very pleased about is that you bring enthusiasm to the job, and I think that is the first and the most important prerequisite.

Three issues. First, this is a picture of Melissa Forelich. She is a poster child for the Red Cross. She is here with us today with her mother. She is a victim of congenital heart defect.

Also with us is the family of Samuel Ellison. His parents, Marcus and Vongi Ellison, are here. My colleague, Ms. Morella, and I are going to sponsor a bipartisan measure that would propose a Medicaid waiver for families such as these so that they would not have to be doomed to poverty as a result of addressing their child's health care problems.

This waiver would kick in after all of their private insurance has been exhausted. I wanted to somewhat vividly illustrate this point, because I hope that you can consider supporting this legislation. I think you are well aware of the problem of congenital heart defects, such as there are multiple operations over the child's life, even beyond the age of 18. And under the current Medicaid laws, these parents, these families would have to literally spend down to poverty and who would otherwise be productive tax-paying citizens would basically have their lives substantially destroyed.

I hope you will consider that and maybe even if you have a moment to talk to the families who are here.

Mr. THOMPSON. I certainly would like to. And I am very appreciative that they are here, and let us hope that we can help them.

Mr. WYNN. Thank you, Mr. Secretary. Second is Head Start. I noted that you say that you are going to be able to serve 915,000 young people in Head Start. With $125 million increase out of a budget of $6.3 billion, that seems somewhat modest; and I would like to know how many young people are eligible beyond the 915,000, because I got the impression that there were probably another 40 million who might be eligible who are not served; and it would seem that we ought to be able to find the money to serve them.

Third, I had an interesting conversation—first of all, let me commend you in this context about your commitment about preventive care. I had a conversation with some State Department folks on the subject of Cuba, and they begrudgingly admitted that Cuba had addressed the problem of preventive health care. Obviously, it is a different system; but I feel bad that our system has not been able to do as good a job as we think we ought to do in that area.

My colleague, Mr. Whitfield, mentioned Community Health Centers. It seems to me that is a move in the right direction. I would like you to amplify on your thoughts on that with the eye toward how can we do this in the most direct way so that there is not a lot of insurance or tax papers and things like that so that the peo-

ple can go in, get preventive care, and we can in turn get the savings of having them healthier.

If you could comment on those latter two issues, I would appreciate it.

Mr. THOMPSON. Well, preventive health care is something that, you know, we need to do in America. Our health system is set up, Congressman, to wait till a person gets really sick, then we pay lots of money to correct it.

Mr. WYNN. And ask them if he has any insurance.

Mr. THOMPSON. And ask them if he has any insurance. I started a program back in Wisconsin and invested $150,000 a year for the abatement of lead poisoning, and a community—through a community health center. And then 5 years for an investment of $750,000, we were able to reduce the lead poisoning in that census track by 60 percent.

Now, what that means is that we have probably saved the Medicare and Medicaid budgets thousands, possibly millions, of dollars; but the more important thing is that we gave young people, especially minorities in that census track, an opportunity to lead, you know, successful lives instead of having lead poisoning.

Diabetes, it is so important for us to get out information on obesity, nutrition, and exercise in order to do that.

I am looking for ideas, because I want to try and focus Congress and America on ways that we might be able to be a more healthy society and be able to change the reimbursement systems toward more prevention.

And I need your advice and ideas on how to do that, because I am there, I know the problem; but I do not have the expertise to bring all of the ideas together without some assistance from Congress and so on. But I think we need to do that.

In regards to your waiver, if you are going to have to pass legislation, we would be more than happy to look at it. Once you get it drafted, send it over, we will make some contact—some comments and look at it.

As far as community health, it is a wonderful way, you know, to get minorities, underserved people in urban areas, as well as in rural areas to get the necessary health care coverage that they need.

This is probably the first avenue for health care for millions of Americans; 11 million are being taken care of right now. We would like to expand that up to 20 million. We would like to expand the number of Community Health Centers by 1,200, which is a laudable, but ambitious, goal. I am appreciative of the fact that we are having bipartisan support for that.

Mr. NORWOOD. Thank you, Mr. Wynn. We will have a——

Mr. WYNN. My time has expired.

Mr. NORWOOD. Yes, it has. We will have a second round.

Mr. NORWOOD. Mr. Secretary——

Mr. GREENWOOD. Mr. Chairman.

Mr. NORWOOD. I'm sorry, Mr. Greenwood. I beg your pardon, sir. You are absolutely recognized.

Mr. GREENWOOD. Thank you, Mr. Chairman. It is not your fault; I was entertaining 50 ninth graders downstairs. I had to leave. They had some tough questions; you think you got tough questions.

Mr. Secretary, you and I spoke yesterday briefly in my office about privacy issues. And as you understand the privacy rule that I had some problems with in the last administration, I have some problems with in this administration. We talked about maybe working together to correct some of that.

I want to ask you two things, but they are very related; and they have to do with privacy and computers.

The health entities that will have to comply with these privacy regulations will have to redesign their computerized health information systems in order to do that, and that is going to be very expensive.

Mr. THOMPSON. Yes.

Mr. GREENWOOD. They also, pursuant to HIPAA, will have to make similar changes to comply with the rule when it is finalized on security and electronic signatures.

And one of the expressions that they have made is that the problem that they have is they are going to have to go in and justify to their boards of directors the expenditures for the revamping of their computers to meet with the privacy—to meet the privacy standards and then wait until the second set of rules comes out on security and electronic signatures and maybe have to go back and do it again, and that it would make a lot of sense in terms of costs to synchronize those two actions to be able to take care of them at the same time.

So part one of my question is, do you think we can figure out a way to blend, merge those two calendars so that they have to comply with both of those rules so they would know what the new rule is in time to comply with both of them at the same time?

Similarly, another privacy and computer issue goes to the other direction, and that is——

Mr. THOMPSON. Congressman, could I just interrupt before you ask me the second question. You know that the privacy effective date is statutory. I have no way to extend it at all. That is written into the law. You will have to——

Mr. GREENWOOD. I think what we will probably have to do is to see what the fastest route you think is to the security and electronic signature rulemaking and see whether you can do that fast enough so that the two can be synchronized or whether we need to make an adjustment in the privacy piece——

Mr. THOMPSON. All right.

Mr. GREENWOOD. [continuing] statutorily, if necessary, to push that out a little bit further, so you can catch up with the other piece. I look forward—you do not even need to go into much more detail than that right now.

Mr. THOMPSON. Okay.

Mr. GREENWOOD. But I would like to work with you.

Mr. THOMPSON. I appreciate your comments on that and would like to work together with you on that.

Mr. GREENWOOD. The second issue related to computers and privacy, as I said, goes the other way, and that is, although the information that your Department has is very personal in nature——

Mr. THOMPSON. Right.

Mr. GREENWOOD. [continuing] particularly over at HCFA. We have been holding hearings in my subcommittee in oversight inves-

tigation into cybersecurity of the Federal Government. We found some pretty alarming information out about how frequently hackers are trying to get into your systems and all of the Federal Government's systems and how frequently they succeed.

There was a recent Inspector General report that found numerous general control weaknesses primarily at HCFA's Medicare contractors. Such weaknesses do not effectively prevent, one, unauthorized access to and disclosure of sensitive information; two, malicious changes that could interrupt data processing and destroy files; three, improper Medicare payments; and, four, disruption of critical operations. So there are vulnerabilities at HCFA that the IG found there. We will be having a hearing soon to have some of your folks come and talk about that.

Have you had a chance in 75 days to become aware of this issue?

Mr. THOMPSON. Yes, I have.

Mr. GREENWOOD. And if so, what do you think you can do about it?

Mr. THOMPSON. First, let me compliment you on holding the hearings. I think it is absolutely vital that we get more information out there about the security of our computer systems and how we might be able to make them more secure.

We are asking, I believe, $30 million in our budget for that particular issue, to correct that problem. And HCFA, of course, is the big one because that is where the computers are and that is where most of the information is. We are looking at that. They have a task force working on how they can continue to improve. And I think they are doing a fairly good job of it, but we need the $30 million to submit it.

But in the meantime, we want to work with you and your staff and your subcommittee on this; and I just would like to, once again, say and reiterate that we are appreciative of the fact that you are holding hearings on this thing, and let us see if we cannot correct it. It is a problem.

Mr. GREENWOOD. I appreciate that. I have seen HCFA's computers. They look pretty fancy; but I think they are pretty old, as you mentioned.

Mr. THOMPSON. They are actually 31 years old, and it is absolutely amazing to me that HCFA is still operating a computer system.

Mr. GREENWOOD. I, for one, will be supportive of the requests for the $30 million. Thank you.

Mr. THOMPSON. Thank you very much.

Mr. NORWOOD. Thank you, Mr. Greenwood.

Mr. Secretary, in your written statement you indicate that there should be some changes in the medical privacy rules that are put out, and I do not want to sit here you and ask you—I do not think it is fair to ask you at this point what those changes should be.

I want to encourage you to work with the health subcommittee, because we are vitally interested in it.

Mr. THOMPSON. I know you are.

Mr. NORWOOD. I want to point out to you that when the Government has rules or laws that they produce and it falls down on the provider to choose between obeying that rule in law versus good care for the patient, that is a very difficult place to be.

And some of these rules interfere with good patient care; and what we do is if we allow that to stay, of course, we turn them into criminals, because they have chosen not to follow the rule versus doing what is best for the patient. And I know you will consider all of that, but we are all really interested.

I was not going to ask you any questions about patient protections; but my good friend over here, Mr. Pallone, stimulates me, usually; and, therefore, I need to just make a point or two with you about that.

Mr. THOMPSON. Thank you.

Mr. NORWOOD. And I would like to defend the President. If I were President, I would sign the Ganske-Dingell bill today. Now, I say that saying I know that it is not perfect. I know that if we got there over 6 years of difficult work—and I think it may be the best we can do to achieve the goals of protecting patients—but if I were the President and I had been in town 100 days, I am not sure I would not want to sign it without trying to make it more perfect.

I want you to know, and everybody in this audience, he is doing that. To say that he is ignoring this subject is not correct.

Mr. THOMPSON. He is doing that.

Mr. NORWOOD. I know for a fact that they are working very hard on that; and our differences are very, very, very slight at this point. There is no reason we cannot this summer, I believe, get a patient protection bill out, maybe even spring.

But you pointed out that there is still two areas of concern: one is scope, which means how many Americans are going to be covered under this bill, and the other is liability.

I think those differences, though, are not that big. This President is on record saying that he wants every American covered. Now, that tends to take care of scope.

It comes down to how hard is it to get every American covered, how difficult do you make it; but when you say that we want every American covered, which he did say in his debates, that means every American, including the teachers and the firemen back home. So there is no reason we cannot come to an agreement, I believe, on scope and at the same time try not to run roughshod over the laws of this country that you so delicately helped put together.

The other thing is about liability. This President is on record saying that he believes any bill we produce should have liability. The Congress is on record in the ranges of 98 percent saying we should have liability, whether they voted for it through the Norwood-Dingell bill or whether they voted for it through the Coburn bill or whether they voted for it on the Senate side through the Nickles bill. Almost everybody in Congress and this President says that we need to have some form of liability.

Now, do you have any suggestions how we get over that hurdle? Why is that—why does that still seem to be the difficult problem as to the liability section in that we all agree that there should be liability? Can you bring—help me. How do we get around that problem, since we all agree anyway?

Mr. THOMPSON. I think it takes a lot more discussion. I think it needs good people like you, Congressman Norwood, and Congressman Ganske to sit down with people that are lobbying this in the

Senate side, and also people that are working on it in the White House; and I want to be helpful as you do.

Mr. NORWOOD. I know you do. That is the reason I am asking that question. I know the President wants us to get there badly.

Mr. THOMPSON. And the President is, you know, has indicated that he—the President really wants a Patients' Bill of Rights. He wants one that works and so do you and so do I.

Mr. NORWOOD. I know.

Mr. THOMPSON. I think there are ways to do it. I think we are just talking at each other and not—and not trying to sit down and solve the problem. I think we need—we need a couple of good afternoons in which we can lock the door and just roll up our sleeves and just get it done.

Mr. NORWOOD. I have had that afternoon every week for the last 8 weeks, and we still—we really are there. It is just that one little arena, whether we go to Federal court or whether we go to State court.

Mr. THOMPSON. Can I be helpful?

Mr. NORWOOD. Perhaps when we have our visit, we can talk about that.

Mr. THOMPSON. Thank you.

Mr. NORWOOD. And I yield back my time and the chair.

Mr. THOMPSON. Thank you, Congressman Norwood.

Mr. BILIRAKIS. Mr. Brown to inquire.

Mr. BROWN. Thank you, Mr. Chairman. I, again, apologize for the rudeness of going downstairs and voting and leaving. I do not like doing hearings this way, but—so that is the way that happens sometimes.

You made a comment in the South Florida Business Journal recommending a change in the entire culture of antibiotic use. Thank you for that comment.

As you know, the Department of Health and Human Services and the Centers for Disease Control and other agencies issued an action plan—released an action plan to talk about antibiotic resistance in four fronts: surveillance, prevention and control, research and product development.

Will that serve as the blueprint for your administration's attack on antibiotic resistance?

Mr. THOMPSON. I would say absolutely. I do not know why it would not.

Mr. BROWN. Okay. I think it would and I talked—Chairman Bilirakis and I are working on some legislation to authorize funds to implement it. And it is—I know there is a hundred things to——

Mr. THOMPSON. If you could, Congressman, you know, bring us in, and, you know, as you are developing this legislation, we would love to work with you and see what we can do.

Mr. BROWN. I very much appreciate that. Let me talk about—the people were mentioning situations in their districts and this is a larger problem than that; but it is very—it is crucially important to a thousand families in the eastern end of my district, near Warren, Ohio, where a steel plant closed.

They are not eligible for COBRA, because the plant declared bankruptcy. They did not just close one plant; the whole company declared bankruptcy. They have been told that they need—they

have been offered insurance, many of these families, for about $1,200 a month. I mean, it is extraordinarily expensive. That may be more expensive than some other places and may not be in every case.

But the tax credit that the administration has proposed is a $2,000 tax credit, but that is the bad news. The good news, and Congressman Barrett told me about Badger Care, and I read about Badger Care in other places. When you were Governor, you used very efficiently and effectively public programs, Medicaid chip, Badger Care, those kinds of things, that have a proven track record of getting the job done.

The Senate—the Senate budget resolution included a bipartisan amendment, Senators Wyden and Smith from Oregon dedicating $28 billion to the constituency fund, not using tax credits but using health coverage, health insurance coverage expansion through program expenditures.

Is that not how we move toward universal coverage? I mean, talk to us for a moment, if you would. With 40 million people uninsured in this country, the number is surely going to get larger as we see these layoffs. Will you support that Smith-Wyden resolution? Will you come down on the side of using public dollars in addition to tax credits where we really do not have the insurance reform that allows tax credits to take care of people when insurance is so much more expensive than the tax credits we seem to offer?

Mr. THOMPSON. Congressman, I do not think you have to have one over the other. I think, you know, if we are—if we really want to address the uninsured issue, which I know you do and I do, you have to look at a whole plethora of ways to do it.

Community Health Centers is the President's primary way of doing it, along with tax credits; and even though you can make the argument that $1,000 and $2,000 refundable tax credit is not enough, the truth of the matter is, it does defray a portion of the health insurance, if not all, part of it, which is a good inducement for doing it.

We think—our analysis means that 6 million more Americans will be covered by it. The third way, which we did in Wisconsin, which was very effective, was expanding the SCHIP program and developing a new program called Badger Care; and a lot of people have indicated that that program is one of the best programs for uninsured, the working poor, in America.

I cannot certainly—I certainly cannot sit here and say I am not going to be supportive of that, because I am. But if you are going to have an expanded SCHIP program and it is expensive—and I do not know where that money is at this point in time—but we are looking at waivers. We are looking at ways to do that.

I would appreciate working with you on this along with Chairman Bilirakis.

Mr. BROWN. Okay, good. Thank you. The last—more a statement than a question, I have been very pleased, as Mr. Wynn said, your enthusiasm to do new things and try new things and make things work in that Department.

Mr. THOMPSON. Thank you.

Mr. BROWN. And I have been real pleased with a great majority of your answers. One I wanted—I was a little confused on the ques-

tions Gene Green asked about the Centers for Disease Control. I just think that this country—a physician told me the other day that we are about 5 percent of the world's people.

We consume almost 50 percent of the world's health care expenditures. We are pumping huge amounts of money into NIH, which I believe, as I think Mr. Strickland said, everyone on this committee agrees, what Mr. Green says, everybody on this committee agrees that we should do that, but we are shortchanging CDC.

And when you said that—when we are talking about diabetes and obesity, research is great, and we support that; but to cut the prevention and the CDC efforts on public health, I mean, we put so much into high-tech medicine, which has worked to help people live longer in this country. But the real advances for life expectancy have come from public health, from everything from buying antibiotics to preventive care, to a better understanding of tobacco and alcohol and safe drinking water and all of those things; and those are CDC kinds of things.

And I would hope that you would reconsider, and understanding you put a lot of money into research, but please also do something more with CDC so we can do better on the prevention side.

Mr. THOMPSON. I happen to be a big fan of what is going on in CDC. And I have been done there, and I do not know if you have been done there or not. I am sure you have, Congressman. It is a wonderful place, and they do great things.

Most of the reduction in CDC was out of the $125 million for the youth awareness program, and that was Congressman Porter's program that went in for more publicity of getting a program out for healthy life styles for our young people, which is laudable.

But we just felt as an administration that we got some problems that we wanted to—we thought a better investment of the dollars, the financial resources was in NIH for research.

You know, you can question that decision; but the decision is based upon what we think is the best, getting the best bang for our dollars instead of spending $125 million for publicity, put the money into research.

We also increased the amount of money for chronic diseases, I think, by almost 11 percent in research. That is a huge increase. It is over a $600 million increase for that kind of program. We are not saying that CDC was not doing a good job. We just think it was a better investment.

Mr. BROWN. I think—and this might sound a bit a more partisan—but I think when we look at—those are great. I mean, we all want you to do with NIH.

But when I came to this Congress, the NIH budget was $12 or $13 billion. The CDC budget was, I do not know, 2.5, maybe. Now the CDC is somewhat over 3 and NIH is up over 20, which is great for NIH.

But we really do—we have this kind—we have an opportunity in this country now with this surplus to do something better with public health, and I wish we would have the same commitment. We talked about doubling it. We all stayed with it, doubling the NIH budget over 5 years.

I wished we would have a similar kind of commitment to do something, something bold with CDC. And I would hope—you have

a reputation as a guy that really cares about public health in Wisconsin. And I hope that you can—even though some people that might be above you in this business—in our committee, I guess, but a couple of people above you may not have the same interests in public health as you do. But I would hope that you would in these meetings speak out for what you really do care about. Thank you.

Mr. THOMPSON. Thank you. As you probably know, I do.

Mr. BILIRAKIS. The Chair thanks the gentleman. And I think to support your last statement that the previous administration for chronic disease prevention health promotion requested $385 million last year, and under this budget, these programs would receive 190 million more dollars over that request, which is an increase of 49 percent.

So I think that is an indication that you do care about chronic disease prevention and health——

Mr. THOMPSON. Thank you.

Mr. BILIRAKIS. [continuing] promotion program.

Mr. Secretary, I commend you, I thank you, whatever, regarding Community Health Centers. Mr. Waxman knows—over the years he so very ably chaired this committee—and I know how strongly I feel about that particular subject. He is still there. And I commend you for the additional dollars and the emphasis on this.

Getting to the National Health Services Corp.'s reauthorization, the way—the way NHSC works now—and I do not think this has changed in the last couple of years—is a person can get out and maybe get himself or herself based in one of these underserved locations where they are direly needed, and then pick up an offer from a large health care firm that offers to buy out their contract. Apparently, they still can do that.

Frankly, I have problems with that, and I just wonder how you might feel about that subject and how you might feel about possibly our legislation preventing that from taking place. I mean, these people have entered into a contract where the taxpayer is taking care of the health care—I mean, their medical education, and then they decide—because with or without big dollars to be able to buy out of that contract. I have problems with that. Any comments?

Mr. THOMPSON. Mr. Chairman, I have to confess I have not looked at that issue. I have not looked at your legislation. I guess I should have realized that problem was there, but I have not really addressed it.

Mr. BILIRAKIS. I think it is a problem. I know that an awful lot of areas lose an awful lot of needed people, as a result of the big dollars coming in from some of these——

Mr. THOMPSON. I would like to take a look at your list and work with you on it. And, you know, coming from a poverty area myself in rural Wisconsin, you touched the right strings for me; and we are an underserved area where I personally live, and so we need to get as much—we need good health care there as well as you do in your area.

Mr. BILIRAKIS. Yes. And we would all like to—Mr. Brown emphasized the uninsured—we would all like to do something about the more vulnerable members of our society in some way. A few years ago, a group of us got together on a bipartisan basis, and we

thought we were doing that; but that legislation did not get anywhere.

But until that happens, we need the Community Health Centers desperately, and we still might continue to need them; but we need them desperately. And we need, I think, the National Health Service Corp. desperately.

Mr. THOMPSON. I applaud your passion for them. They do a great job. I mean, $11 million—most of the Community Health Centers is the first avenue for a lot of underserved people to get medical care.

Mr. BILIRAKIS. Yes.

Mr. THOMPSON. And I applaud the President and this committee for being so supportive of that.

Mr. BILIRAKIS. I will yield back the balance of my time and recognize Mr. Pallone for a second round.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask you, Mr. Secretary, about the Indian Health Service, which is a concern that I have. Myself and Mr. Miller and Mr. Hayworth on a bipartisan basis, we are about in the next few weeks to reintroduce the Indian Healthcare Improvement Act, which seeks to reauthorize and improve upon the existing Indian Health Service.

I just wanted you to be aware of the fact that we were doing that.

There is a great deal of concern among tribes about disparities, if you will, between health care provided to American Indians to the rest of the population; and that is basically what we are trying to address with this legislation.

When you talked about diabetes in particular, I was thinking of American Indians, because it is unbelievable the epidemic that we are witnessing now with diabetes. And, although, you know, they are happy over the fact that there is, I guess, $100 million that was appropriated or, you know, budgeted, appropriated a couple of years ago with regard to diabetes for American Indians, I noticed that the budget actually just leveled funds for diabetes programs for American Indians.

I would like to see more money go to it, particularly for prevention. You mentioned prevention, and I am totally convinced that that is the answer with regard to diabetes in American Indians.

Mr. THOMPSON. So do I.

Mr. PALLONE. We actually had a few forums on the Health Care Improvement Act, and we went to some of the reservations, and one of the ones that I visited was the Tohono reservation in Arizona, which now the majority of the tribe members actually have diabetes, adult onset of diabetes.

There are people there who—there is actually a program there where they would like to use prevention, diet, in particular, as a way to try to prevent that. So maybe I will do a follow-up letter.

But I would like you, if possible, to see more money for diabetes prevention with regard to tribes and also see if maybe we can do some kind of pilot program looking at diet as a way of trying to deal with the problem. And I was hoping maybe I—we could have a meeting maybe with some of the Commerce members and staff to talk about the Indian Health Service. I want to——

Mr. THOMPSON. I would like to do that.

Mr. PALLONE. If I can get back to you about that, I would appreciate it; and we would show you the bill.

Mr. THOMPSON. I would like to do that.

Mr. PALLONE. In addition, at some point, I am hoping after we introduce this that we can get this subcommittee to have a hearing on it, and I will talk to my leadership about that here in the future.

Mr. THOMPSON. No, if you want to get a group together and talk about Indian health, I would like to.

Mr. PALLONE. I appreciate that.

Mr. THOMPSON. I would appreciate getting a copy of your legislation, and so I get a chance to review.

Mr. PALLONE. We will send it to you. Thank you. I wanted to follow up on what Mr. Brown and Mr. Waxman said, though, with regard to the SCHIP program, because I know that you mentioned, you know, the question of funding, in other words, you know, how do we expand SCHIP unless we have significant more funding, and that is a concern I have.

You talked about the waivers. As you know, New Jersey has one of the these waivers also, and we have been now covering adults as part of the SCHIP program as well. But I know from my own State that there is a tremendous demand, and there would be a need for a lot more money even in New Jersey to expand SCHIP to cover family members as opposed to children.

What I do not want to see is that, you know, in expanding it to cover adults, which I think is a good idea, that we cut back or have waiting lines for children. I do not see a significance amount of money—I do not know if there is any increase, but certainly enough extra money in what the President proposed to actually expand SCHIP in a major way.

You sort of suggested that, I think, that that is the case in response to Mr. Brown's question. And I was just wondering then why does the—you know, why does the administration not simply support what Mr. Wyden and some of the other Senators did when they voted for this larger sum of money to cover the uninsured.

In other words, could that not be used, if the administration was willing, to cover more uninsured to expand the SCHIP program?

See, I guess my problem—I would like you to answer the question; but my problem is, as much as I support Community Health Centers, I still think it makes a lot more sense for us to cover people who are uninsured, and I think that is a lot more effective than it is to expand Community Health Services, albeit I would like to do both. But I just do not see where the money is going to come from, and I certainly do not want to see any cutback in services for children.

Mr. THOMPSON. You have raised a lot of issues. Let me try and tick off as many as I can. I do not think by expanding the program to adults that you are going to reduce the number of children that are going to be enrolled. I think just the opposite happens.

I think the studies have shown that if a low-income family is able to enroll as a family, you will have more children enrolled with their parents than if you just have the children enrolled.

Mr. PALLONE. I agree with you. And my only concern is that I am afraid that if there is too much expense, that some of the States

may end up cutting back on the kids. Because it is a block grant, they are not told by you what to do. Right?

Mr. THOMPSON. Well, there is a prohibition from doing that right now in the statutes. You have to get a waiver in order to do that.

Mr. PALLONE. No, but I am saying it is possible that some States could, in expanding, cut back on the number of kids or——

Mr. THOMPSON. It is possible, but most States are looking at ways to expand. I mean, most States are doing an excellent job; and that is why the waiver program has been so effective.

In regards to costs, in regards to costs, Mr. Pallone, you know, this President has treated us very equitably. My overall budget for the Department of Health and Human Services is going up by $436 billion to $470 billion, an 8.2 percent increase. The discretionary funding is going up by 5.1 percent when the overall budgets have been limited to 4 percent. So HHS has been treated fairly.

Next year, I think you are going to see—if we can reform Medicare this year, I think next year, hopefully, it is going to be a reform of Medicaid, if we can get Medicare done this year. And I think then the issue of expansion of SCHIP is a program that we should look at very seriously. And that is what I was referring to to Mr. Brown.

I said costs, but it really is one of delay, that we should take a look at this in the context of Medicaid reform, which I hope we can look at next year after we get Medicare done.

Mr. BILIRAKIS. The gentleman's time is expired.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Dr. Ganske.

Mr. GANSKE. Mr. Secretary, I think that Medicare reform is important in that we need to help make the system function more efficiently; but I have serious concerns about whether realistically Medicare reform, is going to provide much in savings.

And here is why: I think you would agree with me that while there is some abuse in Medicare/Medicaid, it is small. It is watched over by Governors.

We have had several congressional hearings. You are never going to effect the type of savings from further clamping down because you reach a certain level where the costs of the oversight equalize the costs of the benefit from the oversight.

And I would say this, in looking at Medicare and Medicaid recipients in Iowa, I am sure it is the same as in Wisconsin. I just do not see very many people receiving unnecessary care, unless you want to get into issues of euthanasia, end of life. And I would certainly say—and I would be interested in your opinion on this—I do not think Medicare providers and Medicaid providers are overly compensated, do you?

Mr. THOMPSON. I really—you are asking me a question. I do not think so. But I have no empirical data.

Mr. GANSKE. Well——

Mr. THOMPSON. I would think that the Medicare and Medicaid system is based upon reasonable reimbursements, and that is what it was set up to do. I do not think anybody is getting overly rich on this system.

I think some people, you know, may have used the system unfairly or maybe even illegally have gotten more money than they

deserve; but the honest practitioner, like you and other people in your capacity, no, I do not think so.

Mr. GANSKE. So my point is this, if there are not very many Medicare recipients getting unnecessary care and if the costs of the care, by and large, are fair, then the only way you are going to achieve significant savings is basically to tighten rationing and decrease necessary care. That gets me to the issue——

Mr. THOMPSON. I am not ready to buy that conclusion, Congressman. I am willing to work with you on it. I am willing to say that there are savings to be had within the system. We have not really addressed those; you have not as a Congress, and I do not think we have as an administration yet. And I think we need to do that. I think we need to explore those possibilities and see if there are some meaningful ways to save costs without rationing services.

Mr. GANSKE. If you accept the premise that people are receiving necessary care and are not overreceiving care and they are being paid at a reasonable level as the system is now, then it gets me to the point I wanted to get to, and that is, you are either looking at adding a benefit, like prescription drug or addressing the inequity in the payment schedules that we see for certain States like Iowa, Wisconsin, or you are going to have to bring in some additional revenues. You cannot rely on the trust fund.

Because if you rely on the trust fund, you are just going to shorten the life of the trust fund. As I look at a prescription drug benefit, just like any other benefit, there has never been a benefit added to Medicare that has saved money. But the prescription drug benefit could cost easily $300 billion or $400 billion over 10 years, if it is structured as either the Democrats or the Republican bills were last year.

If we do not pass a comprehensive benefit and a Medicare reform bill, then I would like you, Mr. Secretary, to look at a bill that I have introduced which would basically provide help for those in Medicare that are not in Medicaid, they are not supported in Medicaid, but are truly needy, the Qualified Medicare Beneficiaries and the Select Low-Income Medicare Beneficiaries and allow them to utilize the State Medicaid drug programs, but pay for it from the Federal side. So we are not asking the Governors to come up with additional funds, but we take advantage of the types of savings that Governors around the country have utilized in terms of their own prescription drug programs as they have related to Medicaid.

So we do not have to reinvent a wheel; it is there already. It would be simple. It would allow people to utilize a program that is already there. In fact, it might even help Governors in terms of their negotiations with their various health plans. And I think that this would be preferable to a so-called Helping Hand program, because you have a State Medicaid program set up in every State already. I just wondered if you had any response to that.

Mr. BILIRAKIS. Very, very quick response, sir.

Mr. THOMPSON. I would love to look at it. I would like to say that the President meeting Helping Hand is 100 percent federally funded; and that is the one that, you know, that I am most familiar with, but I would be more than happy to look at your program; but I would hope you would look at the President's program as well.

Mr. BILIRAKIS. The gentleman's time is expired.

Mr. Green to inquire.

Mr. GREEN. Mr. Chairman, I was under the impression that Mr. Engel was in here first.

Mr. BILIRAKIS. We are in the second round now.

Mr. GREEN. Have you had your second round?

Mr. BILIRAKIS. If you are yielding to Mr. Engel, that is fine.

Mr. ENGEL. I thank my colleague for yielding.

Mr. Secretary, I just want to reiterate some of the comments made by my colleague, Mr. Ganske. When I go home to New York, I hear my constituents talk about a prescription drug benefit more than anything else.

Mr. THOMPSON. I am sure you do.

Mr. ENGEL. And I just, you know, want to—I know there are many different ways of going about it, and I know that you said that you want to do it as part of a reformation of the Medicare program. But I just want to add my voice to those who are saying that the $153 billion that the budget sets aside for prescription drug program is woefully inadequate.

And I just hope that this thing is not relegated to a back burner; that we really, really tackle it and tackle it soon.

There is a lot less talk about it, unfortunately, now than there was last year; and I hope that does not mean that it is being, you know, relegated to the back burner. The $153 billion for prescription drug benefit was very disappointing to me when I saw that in the President's budget, so I just want to reiterate that.

Mr. THOMPSON. Congressman, I want to assure you that it is not relegated. In fact, we are working very hard. But I want to point out, as I did previously and before you were here, Congressman, is that the President and my Department feel very strongly that we just cannot do the prescription drug in isolation.

We need to reform Medicare at the same time or else I do not think we will ever have this great an opportunity again. And if you just pass prescription drugs, I think maybe then the $153 million will not suffice; but if we reform Medicare and put some efficiencies in there, I think we can still get by. I do not know if it is 153 million, the President says if it is not. We will cost it out, and we will see what it is.

But right now, I just want to allay any fears you have that we are not dedicated, because we really are. This is a cause that this President wants to see solved.

Mr. ENGEL. I appreciate what you have said. I just get very concerned that in some quarters the call for a reform of Medicare because an excuse for an action on prescription drugs. I know that is not your intent, and obviously you are going to push ahead.

Mr. THOMPSON. That is not the President's intention.

Mr. ENGEL. I am happy to hear that, because that is a major concern. I would like to mention something that is very important to my State of New York. Last year, I worked with our Governor, Governor Pataki, and the Clinton administration on a compromise on the Medicaid upper-payment limit——

Mr. THOMPSON. Yes.

Mr. ENGEL. [continuing] to ensure that States like my State, that are sending Federal Medicaid dollars on health care programs for the poor, can continue to do so, while States not using the funds

for health care could not. The compromise provided a phaseout so that these States would not see a dramatic reduction in Medicaid payments that would severely impact the ability to provide basic health care to the poor.

Now, the President's budget references changes to that compromise, while at the same time, the House budget resolution rejected this type of Medicaid cut.

I am obviously more comfortable with the House budget resolution in this regard.

Mr. THOMPSON. I bet you are.

Mr. ENGEL. The projected savings in the budget from altering the UPO rule is $606 million in fiscal year 2002 and $17.4 billion over 10 years. Would the administration consider the language in the House budget rule; and can you tell me if not, where the President believes this savings would be achieved, specifically, which States would lose their Medicaid funding? It is really a matter of grave concern to us.

Mr. THOMPSON. I understand, because I worked on this formerly as a Governor.

Mr. ENGEL. I know.

Mr. THOMPSON. But that was formerly. I am working on it now as the Secretary, and I do not think you are going to see much movement to the extend or expand the upper-payment limits from this administration.

Mr. ENGEL. Well, I hope that we can try to make a case that it is really important in these programs for the poor and it is—the States that are really using the money for what it was supposed to be utilized are not penalized as a result.

Mr. THOMPSON. I understand. As you know, there has been some abuses.

Mr. ENGEL. And the abuses should be corrected.

Mr. THOMPSON. A lot of abuses. And even under the compromise last year, some States are going to be phased out in 2 years; other States are going to be phased out over 8 years. The President's or—our budget, the President, our budget accelerates that to one.

Mr. ENGEL. I just want to ask you one other thing.

Mr. BILIRAKIS. Very, very quickly.

Mr. ENGEL. The Ryan White AIDS programs are frozen at $1.8 billion, you know, at a time when there are many different therapies; and we found in New York City 3,000 people alone increased in the enrollment in terms of those seeking assistance from the AIDS drug assistance program.

It would seem to me that a freezing of the budget $1.8 billion is really unwarranted; and I am wondering if you could look at that and, perhaps, consider increasing the assistance for the Ryan White AIDS program.

Mr. THOMPSON. We have looked at it. And I want to tell you that this is an issue that I am very interested in. Thirty-six million people in this world have—are HIV infected or have AIDS; 25.1 million are in Africa. Forty-three percent of the new tuberculosis cases in the United States come as a result of HIV infected people internationally, 43 percent in America.

This is a problem that is going to be coming to the United States. We have a serious problem, not with the HIV but the tuberculosis.

We have a serious problem. This administration, led by me in this regard, feels that the best hope is to come up with a vaccine.

We are putting huge amounts of money into discovering a vaccine to prevent the spread of HIV. And Ryan White, which is a wonderful program, has had a 50—well, over 100 percent increase in the last 5 years. We decided comparing to the problem that is facing us internationally that we thought that the money should be invested in finding the vaccine as soon as possible and level-funding Ryan White.

That was a decision made by me and members of the administration. We still think it is the right decision, because there is a tremendous problem out there; and we are going to try and solve it.

Mr. BILIRAKIS. The gentleman's time is long expired.

Mr. Pitts to inquire.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. Secretary, the first question I have for you is one that may take some time for you and your staff to research, so I will just mention it now and ask you to get back to me later.

Is the Centers for Disease Control and Prevention currently conducting or funding blind or unlinked HIV surveillance tests? Many have argued that these tests are unethical because they do not disclose positive test results to those who have been diagnosed with HIV/AIDS, thereby denying live-saving treatment.

I would be interested to know your thoughts about these studies and whether you would instruct the CDC to discontinue further blind testing. You can respond later if you would like to that.

But my second question, Mr. Secretary——

Mr. THOMPSON. Congressman——

Mr. PITTS. Go ahead.

Mr. THOMPSON. [continuing] I do not know anything about that; that is the first time anybody has ever raised that. I would like to——

Mr. PITTS. I will give you information.

Mr. THOMPSON. Give me information, and we will get an answer back to you.

Mr. PITTS. Thank you, Mr. Secretary. My second question relates to abstinence funding. In June 1999, then Governor George W. Bush promised that if he became President he would increase funding for abstinence-only education to equal the Federal funding for safe sex programs.

The Bush Campaign conservatively estimated that to bring abstinence funding to parity with safe sex programs, abstinence would need to be funded at a minimum of $135 million from its current funding of $80 million.

As you know, the final budget released last week does not increase abstinence funding of this level of parity. In fact, the official budget contains little or no increase in existing law.

The question is do you intend to keep the President's campaign promise to increase abstinence funding to the $135 million in fiscal year 2002?

Mr. THOMPSON. Congressman Pitts, absolutely the President said that, and he stands behind it. We are going to fulfill it. There has been a 10 percent increase in this budget going from $82 million from $93 million in this budget for abstinence.

We know there is a disparity between abstinence and title 10; and we expect over the years, over the next 4 years, to grow that to parity, not to take away one from the other, but to grow so that they are both equal funding.

Mr. PITTS. Over a 4-year period, not in this budget?

Mr. THOMPSON. I do not think we can do it in this year's budget.

Mr. PITTS. Okay. Mr. Secretary, do you have plans to make sure——

Mr. THOMPSON. We went up 10 percent, I want to you know; and I think that is a very sizable commitment by this administration.

Mr. PITTS. All right. The next question is, do you have plans to make sure that Federal funding is not going to directly or indirectly fund abortion? And how do you plan to increase oversight of programs like title 10 that have never been studied for its effectiveness?

Mr. THOMPSON. Well, Congressman, we have rules in effect and the law is very clear in this regard. The Henry Hyde amendment is very forceful and straightforward, and we think we are complying with it.

If you have—if you have instances where we are not, I would appreciate hearing from you. We will then take a look at it, but it is my understanding that we strictly enforced the law. That is what people tell me.

Mr. PITTS. Okay. We will share information that we have for you.

Mr. THOMPSON. Thank you.

Mr. PITTS. The last question, Mr. Secretary, is, as you are aware, under the previous administration, the FDA approved the abortion pill RU 486 and this drug protocol has been the subject of significant controversy, since together they are known to cause severe side effects, such as hemorrhaging for women.

In fact, as reported in the L.A. Times, the second drug in this two-drug protocol is manufactured in Chinese factories that have been cited in the past for falsifying documents and importing impure drugs into the United States. There are actually 30 known cases of uterine rupture caused by RU 486.

Women in other countries where this drug is legal are protected in significantly greater fashion than here in the U.S., which should concern us. A recent survey of colleges and universities determined that only one of over 30 schools surveyed would offer this drug to their students since the risks were too high for the schools. Many of them admitted that they were unprepared to deal with the known side effects due to the lack of necessary medical equipment at the campus health facilities.

My question is, do you feel RU 486 requires any action at this time by the FDA or HHS; and if so, has any money been budgeted to review or study or monitor the severe side effects caused by RU 486?

Mr. THOMPSON. There is no additional money budgeted for review, other than to tell you that all drugs are reviewed for safety. If there are questions of safety, we review them and with all drugs approved by FDA, we will be monitoring RU 486 for safety and efficacy; and if there are problems that develop, then a more intense review will take place.

But once a drug has been approved, the law does not provide for the withdrawal of any drug, only based upon safety reasons. And to this—to my knowledge, Congressman, there has not been any empirical data submitted to show that there have been safety violations of RU 486; but we will continue to monitor that, as I am sure you want us to.

Mr. PITTS. Especially the imported drugs with the documentation on impurities from China.

Mr. BILIRAKIS. The gentleman's time is expired.

Mr. THOMPSON. Thank you, Congressman. Thank you very much for asking.

Mr. BILIRAKIS. Mr. Green to inquire.

Mr. GREEN. Thank you, Mr. Chairman. I will not talk all of my time. Mr. Secretary, I appreciate your patience today; and we do not always have a Secretary before us. In fact, serving 20 years in the legislature, I was trying to remember in Texas if I ever had a Governor to question, so I appreciate your patience today.

Mr. THOMPSON. So that is why you want to beat me up for so bad?

Mr. GREEN. We are just inquiring; we are not beating anybody up.

Mr. THOMPSON. You have been very good to me. I appreciate it, thank you.

Mr. GREEN. I want to follow up from my other colleagues, both Mr. Barrett and Mr. Brown, in the research and prevention and that discussion. I understand the concern about putting the dollars and the research; and if what we see happens with the Senate, and the tax cut is scaled back, I would hope that you would fight and advocate every way you could for whatever money is available to be able to provide that funding for CDC and for prevention.

I understand the limitations you had, but hopefully that if there is some money there, you will be able to use it for that prevention.

Mr. THOMPSON. Congressman Green, all I can tell you is if you ask OMB, they said I have been very forceful.

Mr. GREEN. I understand. I will also follow up on my colleague Mr. Engel and the concern about the prescription drug benefit for our seniors. And if we continue to link it with the need for Medicare overhaul—and I understand that the force is for us to do—but everyday it seems like you could not hardly leave the building in HHS without having a senior come up to you and say we need it not only this year but we needed this last year with the high cost of prescriptions for everyone, but particularly for seniors who take more prescriptions than any other age group and also have the least ability to work overtime or something else to cover it.

So I would hope that the administration would reevaluate saying maybe we need to do a prescription drug benefit without necessarily having the Medicare overhaul. Because I would like to look at both of them, too; but it just does not seem like that is going to happen in Congress.

Mr. THOMPSON. Congressman Green, the President—that is why the President submitted Helping Hand, because he did not know if we were going to be able to get the reformation of Medicare done with prescription drugs. So he put forth the Helping Hand in case we cannot.

But I have to tell you, I do not see any move whatsoever in this Congress. And I am not being political, I am not being critical, I am just stating my assessment, that I do not see any real effort to reform Medicare unless we do have prescription drugs.

And I think we would be missing a golden opportunity about reforming Medicare, because I think everybody recognizes that Medicare needs some reform, and we can do that and have prescription drugs. It is the catalyst to get the job done, and that is why this administration feels so passionate about having reformation at the same time with prescription drugs, but also recognizing the need of seniors.

We have Helping Hand there in case we cannot get it done immediately; we could pass Helping Hand and get some money to the States so they can pass a prescription drug provision.

Mr. GREEN. And our committees have held hearings on Helping Hand, and I have a very urban district and not a wealthy population, and Helping Hand will not even provide the benefits because, again, the State of Texas has no senior citizen prescription drug program.

There is nothing even talked about in our legislature now, so it would be years away before we get that. Our legislature meets once every 2 years. And at the end of May, they are going to be gone for 2 years. Our Governors also do not want to have them in a special session.

Mr. THOMPSON. As a former Governor, I can understand that. If I could have had the privilege of having my legislature come over once a year, I would have felt very good about it.

Mr. GREEN. President Bush had them once every 2 years, whether they needed them or not. Also I have a question I want to submit to you concerning Medicaid regulations and audiologists and the like.

Mr. Waxman asked if I would ask this question—or do you want me to yield to you so you can do this—on lead poisoning. I know that the advisory committee to end childhood lead poisoning has for years asked that Medicaid be allowed to pay for the lab tests on dust to find the lead poison in children's homes.

We were told that you have the discretion to let Medicaid do that, and will you look at that issue——

Mr. THOMPSON. I will.

Mr. GREEN. [continuing] on lead dust for children?

Mr. THOMPSON. I do not think Congressman Waxman was in here when I said that I invested $150,000 a year to the Community Health Program back in Wisconsin for 5 years, and we were able to reduce the incidents of lead poisoning in that census track by 60 percent, Congressman, by doing that.

It is a tremendous investment, and it is a great way to hold down future medical costs of lead poisoning, especially for minority children, which are usually the ones that get affected.

Mr. GREEN. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. Mr. Greenwood to inquire.

Mr. GREENWOOD. Thank you, Mr. Chairman. I have a question for you, Mr. Secretary, about Medicare+Choice; but before I get there, my colleague from Pennsylvania, Mr. Pitts, in his questions

to you was making a comparison between the funding in your budget for abstinence-only education and the safe sex campaign, and I quickly turned to the budget to see if I could find the safe sex campaign and I am having trouble.

I found the family planning campaign, family planning program which supports the network of 4,600 clinics nationwide serving more than 4.5 million people. These clinics provide access to such areas as reproductive health care, preventative services counseling, routine gynecological care, hypertension screening, screening and referrals for breast and cervical cancer and substance abuse. Abstinence counseling and education are an important part of the program. Service protocol for adolescent clients, that is title 10.

You do not have a secret safe sex campaign funded in this budget that I do not know about, do you, Mr. Secretary? You do not have to answer that.

Mr. THOMPSON. I do not think so.

Mr. GREENWOOD. Medicare+Choice, Mr. Secretary, the crisis with prescription drugs is real; and as everyone has said all morning, we need to fix that. But there is an arguably equally critical issue and that is the relative demise of Medicare+Choice programs over the past several years. What used to be a magnificent option for people to get their Medicare through an HMO without having to pay the costs of MEDIGAP insurance, getting a nice prescription drug benefit and other goodies like glasses and hearing aids and so forth has been underfunded. Part of that is the fault of the Congress, part of that frankly was resistance from the previous administration who hasn't been wild about Medicare+Choice.

The result of that is people who had prescription drug benefits have lost them, people who have had access to managed care have lost it, and people who had it at zero premium are now paying a lot of money for it that they cannot afford. So we really have to fix that.

In my area, it is compounded by the fact that the 1997 average area per capita costs of Medicare, the AACPCC, which was designed to put more money where the costs are higher and less money where the costs are lower, has really led to some problems. One of them is that people from my district in Bucks County go into Philadelphia for headaches; they go to university hospitals and some of our other very fine teaching institutions there.

And I am told by the insurance company that the cost of their care gets attributed back in the 1997 calculation to Philadelphia health care costs, not to the costs of—from the assenting counties. So, therefore, the premiums HCFA was paying to the insurance companies on behalf of my constituents is considerably less than those in Philadelphia; and as a result of that, my constituents are now paying about $60 a month more for the same exact care that folks just across the border in Philadelphia are paying.

We really need to fix that. I think it is a crisis that needs to be fixed probably in the midst of, if not sooner than, doing the whole Medicare reform and prescription drug issue. Some of that is going to take—probably most of that is going to take congressional action, but I would hope that as you settle into this job you become very up to speed on the existing crisis in Medicare+Choice and that we can work together on that.

Mr. THOMPSON. It needs a lot of help and a lot of changes and a lot of support. I think it has got a lot of good possibilities and could have a bright future if we worked together. And I cannot think of anything more I would rather do than work on that subject. I got a couple others.

Mr. GREENWOOD. Something like 15 percent, I think it is, of the Medicare recipients, including the disabled who have come to rely on——

Mr. THOMPSON. You are right.

Mr. GREENWOOD. [continuing] managed care and come to rely on the prescription drug benefit of managed care. I have constituents who had a good—disabled constituents who had a good prescription drug benefit up until January 1 of this year; and when their prescription ran out, they lost any option they had to get a prescription drug that they had been taking for years.

I have one instance where a man who was 45 years old struck by a car, a former computer programmer, is in such pain, without his pain medication he becomes suicidal. That is, I think, a poignant instance of the urgency of this issue.

Mr. THOMPSON. Thank you very much, Congressman. I want to work with you on it. Please if you got ideas, send them to you. As I once again reiterate to any members of the committee, if you got ideas on how I can do my job better for you and how we can improve the system, please let us know.

Mr. BILIRAKIS. The gentleman from Ohio, Mr. Strickland.

Mr. STRICKLAND. Mr. Chairman, I do not want to give up my opportunity to ask questions, but I would like to allow Representative Waxman to go before me, if he may.

Mr. BILIRAKIS. I am amenable to it.

Mr. WAXMAN. I thank the chairman, and particularly Mr. Strickland for letting me go ahead of him.

Mr. Secretary, I have to tell you, I think it is absurd that we are going to freeze funding for the family planning program which not only provides contraception, but reduces infant mortality, maternal mortality, and low birth-weight babies, in order to give more money for a chastity program on abstinence, which I do not think anyone can argue is nearly as important as the family planning program.

Second, I want to point out that to limit the amount of money that goes into the Ryan White program, while you are working on a vaccine, is to tell all of those people with HIV infections that they may not be able to survive if we cannot afford to buy the drugs for them.

We have not been able to limit the epidemic. I think the problem we have is given the overall budget, you have indicated you are going to increase the Community Health Centers, but you are going to decrease the Community Access Program. We are going to increase diabetes research, but then we are going to take money away from the CDC.

We are going to give less for Ryan White and more for an AIDS vaccine. So that seems to me moving the money around at a time when the Congress and the President is saying let us give billionaires more money by repealing the estate tax. And I just point that out more rhetorically than anything else.

There are a couple of——

Mr. THOMPSON. May I respond, Congressman?

Mr. WAXMAN. Sure. But my problem is I only have 5 minutes. Let me touch on a few other things, then you can respond to everything.

Mr. THOMPSON. Okay. Thank you, Congressman.

Mr. WAXMAN. There are a couple of areas where I hope we can be together. Congressman Diaz-Balart from Florida and I are the lead sponsors of what is a bipartisan proposal to cover immigrant children under Medicaid. It allows the States to decide to cover those kids, rather than make them wait 5 years and it eliminates other barriers that may even keep them permanently from getting health care coverage.

The National Governors Association supports this change, and I hope the administration will look at it favorably as well.

The second area is this: there is a large bipartisan group of members on this committee and the House and the Senate who support the Family Opportunity Act to allow severely disabled children to access Medicaid coverage. I hope you will look favorably on that program, too.

And then I do want to comment on the fact that today it has been very clear from your testimony that you are committed to the promise of NIH research. In that regard, I want to note the tremendous promise of stem cell research and hope that you will keep that very much in mind as we look at that issue of research.

And then my last comment is to just point out something that Columnist Matt Miller recently wrote about when he talked about coverage for all the people that are uninsured. There are 43 million uninsured in this country. There are 43 million Americans today without health insurance, and President W. Bush wants to help 6 million buy coverage.

But back in 1992, there were only 34 million uninsured, and the first President Bush would have helped 30 million of them get insurance. So what we have is President Bush, the son, proposing to help so many fewer uninsured Americans than President Bush, the father, did even though we are at a time when there are more in need. I think that goes to the other point that I was making.

We are spending the money, in effect, by giving tax breaks to the people at the upper income; and those who have no health insurance who have to rely on government assistance, programs like the CHIP program or Medicaid, they cannot get that coverage.

So with that, I just wanted to make those points to you; and I hope we can work together on them, and certainly I want to hear any response you have.

Mr. THOMPSON. Congressman, I want to work with you; I really do. And there are philosophical differences. This President, you know he won. He ran——

Mr. WAXMAN. And he got to be President. He did not win.

Mr. THOMPSON. He won. That is another philosophical difference that you and I have. He won and he campaigned on a tax cut. He campaigned on making equity between abstinence and family planning. He campaigned——

Mr. WAXMAN. I did not hear that one, but all right.

Mr. THOMPSON. He campaigned on doubling the NIH budget. This budget really is a reflection of what this President ran on in

the campaign. I have to give him a lot of credit for carrying through on what he said he was going to do.

Now, our Department—and you are passionate, and I applaud you for your positions on a lot of issues. You are passionate about it; so am I. I am passionate in giving the best health care for Americans from California through Wisconsin to Florida and every State.

This budget has treated our Department very favorably. It has gone up from $436 billion to $470 billion, an 8.3 percent increase. That is a huge increase. Ryan White had an 81 percent increase over 5 years, $811 million over Ryan White. It is a good program.

I used it very effectively in Wisconsin, but we have an international AIDS problem that needs attention. And in order for us to do that, we thought, in order to really get some direction, some way to really control HIV in the world and also in America was to find the best way to come up with a cure or a vaccine, not a cure, a vaccine, and I know you applaud that, because you will be the first one there to help us support that, but there are priorities.

And, you know, you do not like a tax cut. And as it is obvious you do ot, I happen to think that we can have both. We can do an excellent job of improving the health care and have a tax cut that the President campaigned on. Besides that—forget about the tax cut. In other areas, I want to work with you, I want you to give me your best ideas, and I will come back with our suggestions.

And if we can develop a bipartisan way to solve these problems, I think not only will we be better off; but America will be better off, and that is all I can offer you.

Mr. WAXMAN. Thank you for your answer.

Mr. BILIRAKIS. Mr. Strickland.

Mr. STRICKLAND. Thank you. Mr. Secretary, I have sat here and I watched you today and I thought of your experience not being dissimilar to mine when I go to my district and I go to the supermarket or I go somewhere shopping and people bring me case work, and we have brought you a lot of casework today.

Mr. THOMPSON. You are right.

Mr. STRICKLAND. You have spoken about being willing to accept information about my constituents, and I have heard you say to other members here you wanted to hear specifically about their concerns.

Mr. THOMPSON. Yes.

Mr. STRICKLAND. I appreciate that. As I said to you earlier, I have been encouraged by what I have perceived to be your attitude of genuine concern. I just wanted to say 2 or 3 things.

Many of us feel very strongly about research and specifically about stem cell research and the great promise it holds. I would just encourage to you do whatever you can within the administration to make sure that legitimate scientific life-affirming research is not interfered with because of idealogical concerns.

Second, we have heard a lot of talk about the tax cut and George W. Bush is our President, and we must embrace him as such; but many of us also understand that over one half million people voted for the other person in terms of a popular vote.

So we think that there is a necessity for us to compromise on whatever agenda that is moved through this Congress, because we

do think that not every aspect that the President campaigned on was, in fact, endorsed or embraced by the majority of the American people.

I have just one final question—and you have been incredibly patient, and I thank you for that—but in your budget, you increase substance abuse treatment services funding by $100 million, and I applaud you for that. However, your budget decreases funding for mental health treatment services.

As you know, this program provides desperately needed treatment services for mentally ill, around 13 percent of whom are also substance abusers. Last year the Surgeon General's report on mental health reported that less than ⅔ of adults with severe mental illness actually received treatment. Yet this budget—the effect will be a decrease in monies received by 33 of the States, including the State of Ohio.

Can you tell me if there are any circumstances under which the administration would reconsider its proposal regarding mental health treatment programs and, perhaps, support an increase that would be at least commensurate with the increase that you are making available for substance abuse treatment?

Mr. THOMPSON. First, let me thank you for your comments, Congressman Strickland, and I do—you did offer me a lot of cases, and I sort of thrive on that. I am a Governor. I like to have problems; I like to solve them like you do.

Mr. STRICKLAND. Can I say one word to you? I was hypercritical of HCFA. I have been, people on this committee know that, because I have been frustrated in the past that it seemed impossible to get any action, and I wanted someone in a position of authority to be able to make decisions. You appear to be such a person, and that gives me some considerable hope.

Mr. THOMPSON. Thank you very much. I can do a much better job if I can get some of my assistant Secretaries and Deputies confirmed, and we are still running a Department with the few young people I brought from Madison and Washington.

But be that as it may, mental health is a serious problem. And I do not know where you are getting your figures, because according to the figures I have here, we are going up by 100—by $100 million and maybe there is some way that we can reconfigure.

Mr. STRICKLAND. A block grant program?

Mr. THOMPSON. I believe so. I believe we can reconfigure the overall budget was $100 million, maybe we can reconfigure some things to do things, because, you know, this is a budget that I got—that was pretty much a budget put together before I got there. And so I am willing to work with you on it. I do not know the exact figure that you are looking at. I know your staff is looking at it. I have to talk to my staffs.

Mr. STRICKLAND. Yes. According to the information I have, although there is a substance abuse increase, as I say, I applaud you for, there is a significant decrease in the mental health portion of that.

According to the allocation formula that I am familiar with, some 33 States will actually receive a decrease in, and Ohio will receive a significant decrease in, the funding for that program.

Mr. THOMPSON. You are right with your figures. You are in the mental health straight line, and we put $100 million in the drugs for that. Maybe there is some way we can work together during the budget negotiations to try and figure out how to do it.

Mr. STRICKLAND. If we could, here again I keep saying——

Mr. THOMPSON. I am not locked into these. If there is some way that we can adjust the figures and make it more compatible with what your constituents and what you want and what dictates to with a bipartisan committee, I would be more than happy to.

Mr. STRICKLAND. Thank you, Mr. Secretary, and thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. THOMPSON. Nice meeting you.

Mr. BILIRAKIS. I had a request from Mr. Pallone to insert these letters into the record, two letters to Mr. Thompson, one dated April 6 of this year, and the other dated March 29 of this year. And I ask unanimous consent they be made a part of the record.

[The letters are retained in subcommittee files.]

This hearing is about to be adjourned. Mr. Secretary, there always are questions that we submit to you, and I know that you do not mind responding to those. I do not know how close we are to reforming Medicare and our patients versus HCFA program; but obviously, we want to work together; and I think that I can speak for the entire committee how very impressed we are with your concern, with your wanting to work with us; and we really look forward to great things.

Is it true, you are camping at HCFA for a couple of weeks?

Mr. THOMPSON. One week.

Mr. BILIRAKIS. One week.

Mr. THOMPSON. I am going to set up Monday morning at HCFA and run the——

Mr. BILIRAKIS. Good for you. That is just great. Well, that being the case——

Mr. THOMPSON. Come and visit me, Congressman Strickland and Congressman Bilirakis.

Mr. BILIRAKIS. There is so much of the cost-plus point that you raised earlier regarding the contractors that we can help you to do your job so much better. Please, do not hesitate to submit to us or even wait until we request it, things that we can do in order to help the Department function even more efficiently. Thank you very much.

Mr. THOMPSON. Thank you. You are wonderful.

Mr. BILIRAKIS. Thank you, sir.

[Whereupon, at 1:20 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

RESPONSES FOR THE RECORD OF HON. TOMMY G. THOMPSON, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Question 1. Your staff reported that the HCFA Program Management request, $2.351 billion, is higher than any year requested by the Clinton-Gore Administration. What do you intend to do with this extra money? What is the state of the accounting and information systems at HCFA?

Response: The request for the Centers for Medicare & Medicaid Services (CMS's) Program Management funding, $2.35 billion represents a 4.9 percent increase over the FY 2001 appropriated level. This is comparable to the President's Budget overall government-wide increase of 4 percent.

Most of the proposed $109 million increase in CMS's Program Management account is targeted for the Medicare contractors who process almost 1 billion claims a year. Some of the increase will help CMS improve its information technology infrastructure and some of it will go to building a uniform accounting system at the Medicare contractors and to replace the CMS administrative financial systems. The balance of the budget increase is for implementing legislation and covering payroll expenses.

Modernizing and stabilizing the Medicare claims processing systems is one of our highest priorities for CMS. These systems are rooted in the 1970's, when the claims being processed were a fraction of the volume being processed today. They are based on outdated technology that is expensive and difficult to maintain. Our ability to keep up with the increasingly complex and rapid pace of change in our programs depends on updating these payment systems and expanding their capabilities.

Another priority is improving the financial management systems. CMS spends hundreds of billions of dollars each year on Medicare benefits, yet the Medicare contractors use ad hoc, piecemeal systems to account for these funds. The General Accounting Office and the HHS Inspector General have both expressed concerns about CMS's current financial management system. It is simply inadequate for detecting and collecting debt, for retaining a clean audit opinion, and for complying with statutory requirements. For these reasons, the President's Budget includes funding in FY 2002 to begin building a uniform accounting system at the Medicare contractors and to replace CMS's administrative financial systems. This is a multi-year commitment, but with billions of trust fund dollars at stake, we believe it is worth the investment.

Question 2. On page 8 of your written testimony, you indicate that you would like the Secretary of HHS (as opposed to the Part A provider) to contract for and assign fiscal intermediaries to perform claim processing. Do you anticipate that this will improve quality and lower costs?

Response: Yes, I do believe it will improve quality and lower costs. In order to manage an evolving Medicare operational and business environment, and to bring more competition into its contracting fee-for-service processes, I believe that CMS needs the authority to contract for Medicare claims processing and payment functions through full and open competition. Specifically, we need the ability to contract with any entity qualified to perform specified Medicare claims processing and payment functions. We submitted our legislative proposal to reform the current contracting environment on June 28, 2001.

The major benefit of this proposal is that CMS would be able to involve the broad expanse of capable business entities such as entities with expertise in customer service, claims processing or education B in meeting the needs of the evolving Medicare program, providers, and beneficiaries.

In the new Medicare environment, there will need to be more alignment between the marketplace, the government's requirements, and available funding. CMS needs to increase its ability to leverage the forces of competition and our proposal to move to performance-based contracting should help ensure that contractors deliver effective Medicare services on a best-value basis.

With regard to lowering costs, in the longer term, contracting reform should save money. That is because the consolidation to fewer contractors will reduce overhead and provide economies of scale. New contracting methods will promote more efficient operations through financial incentives for innovation and effectiveness.

CMS is engaged in a modeling effort to estimate cost and savings over the first few years following contracting reform. We have extensive experience with the cost of transitions; the more difficult part of the equation is working with the factors and assumptions to estimate the longer-term savings of consolidation and innovation. How will you use the Government Performance and Results Act process to generate information needed by your managers to reform and streamline their programs? Will the need to accomplish higher goals with fewer resources lead to more cooperation with private sector organizations?

In the short term, contracting reform may cause some increase in the cost of program administration. As we transition from the current environment to the post-contractor reform environment it will be necessary to meet the costs of increased contractor transitions and terminations. In addition, it may be necessary to provide incentives in the first phases of the new environment that will not produce overall administrative savings in the short term.

Question 3. How will you use the Government Performance and Results Act (GPRA) process to generate information needed by your managers to reform and streamline their programs? Will the need to accomplish higher goals with fewer resources lead to more cooperation with private sector organizations?

Response: CMS's performance goals represent its vast programs and responsibilities. Performance planning under the Government Performance and Results Act provides CMS the opportunity to learn from approaches that work well and those that have been less successful as the Agency strives for meaningful improvement.

Performance measurement results will provide a wealth of information about the success of CMS's programs and activities to inform all levels of management. It also will identify opportunities for improvement and ways to better shape CMS's programs, policies, and management choices for short and long-term goals. At CMS, Government Performance and Results Act performance measures are included in annual evaluations for SES-level managers, which underscores the importance of performance measurement in CMS culture.

Our programs, as reflected in many of our Government Performance and Results Act performance measures, entail partnerships with the public and private sectors. Since many CMS responsibilities involve external partnerships through the Medicare contractors, and many States, etc., a major intended outcome of tracking performance is more effective and efficient program management. We also know that working in partnership leverages resources and increases coordination.

Question 4. At what time should Congress expect the nomination of an FDA Commissioner?

Response: We are in the midst of the search and selection process. We intend to make a selection as soon as possible.

Question 5. The President's budget calls for $40 million to be spent on mandatory cost-of-living and pay-related increases for FDA employees. Such pay increases were never proposed during the Clinton Administration, so they were paid for by decreased funding elsewhere within FDA. Why did the President feel it was important to include FDA pay-related increases in his budget?

Response: You are correct that in some recent years, FDA has reduced the amount of work it accomplished in some areas to fund pay raises and other inflationary costs. The President's budget reflects the importance of increasing, not decreasing, the front-line FDA staff who work to ensure the safety of our foods and medical products. For example, last year, FDA was able to meet only about half the statutory requirements for inspecting drug and device facilities. The request for $40 million for pay raises ensures that FDA can maintain inspection rates and product approval time frames at the same time it expands efforts in specific areas, such as mad cow disease, oversight of imports, food safety, patient safety, and research subject protection.

Question 6. As Secretary of HHS. You are required to rule on the safety and cost savings of reimporting prescription drugs. What are your initial thoughts on that issue and when should Congress expect a final decision?

Response: My decision on this matter was announced in a letter to Senator Jeffords on July 9, 2001. After a careful review of the factors that affect the safety of imported drugs and the expected savings, I concluded that the determinations required under the law could not be made and that I therefore could not implement the program. I do not believe that we should sacrifice public safety for uncertain and speculative cost savings.

Question 7. How will the $15 million funding increase for Mad Cow Disease prevention proposed in the budget better enable FDA to ensure the disease never makes its way into America?

Response: Bovine Spongiform Encephalopathy (BSE) belongs to a group of progressive degenerative neurological diseases known as Transmissible Spongiform Encephalopathies (TSE), which are always fatal. To prevent the spread of BSE through certain animal feed products, in August 1997, FDA published a regulation that prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants (Title 21, Code of Federal Regulations (CFR) Part 589). With the strong support of renders, cattle owners feed manufacturers, and feed lot owners, FDA launched a compliance and education program, including a rigorous inspection program to implement the regulation.

In addition, in April 2001, FDA implemented its TSE Action Plan, a comprehensive approach to addressing FDA's responsibility in this important public health issue. This plan will protect the public health by:

—strengthening our efforts to keep BSE out of the American cattle herd and to keep it from amplifying in the herd were it ever to be found in American cattle;
—strengthening our vigilance to keep potentially TSE-infected foods and other FDA-regulated products from Americans; and
—enhancing the research needed to better understand TSEs and to develop needed diagnostic tools, therapies, and preventive measures for humans and animals.

The proposed FY 2002 budget, which includes an increase of $15.0 million for BSE activities, is a down payment on better enabling FDA to help industry achieve

compliance with the 1997 feed rule and will assist in the implementation of the FDA TSE Action Plan.

The specific activities proposed for FY 2002 that would be partially funded by this $15.0 million that implement the 1997 feed rule and the TSE Action Plan are as follows:

Foods Program, $1.1 million:

1. expand work efforts to identify food and cosmetic products containing brain, spinal cord, and other specific risk materials (SRMs); the origin of the animal; and country of origin;
2. research the risk factors and mechanism for chronic wasting disease (CWD), a TSE that affects elk and deer in several western US states; and
3. participate in international BSE meetings to help ensure safety of the U.S. food supply by providing up-to-date information on this emerging public health issue.

Biologics, $0.5 million:

4. help address the potential BSE threat to the safety of biological products. Two biological product areas affected include the safety of the blood supply and the safety of vaccines derived from bovine-source material.

Animal Drugs and Feeds $13.1 million ($2.2 million Center, $10.9 million Field):

5. conduct targeted BSE inspections of all known renderers and licensed and non-FDA licensed feed mills handling prohibited material, such as meat and bone meal, on a yearly basis, and conduct reinspections of those with compliance deficiencies, taking appropriate enforcement actions for repeated or egregious violations;
6. leverage with State agencies by funding approximately 4,000 contract inspections of feed mills and renderers, and conduct compliance, follow-up, and audit inspections to state contracts
7. review and evaluate field inspection data and take enforcement action when necessary;
8. develop a domestic sampling plan, collecting and analyzing 600 domestic feed, and feed component samples for BSE related contaminants. In addition, the Animal Drugs and Feeds Program will increase the number of import samples by 600. This sampling will help ensure that imported products are properly declared on their import manifests;
9. provide intensive line entry and label review, when appropriate, of an anticipated 175,000 import line entries for use in domestic commerce for the Animal Drugs and Feeds Program by expanding import staff by 17 FTE;
10. conduct additional training for Federal and State inspectors on the BSE feed regulation, update them on the current European Union situation, Animal and Plant Health Inspection Service (APHIS) authority and approach, and what to look for and how and when to sample;
11. modernize the existing information technology infrastructure to facilitate electronic inspection reporting and information collection and distribution; and
12. educate industry and the general public on BSE through public meetings, publications, and FDA's website.

Other Activities, $0.3 million:

13. provide advice and counsel on legal matters, render opinions, and support rulemaking proceedings, legislative matters, policy deliberations, and domestic and international negotiations; and
14. provide litigation support for enforcement, defensive and third-party matters.

Question 8. The President proposes to increase the FDA's budget by nearly 10%, which is more than nearly every budget proposed by President Clinton. Also, the 10% increase represents the second highest discretionary increase within HHS, Why did you ensure that the FDA would receive this amount of funding?

Response: The relative size of these increases reflects the importance of a strong FDA. There are many public and statutory expectations that FDA cannot meet now. FDA's responsibilities are broad, and the FY 2002 Budget proposes resources to match. We need to improve oversight over all imports; improve the use of medical products to reduce adverse events; make sure food is safe and protect against mad cow disease; and make sure human research subjects are not endangered.

Question 9. The budget allocates $10 million to protect human subjects in clinical trials. How will this impact the number of clinical trial-associated inspections?

Response: FDA, whose product reviews depend on the validity of clinical trial data, monitors the entire system of safeguards for all clinical trial participants. Currently, the Agency conducts about 1,200 trial-associated inspections per year, with approximately 1,100 domestic and foreign. These inspections may involve extensive

interviews with sponsors, monitors, investigators, site staff, and IRB administrators, and examination of their records, procedures, and responsiveness to participants' concerns.

With the requested FY 2002 $10 million increase, the number of annual inspections will increase by more than 20 percent with an emphasis on high-risk trials, such as those enrolling vulnerable populations such as the mentally impaired and children. The increase will also enable FDA to review and provide an initial follow-up on virtually all complaints concerning clinical trials within 30 days of receipt.

FDA views the protection of human subjects in product studies as highly important for both the health and safety of the study participants and for the integrity of the drug development process.

Question 10. As you are aware, under the previous Administration the FDA approved the abortion pill regimen, RU 486. Has there been any decision to examine the FDA's approval process, and does the Department's budget reflect this? Do you feel any money needs to be used to explore the FDA's drug approval process?

Response: While RU 486 is a unique and controversial drug, there is no evidence that the drug approval process was compromised in any way. The same high standards of safety and efficacy were applied to RU 486 as with any other drug product. We see no evidence of problems with FDA's drug approval process that merit investigation.

Question 11. Has any money been budgeted to educate ob/gyns and other medical and health care professionals on the potential dangers and risks of RU-486? Do you think the Department should spend time and resources to educate doctors and clinics and abortion providers about the very real dangers involved with RU 486?

Response: Although there is no specific money budgeted, in approving mifepristone (RU-486), FDA did put in place a detailed risk management plan to be carried out by the drug manufacturer to help ensure that the drug would be used only by qualified physicians and that there would be widely disseminated information explaining the risks and benefits of the drug. An important component of this program is the education of both physicians and patients about the safe and effective use of this product. FDA determined that a Medication Guide, written information for patients explaining important safety information and instructions for use, was necessary for women to be able to effectively and safely use mifepristone. The Medication Guide is important for women to be fully informed about how mifepristone works and about its risks, as well as the need for follow-up visits with their health care provider. In addition, patients are asked to sign an agreement that explains what mifepristone is used for and how it is administered to patients. Also, the company agreed to provide mifepristone only to physicians with particular qualifications who signed agreements that they understood certain information about the drug and that they would provide the Medication Guide to each patient. The current patient and physician information is approved by FDA. These materials, combined with the other components of the risk management program, provide the appropriate information about the potential risks and benefits of mifepristone. FDA currently maintains a web page on its website that contains all of the mifepristone information. The address is www.fda.gov/cder/drug/infopage/mifepristone.

Under the terms of the FDA approval, mifepristone is distributed as follows:

MifeprexJ must be provided by or under the supervision of a physician who meets the following qualifications:

—Ability to assess the duration of pregnancy accurately.
—Ability to diagnose ectopic pregnancies.
—Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
—Has read and understood the prescribing information of MifeprexJ.
—Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well.
—Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an ongoing pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure.
—Must report any hospitalization, transfusion or other serious events to the sponsor or its designate.
—Must record the MifeprexJ package serial number in each patient's record.

Question 12. Part of the problem of getting adequate health care in undeserved areas is the lack of health care providers. Do you agree that we should make sure that there are no barriers to faith-based charities serving as Community Health Centers?

Response: We agree that faith-based charities should be considered for funding as community health centers along with other public and private nonprofit entities that meet the statutory requirements of section 330 related to the provision of services, governance, management and finance.

Question 13. How will the proposed $3 million HHS Center for Faith-Based Community Initiatives work with the Community Health Center program?

Response: The HHS Center for Faith-Based and Community Initiatives will support the ongoing work of the Community Health Centers (CHC) Program. The CHC Program is an example of how HHS already works with faith-based organizations to improve access to quality care. The two programs will work together to ensure that faith-based charities are considered for funding as community health centers along with other public and private nonprofit entities that meet the statutory requirements of section 330 related to the provision of services, governance, management and finance. Several faith-based organizations currently receive CHC funding.

Question 14. This year one of the most critical public health reauthorization before our Committee is the Community Health Centers program. While there are some changes needed to strengthen the program, we are interested in your views concerning desirable changes. Are there other issues concerning the reauthorization of the health centers program that you would like to share with the Committee?

Response: Reauthorization and expansion of the Community Health Centers programs is a priority for the Administration. The President's fiscal year 2002 budget requests an increase in funding of $124 million for the health centers program. Our goal is support 1200 new or expanded sites over five years and provide quality health care services to an additional one million individuals in fiscal year 2002. The long-term goal is the double of the number of people served by community health centers. With these goals in mind, the Department will carefully review any proposed changes to the program

Question 15. Last year, one of the top priorities of this Committee in the Beneficiary Improvement and Protection Act was the establishment of a new Medicaid prospective payment system for health centers. The Committee established the PPS to stabilize the health center safety net by making sure that state Medicaid programs pay their fair share for the care of health center Medicaid patients. In doing so, the Committee is ensuring that the Public Health Service grants we authorize for care of the uninsured are utilized fully for that purpose and are not used to subsidize Medicaid underpayments. Full implementation of the PPS is critically important to this Committee. Can you please tell us what the Department and HCFA are doing to implement the PPS and how states are responding to the new system?

Response: To date, all fifty States and the District of Columbia have submitted the required State Plan Amendments to implement the changes in their payment rules for federally qualified health centers. CMS has approved most of these State Plan Amendments and have been working closely with the States whose amendments were not approvable, as submitted, to get the amendments into approvable form.

This, however, is just the first step to full implementation. States are reconciling cost reports and gathering other pertinent payment data for fiscal years 1999 and 2000 in order to accurately the calculate the baseline payment rate for the PPS system. While that process is taking place, States are reimbursing centers/clinics based on the payment methodology in place on December 31, 2000. Once the baseline rate for the PPS system has been determined States will make clinics whole for any shortfall between the interim payment rate and the new PPS rate back to January 1, 2001.

Question 16. Another important public health program is the National Health Service Corps. This program places health professionals in undeserved locations across the country by offering to pay for a portion of their medical education. The program works very closely with the health centers program and others to provide care to the most vulnerable in our country. The authorization for the NHSC expired last year. In his budget submission, the President has stated that he thinks the NHSC should be reformed to better target needy communities. What specific ways do you think the NHSC should be reformed?

Response: We are examining the ratio of scholarships to loan repayments awarded as well as other set asides to ensure maximum flexibility to better meet community requests for NHSC providers. To more accurately define shortage areas and target placements, the Administration will seek to amend the shortage area definition to reflect other non-physician providers practicing in communities. We are also plan-

ning to enhance coordination with immigration programs such as the J-1 visa program.

Question 17. In his budget, President Bush proposes to create a $400 million "Healthy Communities Innovation Fund" will work? How will it fit with other programs this Committee oversees?

Response: The President's fiscal year 2002 budget proposes $400 million annually for The Healthy Communities Innovation Fund for local demonstration and pilot programs aimed at addressing local health problems. Activities will target health risks, increasing access and improving health care quality. The Healthy Communities Innovation Fund will improve coordination and increase innovation among certain activities of the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA) and the Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration).

HRSA programs included in the Fund ($221 million in FY 2002) are: Healthy Start, Maternal and Child Health National and Regional Special Projects, Community Integrated Service Systems, and Community/Migrant Health Centers-Integrated Service Delivery. CDC programs included in the Fund ($183 million in FY 2002) are: Cardiovascular Disease Prevention, Diabetes Prevention and Control, Comprehensive Cancer Prevention and Control, Tobacco Use-Reduction State, Local and Community Awards, and Racial and Ethnic Approaches to Community Health (REACH). The CMS included is the Fund ($10 million in FY 2002) is the Community Innovation Fund.

Question 18. Your written testimony on page 3 indicates that the budget keeps the President's commitment to double NIH's FY 1998 funding level by FY 2003, with a request of $2.75 billion, which will be the largest dollar increase ever for NIH. How will NIH set priorities for its research? Why are thee such a large research-dollar-per-mortality disparity among diseases? Should we expect those ratios to be more comparable with one another in the future?

Response: *How will NIH set priorities for its research?* NIH will set the priorities for the budget increase according to long established policies and practices used each year to allocate the agencies budget. The allocation of NIH funds during a given year is the culmination of a lengthy, comprehensive, and ongoing process. Many factors are considered in the allocation of funds from the NIH budget public health needs, a commitment to support work of the highest scientific caliber, a responsibility to seize the scientific opportunities that offer the best prospects for new knowledge and better health, a need to maintain a diverse portfolio that supports work in many scientific disciplines and on a wide range of diseases, and an obligation to insure a strong scientific infrastructure, with a high quality workforce and excellent research facilities. The allocation of the NIH budget reflects the use of the best available information and judgments regarding balancing the criteria for budget decisions.

To evaluate these many criteria for making decisions, the NIH seeks information and advice from many individuals and groups, including the extramural scientific community, patient advocacy groups, Congress, and the Administration. For example, each Institute and Center (IC) convenes meetings of national advisory councils or boards, with members from the public, medical, and scientific communities, to review a broad range of IC policies, and many conferences and workshops are organized each year to gather opinions on specific scientific, health, and management issues. The IC's efforts to seek public input are augmented by those carried out by the Director, NIH. The views of the scientific community and the public are gathered through meetings of the Advisory Committee to the Director (ACD), NIH, the NIH Council of Public Representatives (COPR), and other meetings and workshops. In addition, the NIH holds an annual Budget Retreat to help develop its priorities for the President's budget. The meeting involved the NIH leadership along with external advisors, from the ACD and from the COPR. Efforts to encourage and coordinate public participation in NIH programs have been undertaken through the public liaison offices that have been established in the Office of the Director and in each IC.

To help in explaining the NIH process for setting priorities, NIH prepared a brochure entitled, "A Setting Research Priorities at the National Institutes of Health." In addition, the FY 1998 DHHS Appropriations Act required the Secretary to contract with the Institute of Medicine (IOM) to conduct a comprehensive study of the policies and processes used by the NIH to determine funding allocations for biomedical research http://www.nih.gov/news/ResPriority/priority.htm. The IOM Committee released its report, *Scientific Opportunities and Public Needs: Improving Priority Setting at the National Institutes of Health* on July 8, 1998. http://www.nap.edu/books/030906130X/html/index.html The IOM report made several rec-

ommendations to enhance the NIH priority setting process and it endorsed the criteria used by the NIH to set priorities.

Why is there such a large research-dollar-per-mortality disparity among diseases? First, I want to assure you that information on burden of illness (BOI) is widely and routinely used to inform the NIH priority setting process. I would like to make three points in response to the implicit suggestion that funds should be allocated in proportion to the number of persons who die from the disease. First, the number of people who die from a disease is an incomplete and imperfect indicator of public health need or burden associated with a specific disease or condition. Second, coding or classifying research expenditures to a particular disease or condition is an inexact art, which can only be done approximately, at best. Third, the allocation of research resources is influenced by scientific opportunities as well as public health need.

It is arbitrary and misleading to select one measure, whether deaths, the number of cases, or dollars spent on treatment, to rank diseases in terms of burden. For example, funding according to the number of individuals affected by each disease would emphasize common diseases, but might have a limited effect on overall health and survival. By that criteria, much research would be done on the common cold and allergies, but little would be allocated to childhood cancers. More inclusively, the burden of illness includes the degree to which a disease cuts short a normal, productive, comfortable lifetime the years lost to premature death; the pain, suffering, and reduced functioning associated with a disease; and the number of people who have a particular disease. The economic and social costs associated with a disease are an important additional consideration, but only partially reflect the personal costs of mortality and morbidity. The extent to which the threat of a disease is expected to increase or spread over time must also be included as an element of burden (e.g., increasing threats may result from a recently detected infectious disease, a manifestation of an environmental hazard, aging of the population, e.g., Alzheimer's disease).

Unfortunately, there is no simple formula or index that summarizes all the dimensions of burden into a single number. The simple counting of deaths is clearly an incomplete proxy for burden. Without consideration of age at death it fails to capture the potential life years lost. It does not capture the economic and social costs associated with morbidity and if fails to reflect trends in the relative threat of disease over time.

Allocating burden to a specific disease is also difficult. Many people suffer from more than one condition, which may or may not be inter-related. One disease or condition such as diabetes or HIV may lead to a complication or vulnerability to another condition. For example, a person with diabetes who dies secondary to diabetic kidney failure may appear as a death due to kidney failure without mention of diabetes. Available statistics on disease-specific burden are based on somewhat arbitrary decision rules and do not always recognize the contribution to burden of comorbidities and underlying causes. The allocation of burden may be further biased when certain conditions are systematically misdiagnosed or are under reported because of social stigma.

Similarly, assignment of research funding to a particular disease category may be somewhat arbitrary. It is extremely difficult to assign the large investments in basic research, research instruments and equipment, and training investigators to any one disease. Also, from long experience we know that research aimed at one target often hits others as well. For example, cancer research, i.e., research on retroviruses, laid an important foundation for relatively quick progress in the development of drugs for the treatment of HIV/AIDS.

Finally, even if consistent and comprehensive estimates of the relative burdens of specific diseases were available, decisions regarding research priorities would also have to include the importance of scientific opportunities. A recent research advance often creates greater scientific opportunities for research and development in one disease area than in others. Conversely, a lack of knowledge regarding underlying pathophysiological processes can inhibit the development and evaluation of diagnostic and therapeutic technologies for other conditions, regardless of their social burden. Increased spending on a disease is wasteful when there are neither promising pathways to follow nor an adequate number of qualified investigators to fund.

Should we expect those ratios to be more comparable in the future? Because trends in disease-specific burden and the distribution of scientific opportunities do not change rapidly, it is not necessary or desirable to radically readjust the allocation of program funding from year to year. An across the board increase in funding for each program is a reasonable starting point for allocating increases in annual appropriations. The program funding increases are modified up or down to adjust for any perceived changes in disease-specific burden or to capitalize on newly generated scientific opportunities. But those year to year changes will generally be slight.

It is important to recognize that much of the planning of NIH-sponsored research is centered on broad scientific themes (such as genome projects, development of instrumentation, training in clinical research, or developments in basic science), without reference to the many specific diseases that might be addressed through these efforts. The success of individual applicants for NIH grants, the nature of their interest, and the specific knowledge generated by the non-disease-related projects, will gradually uncover new opportunities and will influence subsequent disease-oriented planning and disease-specific spending patterns.

The substantial base of research funds already committed to grant recipients and the need to provide stable support for scientific work restrict the degree to which funds can be directed. Scientific work is not simply a commodity that can be purchased; the effective shifting of priorities requires new ideas and new personnel as well as budgetary realignments. To augment research on specific topics in a more responsible fashion, it is necessary to show that under-explored opportunities exist and that they can attract investigators either newly trained scientists or scientists from other fields who will then propose meritorious projects.

In conclusion, the number of deaths associated with a disease is an imperfect guide to research resource allocation. It is not an adequate standard by which to evaluate the allocation of NIH funding. The NIH is responsible for conducting research on the broad array of health problems affecting people in this country, but it cannot simply allocate funds to research on one disease or another according to a set formula.

Question 19. Many members of this Committee support an increase in funding to NIH for cures to devastating diseases. However, the Committee wants to ensure that these large increases will be accompanied with appropriate oversight. What kind of oversight will HHS put in place to monitor the NIH increases?

Response: The recent increases in the NIH budget have enabled us to better capture scientific opportunities, translate research from bench to bedside, complete the Human Genome Project in less time than anticipated, and engender excitement about research among the young investigators. NIH recognizes that in this optimal budget climate, it is important to maintain the highest quality of science by upholding the rigor of peer review. We continue to seek advice and input from the Institutes and Centers (IC's) advisory councils on funding decisions, priority setting and other portfolio management issues. We are keenly aware that the increased budgets must be accompanied by enhanced oversight to ensure proper stewardship of public funds. For example, in the area of clinical trials, the NIH supports more than five thousand clinical trials involving several million-research participants. With the recent increases in the NIH budget, these numbers have gone up. However, even with the increased number of clinical trials, we must ensure that the overall system for protection of research subjects is intact. Moreover, the NIH has recently taken steps to strengthen the oversight of clinical trials. Since 1979, NIH has had a long-standing policy of requiring data and safety monitoring for clinical trials. Monitoring is commensurate with the level of risk, the size and complexity of the trial. For most phase III trials, a data and safety monitoring board is required.

New steps taken include:

—Beginning with the October 1, 2000 receipt date, applicants must submit a monitoring plan for phase I or II trials. The plan is subject to the review and approval of the funding Institute and Center, and awards are contingent on their approval.

—Principal investigators must report certain types of FDA communication to the NIH. These include warning notices and letters, consent agreement and clinical hold letters. Investigators must report to funding IC within 72 hours of receipt. Failure to comply may result in corrective and/or enforcement action.

—Required education on the protection of human subjects—Beginning Oct 1, 2000, the NIH requires investigators, i.e., key personnel, who are responsible for the design or conduct of research involving human subjects to be educated on the protection of human subjects. To facilitate implementation, the NIH made available a number of ready-to-use curricula, including two online modules developed by the NIH. Investigators have some flexibility to determine what is an appropriate level of education. Documentation of education is required before funds are awarded.

Question 20. The NIH is in the process of organizing the new National Institute of Biomedical Imaging and Bioengineering (NIBIB). The NIH reported in a 1998 letter to Chairman Bilirakis and in testimony before this Subcommittee just last September, that it invested $217 million in basic bioimaging research in FY 1997 and indicated that spending in this field had increased since then. Earlier this year, the NIH leadership directed each individual Institute to identify existing grants in its

portfolio that are primarily fundamental imaging research for transfer to NIBIB. Despite the previous NIH claims about the magnitude of its investment in basic imaging, it looks like the amount of grants to be transferred will fall short of the amount reported earlier.

Mr. Secretary, either the NIH exaggerated its investment in imaging then or the NIH is now attempting to thwart the will of Congress in creating the new Institute. In either case, it appears that NIBIB will be severely underfunded. It also appears that the NIH is delaying release of the amount to be transferred to NIBIB to ensure that the Appropriations Committees will not have complete and accurate information to consider in setting a funding level for NIBIB.

Mr. Secretary, can you look into this matter and report back to this Subcommittee on the relationship between the previous NIH testimony and the current process of identifying grants for transfer to NIBIB?

Response: We are excited about the new opportunities that the new National Institute of Biomedical Imaging and Bioengineering (NIBIB) will create for support of fundamental research that applies principles of engineering, mathematics, computer science and the physical sciences to biological processes, disorders and diseases.

The President's budget request for NIBIB for Fiscal Year 2002 is $40 million. These funds will be supplemented through a transfer of appropriate grants to NIBIB from other NIH Institutes and Centers (ICs). The transfer of grants to NIBIB is intended to strengthen and complement, not subtract from or substitute for, research programs in the other NIH ICs. NIBIB will support *undifferentiated* research not related on a one-to-one basis to the mission of another IC and act as a unique focal point for multidisciplinary research planning and strategic development. The other NIH ICs will continue those studies that are a natural fit within their current organizations—those focused on specific diseases or conditions. The ICs and key constituencies in the imaging and engineering communities have endorsed this strategy for building the new Institute and continuing to support these studies across NIH.

The process for identifying the appropriate grants for transfer is underway. After we review the entire slate of grant transfer candidates, NIH will submit the transfer information to the House and Senate Appropriations Committees for final approval and incorporation into the FY 2002 budget for NIBIB.

Question 21. Can we have your assurance that NIBIB will have the resources necessary to fulfill its extremely broad and important mission? This institute has the potential to produce dramatic breakthroughs in the detection, diagnosis, and treatment of a wide range of diseases, but that potential will not be realized if NIBIB is starved.

Response: We believe that the Fiscal Year 2002 budget request of $40 million, plus the appropriate grants transferred from the other ICs, will establish an adequate base upon which to build future year funding requests for the NIBIB and will permit careful stewardship and oversight of research programs in the first year of this newest of the NIH ICs. As rich opportunities emerge, we will adjust our future budget requests accordingly

Question 22. In light of recent studies proclaiming the Connecticut Baby AIDS law a success and the remarkable data from the New York Baby AIDS law, will you direct the CDC to re-evaluate the agency's opposition to routine diagnosis of women and newborns of HIV?

Response: CDC does not oppose the routine diagnosis of women and newborns for HIV. Focusing testing on newborns, however, offers much less chance of successful interventions to prevent perinatal HIV transmission than do efforts to encourage pregnant women to seek testing and providers to increase prenatal voluntary counseling and testing and antiretroviral interventions during pregnancy. CDC recommends that voluntary HIV testing should be a routine part of prenatal care. Based on data from all States, including New York and Connecticut, the *U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women* are being revised. The revised guidelines should be published in late summer and will strengthen the recommendations that all pregnant women be tested for HIV, emphasize HIV testing as a routine part of prenatal care, recommend that providers explore and address reasons for refusal of testing, and place more emphasis on HIV testing and treatment at the time of delivery for women who have not received prenatal testing and chemoprophylaxis. The New York law's major effect appears to be associated with increased efforts by providers to offer prenatal voluntary counseling and testing. Increased prenatal voluntary counseling and testing offers the best chance of maximally reducing the risk of perinatal transmission because it increases the opportunity to lower maternal viral load to nondetectable levels near delivery and provide chemoprophylactic therapy to the baby during labor, delivery, and afterwards. States other than New York have excellent

prenatal voluntary counseling and testing rates in the absence of mandatory HIV testing in newborns. For example, data on HIV testing in 1998 indicated that in Arkansas 85 percent of pregnant women were tested during pregnancy or at delivery. In Colorado and Florida, these numbers were 79 percent and 84 percent, respectively.

Question 23. The Bush Administration and John Walters, the Director of the White House Office of National Drug Control Policy, have set as a priority stigmatizing drug abuse. Yet the CDC is claiming that the stigma associated with drug abuse and other high-risk behaviors is, in large part, responsible for HIV infection. Recently, the CDC held a national teleconference to address how to remove such stigma. The CDC admits no studies have been conducted to substantiate claims about a link between HIV infection and stigma. What are your views on this issue and do you think it is appropriate for the CDC to invest limited resources in a campaign to remove the stigma associated with drug abuse and other risk behaviors?

Response: Between 800,000 and 900,000 persons in the United States are estimated to be living with HIV or AIDS. Many of these people face stigma and active discrimination because of their health status or related reasons. Stigma finds its roots in fear and misunderstanding about how HIV is transmitted and in underlying attitudes about the populations most heavily affected by this epidemic.

CDC and other organizations have found that HIV prevention efforts are significantly hindered by biases and stereotypesBin fact, some communities are reluctant to even discuss risk behavior and transmission, resulting in community members not being able to receive appropriate information and prevention services to prevent HIV infection and transmission.

Focus on this area also was recommended by the Institute of Medicine (IOM) in its September 2000 report *No Time to Lose: Getting More from HIV Prevention.* In this document the IOM Committee described stigmatization of persons with HIV as a pernicious barrier to preventing new infections, and specifically said that it believes that the protection of human rights, privacy, and equity continues to be a significant concern, and that concurrent efforts at the federal, state, and local level to remove or at least lessen the impact of stigma and discrimination are necessary.

CDC's interest in this important prevention issue is not to support illegal drug injection or specific sexual behaviors, but rather to eliminate stigma and discrimination as a barrier to reducing new HIV infections and accessing prevention services and care. As the nation's prevention agency, CDC must recognize and address barriers to disease prevention and health promotion in order to fulfill our mission of protecting the public health.

In June 2000, CDC convened a group of experts from across the country to discuss the role stigma plays as a barrier to HIV prevention. Several action steps were recommended, and CDC has been working to implement many of them. Although there are numerous articles describing research related to stigma and health effects, one area of concern was the lack of specific data regarding HIV-related stigma, particularly population-based data on which to base decisions regarding communications and programs. As a first step in acquiring such data, CDC conducted a study that was reported in the December 2000 issue of the *Morbidity and Mortality Weekly Report,* which found that of the 6,000 American adults surveyed, 1 in 5 believed that people who got AIDS through sex or drugs got what they deserved. This research indicates that addressing this important subject is critical to our efforts to decrease the number of persons becoming infected and to ensure that those infected receive appropriate care and prevention services.

Question 24. The Centers for Disease Control and Prevention is the lead agency in the federal government to help prevent disease. Yet many CDC programs focus on methods to reduce the consequences of risky behavioral practices instead of preventing those behaviors in the first place. In fact, in respect to HIV/AIDS and sexually transmitted disease prevention, the CDC actively promotes condoms as the best protection for preventing infection. What should be the response of the CDC should medical data reveal that condoms are far less efficacious than was previously thought?

Response: When important new scientific information becomes available, CDC updates its policies and recommendations to reflect this new information. For example, the 1995 recommendations for HIV counseling and voluntary testing of pregnant women are being revised to reflect lessons learned since the first guidelines were published.

Question 25. What criteria does CDC use in selecting members of its HPPC? Does the CDC consider the views of members as part of a selection process for membership on an HPPC?

Response: CDC requests clarification from the committee as to what the acronym "HPPC" represents.

Question 26. Last year, Congress specifically directed federal HIV/AIDS; care programs to include HIV data funding formulas to ensure that racial and demographic disparities noted by the General Accounting Office are eliminated. The Committee is concerned that states with unreliable HIV tracking systems using on code reporting will continue to shortchange minority communities. Can you assure us that by allowing states to experiment with coded surveillance systems—which even the CDC has fund to be faulty—that data will be properly and fully reported so that these disparities will indeed be eliminated?

Response: CDC has adopted minimum performance standards for HIV reporting that all States must meet over time. These standards were published in the recent *Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome.* The performance standards include using methods that provide complete and timely data, result in accurate case counts, and ensure that demographic and risk information is complete. In addition, States must collect the recommended standard data in a reliable and valid manner, allow matching to other public health databases (e.g., death registries) to benefit specific public health goals, and allow identification and follow-up of certain individual cases, such as perinatally exposed infants, to identify infection status. To date, of those States that have implemented HIV reporting using non-name-based methods, none has completed CDC evaluations addressing all performance standards. However, Massachusetts and Washington have had time to establish routine surveillance methods for collecting HIV data. An evaluation of how well the code identifies one and only one person has been completed for these states. Both report that the current system meets this aspect of the recommended performance standards. Other performance criteria have not yet been evaluated in these states. One other State, which previously published an initial evaluation, is currently conducting CDC-recommended modifications to their evaluation methods. CDC will continue to work with States to complete these evaluations, strengthen their systems, and promote comparability of data throughout the United States.

CDC collaborates with all 50 States, the District of Columbia, US dependencies and possessions, and independent nations in free association with the US to report AIDS cases using a uniform case definition and report form. Basic elements collected on all cases include information about the AIDS diagnosis, demographic characteristics, exposure and death information. As of January 1, 2000, CDC and the Counsel of State and Territorial Epidemiologists expanded the surveillance case definition to include the reporting of HIV infection and recommended that all areas conduct HIV case surveillance as an extension of current AIDS case surveillance activities. As of April 2001, 33 states, the Virgin Islands, and Guam have implemented HIV case surveillance using the same confidential system for namebased case reporting for both HIV infection and AIDS; two additional states conduct pediatric surveillance only using the same method. Seven states are currently using a coded identifier rather than patient name to report HIV cases and three states are using names to initiate HIV reports which are later converted to codes after public health followup. Published guidelines for HIV surveillance include recommended best public health practices and minimum performance standards for integrated surveillance systems. Surveillance programs are currently conducting or planning evaluation studies to measure the accuracy, quality and timeliness of their HIV/AIDS surveillance systems. Additional funding and technical assistance for evaluations of integrated HIV/AIDS surveillance using standardized CDC protocols will be announced in the fall of 2001.

In regard to the CARE Act, its goals and objectives focus on the extent to which programs serve lowincome, medically underserved populations and remove barriers and enhance access to care for these vulnerable populations. HRSA is in the process of establishing an interagency agreement with CDC in order to jointly pursue a task order with the Institute of Medicine (IOM). This work will help determine whether the core integrated HIV/AIDS surveillance system provides adequate data to allocate Ryan White funds at the State and local levels; what data can be used to determine a communities severity of need for the purposes of resource planning and allocation; and what data on HIV primary care and support services can be used to measure outcomes and quality of services in low income, under and uninsured populations. Section 501 of the Ryan White CARE Act Amendments of 2000 requires that the IOM conduct this study.

Specifically related to the use of HIV data in federal funding formulas, the IOM study shall determine:

1. Whether the surveillance system of each of the states regarding HIV provides for the reporting of cases in a manner that is sufficient to provide adequate and

reliable information on the number and demographic characteristics of cases, at the State level and for specific geographic areas within the state.

2. Whether the case reports are sufficiently accurate for purposes of formula grants under parts A and B of title XXVI of the PHSA.

If the study identifies inadequacies or unreliable information, the IOM is to make recommendations for improvements in the core surveillance system. Not later than July 1, 2004, The Secretary shall take into consideration the findings of this study in rendering a determination as to whether there is data on cases of HIV disease suitable for such use in allocating funds.

Question 27. How will you ensure that recent changes to Ryan White will only pay for "support services that are health care related?" What are your plans to evaluate grantees that expend resources on non-health care related activities? How will programs be evaluated that expend resources from any source that encourage or destigmatize risk behaviors?

Response: The HRSA HIV/AIDS Bureau has through letters, program guidance and technical assistance activities informed all of the CARE Act Title I and II grantees and Planning Councils, about the new amended CARE Act requirements regarding health related support services. We will monitor grantee compliance through ongoing program monitoring activities such as site visits, monthly monitoring calls, and review of progress reports and expenditure data. Moreover, the HIV/AIDS Bureau each year reviews the amount of funds allocated by Title I and II grantees to several service areas. This activity has been under way for some time so there is sufficient information to assess any significant changes in the grantees funding of support services.

Where we find inconsistencies with this guidance and policies we will allow grantees reasonable time to correct the inconsistency. Failure to satisfactorily correct the inconsistency could result in the imposition of grant restrictions.

Annual application guidance to grantees asks them to describe and discuss the impact of non-CARE Act funding which assists in the provision of HIV care and treatment services. We view this area as very important because it demonstrates the grantees ability to successfully coordinate CARE Act funds with other appropriate funding streams. CARE Act funds are viewed as the A payer of last resort and therefore should not be used to pay for services where it is expected that services be covered under any other Federal or State program.

HRSA has recently completed a series of locally based evaluations that look at the association of the provision of support services and entry into and retention in HIV primary care. The results from these targeted evaluations will soon be disseminated along with descriptions of methodological approaches for such evaluations. HRSA is currently in discussion regarding a proactive technical assistance approach that supports local evaluations and provides useful methods for conducting focused evaluations with limited resources.

Question 28. Last year, Congress passed and the President signed legislation to address the prevention of Human Papillomavirus infection (P.L. 106-554). What is the status of the enactment of this law?

Response: CDC has begun research efforts to help develop science-based messages and educational materials regarding human papillomavirus (HPV) prevention and consequences of infection. They will be based on sentinel surveillance and epidemiological studies to better define prevalence and progression of HPV and its health consequences; formative research on HPV knowledge and attitudes about HPV healthcare and sexual behaviors, as well as HPV informational needs; and a healthcare provider survey of perceptions, healthcare practice, barriers and facilitators to HPV risk assessment, diagnosis, treatment, counseling and partner services.

CDC is working to ensure that any educational materials on STDs, and HPV in particular, which are under development, are in compliance with the requirements of P.L. 106-544. CDC's National Center for HIV, STD, and TB Prevention has informed its HIV and STD grantees, subgrantees, contractors, and a wide range of public health partners about the requirements of P.L.106-554, especially these requirements regarding educational materials. Organizational components of CDC affected by the legislation have been similarly notified. In addition, CDC has notified both the National Coalition of STD Directors and the National Alliance of State and Territorial AIDS Directors who represent state and local health department STD and HIV programs.

Question 29. The budget plan includes a request for $20 million for the purposes of increasing organ donation. How will those resources be used to increase donation among minorities who have very low donation rates?

Response: A large portion of HRSA's donation funds supports a grant program focused on model interventions to increase donation. Sixty-five percent of the cur-

rently funded projects specifically target minorities. HRSA will continue to emphasize the need for minority-focused projects in at least the same proportion.

In addition, as the key HHS agency responsible for implementing Secretary Thompson's new campaign to increase donation, HRSA is currently developing an outreach strategy to involve minority businesses and organizations. As part of this strategy, outreach efforts have already begun with the NAACP and other minority organizations.

In keeping with the Administration's interest in working with faith communities, HRSA will work with the Congress of National Black Churches (CNBC) to promote organ and tissue donation through CNBC's membership of more than 65,000 churches and 20 million individuals. HRSA will also implement a strategy to encourage donation through community health centers, the clientele of which is approximately 43 percent minority.

HRSA plans to promote minority donation in various other ways. Among these are exhibiting at minority meetings and conferences, developing brochures and other education materials targeted specifically to minorities, and promoting donation on the campuses of Historically Black Colleges and Universities, Hispanic Serving Institutions, and schools with high Asian populations.

Question 30. What is going to be HHS's approach to the organ allocation regulation, which went into effect last year? As Governor, you filed suit to enjoin the agency from enforcing the rule. What will be the approach to revising or modifying the Clinton Administration's rule?

Response: The suit to enjoin the agency from enforcing the rule has been withdrawn. There are no plans to rescind or change the rule. The Department is enforcing the rule and is working cooperatively with the transplant community to implement the rule in a very fair and balanced manner. There has been good progress toward fulfilling the requirements of the rule. For example, the Organ Procurement and Transplantation Network has proposed, and is testing the feasibility of a new liver allocation policy that would greater emphasis on patients' illness severity and less emphasis on waiting time as a basis for priority on the waiting list.

Question 31. The HHS budget on page 5 requests $33 million for a new program to support group homes for teenage mothers. How will the Department ensure that women seeking counsel or treatment at Title X-funded programs will receive information about this program? How will the Infant Adoption Awareness Act be coordinated with the program supporting homes for teenage mothers?

Response: The President's budget for FY 2002 requests $33 million to fund Maternity Group Homes, community-based, adult supervised group homes for young mothers and their children. These homes will provide safe, stable, nurturing environments for mothers who cannot live safely with their own families and will assist them to move forward with their lives by helping them to complete their education, obtain job skills and learn to be good parents. The budget also requests $10 million to continue funding the Infant Adoption Awareness Act, first authorized and funded by Congress in FY 2001. That program is intended to train designated staff of eligible health centers (including Title X family planning clinics) in providing accurate adoption information and referral to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women

Because women facing unexpected pregnancies may be in need of a multitude of services, the Department will also ensure that eligible health centers are provided with information on the Maternity Group Homes (providing funds are appropriated for that initiative) for their clients who may be in need of that type of program. In addition, subject to the availability of funds, the Department will ensure that Maternity Group Home grantees receive information on adoption information and referral for young women who might choose to place a baby for adoption after entering a Maternity Group Home program.

Question 32. Could you please describe some of the ongoing initiatives and activities at the Office of the Secretary's Office for Human Research Protections?

Response: The recently created Office for Human Research Protections (OHRP), together with other HHS agencies, launched a new approach to the protection of human subjects in research, one based upon the concept that the primary responsibility of everyone involved in the human research process is to protect the rights, interests and well-being of those individuals who voluntarily participate in research activities. The new system will not to be simply an improvement of the existing oversight and sanction approach, but a system focused on *prevention.* The Department's reform plan specifically addresses the five major recommendations of HHS' Office of Inspector General (OIG in its 1998 Report.

Working with other federal agencies, OHRP has developed and implemented a unified Federal registration system for all human research review boards, regardless of the source of research funding. This will provide an important database for im-

proved communications with IRBs and an important first step toward establishing greater uniformity in the IRB process. In December 2000, OHRP implemented a simplified assurance process. With the resources freed from the former, overly complex assurance process, OHRP is implementing a new program that emphasizes education and support as part of a broad quality improvement effort that will be administered through a combination of proactive site visits, video conferences, and directed self-evaluations. The assessment tools and procedures are undergoing pilot testing in voluntary cooperation with institutions across the country in anticipation of formal implementation. When fully implemented, and with sufficient resources, OHRP expects to conduct 60 quality improvement evaluations every month, and will conduct quality improvement evaluations at every major medical school in the United States during the first year of the program.

For greater uniformity and public accountability in the review and approval process, OHRP, through the Department, contracted last October with the Institute of Medicine (IOM) of the National Academy of Sciences to recommend uniform performance and resource-based standards for private, voluntary accreditation of human research protection programs. In April 2001, the IOM issued its report on accreditation of human research protection programs, and pilot testing began in July 2001 in selected medical centers in the Department of Veterans Affairs and other institutions, including NIH. Having completed the first phase of its project, the IOM began work on a study of the evolving human research system to determine the extent to which the issues and concerns raised by the OIG, the General Accounting Office, the National Bioethics Advisory Commission, and other national groups are being addressed within the current program of reform. The IOM working group has also been charged with developing objective measures for the effectiveness of the system for protection of human subjects in research.

OHRP, the FDA, the NIH, and other federal agencies have just launched an effort to carefully examine the continuing review process and to develop guidance for institutions and review boards regarding appropriate mechanisms for ongoing monitoring of approved research, particularly recognizing the need for more effective monitoring and management of adverse events. Toward this end, the Department will seek support for the development and implementation of an integrated electronic information system and database to carry out this process.

In the past year, OHRP staff members have given over 50 presentations to institutions, IRBs, investigators, and professional societies. In February, OHRP and the DHHS Office of Research Integrity hosted the first Human Research Education Summit, attended by representatives from both the academic and corporate sectors, as well as representatives from almost every federal agency subscribing to the Common Rule. This meeting was an initial step toward developing a system of shared resources and best practices. A second summit is scheduled for August 2001. OHRP has developed and implemented web-based educational modules for institutional officials, IRB managers, and IRB chairs to ensure that these individuals are fully cognizant of their responsibilities under their assurances.

IRBs and institutions are trying to shoulder what seems to be an ever-increasing burden of compliance activities. OHRP is convening the SUEE Task Force (Simplicity, Uniformity, Efficiency and Effectiveness) with the Human Subjects Research Subcommittee (HSRS) later this fall to identify and recommend opportunities for reducing unproductive administrative burdens. At the Executive Branch level, the HSRS, chaired by the Director of OHRP, is working to integrate the activities of federal offices, agencies and departments that share responsibilities in this oversight process. Under its charter, the working groups of HSRS have taken on issues such as conflicts of interests in clinical research and appropriate application of the federal policy for protection of human subjects in non-biomedical, social and behavioral sciences research. The HSRS has become the Acentral nervous system of the federal system for human research oversight. Its role and its effectiveness continue to grow.

Following the very successful August 2000 HHS-sponsored conference on financial conflict of interest and human subject protection, an HHS working group developed and in January OHRP disseminated widely for comment the A Draft Interim Guidance *Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider When Dealing With Issues of Financial Interests and Human Subject Protection* on the OHRP website and taking steps to expand its scope to include all Common Rule agencies. Next steps include reviewing the comments received from the public and NHRPAC, revising the document, and then formally sharing the revised document with the human subject protection community for additional suggestions. The Department anticipates publication of new guidance this fall.

Last March, OHRP created a new component Office for International Activities to lead and coordinate Departmental activities in the international domain. OHRP is

working with the World Medical Association, the European Forum on Good Clinical Practice, the Council of International Organizations of Medical Societies and other international organizations to refine the interpretation and application of the revised Declaration of Helsinki.

Question 33. When will the HHS review on the meaning of the Dickey Amendment regarding human embryo experimentation be completed?

Response: The Dickey appropriations rider prohibits the use of federal funds for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The Administration has determined that the research that the President has agreed to fund (using existing stem cell lines where the life and death decisions have already been made) does not violate the Dickey amendment. No Federal funds will be used for the destruction of human embryos or the derivation of stem cells, and no Federal funds will be used for research on stem cell lines created from human embryos that are alive as of this date. HHS will fund research and will conduct its own research consistent with this determination.

Question 34. Because many faith-based organizations direct the majority of their resources to services, they often have little expertise to navigate the maze of federal grant programs that could help them serve the sick and needy. What steps do you think need to be made to educate and assist faith-based organizations so that they have an equal opportunity to the assistance the federal government provides non faith-based community organizations?

Response: In order to build the capacity and competency of charitable faith-based organizations, this Administration proposes the establishment of a Compassion Capital Fund and Best Practices Research Initiative. Under this proposal, a national funding source would be established to support charitable organizations in expanding or emulating model social service agencies through public-private partnerships. The organizations supported by this funding source would work with community and faith-based organizations in:

—providing technical assistance to help small community and faith-based charities increase their capacity to provide service delivery, improve competence and expand program availability;
—operating a revolving loan fund to provide bridge loans which would enable smaller groups to cope with the slow flow of procurement; and
—providing grants for start up and operation to qualified charitable organizations.

These capacity-building entities also would be responsible for obtaining private matching funds to support their efforts, in addition to their responsibilities in assisting community and faith-based organizations. Further, we propose the establishment of a national funding source to support and promote research on A best practice among charitable organizations, called the Best Practices Research Initiative. This new authority would be created specifically to research and disseminate information on the effectiveness of service programs for low-income individuals operated by charitable social service organizations. Information regarding successful programs identified through the Best Practices Research Initiation would be disseminated among charitable organizations so that such models could be duplicated and expanded.

The FY 2002 budget request for the Compassion Capital Fund is $67 million, and for the Best Practices Research Initiative, the budget request is $22 million.

Question 35. Research has found that families that contain a mother and a father provide significant health and behavioral benefits to their children. What steps are you taking to make sure HHS programs strengthen families, and support marriage and responsible fatherhood?

Response: We have funded eight-child support enforcement responsible fatherhood demonstration projects that will help bolster fathers' financial and emotional involvement with their children. Each project is different, although they all provide a range of services to aid in collecting child support, such as job training, access and visitation, and social services.

We have provided over $1.5 million to the National Center for Strategic Nonprofit Planning and Community Leadership (NPCL) to work with grassroots fathers' organizations to help unemployed and underemployed fathers become responsible parents. In addition, we have approved ten State waivers supporting the Partners for Fragile Families, a set of projects to test ways for child support enforcement programs and community and faith-based organizations to work together to improve the opportunities of young, unmarried fathers to support their children both financially and emotionally. Further, Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA), created a $10 million access and visitation program for States, serving more than 22,000 individuals in 1997 and an estimated 50,000 in 1998.

Most recently, President Bush and I made a clear commitment to promoting involved, committed and responsible fatherhood as a national priority by emphasizing it the FY 2002 budget request. One of the many goals of the Administration's FY 2002 proposal is to provide $64 million for the first year to support low-income families by helping low-income non-custodial parents (mainly fathers) support their children by paying child support and connecting or reconnecting with their children.

Question 36. The budget request includes $10 million for the Infant Adoption Awareness program, enacted as a part of the Children's Health Act. How will HHS ensure that women seeking pregnancy options counseling at federally funded centers receive information and referral on adoption? Aren't they required to provide this information already?

Response In order to implement Title XII, Subtitle A, Infant Adoption Awareness of the Children's Health Act, the Department will enter into cooperative agreements for the purposes of developing and implementing programs to train designated staff of eligible health centers in providing accurate adoption information and referral to pregnant women. Although some adoption counseling may already be provided by federally funded health centers, studies show that adoption is an infrequent outcome for women who go to title X clinics. Implementation of this legislation will ensure that clear and accurate information about adoption is presented, giving women choices and the opportunity to make decisions based on clear and accurate information.

Question 37. How will the $89 million Compassion Capital Fund works? How will effective charitable programs and social service organizations be identified?

Response: The FY 2002 budget includes $89 million for a new Compassion Capital Fund. The Fund will support several grants to public/private partnerships to provide start-up capital and operating funds to qualified charitable organizations that wish to expand or emulate model social service programs.

The fund will also provide funds for research on best practices among charitable organizations.

The HHS Center for Faith-Based and Community Initiatives and the Administration for Children and Families (ACF) are working with the White House Office of Faith-Based and Community Initiatives to develop guidelines or recommendations for specific proposals from charitable organizations.

Question 38. The Administration is requesting $90 million for the Healthy Start program. Will the Bush Administration help seek funding for initiatives recently authorized by this Committee within the Healthy Start program, such as mobile health clinics and pre-natal surgery?

Response: Health centers funded under section 330 of the Public Health Service Act provide, either through the staff or through contracts or cooperative arrangements, primary health services for all residents of the area served by the center. The required primary health services are defined at section 330(b) and include preventive health services with voluntary family planning services specifically identified. The HRSA's Bureau of Primary Health Care issued a policy notice on August 17, 1998, entitled *Health Center Program Expectations,* describing its expectations for all health center programs covered under section 330. The program expectation related to Clinical Systems and Procedures requires health centers to have written policies and procedures that address a number of elements including the use of clinical protocols. These clinical protocols should reflect the current guidelines established by health agencies or professional organizations. For example, the Guidelines for Women's Health Care issued by the American College of Obstetricians and Gynecologists indicates that, in the event of an unwanted pregnancy, the patient should be counseled about her options, one of which is to continue the pregnancy to term and offer the infant for legal adoption. Further, we are confident that the Infant Adoption Awareness training to be offered to health center staff will serve to enhance their knowledge about providing adoption information. Monitoring of health centers' use of appropriate clinical protocols is accomplished either through national accreditation reviews or the Bureau's Primary Care Effectiveness Reviews.

Question 39. How does the budget reduction for training health providers effect pharmacist training?

Response: The training of allied health care professionals under the Title VII Section 755 grant authority does not include the training of pharmacists. Pharmacists are excluded by definition as an allied health provider as are physicians, dentists and registered nurses. The budget reduction would, therefore, have no effect on pharmacist training. It would have a possible impact on the training of pharmacist technicians since they are considered an allied health profession.

Question 40. Can we expect a specialty designation for interventional pain physicians? If so, when?

Response: Recognized medical specialties in the United States meet the requirements of, and are recognized by, the American Board of Medical Specialties (http://www.abms.org), a private non-governmental 501(c)(3) organization. Additionally, there are special certifications for subspecialties within some, but not all, ABMS member organizations. A subspecialty pain certification is currently available through these recognized specialties: anesthesia, psychiatry and neurology, and physical medicine and rehabilitation.

All physicians should be familiar with basic pain management techniques and many disciplines include it in certification requirements and examinations. The discipline pf palliative care and American Board of Hospice and Palliative Medicine (ABHPM) focuses on pain management as well as management of other symptoms (such as shortness of breath, fatigue, and nausea) which cause suffering in the ill. The ABHPM has not been recognized by the ABMS and the desirability of doing so is subject to considerable debate and discussion.

Question 41. Congress mandated HCFA to implement a national Medicare ambulance fee structure by January 2000, and despite HCFA having its negotiated rulemaking Committee's recommendations in hand for over nine months, it has failed to release final regulations. And, in keeping with reimbursement policies enjoyed by the other 48 states, Congress also mandated that HCFA reimburse in-country ambulance mileage for both North Carolina and Tennessee by July 1, 2001, which the agency has also delayed. When will we see implementation of these two very important congressional mandates?

Response: CMS published the proposed ambulance fee schedule on September 12, 2000. Although the proposed rule was based on the negotiated rulemaking committee's recommendations, over 340 comments were received by the end of the comment period on November 13, 2000. CMS is carefully reviewing and analyzing all of the comments as they prepare the final rule. CMS shares your interest in implementing the fee schedule and is working expeditiously to publish the final rule.

Section 423 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act, required CMS to structure the phase-in of the ambulance fee schedule so that the Agency make payments for in-county mileage in certain states (e.g., North Carolina and Tennessee) for both the fee schedule portion of the payment, as well as the portion of the payment that is calculated under the payment method in place prior to the implementation of the fee schedule. This provision will be implemented concurrently with the fee schedule.

Question 42. North Carolina runs one of the most successful SCHIP programs in the United States. Unfortunately, last year the state was forced to freeze enrollment at 69,000 because the number of children wanting to enroll in Health Choice (100,000+) far exceeded the federal government's estimated number of potential enrollees (71,000). North Carolina simply did not have a large enough allocation from the federal government because of the poor estimate. Are you interested in revising future allocations using more accurate numbers?

Response: As you may know, in November 2000, North Carolina submitted their 5th amendment to establish a freeze on new enrollments in SCHIP. The amendment was approved in February 2001. At the time of the freeze, however, North Carolina had budgeted only $61.3 million of the $89.2 million in federal funds allotted to the state for FY 2000.

The SCHIP allocation formula was revised in the Balanced Budget Refinement Act which made changes to the SCHIP allotment formula stabilizing State allotments, imposing floors and ceilings on changes from one year to the next, and using a blend of low-income children and uninsured children starting in FY 2000. The Balanced Budget Refinement Act also included $10 million for the Department of Commerce to increase the sample size of the Current Population.

Survey to increase the reliability of the estimates of uninsured children by age, income, and race on a State by State basis. These changes, in combination with additional state funds, will enable North Carolina to enroll eligible children now on a waiting list and use all of their federal SHIP allotments.

Question 43. Last year, Congress passed and the President signed into law the Pubic Health Threats and Emergencies Act. How does the Department's FY'02 budget request reflect needed changes, infrastructure improvements and the like as required by that legislation?

Response: The Public Health Improvement Act authorizes HHS to undertake a broad range of activities to ensure that the Nation's health and medical systems are prepared in the event of bioterrorist attack. The Department's FY 2002 budget includes $353 million, an increase of $50 million (+17%) over FY 2001 and $93 million (+35%) above FY 2000, for the Department's bioterrorism preparedness activities authorized under the act. This includes:

- *Bioterrorism Core Activities:* $322 million from funds solely dedicated to HHS's Bioterrorism initiative, including surveillance and medical response activities.
- *NEDSS:* $27 million for the National Electronic Disease Surveillance System (NEDSS) at CDC, which supports bioterrorism detection and, communication in addition to surveillance for naturally occuring infectious diseases.
- *Centers for Public Health Preparedness:* $4 million provided to CDC's partners at State public health departments and academic institutions for demonstration projects designed to implement new technologies and training for bioterrorism preparedness and other public health emergencies.

The Act authorizes the Secretary of HHS, in coordination with the Secretary of Defense to establish a joint interdepartmental working group on preparedness and readiness for the medical and public health effects of a bioterrorist attack on the civilian population. The working group is tasked with the following responsibilities:

- *Coordinate research on likely bioterrorist pathogens including development of detection equipment, and shared standards for detection and protection (319F (a)(1)(2)(3)); Develop priorities for future research related to bioterrorism epidemiology, pathogenesis, and development of vaccines, therapeutics and medical diagnostics (319F(f)(1)(2)(3)(4)):* $123 million, an increase of $21 million (+20%) over FY 2001 and +$28 million (+29%) over FY 2000 for NIH biomedical research, CDC anthrax efficacy studies and development of the rapid toxic screen and smallpox and anthrax vaccine research and development.
- *Coordinate the development, maintenance and procedures for the release of strategic reserves of pharmaceutical supplies needed after a bioterrorist attack (319F(a)(4)):* $53 million for the maintenance and deployment planning of the National Pharmaceutical Stockpile at CDC and the National Medical Response Team medical caches supported by the HHS Office of Emergency Preparedness (OEP).
- *Train health care and public health personnel to recognize symptoms of bioterrorism, rapidly identify the pathogens, and coordinate medical care (319F(c)(3)(A)(B)(C)):* $64 million, an increase of +$17 million (+34%) above FY 2001 and +$25 million (+61%) above FY 2000 for CDC support of the Epidemic Intelligence Service, State & local planning and epidemiological capacity, and OEP's support of medical response teams, Metropolitan Medical Response Systems and training of medical and other personnel at Noble Training Center.
- *Coordinate rapid communication of data generated from a bioterrorist attack between national, State and local agencies and health care providers (319F(c)(3)(A)(B)(C)):* $71 million, an increase of +$9 million (+15%) over FY 2001 and +$21 million (+43%) over FY 2000 for development of the Health Alert Network, the National Electronic Disease Surveillance System (NEDSS), and the Department's new Cyber-Security Initiative to protect and improve HHS information systems needed for bioterrorism preparedness and response.
- *Develop and implement education programs to instruct public health and medical officials to recognize and treat victims of bioterrorism, and laboratory personnel to identify potential bioterrorist pathogens (319F(e)(1)(2)):* $38 million, an increase of +$4 million (+10%) over FY 2001 and +$18 million (+86%) over FY 2000 for CDC's national planning for preparedness and response, implementation of the Select Agent rule and laboratory training and support.
- *Make grants for not more than three demonstration projects to improve detection of pathogens and development of plans and measures to respond to bioterrorism (319G(a)). Demonstration Projects to Improve Detection and Planning:* $3.5 million, an increase of +$.5 million (+17%) over FY 2000 for Centers of Public Health Preparedness communications and training related to bioterrorism.

Question 44. What other steps does HHS intend to take to improve our nation's public health infrastructure? How are those steps reflected in the budget?

Response: The Fiscal Year 2002 Budget reflects a major change of displaying CDC's public health infrastructure programs in a single line, allowing for greater coordination and accountability in the areas that constitute Public Health Improvement: strengthening public health practice, awarding prevention grants to universities, eliminating racial and ethnic health disparities, building the National Electronic Disease Surveillance System, and building cross-cutting capacities and expertise. Categorical programs such as antimicrobial resistance and bioterrorism preparedness and response build upon these foundational activities. Within this new line, an increase of $1 million is targeted to begin implementation of the infrastructure portion of the Public Health Threats and Emergencies Act. Activities planned for FY02 include developing capacity performance standards for public health systems, measuring gaps, and building standards-based capacity on the foundation lay by the National Public Health Performance Standards Program. The following ac-

tivities are included in the FY2002 budget and illustrate how HHS will work to improve the nation's public health infrastructure:

- Provides technical assistance to 50 states to establish rapid communications capacity, access to training via distance-learning mechanisms, and Internet access for local public health officials through the Health Alert Network;
- Continues work with public health partners on the Global and National Implementation Plan for Public Health Workforce Development and, as part of this plan, the continuation of the Centers for Public Health Preparedness based in schools of public health;
- Supports the Public Health Grand Rounds program, a combined broadcast/Webcast series of public health program and case studies, with live satellite programs on such topics as Disaster Management, Genetics, and Asthma;
- Monitors and provides technical assistance for the 55 prevention grants to universities, with investigators at schools of public health, state and local health departments, and other academic- and practice-based organizations;
- Provides states with the capacity to tailor prevention programs to their health priority needs through the Preventive Health and Health Services Block Grant. The strategy behind the Block Grant is that it can be used to fund categorical services that may otherwise go unfunded. It can also supplement priority state programs funded through other means. States can use the Block Grant to address urgent, rapidly developing health hazards such as those that would occur during a bio-terrorism event. Funds could also be used for preparedness activities. For example, one state funded the development of a medical and health preparedness emergency response system for eight counties using monies obtained through the Block Grant.

A strong public health infrastructure is necessary if the US is to mount a rapid, effective, response to a bioterrorism event. Building on the activities targeted to improve public health infrastructure overall, the FY02 Budget provides a total of $182 million for CDC's bioterrorism preparedness activities. These funds will enable CDC to continue to assist states, US territories, and major metropolitan areas to develop and maintain core capacity for the primary components of a bioterrorism preparedness and response effort. For example, bioterrorism activities targeted for increased funds in the FY02 Budget include the following:

- Updating a national strategy for public health preparedness for bioterrorism;
- Increasing the detection and investigation capabilities for infectious disease outbreaks and rapid collection, analysis and dissemination of data;
- Rapid laboratory diagnosis of biologic agents and identification and management of chemical exposures; and
- Maintaining the National Pharmaceutical Stockpile to assure rapid availability of pharmaceuticals, supplies and medical equipment in the event of an attack. The Stockpile includes 8 A push packages containing antitoxins, therapeutic drugs, antidotes, and other supplies ready for rapid deployment to the site of a bioterrorism incident.

Antimicrobial resistance (AR) continues to be a worsening global problem that affects virtually all of the pathogens previously considered being readily treatable. Many important drug options for the treatment of common infections are becoming increasingly limited and expensive, and in some cases, nonexistent. In collaboration with numerous federal partners, A *Public Health Action Plan to Combat Antimicrobial Resistance,* released in January 2001, addresses this growing problem. The *Action Plan* calls for (1) developing a coordinated national AR surveillance plan for monitoring AR in microorganisms that pose a threat to public health; (2) promoting the appropriate use of antimicrobial drugs and preventing the transmission of infections (whether drug-resistant or not); (3) increasing our understanding of microbial physiology, ecology, genetics and mechanisms of resistance, and translating research findings into clinically useful products, such as novel antimicrobial therapeutics, diagnostic tests, vaccines and other tools that prevent AR emergence and spread; and (4) developing or evaluating new products to prevent, diagnose, and treat infections. With sustained funding of $25 million, CDC will continue the following activities:

- Provide grants to academic research institutions for applied research on antimicrobial resistance;
- Provide support to state/local health departments and healthcare systems for surveillance, prevention, and control of antimicrobial resistance; and
- Implement comprehensive community-based demonstration projects on antimicrobial resistance prevention and control.

Question 45. Does the Department foresee any changes in the operations of the Office of Emergency Preparedness? Is the $14 million request sufficient for the office

to provide medical and health-related services under Emergency Support Function 8 of the Federal Response Plan?

Response: The Department foresees some changes in OEP's activities. We will be expanding the number of Metropolitan Medical Response Systems (MMRS) beyond the original 120 envisioned in the Defense Against Weapons of Mass Destruction Act of 1996. OEP will be working with communities to link the local MMRS with rural areas as well as state systems. In addition, OEP will be working with hospitals to ensure that they are linked to MMRS activities and are prepared to accept WMD victims. The $14 million request in the General Departmental Management (GDM) is a part of the overall OEP budget request for FY 2002. While the budget request is divided between GDM and the Public Health and Social Services Emergency Fund (Emergency Fund), the request is not divided between ESF #8, WMD, or chemical, radiological or biological terrorism. Rather, the request encompasses an all hazards approach to disaster response. Similar to CDC's approach to building a bioterrorism response on a sound public health infrastructure, OEP has continued to build on a basic disaster preparedness and response for mass casualties and impacts to the health and medical infrastructure. The FY 2002 President's budget request for OEP (GDM and Emergency Fund) is sufficient for current infrastructure activities, as well as for the special WMD activities (MMRS, hospital development, Noble Training Center, and NMRT equipment, team maintenance and training/exercises). Provision of ESF #8 activities as part of the Federal Response Plan is centered in the all hazards approach to the emergency preparedness infrastructure.

Question 46. Can the Department describe its pharmaceutical stockpile management agreement with the Department of Veterans Affairs? Does HHS intend to continue using the VA to manage the medical response teams' stockpiles on a daily basis?

Response: CDC has responsibility for managing all aspects of the National Pharmaceutical Stockpile. CDC has a memorandum of agreement with the DVA's National Acquisition Center which enables CDC to utilize the multi-billion dollar purchasing power of the VA in procuring pharmaceuticals, medical supplies and equipment for the National Pharmaceutical Stockpile. However, CDC maintains full management responsibility for all aspects of the stockpile, including that purchased through the National Acquisition Center. Can the Department describe its pharmaceutical stockpile management agreement with the Department of Veterans Affairs? Does HHS intend to continue using the VA to manage the medical response teams stockpiles on a daily basis?

OEP has an agreement with VA to provide daily management of OEP's medical response team stockpiles. VA ensures that: the stockpiles are stored in secured facilities, with appropriate temperature and other controls; inventory records are maintained; the pharmaceuticals are appropriately rotated as expiration dates approach; HHS/OEP intends to continue to use the VA for this activity.

Question 47. Does HHS intend to expand the number of Disaster Medical Assistance Teams (DMATs) or National Medical Response Teams (NMTTs)?

Response: At this time, we do not have plans to increase the number of NMRTs (which currently total four). However, we are trying to increase the number of NMRT members in order to ensure that full team complements can be deployed as required. HHS is always ready to increase the number of DMATs, and we actively recruit team members as well as new teams and their sponsors. In addition, OEP works to increase the number of level-1 DMATs. These are teams that can field 35 medical professionals and support staff, can be ready to deploy to a disaster area within hours, and can be self-sufficient in hazardous and austere conditions for up to 72 hours. Currently, the National Disaster Medical System has a total of 27 level-1 teams.

Question 48. Does the Department foresee the various bioterrorism programs operated by the agency (Office of Emergency Preparedness, CDC, etc) working together?

Question 49. Your written testimony on page 18 indicates that there are still problems with the privacy regulation that will have to be fixed through guidelines and additional modifications. What kinds of changes do you believe are necessary?

Response: On July 6, 2001, the Department issued the first guidance package on the Privacy Rule. The guidance provided is meant to communicate as clearly as possible the privacy policies contained in the Rule. Each section has a short summary of a particular standard in the Privacy Rule, followed by "Frequently Asked Questions" about that provision. Among the privacy provision addressed in the guidance material are consent, minimum necessary, oral communications, business associates, parents and minors, health-related communications and marketing, research, and restrictions on government access to health information. Additional guidance materials and other forms of technical assistance will be provided by the Department to

facilitate implementation of and compliance with the Privacy Rule. In addition, the guidance identified areas of the Privacy Rule where a modification or change to the rule is necessary. For example, standards in the Privacy Rule for which we will propose changes are:

- *Phoned-in Prescriptions*—A change will permit pharmacists to fill prescriptions phoned in by a patient's doctor before obtaining the patient's written consent.
- *Referral Appointments*—A change will permit direct treatment providers receiving a first time patient referral to schedule appointments, surgery, or other procedures before obtaining the patient's signed consent.
- *Allowable Communications*—A change will increase the confidence of covered entities that they are free to engage in whatever communications are required for quick, effective, high quality health care, including routine oral communications with family members, treatment discussions with staff involved in coordination of patient care, and using patient names to locate them in waiting areas.
- *Minimum Necessary Scope*—A change will increase covered entities' confidence that certain common practices, such as use of sign-up sheets and X-ray lightboards, and maintenance of patient medical charts at bedside, are not prohibited under the rule.

We continue to review the input received during the recent public comment period to determine what changes are appropriate to ensure that the rule protects patient privacy as intended without harming consumers' access to care or the quality of that care. Other changes to the Privacy Rule may, therefore, be considered as appropriate. For example, HHS may reevaluate the Privacy Rule to ensure that parents have appropriate access to information about the health and well-being of their children.

Question 50. How will the Department distinguish State laws that are to be superceded and those, which are to remain, unimpaired?

Response: The statute provides specific criteria for which State laws are exempt from preemption by the Privacy Rule. State laws that meet the statutory criteria will remain unimpaired. In addition, the Privacy Rule provides a definition of "more stringent" which should aid in the identification of State laws which are exempt from preemption.

Question 51. What are the staffing and budgetary requirements for enforcement of this regulation by the Office of Civil Rights?

Response: In FY 2001, the Office for Civil Rights ("OCR") received $3.4 million for implementation and compliance activities associated with the Privacy Rule. In FY 2002, OCR has requested $ 5 million, which will allow for staffing of 33 FTEs focused on education, policy guidance and technical assistance activities. The resources required for compliance monitoring and enforcement will be reflected in OCR's FY 2003 budget request, since the rule will not be enforceable until April 2003.

Question 52. What is the impact of the privacy rule for the Medicare and Medicaid Programs and providers (such as Pharmacy Benefit Managers) participating in the programs?

Response: [Referred to CMS for response]

Question 53. According to a letter dated March 12, 2001 from American Psychiatric Association ("APA") to you, Mr. Secretary, "*Patients will lose some existing privacy protectionY as a result of the regulationY For example, currently when hospitals or doctors receive a request for a medical record from an attorney for civil and administrative purposes, they will generally not disclose medical records information without notice to the patient and /or the patient's consent. But the new regulation would allow providers to disclose medical records information to attorneys who write a letter 'certifying that the Y information requested concerns a litigant to the proceeding and that health condition of such litigant is at issue.' These procedures provide no check on attorney's behavior in requesting records of marginal relevance to a case or for the purpose of embarrassing or intimidating opposing parties*." Is this an area that you believe will need to be changed?

Response: According to a letter dated March 12, 2001, from American Psychiatric Association ("APA") to you, Mr. Secretary, "Patients will lose some existing privacy protection . . . as a result of the regulation. For example, currently when hospitals or doctors receive a request for a medical record from an attorney for civil and administrative purposes, they will generally not disclose medical records information without notice to the patient and/or the patient's consent. But the new regulation would allow providers to disclose medical records information to attorneys who write a letter 'certifying that the information requested concerns a litigant to the proceeding and that health condition of such litigant is at issue.' These procedures provide no check on attorney's behavior in requesting records of marginal relevance to a case

or for the purpose of embarrassing or intimidating opposing parties." Is this an area that you believe will need to be changed?

First, the APA unfortunately quoted a condition on the permissible disclosure of protected health information in a judicial or administrative proceeding that was contained in the Notice of Proposed Rulemaking issued in November, 1999. That provision was changed in the final Privacy Rule, issued in December, 2000. The final Privacy Rule permits the disclosure of protected health information in a judicial or administrative proceeding if there is a court order for such information or if there is otherwise adequate assurances provided that the individual whose medical information is being sought has been notified of the request in order to raise objections to the release of the information or that the information will remain confidential pursuant to a protective order.

Second, despite the change in the final Rule, some commenters continue to favor a stricter policy of requiring a court order for the release of any protected health information sought in a judicial or administrative proceeding. The Privacy Rule in no way impedes a covered entity from continuing a policy of releasing protected health information to a court or administrative tribunal only pursuant to a court order or the individual's consent. Given that the standard for disclosures for judicial or administrative proceedings is permissive in nature, and does not preclude practices that are more protective of privacy at the discretion of the covered entity, the Department is not contemplating any change to this standard at the present time.

Question 54. On page 17 of your written testimony, you state that the Administration is seeking an additional $26 million for research on health quality, and that a portion of those resources will be used to implement the Institute of Medicine's recommendations to eliminate medical errors. According to the 1999 Institute of Medicine report, To Err Is Human: Building a Safer Health System, in hospitals alone, almost 100,000 Americans die each year due to medical errors. If nursing homes, ambulatory care centers, home health services, and doctors' offices were included, estimates of the number of unnecessary deaths would be much higher. As the IOM stated in its report, "more people die in a given year *as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516)*." After months of investigation and research, the IOM reported:

The decentralized and fragmented nature of the health care delivery system (some would say "nonsystem also contributes to unsafe conditions for patients, and serves as an impediment to efforts to improve safety. Even within hospitals and large medical groups, there are rigidly-defined areas of specialization and influence. For example, when patients see multiple providers in different settings, none of whom have access to complete information, it is easier for something to go wrongY(Institute of Medicine, To Err Is Human: Building a Safer Health System, 2-3). If insufficient information leads to lower quality patient care, don't you believe that the "minimum necessary" standard needs to be rewritten so as to permit the development of common-sense practices in the health care setting to reduce medical errors?

Response: The Agency for Healthcare Research and Quality (ARHQ) is pursing a vigorous research program to identify and validate patient safety practices that can reduce the risk of injury to patients. ARHQ has just released a report that reviews the available scientific evidence on patient safety practices and rated 73 practices that are likely to improve patient safety and describes 11 for which there is strong evidence of effectiveness. During this current fiscal year, AHRQ plans to award over 60 research and demonstration patient safety grants. As our knowledge grows regarding which patient safety practices are scientifically demonstrated to be effective, the Department will continuously assess the standards governing our health care service delivery and payment programs to ensure that they facilitate, not frustrate, the safety and quality of patient care.

Question 55. As you know, it was under tremendous pressure from consumers, patient groups, and others that Congress passed FDAMA to speed up the approval process for new drugs, biologics and devices. This rule may in fact slow down that process, because although the rule sets out explicit standards for collecting information for future clinical trials, under the proposed rule it may be impossible or illegal to get information from subjects of previous clinical trials. How will you account for the best interests of patients and consumers as you fashion guidance for this regulation?

Response: We do not anticipate that this rule will affect access to information from prior clinical trials or affect in any way the timeliness of drug approvals by the FDA.

Question 56. Under the regulation, all covered entities will have to recontract with their business associates to require that the associates comply with the entities' privacy policies. We hear from hospitals and health plans that they may have upwards of 700 business associates each, some of whom may also be covered entities. Even

if they started today, they would have to sign a new contract on nearly every day in order to be in compliance in two years. Considering this was an administrative simplification requirement to start with, how does the Department plan to address this formidable paperwork requirement in crafting guidance for the final rule?

Response: The claim of hundreds of business associates for a given covered entity highlights the need for the business associate standards. Without any standards, an individual's private medical information could be handed over to vast numbers of commercial enterprises, most of which would have little or no obligation to protect the confidentiality of the information. The Privacy Rule does not interfere with these necessary business relationships, but it does require covered entities to obtain a written assurance from these business associates that they will appropriately safeguard the individual's protected health information. On July 6, 2001, the Office for Civil Rights (OCR) issued the first in a series of ongoing guidance and technical assistance materials to assist covered entities and others in better understanding what the Privacy Rule does or does not do. The business associate standards were one of the many topics addressed by the guidance. In the July guidance materials, we responded to three frequently asked questions concerning the limits of the Secretary's authority under the HIPAA statute with respect to business associates, the extent of their contractual obligations to the covered entity, and whether covered entities are liable for the privacy violations of their business associates.

Question 57. What if two covered entities are contracting with each other and their privacy policies vary slightly: What if a hospital has ten business associates who are covered entities with varying privacy policies? Does the Department have any guidance on this situation?

Response: As we make clear in the July guidance, the Privacy Rule's requirements are not A passed through to the business associate. There is no requirement that the ten business associates of the hospital follow the hospital's privacy practices. The business associate is required to provide assurances that protected health information will be appropriately safeguarded and used or disclosed to others only for purposes that are necessary to carry out its business associate functions. For example, if a hospital contracts out its billing function, the business associate must safeguard the protected health information received from the hospital and use or disclose that information only for the billing services that it provides and other activities needed to operate its business. A covered entity may be the business associate of another covered entity, in which case, its own privacy policies under the Rule would suffice as the appropriate safeguards required by the business associate provisions. The Privacy Rule does not required the covered entity that is acting as a business associate to conform to B or even know the details of B the other covered entities privacy policies.

Question 58. What is the Administration's timeline for putting the Security and Electronic Signatures standard in place?

Question 59. We understand that a need to clarify the most basic issue—the very definition of what is "individually identifiable health information," which is protected and governed by the rule, has been brought to your staff. The claim has been made that HIPAA allows states to regulate "individually identifiable health information: in a more stringent manner than the rule that has taken effect, but does not allow States to change the definition of what the rule covers. Further, If States can change what is and isn't governed by the rule the use of de-identified health data will be at risk. Can you tell our Committee if your staff has decided on the need to issue guidance or to make a modification to the rule on the basic definition of what the rule covers and what it does not?

Response: The preemption provisions of the statute, sections 1178 of the Social Security Act and 264(c)(2) of HIPAA, concern the issue of conflict between provisions of State law and the federal rule that imposes "requirements, standards, or implementation specifications." In general, we do not think that the definition of "individually identifiable health information" comes within this statutory preemption framework. We also note that the term "individually identifiable health information" is defined at section 1171(6) of the Social Security Act. In light of these considerations, we do not see a need to issue guidance or a modification of the rule concerning the definition of "individually identifiable health information."

Question 60. In the past, Members of the Committee have raised concerns about having a Federal floor instead of a Federal ceiling on privacy laws. A claim has been made that HIPAA allows States to regulate "individually identifiable health information" in a more stringent manner than the rule, but dos not allow States to change the definition of what the rule covers. Further, I've been told that if States can change what is and isn't governed by the rule, the use of de-identified health data will be at risk. Are you going to issue guidance on what States can or cannot do to regulate " individually identifiable health information?"

Response: As noted above, the preemption provisions are statutory. Therefore, the Department cannot address through guidance the Committee's concerns about the federal privacy provisions operating as a federal floor rather than a federal ceiling.

Question 61. Even before the April 14 effective date of the rule, we had an illustration of what may happen when State privacy laws are alleged to apply to the uses and disclosures of individually identifiable health information. The dispute between Quintiles Transnational and WebMD illustrates at least two of the problems likely to result from State preemption of federal privacy standards: first, that States may lack the expertise to address certain aspects of health information privacy, such as trying to define statistical methods for the de-identification of health information that ate "more stringent" than the federal standard and still allow the use of data for health research and vital public health purposes; and, second, that such State actions will be employed not to protect individual privacy but as part of a contractual dispute between covered entities and their business partners. Are you aware of the dispute between Quintiles Transnational and WebMD regarding the creation and transmission of de-identified health data, and a United States Federal District Court ruling that addresses the potential impact of the U.S. Constitution's Commerce Clause regarding any State's ability to interfere with commercial transactions that occur in other states?

Response: We are aware of the dispute in *Quintiles Transnational Corp. v. WebMD Corp.,* Civ. No. 5:01-CV-180-BO(3), E.D.N.C. We note that, in a ruling entered on March 21, 2001, the District Court granted Quintiles Transnational's request for a preliminary injunction requiring WebMD to continue to abide by the terms of the Data Rights Agreement between the parties. The court held that the Dormant Commerce Clause prevents the individual States from regulating the interstate transmission of data, and that WebMD, therefore, erred in relying on the privacy laws of some States to excuse its failure to perform its obligation to transmit data to plaintiff under the Data Rights Agreement.

Question 62. When can we expect to have all the regulations on administrative simplification finalized—security, enforcement, and national identifiers (provider, employer, and health plan)? In addition, when can we expect the national identifiers to be available for distribution?

Response: I have an ongoing, concentrated effort to implement the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996. Of the nine rules that comprise Administrative Simplification, five Notices of Proposed Rulemaking have been issued. Two of these, the Privacy and Transaction and Code Sets, have been issued in final, with corresponding compliance dates. CMS hopes to have the final Security and Employer Identifier rule published by this fall.

The Notices of Proposed Rulemaking have generated a large number of comments by the covered entities, including 17,000 comments on the Transaction and Code Sets, and in excess of 50,000 comments on the Privacy Notice of Proposed Rulemaking. Significant progress has been made on issuing notices of proposed rulemaking, categorizing, reviewing, and responding to the comments received, and issuing final rules. CMS is working as quickly as it can to complete work on the remaining rules.

Regarding the regulation and implementation of provider and health plan identifiers, the Department is reviewing how best to achieve this goal, as well as evaluating the budget implications.

Question 63. The industry anticipates significant modifications to the final rule on Electronic Transactions Standards as permitted under HIPAA. Do these changes need to go through an NPRM and Final Rule process? When do you think these changes will be in their final form?

Response: Yes, changes to the implementation guidelines recommended by the Designated Standards Maintenance Organizations must go through the Department's regulation process. The Department will be publishing a notice of proposed rulemaking, proposing the Designated Standards Maintenance Organizations' changes. Also, the specific proposed changes will be available shortly from the American National Standards Institute Accredited Standard Committee X12, Health Care Task Group—the nationally recognized electronic data interchange standards development organization for all forms of electronic commerce.

Question 64. What actions has the Department taken to educate physicians, hospitals and other providers on these regulations?

Response: There are substantial, on-going efforts to inform and educate all covered entities regarding the Administrative Simplification regulations. These include:

- Publication of all Notices of Proposed Rulemaking and Final Rules in the Federal Register, including any technical corrections
- A comprehensive, up-to-date website with all information relating to Administrative Simplification—available on the Web at: http://aspe.hhs.gov/admnsimp

- Active participation in meetings of standard setting organizations such as the Workgroup on Electronic Data Interchange, as well as congressionally mandated advisors such as the National Committee on Vital and Health Statistics;
- The issuance of *Guidance Documents* to help health care providers and health plans come into compliance with the regulations. The guidance is available on the Web at: http://www.hhs.gov/ocr/hipaa.

CMS is reaching out to educate physicians and other providers in a variety of ways. For Medicare, they are focusing on reaching providers, both directly and through the Medicare contractors. They expect that CMS Medicare contractors will be ready to begin testing HIPAA transactions for claims and remittance information this Fall.

- Disseminating articles through contractor bulletins and websites. The first article went out last Fall, and dealt primarily with transactions. CMS is planning additional articles regarding privacy, the National Provider Identifier, testing, security, and claims attachments.
- Offering web-based training for providers, including an overview of HIPAA. CMS also is developing self-assessment guidance. A draft of the full course on self-assessment will be completed in August, and the course should be available by the end of 2001.
- Offering several Web resources, a summary of which will be published on the Medlearn page by the end of July. Pointers will be provided to materials at Washington Publishing Company, Workgroup on Electronic Data Interchange, and other websites.
- Broadcasting information, via satellite, that is now available from our web-based training and presentation materials. The first broadcast is scheduled for later this year and should reach several thousand providers at 600 satellite sites. We will rebroadcast the information 3 or 4 more times.
- Developing a HIPAA brochure to be distributed at provider conferences.

My focus is on the State Medicaid programs and their critical intra and interstate trading partners, such as for Medicaid, the State Departments of Human Services that provide health, screening, diagnostic and nutritional services to low income children, mothers, the elderly and disabled.

While I expect each State to conduct their own HIPAA outreach efforts with physicians, hospitals, laboratories, pharmacies, nursing homes, and beneficiaries, CMS's role is to support State efforts and be a national resource on Medicaid HIPAA. To that end, CMS is working with staff at all levels of State government, including Department heads, Commissioners of human service agencies, State CIO's, legislative staff and the Governor's offices, who can provide executive support and resources to State HIPAA implementation efforts. CMS also has developed and distributed a 10-page bi-monthly newsletter, HIPAA Plus, covering news from national and regional sources. In April, CMS held the first annual National Medicaid HIPAA conference. Over 500 people from all 50 States and Guam attended the 3-day conference. They plan to hold the second annual conference in April 2002. In addition, CMS has developed an interactive tool States can use to conduct a HIPAA "gap analysis," called the Medicaid HIPAA Compliant Concept Model. This tool helps to highlight areas where States need to take action to ensure compliance. CMS has identified a representative in each State to assist with implementation of the model, and will hold monthly conference calls with States to share information. CMS will hold a working lunch at the MMIS conference in New Hampshire to review the new Version 2 of the model. The model is available on CD and on the web at Washington Publishing Company. Also, two brochures on the Medicaid HIPAA Compliant Concept Model have been distributed to the States, and a new brochure is in development now. Ultimately, one brochure will include a detailed view of HIPAA, a second will explain the Medicaid HIPAA Compliant Concept Model, and a third will be tailored for audiences requiring basic information on HIPAA.

In the Medicare+Choice area, CMS's focus is on the plans themselves. CMS expects that they will conduct their own outreach to their providers and trading partners. In addition, CMS is planning a managed care HIPAA conference for September, at CMS headquarters in Baltimore, and CMS is developing a HIPAA self-assessment tool specifically for managed care plans.

Question 65. With the recent announcement that HHS would implement the HIPAA as scheduled and as written, the President and HHS have taken a bold step towards protecting an individual's medical information. However, it is becoming increasing apparent that there are some flaws with the regulations. As an example, the regulations do not acknowledge that there are benefits to the public to know, through the press, about some basic health information. For instance, as presently written, some have argued that the public would not have been able to learn the status of the students shot at Columbine High School, the misconduct of health pro-

viders at a local hospital, or the medical condition of people involved in widespread or highly dangerous epidemics or diseases—unless, of course, each of the individuals consented to having this information released. Does HHS plan to address the lack of access to basic information that the public, including journalists, has the right to know or should know?

Response: The Department is aware of the concern of journalists and other members of the press that the Privacy Rule does not place the public's right to know above the individual's right to decide whether to disclose his or her private medical information. A proper weighing of the public v. private benefits is made particularly difficult in this case due to the widely disparate views on what is A newsworthy and what is merely commercially profitable. The balance struck in the Privacy Rule was that, provided the individual did not object, the public B including the press B would have access to basic information about an individual who has been admitted to a health care facility. Basic information would include the person's name, location in the facility and general condition. The only condition on access is that the person making the inquiry knows the name of the individual whose basic information is being sought. In addition, as the question acknowledges, the individual can authorize the release of the information. Finally, there is no problem with covered entities releasing information that does not identify the individuals involved. For example, a hospital could release numbers of persons admitted following an accident and how many were in serious condition. We will evaluate the comments made by journalists, as well as others, to determine if these requirements unduly burden freedom of the press.

Question 66. It is alleged by some that the recently implemented HIPAA regulations provide whistleblowers with no protection if they choose to go "outside the system." If for instance, a paramedic becomes aware that the ambulance service he or she works for will not service certain areas, that paramedic is prohibited from objecting to that policy to anyone but an attorney, a health care agency, a public health authority or a health care accreditation organization, and then, only under certain limited conditions As has been often documented, the working relationship between regulators and the regulated often results in situations where few complaints are found meritorious and regulators sometimes fail to perform their jobs. Does HHS plan to permit a whistleblower to go outside the system without being subject to criminal liability?

Response: The Privacy Rule provides when it would be permissible for a whistleblower to use or disclose protected health information in the course of exposing unlawful conduct, violations of professional or clinical standards, or other conduct that may endanger others. In many instances the complaint can be made without revealing the private medical information of any individual. The example used in the question demonstrates this. The Privacy Rule would not prevent a paramedic from publicly objecting to ambulance service disparities, including identifying areas of town which are underserved. It is not necessary to disclose individually identifiable health information to raise such objections.

Question 67. Given recent reports of increased drug prices, does the Administration believe that $150 billion over 10 years is adequate to provide a prescription drug benefit? How does the President purpose implementing his state-run plan given the extensive opposition by the states?

Response: The Administration is now proposing to spend $190 billion over the eight year period [FY2004-2011] on the Medicare drug benefit. We want to working closely with Congress in establishing the final specifications and administrative details of this program.

Question 68. The NIH testified last September that it invested $217 million in basic bio-imaging research in FY 1997 and indicated that spending in this field had increased since then. It is the Committee's understanding, however, threat NIH plans to transfer a much smaller amount of basic imaging and bioengineering grants to NIBIB. What is the funding level, which NIH has dedicated to NIBIB? How does this relate to the NIH resources dedicated to bio-imaging and bioengineering research in the past?

Response: We are excited about the new opportunities that the new National Institute of Biomedical Imaging and Bioengineering (NIBIB) will create for support of fundamental research that applies principles of engineering, mathematics, computer science and the physical sciences to biological processes, disorders and diseases.

The President's budget request for NIBIB for Fiscal Year 2002 is $40 million. These funds will be supplemented through a transfer of appropriate grants to NIBIB from other NIH Institutes and Centers (ICs). The process for identifying the appropriate grants for transfer is underway. After we review the entire slate of grant transfer candidates, NIH will submit the transfer information to the House and Senate Appropriations Committees for final approval and incorporation into the

FY 2002 budget for NIBIB. We believe that this initial budget will form an adequate base upon which to build future year funding requests for the NIBIB and will permit careful stewardship and oversight of research programs in the first year of this newest of the NIH ICs. As rich opportunities emerge, we will adjust our future budget requests accordingly Institutes. As rich opportunities emerge, we will adjust our future budget requests accordingly. The transfer of grants to NIBIB is intended to strengthen and complement, not subtract from or substitute for, research programs in the other NIH ICs. NIBIB will support *undifferentiated* research not related on a one-to-one basis to the mission of another IC and act as a unique focal point for multidisciplinary research planning and strategic development. The other NIH ICs will continue those studies that are a natural fit within their current organizations those focused on specific diseases or conditions. The ICs and key constituencies in the imaging and engineering communities have endorsed this strategy for building the new Institute and continuing to support these studies across NIH.

Question 69. The President has stated publicly his opposition to medical research on human embryonic stem cells. In fact, Mr. Secretary, you recently canceled a meeting of the NIH Committee responsible for reviewing applications from scientists seeking federal funds for this type of research. Please provide for the Committee the findings upon which President Bush has based his position that human embryonic stem cell research should be limited. Please also include a detailed description of the Bush Administration's position on stem cell/fetal tissue research, including when it is or is not appropriate.

Response: The President is consulting with advisors and appropriate agencies who have been formulating policy recommendations in this area which is receiving close and careful attention.

Question 70. Can you assure us that Congress' intent to provide adequate Medicaid payments to health centers will be protected by not applying the Upper Payment Limit to Medicaid payments made to individual Federally qualified health centers or, likewise, to all health centers in a State?

Response: CMS has not previously had to examine the interplay between its regulations on maximum payments to clinics and its payment rules for Federally Qualified Health Centers. In order to respond to your question, I have taken a look at the issue, but my answer here is preliminary at best.

It appears that because Federally qualified health centers fall into the clinic provider category, they are covered by the provisions of the Upper Payment Limit regulatory changes implemented in March of this year. However, since Federally Qualified Health Centers also have specific payment rules that were based on reasonable costs and are now governed by the new Prospective Payment System, I also believe that the Upper Payment Limit provisions would not come into play. So even though Federally Qualified Health Centers may be covered by the Upper Payment Limit regulations, those regulations should not result in any adverse impact on Federally Qualified Health Center payments.

Question 71. Some have expressed a concern that Congress is giving NIH too much money without any guidance on where that money should be spent. While we have teaching hospitals and researchers all around the country that would benefit from extramural NIH grants, a significant amount of the money is spent on campus at NIH, and it seems likely that a large portion will be spent on bricks and mortar construction. Would you support that use of research money?

Response: The NIH budget supports the individual research projects conceived of and conducted by either government scientists working in the NIH facilities or scientists working at universities or other institutions across the country and around the world. NIH support of these research projects includes, in whole or in part, the salaries of scientists and technicians, and the cost of equipment, supplies and procedures employed in the research. Biomedical research funding also encompasses the costs associated with providing and maintaining the physical infrastructure that is an essential component of the research enterprise.

The Buildings & Facilities (B&F) appropriation supports the essential physical infrastructure required to carry out the intramural part of NIH's biomedical research mission. Rapid advances in the understanding of basic biology and the complexity of human disease are providing unique research opportunities for new treatments and cures. As the approaches to basic and clinical research evolve, the demands for, and on, research facilities change as well. Properly planned and equipped, safe, and flexible research facilities are important resources in the formula for achieving the next scientific advance or biomedical breakthrough. These facilities underpin the pace at which research can advance by accommodating new research tools and instruments, providing infrastructure, such as information technologies, and supporting animal models to investigate new therapies.

More than 80% of the NIH budget goes to extramural programs, about 10% is for intramural research, and only about 1% is for the NIH facilities infrastructure. The Congress reviews the programs in the NIH B&F budget request as line items, and the amount appropriated is balanced in terms of the intramural research needs and those of the entire NIH supported research enterprise. The B&F budget is the product of a deliberate, corporate, facilities planning process that addresses the immediate and longer-range facility requirements to meet the research needs of the entire agency. It strikes a balance among three critical facility priorities: the creation of new facilities for new and expanding scientific opportunities, the upgrading of existing facilities to keep pace with the changing requirements of ongoing NIH programs and the responsible stewardship of the entire NIH real estate portfolio. The proposals for new construction, renovations and maintenance are key elements to ensuring the vitality of the NIH biomedical research enterprise.

Question 72. Regarding the cuts in rural health for telemedicine and outreach programs. Why is the President proposing to cut one of the most innovative and cost effective mechanisms that ensures access to specialty services for rural patients? The health care community has slowly been moving in the telemedicine direction for many years, slowly due to the high cost of technology.

Response: The reductions in both the telemedicine and outreach programs are not cuts. The reductions are due to the removal of earmark funding from both authorities. The Outreach Line in FY 2001 had $19.5 million in congressionally earmarked projects. The base amount for the program, the amount that was given out in competitive grants, was $31.067 million. For FY 2002, the Administration is proposing flat funding for this program with a total of $31.067 million.

Question 73. Regarding the cuts for health professions training programs from $353 million in '01 to $140 million in '02, a cut of $213 million. This funding supports training for a number of health care professionals including allied workers. We are facing a shortage of health professionals in the health care community. How can the President propose to help the uninsured through tax credits, thereby increasing utilization of health care services and at the same time cut programs that support training of health care professionals? Who is going to take care of the newly insured individuals when they try to access the health care system?

Response: The Department is very concerned with health professionals workforce issues. HRSA's health professionals programs have worked to expand the health professionals workforce as well has recruit providers to underserved areas of the country. With regard to physicians, there is no longer an overall shortage. Between 1970 and 1988, the supply of physicians grew 127% and current data indicate that the physician to population ration remains steady. The Department is working to address emerging shortages in the disciplines of nursing and dentistry. The President's fiscal year 2002 budget requests an increase of $5 million for Nursing Workforce Development and an increase of $1.4 million within the Public Health Workforce Development cluster for dental public health programs. Additionally, Secretary Thompson is using his transfer authority to increasing funding to HRSA's Nursing Loan Repayment Program by $5 million this fiscal year. Finally, the Department is considering management reforms to the National Health Service Corps to improve the programs ability to recruit and retain qualified primary care providers to underserved areas.

Question 74. I represent a rural state, Wyoming, so I am naturally concerned about ensuring adequate health services in rural areas. How does the President's budget specifically address the needs of rural communities?

Response: The Administration continues to support rural health. For FY 2002, the Administration proposes level funding for all of the key rural health programs: Outreach, Telehealth, State Offices of Rural Health, the Rural Hospital Flexibility Grant Program and the Rural Health Research Center program. These programs help build rural health infrastructure development through grant awards under the Outreach Program and the Rural Hospital Flexibility Grant Program. The State Offices of Rural Health Program provides matching grants to states to maintain a rural focal point within each of the 50 states. In addition, the Rural Health Research Center grant program provides grants to six rural health research centers to conduct policy relevant and rural specific health services research. The Administration also provides level funding to the policy activities of the Federal Office of Rural Health Policy to continue its work within the Department on behalf of rural communities.

Question 75. The National Health Service Corps is a very beneficial program in helping to recruit and retain health care providers in my state. The President has expressed his support for this program, and has provided an increase in funding for it in the budget. I also understand that the President is calling for various reforms

within the program. Could you please explain what specific reforms the President is proposing?

Response: We are examining the ratio of scholarships to loan repayments awarded as well as other set-asides to ensure maximum flexibility to better meet community requests for NHSC providers. To more accurately define shortage areas and target placements better, the Administration will seek to amend the shortage area definition to reflect other non-physician providers practicing in communities. We are also planning to enhance coordination with immigration programs such as the J-1 visa program.

Question 76. The President's budget calls for reductions in funding for Health Professions and the elimination of the Community Access Program, both of which service rural areas. Can you please explain the rationale behind this?

Response: The Bureau of Health Professions' program that primarily supports rural areas is the Quentin N. Burdick Program for Rural Interdisciplinary Training. While successful, this program supports relatively small training efforts that have secured support from other funding sources, including other Federal programs such as the Administration on Children and Families and private foundations, such as the Robert Wood Johnson Foundation. States participating in this program have found it to be a significant healthcare workforce pipeline for rural underserved areas. Since rural health workforce shortages are evident in all 50 states, we believe that we must work to attract health care students to the rural areas with rural clinical training experiences that are supported by training programs like the Quentin N. Burdick Program for Rural Interdisciplinary Training. To accomplish this goal the Bureau of Health Professions promotes the inclusion of a rural component in all of its grant programs.

Question 77. I have concerns about Medicare reimbursement rates as they apply to rural vs. urban areas. There currently seems to be a great deal of disparity, and it is having a negative impact on the providers in my district.

Take for example the town of Jackson Hole, in my home state of Wyoming. It is an affluent area with a cost-of-living comparable to the New York area. Medicare's allowable charge for a routine EKG in WY is about $25, in NY $59. A physician would be reimbursed $20 in WY for that EKG whereas in NY reimbursement would be $47. I have trouble understanding that disparity, especially when it is the very same test being administered in both places. This is causing many providers in rural areas to pull out of Medicare.

Knowing that Medicare reform is a priority for this Administration, I would like to know if you see the Medicare reimbursement formula as problematic? If yes, does the Administration plan to address this, and how?

Response: I recognize rural providers frustration with this system, and Congress, CMS, and I have worked to ensure all providers are paid appropriately. Rural states have long argued that, due to the way the wage index is calculated, payment amounts are weighted toward urban areas. There is a strong argument to be made, and obviously this is a difficult issue to address. I also share your concerns about providers in rural areas pulling out of Medicare, and I want to work with you to ensure that all Medicare beneficiaries have access to affordable, quality health care, regardless of where they live.

As required by law, physician services paid under the physician fee schedule are divided into three components: 1) physician work, 2) practice expense (such as employee wages, rents, and medical equipment and supplies), and 3) malpractice insurance. On average, physician work represents 54.5 percent of the total relative value, practice expenses represent 42.3 percent, and malpractice represents 3.2 percent. Payments for a particular service vary among 89 geographic fee schedule payment areas only to the extent that the resource cost of providing such services varies. This variation is measured by geographic practice cost indices which, by law, compares the local costs in each of the 89 areas to the national average for each of the three components.