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A REVIEW OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES FISCAL YEAR 2009 BUDGET

HEARING

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

FEBRUARY 28, 2008

Serial No. 110–90

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE
49–472 PDF WASHINGTON : 2009

For sale by the Superintendent of Documents, U.S. Government Printing Office
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C O N T E N T S

	Page
Hon. John D. Dingell, a Representative in Congress from the State of Michigan, opening statement	1
Prepared statement	2
Hon. Fred Upton, a Representative in Congress from the State of Michigan, opening statement	3
Hon. Henry A. Waxman, a Representative in Congress from the State of California	4
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey	4
Hon. Sue Wilkins Myrick, a Representative in Congress from the State of North Carolina, opening statement	6
Hon. Tim Murphy, a Representative in Congress from the Commonwealth of Pennsylvania, opening statement	6
Hon. Bart Stupak, a Representative in Congress from the State of Michigan, opening statement	7
Hon. Eliot L. Engel, a Representative in Congress from the State of New York, opening statement	7
Hon. Marsha Blackburn, a Representative in Congress from the State of Tennessee, opening statement	8
Hon. Lois Capps, a Representative in Congress from the State of California, opening statement	8
Hon. Jane Harman, a Representative in Congress from the State of California, opening statement	9
Hon. Hilda L. Solis, a Representative in Congress from the State of California, opening statement	9
Hon. Albert R. Wynn, a Representative in Congress from the State of Maryland, opening statement	10
Hon. Jan Schakowsky, a Representative in Congress from the State of Illinois, opening statement	10
Hon. Gene Green, a Representative in Congress from the State of Texas, opening statement	11
Prepared statement	12
Hon. Edolphus Towns, a Representative in Congress from the State of New York, prepared statement	62

WITNESS

Michael O. Leavitt, Secretary, Department of Health and Human Services	13
Prepared statement	14
Answers to submitted questions	63

A REVIEW OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES FISCAL YEAR 2009 BUDGET

THURSDAY, FEBRUARY 28, 2008

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

The committee met, pursuant to call, at 9:40 a.m., in room 2123 of the Rayburn House Office Building, Hon. John D. Dingell [chairman of the committee] presiding.

Members present: Representatives Dingell, Waxman, Markey, Pallone, Eshoo, Stupak, Engel, Wynn, Green, DeGette, Capps, Harman, Schakowsky, Solis, Gonzalez, Inslee, Barrow, Hill, Barton, Hall, Upton, Shimkus, Wilson, Fossella, Pitts, Terry, Ferguson, Myrick, Murphy, and Blackburn.

Staff present: Bridgett Taylor, Purvee Kempf, Amy Hall, Yvette Fontenot, Hasan Sarsour, Melissa Sidman, William Garner, Jeanne Ireland, Jack Maniko, Jessica McNiece, Virgil Miller, Jodi Seth, Brin Frazier, Lauren Bloomberg, Jonathan Brater, Jonathan Cordone, Dennis Fitzgibbons, Ryan Long, Nandan Ken Kermath, Chad Grant, Melissa Bartlett, and Linda Walker.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Today the Committee will hear testimony from the distinguished Secretary of Health and Human Services in support of the Administration's fiscal year 2009 budget request.

The Chair advises members that we will follow the usual procedures as prior full committee hearings have done with respect to opening statements and questions. In brief summary, members who are present when the committee is called to order will be recognized in order of their seniority on the full committee. Second, members who arrive after the committee is called to order will be recognized in the order that they arrive at the hearing. But all members in this category will be recognized after members who were present when the Chair called the committee to order, and the clerk will make the necessary notations.

Without objection, the full statement of the Chair will be inserted in the record, and Mr. Secretary, we welcome you and thank you for being here. I would just say in my welcoming remarks, unfortunately, Mr. Secretary, you appear before the committee under circumstances I think neither of us would have sought and I would

observe that the differences that are probably going to be existing between you and the members of the committee and the Chair will be related to activities of persons elsewhere rather than either of us.

In any event, first on February 1, the Committee sent a detailed request for information regarding important programs administered by the Department including Medicare for seniors, SCHIP for children, Medicaid for low-income families and the safety of food and drug supplies. The response to that letter was received approximately 12 hours ago, I note not in sufficient time to assist the Committee in its inquiry today.

Second, recently a distinguished panel of experts from FDA Science Advisory Board recommended the agency's non-user fee budget be increased by $375 million for 2009. That is regrettably seven times greater than the budgetary request that you have been permitted to submit to the Committee, Mr. Secretary.

Third, over the next 10 years the budget proposal would cut Medicaid by nearly $83 billion, reduce Medicare spending by $576 billion and inadequately fund the State Children's Health Insurance Program below the levels of the discussion in the fight we had over this program last year and early this year. This is the very same program that we tried to improve on a bipartisan basis but was twice vetoed by the President.

Fourth, the budget proposal would cut traditional Medicare providers while protecting the interests of private HMOs and fails to help physicians with a looming 10 % cut in their fees.

Mr. Secretary, this Committee is going to have to continue its vigorous review of your department's programs to ensure that the American people are protected and that their government fulfills its promises to them to provide healthcare for its most vulnerable citizens. We look forward to your cooperation, and I know you share these objectives personally even if the evidence is available that the Administration does not.

[The prepared statement of Mr. Dingell follows:]

STATEMENT OF HON. JOHN D. DINGELL

Today we are pleased to have Secretary Leavitt to discuss the President's Fiscal Year 2009 Budget for the Department of Health and Human Services.

This year's budget request proposes significant cuts in vital health coverage and public health programs that would actually hurt efforts to provide health insurance to our Nation's children. It would not provide enough funding to preserve coverage for the children currently enrolled in the State Children's Health Insurance Program (SCHIP). It would unwisely eliminate SCHIP coverage for children in families with incomes above $44,000 a year, and it would restrict the ability of States to cover children in families with incomes above $35,200.

Coupled with Medicaid cuts of nearly $83 billion over the next 10 years, and an unauthorized regulatory assault on the Medicaid program, it appears that the mission in the waning days of this administration is to shred the health insurance safety net. We have heard from several Governors that these regulations are excessively burdensome for the States and for Medicaid beneficiaries.

This budget also proposes a reduction of $576 billion over the next 10 years in Medicare program spending. That is an astonishing figure, but what is more astonishing is that it proposes drastic cuts to traditional Medicare providers such as doctors and hospitals, while protecting private HMOs. Private HMOs in Medicare will continue to receive excessive payments at the expense of beneficiaries, other providers, and taxpayers.

In order to protect special interests and advance its privatization agenda, the Bush Administration continues to ignore recommendations from outside experts

that HMO payments be reduced. Under this budget, beneficiaries will lose their choice of doctor and hospital and be forced into HMOs. The vision in this budget, if it has one, is that traditional Medicare will, in the words of former Speaker Gingrich, "wither on the vine."

Beneficiaries would also take a direct hit from this budget. It would dramatically increase the number of beneficiaries paying a higher Part B premium, and it proposes tying Part D premiums to income.

Finally, the President's budget does nothing to address the pending 10 % cuts to physician fees, a real failure of leadership. This decision, combined with the new cuts proposed for both Medicare and Medicaid, leaves little doubt that the Administration is dramatically unraveling our national commitment to provide health care to our most vulnerable citizens.

Unfortunately, public health priorities in the President's FY2009 budget fare little better. Under the Administration's proposal, six of the eight Public Health Service Act agencies charged with protecting the Nation's health and well-being would receive critical cuts to their budget. As for the other two agencies, the National Institutes of Health (NIH) would receive flat funding and the Food and Drug Administration (FDA) increase is woefully inadequate.

I am particularly disappointed in the level of increase that the Administration has allocated for the FDA FY2009 budget. After the number of food and product recalls last year, many had hoped that the Administration would finally request the resources needed to ensure that the FDA could fulfill its mission to protect the public health. Unfortunately, that does not appear to be the case.

In fact, the Chair of the recent FDA Science Board subcommittee report testified before the Subcommittee on Oversight and Investigation that FDA's science base and resources had eroded so much that the Science Board concluded that "Americans lives are at risk."

Furthermore, the Administration budget proposes only flat funding for the NIH. This would further erode the Nation's premier biomedical research capacity, harming the health of Americans now and in the future. Because 80 % of NIH's annual funding goes out through grant, contract, and training awards to extramural scientists throughout the country, it provides important investment in many economically troubled regions of the country, including my State of Michigan.

The Centers for Disease Control and Prevention (CDC), the premier public health disease prevention and control agency, is slated for a $433 million cut. This would threaten our Nation's capability to prepare, detect, and control infectious diseases. It would also threaten our capacity to adequately conduct bioterrorism preparedness. Finally, it would threaten our capacity to provide vaccines to children. Unfortunately, CDC is one of six public health agencies for which the Administration has proposed budget cuts.

In closing, I would like to point out an inconsistency in the President's budget proposal. The President's budget would slash funding for many important health programs, and it would eliminate some altogether, such as the Prevention Block Grant and Health Professions programs.

As justification, President Bush states that the programs are "not based on evidence-based practices" and, in another case, that "evaluations have found these activities do not have a demonstrated impact." I am confused as to why the President does not apply these same standards to the "abstinence-only" programs, for which he has proposed another huge increase of $28 million, despite the fact that study after study, including a 10-year study commissioned by the President's own Administration, has shown these programs to be ineffective at best, and in some cases actually counterproductive.

Mr. Secretary, we have many questions about the Administration's budget for Fiscal Year 2009. The Committee welcomes you as we look to the Administration to explain its justifications for many problematic proposals.

Mr. DINGELL. Mr. Secretary, the Chair recognizes now our good friend, Mr. Upton.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman. I just want to say, I am not sure—I have got other committee business this morning. I may not be here, knowing that we have got a lot of questions that

will be here. I welcome your attendance and I respect you quite a bit. I look forward to continuing to work with you.

I just hope in your testimony you are able to talk a little bit about the Medicare physician fee schedule, which as you know expires or we come to a threshold decision date come July 1. I note that there was nothing in the President's budget relating to that, and I sure would welcome in your testimony this morning ways for us to work together to address that. It is an urgent need certainly in Michigan where we see a number of physicians deciding not to accept patients if we don't deal with this issue, and again, I welcome you here today and I look forward to your testimony. I yield back.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes now the distinguished gentleman from California, Mr. Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Secretary, I want to welcome you to our committee. I wish you were here to give us better news about the budget that the President is proposing instead of what we will hear is that the most that an agency could hope for in this budget is to be flat-funded, and more typically, budgets were slashed.

I am particularly concerned about the President's budget for FDA. The most recent of many reports indicating FDA is in serious trouble came from FDA's own Science Board. This chronic underfunding has jeopardized the FDA to the point that American lives are now at risk. We have asked the Science Board for their review of the budget. They told us FDA would need an increase of over 5 times what the President had requested. It is clear that Congress is going to have to adjust the President's budget proposals to reflect the realities of public health that we face.

The budget also creates a crisis that doesn't now exist by including seven new Medicaid regulations that will go into effect. Just the other day we heard from governors on a bipartisan basis, they expressed their really enormous concern about those Medicare proposals. I hope we can discuss them further today and in the future, and I stayed a little bit within the 1 minute but exceeded it by a few seconds, but thank you very much.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes now the gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I will defer for questions.

Mr. DINGELL. The gentleman waives. The Chair recognizes now the distinguished gentleman from New Jersey, Mr. Pallone.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

The President intends to slash roughly $200 billion from the Medicare/Medicaid programs. He is proposing to do this by shifting

costs to the States, providers and beneficiaries, and in the wake of an economic downturn, I can't imagine a worse idea. States are already struggling with a lack of funding. In my home State of New Jersey, for example, our governor had to freeze State spending in order to close our budget shortfall, and more and more hospitals are closing in New Jersey including Muehlenberg Hospital in my district, which announced its closing last week.

The Bush Administration has launched an all-out attack on Medicaid over the last year. Two days ago we had a hearing in the Health Subcommittee to discuss some of the very harmful regulations that have been recently issued, and this budget proposal is no different. It includes $33 billion in cuts to the Medicaid program. For the Medicare program, the President has proposed $116 billion in cuts over 5 years, and these cuts are focused mostly on hospitals, nursing homes and healthcare providers, the exact services that our seniors need the most: access to healthcare, inpatient treatment and long-term care.

Perhaps the most infuriating aspect about these Medicare cuts is that they will be used in part to finance overpayments to HMOs. MEDPAC, the Medicare Payment Advisory Commission, our expert advisory body on Medicare payment policy, recently reported that CMS is paying the private insurers on average 13 % more than traditional Medicare pays for the same treatment. MEDPAC actually called for the elimination of these overpayments and, forgive me, but it seems wrong to cut funds for vital Medicare services that our seniors need to stay healthy in order to overpay insurance companies.

Another alarming aspect of this budget proposal is the way the President has portrayed the request for CHIP monies as a funding increase. In his budget, however, the President only requests $19.7 billion for CHIP while the Center on Budget and Policy Priorities estimates that CHIP needs a funding increase of $21.5 billion to simply sustain the current programs.

And finally, I would like to mention the funding for the FDA. Just a few days ago, the Energy and Commerce Committee received a report from the Science Board that estimated the cost of adequately funding the FDA. The FDA is in need of a serious infusion of cash and talent in order to fulfill its scientific and regulatory mission yet unfortunately the Administration shortchanges this critical agency, thus imperiling the public health.

Now, Mr. Chairman, I have a lot of other concerns with the President's budget proposal, which I will get to during the questioning, but I think in the last few days between our Health Subcommittee hearing and these Medicaid rules and what we have heard in the oversight on FDA, we need to make a lot of changes. This budget really is a disaster, in my opinion, for the healthcare system.

Thank you, Mr. Chairman.

Mr. DINGELL. The Chair thanks the gentleman. The Chair recognizes now the gentleman from Nebraska, Mr. Terry.

Mr. TERRY. I waive.

Mr. DINGELL. The gentleman waives. The Chair recognizes now the gentlewoman from California, Mrs. Eshoo.

Ms. ESHOO. Mr. Chairman, thank you. I will defer for questions. Thank you.

Mr. DINGELL. The gentlewoman defers. The Chair recognizes now the distinguished gentlewoman, Ms. Myrick.

OPENING STATEMENT OF HON. SUE WILKINS MYRICK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Ms. MYRICK. Thank you.

Mr. Secretary, welcome, and I just want to echo Mr. Upton's comments relative to the doctor payments, and the only other thing I wanted to say is, I really hope that we can look at the Medicare issue in a broader context because we have got to deal with it and we just keep tinkering around the edges, which is going to cost us more in the long run. I am interested to hear what you have to say.

Mr. DINGELL. The time of the gentlewoman has expired. The Chair recognizes now the gentleman from Massachusetts, Mr. Markey.

Mr. MARKEY. I would like to reserve my time.

Mr. DINGELL. The gentleman reserves his time. The Chair recognizes now the gentleman from Pennsylvania, Mr. Murphy.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman.

As we look at this budget for health and all the areas it encompasses, I know you have continued to push for areas of transparency, and what I still believe in the coming months that can be done that I hope that we can make sure there is adequate funding for a few areas.

Number one, we still face the problem with 90,000 deaths of a year, 2 million cases and $50 billion a year wasted on infections people pick up in the hospitals. We still have perhaps $28 billion or more a year we waste on people having prescription errors and the medication problems that come with that and we can move forward with electronic prescribing. We still have massive amounts of money, as you know, that we waste from not having electronic medical records whereby people have tests done and procedures done that we could bypass.

I hope that you will continue to be highly energized on working on these issues because I believe, as I believe you do, that people have a right to know, and by engaging them with Medicare and Medicaid and every other branch that your department has, that we ought to be changing this. It still puzzles me that people can find out if they are going to leave the airport on time with their airplane but they can't find out if they are going to leave their hospital at all, and we have to change that and people have that right to know.

Thank you.

Mr. DINGELL. The Chair recognizes now the distinguished gentleman from Michigan, Mr. Stupak.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. The Subcommittee on Oversight and Investigation has held five hearings on food safety in this Congress, most recently our hearing on Tuesday with representatives from the companies that have issued food recalls. Americans have witnessed one food safety disaster after another with 91 recalls over the past 14 months. Each year 76 million Americans will suffer from foodborne illnesses, 325,000 will require hospitalization, and at least 5,000 will die. In fact, during our food safety hearing on Tuesday, FDA announced two more recalls, one on crackers and another on dried fish coming from Asia. The FDA's Science Advisory Board has acknowledged that the FDA's current condition is putting American lives at risk.

I was looking forward to see what the Administration planned to do to fix this fragmented food and drug safety system in its fiscal year 2009 budget. Needless to say, I was disappointed. Unfortunately, I don't believe this Administration is serious about protecting the safety of our food and drug supply.

My time is up, and I look forward to hearing your answers to our questions. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

Mr. DINGELL. The Chair thanks the distinguished gentleman. The Chair recognizes my distinguished friend and colleague, Mr. Pitts.

Mr. PITTS. I reserve my time.

Mr. DINGELL. The gentleman reserves his time. The Chair recognizes now the distinguished gentleman from New York, Mr. Engel.

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

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

I am dissatisfied with the budget. It clearly is intended to achieve cost savings by any means regardless of the damaging health outcomes, but I want to, Mr. Secretary, highlight an issue of very big importance to us in New York but really for the whole country, and that is, following the terrorist attacks on September 11 and the collapse of the World Trade Center towers, hundreds of thousands of people including responders, area residents, workers and students were exposed to toxins, pulverized building materials and other environmental contaminants. These people are suffering, they are dying, and we need a national response.

I am angered that this proposal includes a 77 % funding cut for September 11 healthcare programs from $108 million appropriated for fiscal year 2008 down to $25 million for fiscal year 2009. This is a disgrace. Last month New York delegation members sent a letter to the President asking him to ensure that 9/11 health clinics, which are expected to need more than $200 million this year alone, are fully funded in his fiscal year 2009 budget and I would hope that you could achieve that, Mr. Secretary. We were told by Christie Todd Whitman at the time that the air was okay to breathe. We were lied to by the government. This is an attack on

America, not a New York issue. Every district has people living in it that had first responders and we really need to act, and this budget doesn't do it.

I was there with the President 3 days after September 11 when he had the bullhorn and he said that we would never forget what happened and never forget the people. This budget forgets the people and we need to have money appropriated so that our first responders are not sick and dying and that the government takes care of them, so I would hope that we can talk a little more about that later on. Thank you.

Mr. DINGELL. The Chair thanks the gentleman. The Chair recognizes now the distinguished member, Ms. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman, and Mr. Secretary, welcome. We are delighted you are here.

I am looking forward to talking with you and continuing to work with you on a couple of issues: Number one, the trajectory that Medicare and Medicaid spending is on, going from 4½ % of our GDP to when you look at 2050 and the outlying years the %age, 22 % of the GDP, the Medicare trigger and what we are going to do about that as it is projected to exceed 45 % of general revenue by 2012. That is of tremendous concern to me. I think we need to look at some long-term reforms.

I am also a bit concerned about SCHIP and the $19 billion for expansion there. Of course, you and I have visited many times about our experience in Tennessee. We have learned a lot of lessons there and I hope that those lessons are not lost on us as we look at the SCHIP program and how to properly deliver the services for the intended recipients. But welcome.

Thank you, Mr. Chairman. Thank you for the time and I look forward to continuing the conversations.

Mr. DINGELL. The Chair thanks the distinguished gentlewoman. The Chair recognizes now the distinguished gentlewoman from Colorado, Ms. DeGette. Not here? Okay. The Chair recognizes now the distinguished gentlewoman from California, Ms. Capps.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. Thank you, Mr. Chairman, and welcome, Mr. Secretary.

I am sad to say this budget reflects a complete disconnect with reality as far as the true healthcare needs of this country are concerned. The priorities are just so wrong. I can only chalk it up to this Administration being a lame duck. I am of course horrified by the proposed cuts to nursing education by 30 % and eliminating children's hospitals' graduate medical education altogether. This budget doesn't hesitate to cut funding from patients, from doctors or nurses but heaven forbid we should stop overpaying Medicare Advantage plans run by companies with multi-billion-dollar profits. With the Medicaid rules looming over us, how can we fulfill our

moral obligation to serve our neediest families with a budget that fails on so many levels?

I am also concerned of course about the need for fixes for the Geographic Practice Cost Index and the flawed Recovery Audit Contractor Program moving forward and the wasteful spending on ineffective abstinence-only education, but the rules only allow me 1 minute and so I will just urge my colleagues to reject this budget proposal and work together to pass a budget that reflects commonsense investments in our Nation's health infrastructure.

Thank you, Mr. Chairman.

Mr. DINGELL. The Chair thanks the gentlewoman. The Chair recognizes now the distinguished gentlewoman from California, Ms. Harman.

OPENING STATEMENT OF HON. JANE HARMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. HARMAN. Thank you, Mr. Chairman.

Secretary Leavitt, we met when you were involved with the Markle Foundation in a major project on homeland security. I know you understand the threats we face from terror attacks including biological attacks like pandemic flu. My district in California surrounds the top terror targets in Los Angeles including LAX, Los Angeles International Airport, and the ports of Los Angeles and Long Beach. The only level I trauma center and the closest hospital, Harbor UCLA, has been cited for overcrowding in its emergency room. Harbor is also a national teaching hospital. In my view, Mr. Secretary, this budget takes us backwards and makes us less safe. It won't cover a surge in mass casualty care. It is a purge in mass casualty care. I look forward to hearing what you have to say about this and hearing how we are going to protect America's communities.

I yield back.

Mr. DINGELL. The Chair recognizes now the gentlewoman from California, Ms. Solis.

OPENING STATEMENT OF HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. SOLIS. Thank you, Mr. Chairman.

I too am very concerned about the programs that we are going to see reduced, especially when we are talking about—and I have heard the Secretary this time and again about eliminating healthcare disparities. Again, Latino families that we represent in areas like mine are going to have a hammer to their heads about where they are going to find relief in terms of better healthcare.

I am also disturbed with respect to the August 17th directive. The other day we heard from some of our governors, both Republican and Democrat, who said that they were not in agreement with the new directive that has been placed upon them to try to enroll more low-income children in the SCHIP program without having the ability to actually do outreach and recruitment to get more families involved. I hope you can take a second look at that.

The other part we heard from was the Medicaid citizenship documentation, that it is actually costing more States more money just

to implement auditing procedures to go through to find out and potentially weed out people who are not eligible. We found hearing from the governor of Washington State, Mrs. Gregoire, that they only found one person out of over 300 cases that were examined and it cost the State, I think it was $5 million. I mean, that is horrendous. That money could be used for better healthcare services. So I hope you will reexamine that.

The other thing is that I know HIV and AIDS is a continuing epidemic, especially in the Latino community, but more importantly in the territory of Puerto Rico. So I would like to hear what your intentions are there and how we can mitigate those problems.

So thank you, Mr. Chairman, for having this hearing this morning.

Mr. DINGELL. The time of the gentlewoman has expired. The Chair recognizes now the distinguished gentlewoman from New Mexico, Ms. Wilson. Does the gentlewoman desire to waive?

Ms. WILSON. Yes.

Mr. DINGELL. Her time is waived and she will be recognized later. The Chair recognizes now the distinguished gentleman from Texas, Mr. Gonzalez.

Mr. GONZALEZ. I waive opening.

Mr. DINGELL. The gentleman waives. The Chair recognizes now the distinguished gentleman from Maryland, Mr. Wynn.

OPENING STATEMENT OF HON. ALBERT R. WYNN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. WYNN. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. I want to first join my colleagues in expressing my extreme disappointment with this budget, particularly with respect to SCHIP. In the case of my own State of Maryland, I don't believe the funding level that is in this budget will allow us to maintain our existing programs. It certainly will not allow us to expand and this is compounded by the fact that the President is objecting to any attempt to provide health insurance to families making over $35,000 a year, so basically moderate-income families are not going to be helped by this budget.

Second, I am very concerned about the problem of dental care and the cuts in the dental program. We had a tragedy in my district. This budget doesn't respond to that.

And third, I would note that federally qualified health centers are only increased by 1 %. This is absolutely critical when you consider that one in five citizens in America don't have reliable access to healthcare. Community-based health centers are absolutely critical, and it is unfortunate that this budget doesn't recognize that reality and provide more funding for community-based health centers.

Thank you, Mr. Chairman. I relinquish the balance of my time.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. DINGELL. The Chair thanks the gentleman. The Chair recognizes now the distinguished gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

I ask my colleagues to take a look at this budget through the eyes of seniors and children and pregnant women, people with disabilities, hardworking families. People are looking for help so that they can lead healthy and productive lives, and from a fiscal perspective, cost-effective programs with low administrative costs like Medicare and Medicaid are being cut while bureaucratic and costly private insurance are being hyped, and in terms of priorities, more than $10 million an hour for Iraq and cuts in children's health. What you will find are significant cuts in Medicare and Medicaid, the failure to fix the Medicare part D program, eliminate the donut hole, provide for our children through adequate SCHIP funding and a failure to provide needed resources for the NIH, CDC and SAMSA.

Mr. Chairman, it is my hope that this Committee will work to reject these cuts, reject any budget that prioritizes a misguided war and tax cuts for the wealthy over meeting the needs of American families. Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentlewoman has expired. The Chair recognizes now the distinguished gentleman from Georgia, Mr. Barrow.

Mr. BARROW. Thank you, Mr. Chairman. I will waive opening and reserve my time.

Mr. DINGELL. The gentleman waives. The Chair recognizes now the distinguished gentleman from Texas, Mr. Green.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, and I want to welcome the Secretary here, and we are trying to go through as quickly as we can so your time is valuable like everyone else's. But I have to say, I am concerned because over the past 8 years the Administration has continued to make cuts in HHS budget. The trend of the Administration has been to cut funding for programs that need the support such as SCHIP and Medicaid to fund costly programs that aren't necessarily working. Unfortunately, this year's budget is no different than previous years. It is disheartening, to say the least.

The budget abandons the most vulnerable members of our population, children and the elderly. Don't let the Administration fool you. This budget is not the solution to healthcare issues we are facing on our way to balance our budget. In my opinion, the budget focuses on across-the-board reductions in the most needed programs over continued funding the Administration's projects such as privatize healthcare and shifts costs to the States. In fact, a GAO report released today found that the private Medicare plans such as Medicare Advantage cost beneficiaries more than traditional Medicare yet the Administration continues to push the low-income population to privatized health plans that cost more, deliver less and continuing the trend of passing on costs to the States and the taxpayers.

I and many of my colleagues disagree with the Administration's budget request for LIHEAP. This is not the time to cut another 22 % out of this vital program which serves at-risk households with senior citizens and disabled Americans and the very young chil-

dren. With sufficiently funded LIHEAP, we can save lives in Texas and across the Nation. LIHEAP's funding shortfall is so serious that in my own State we reach just 6 % of the eligible families. LIHEAP reform needs to be permanent and not episodic.

This budget does nothing to reduce the number of insured children. In Texas, 1.5 million children are uninsured. This budget proposes a slight increase in funding to SCHIP. However, it offsets that increase by forcing States to take more of the costs of SCHIP which really is no increase at all and does nothing to reach the number of uninsured children in my State. Not only that, the budget reduces funding for physicians for the children's graduate medical education program. The child population is rising and the elderly need more healthcare but this budget wants to reduce the number of pediatricians, pediatric specialists, and again SCHIP. So where do we expect our children to receive healthcare?

I would like to discuss all the shortcomings but my time is short. If we continue to underfund programs like Medicare and Medicaid and SCHIP, we are going to have a terrible burden and leave one heck of a mess for future generations.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Green follows:]

STATEMENT OF HON. GENE GREEN

Thank you, Mr. Chairman, for holding this hearing today on the HHS budget. I'd like to welcome Secretary Leavitt to the committee and thank him for appearing before us today.

Over the past 8 years the Administration has continuously made cuts to the HHS budget. The trend of this Administration has been to cut funding for the programs that need the support like SCHIP and Medicaid to fund costly programs that aren't necessarily working.

Unfortunately, this year's budget is no different than in previous years, which is disheartening to say the least. This budget abandons the most vulnerable members of our population: children and the elderly.

Don't let the Administration fool you- this budget is not the solution to the health care issues we are facing or a way to balance the budget.

In my opinion, this budget focuses on across the board reductions in the most needed programs only to continue overfunding the Administration's pet projects, push privatized health care, and shift costs to the States.

In fact, a GAO report released today, found that Private Medicare Plans such as Medicare Advantage cost beneficiaries more than traditional Medicare. Yet, the Administration continues to push the low income population to privatized health plans that cost more, deliver less, and continuing the trend of passing on costs to the States and taxpayers.

I and many of my colleagues disagree with the Administration's budget request for LIHEAP. This is not the time to cut another 22% out of this vital program, which serves at-risk households with senior citizens, disabled Americans and very young children.

When sufficiently funded, LIHEAP can save lives in Texas and across our nation. LIHEAP's funding shortfall is so serious, that in my State, we can reach just six % of eligible families. LIHEAP reform needs to be permanent—not episodic.

This budget does nothing to reduce the number of uninsured children. In Texas, 1.5 million children are uninsured. This budget proposes a slight increase in funding to SCHIP; however it offsets that increase by forcing States take on more of the costs of SCHIP, which is really no increase at all and does nothing to reduce the number of uninsured children in my state.

Not only that, but the budget reduces funding for physicians and for the Children's Graduate Medical Education program. The child population is rising and inevitably they will need medical care, but this budget wants to reduce the number of pediatricians, pediatric specialists, and SCHIP. Just where do we expect our children to receive medical care and from whom?

I would like to discuss all of the shortcomings of the HHS budget, but my time is limited so I will conclude with this point. If we continue to underfund programs like Medicare, Medicaid, and SCHIP we are going to leave a terrible burden and one heck of a mess for future generations to clean up and that just isn't fair.

Thank you Mr. Chairman, I yield back my time.

Mr. DINGELL. The time of the gentleman has expired. Are there other members desiring recognition at this time? The Chair hears none.

Mr. Secretary, thank you for being with us. We recognize you and will hear such statement as you choose to give.

STATEMENT OF THE HON. MICHAEL O. LEAVITT, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary LEAVITT. Thank you, Mr. Chairman. You are always gracious and fair, despite our occasional disagreements. In the spirit of short opening statements, I will just summarize the statement that has been provided to the members.

This budget will recognize four basic objectives. The first one of course is carrying out our crucial mission of helping those in our country in hardship but it does recognize the need for us to balance the budget and focuses intensely on doing so by 2012. A third objective is to make the entitlements upon which so many in our country rely sustainable and also making certain that premiums that are charged to those who are beneficiaries are affordable.

My opening statement expresses grave concern about Medicare and Medicaid, and I do not suffer the illusion that this budget will be received with enthusiasm by many, but I hope they will receive it as a warning because at some point in time decisions like those made in this budget will have to be made by someone, no matter what party is in control. This has to be dealt with, and I express in my opening statement the view that at the heart of the problem is a system that is essentially planned and priced at a government price setting. I believe that we would be far better if we could begin to move toward a system where we reward value and not volume, and I hope we will have a chance to talk about that, Mr. Chairman.

In the spirit of briefness, I will leave it at that and look forward to interacting with you and other members of the Committee.

[The prepared statement of Mr. Leavitt follows:]

Testimony of

The Honorable Michael O. Leavitt

Secretary, U.S. Department of Health and Human Services

before the

Committee on Energy and Commerce

United States House of Representatives

February 28, 2008

Chairman Dingell, Congressman Barton, and Members of the Committee, thank you for the invitation to discuss the President's FY 2009 budget request for the Department of Health and Human Services (HHS).

I wish to begin with Medicare, which makes up 56 percent of the $737 billion budget HHS presents today.

The Medicare portion of this budget should be viewed as a stark warning. Medicare, on its current course, is not sustainable. In 2007, the Medicare Trustees reported the Hospital Insurance Trust Fund will be exhausted in 2019 -- 11 years from now – and Medicare represents a $34.2 trillion unfunded obligation for the federal budget over 75 years. This is a serious matter.

Let's acknowledge that American sensitivity to entitlement warnings has become numbed by a repeated cycle of alarms and inaction. Such warnings have become a seasonal occurrence, like the cherry blossoms blooming in April, part of life's natural rhythm. We hear the warnings, but do nothing

This budget warns in a different way. It illuminates with specificity the hard decisions policy makers, no matter what their party, will face every year until we change the underlying philosophy. We can keep our national commitment to insuring the health of beneficiaries, but we need a change in how we manage Medicare.

Currently, the Medicare fee-for-service program is a centrally-planned, government regulated system of price setting. Price setting systems allow government regulators to decide the priorities.

Government's tools are blunt and inexact. Government decides which treatment to cover. Government decides how much treatment is provided based on how much government is willing to pay for. Government tries to determine how much value different procedures have. It is a bad system and needs to be changed.

If consumers were allowed to make these decisions through an efficient and transparent market, their decisions would be far more precise and wise.

One need look no further than our experience with Medicare's prescription drug benefit, where government organized a market and let consumers decide what drug plan worked best for them. Entering the third year of the program, we see enrollment continuing to rise, beneficiary satisfaction extremely high, and costs to beneficiaries and taxpayers considerably lower than originally projected.

Just last month we announced that, compared to original Medicare Modernization Act (MMA) projections, the projected net Medicare cost of the drug benefit is $243.7 billion lower over the 10-year period (2004-2013) used to score the MMA. Beneficiaries are saving as well. The most recent CMS estimate of the actual average premium beneficiaries will pay for standard Part D coverage in 2008 is roughly $25. This is nearly 40 percent lower than originally projected when the benefit was established in 2003.

While there are several important factors that contribute to lower costs, a key factor is that competition has been strong from the beginning of the program and the plans have achieved greater than expected savings from retail price negotiations, manufacturer rebates, and utilization management.

That said, however, using the blunt instruments we have available to us in other parts of Medicare, we have prepared a budget with three goals in mind: long term sustainability, affordable premiums for beneficiaries and a balanced national budget by 2012.

Some will be unhappy with this budget. While Medicare spending will increase by an average of 5 percent annually under our budget, they will see any attempt to slow the rate of Medicare's growth as a cut.

Our proposed budget includes a group of legislative and administrative improvements aimed at extending Medicare's viability for today's seniors and future generations. The slower growth rate they produce saves $183 billion over five years.

The proposals include:

- Encouraging provider competition and efficiency
- Promoting high quality care
- Rationalizing payment policies
- Improving program integrity
- Increasing high-income beneficiary responsibility for health care costs

The slower growth rate also reduces the premiums beneficiaries face by $6.2 billion over the next five years. Let me emphasize that generally, changes we make that reduce future government spending also give a financial break to beneficiaries.

I mentioned Medicare warnings earlier. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress included a provision requiring the Medicare Trustees to issue a formal warning if two consecutive annual reports show that regular tax dollars exceed 45 percent of total Medicare spending within the current or next six years. I am a Trustee of the Medicare Trust Fund. Last year we triggered the alarm. As usual, there has been no action.

The same law calls for the President to propose legislation that will change the trajectory enough to bring general revenues back below 45 percent. The President believes it is important to respond to the 2007 warning about the future fiscal health of Medicare.

I was designated by the President as the official responsible for this response and on Friday, February 15, I submitted legislation to Congress.

This legislative package addresses the immediate problem identified by the 2007 warning and helps lay the foundation for transforming Medicare so it becomes a program based on the highest quality and the greatest value. This proposal should be enacted in conjunction with the Medicare savings in the 2009 budget, which addresses nearly one-third of the program's $34 trillion unfunded obligation.

The legislation we propose offers a three-step approach to the problem of unsustainable Medicare spending growth.

Title I provides the HHS Secretary with the authority and responsibility to introduce value-driven competition into the Medicare program. These principles are intended to reduce Medicare spending by increasing provider efficiency and helping beneficiaries to be wiser consumers. Specific elements in the legislation include:

- Adoption of health information technology, such as electronic medical records and e-prescribing;
- Transparent pricing information;
- Transparent quality information; and
- Incentives for providers to deliver and beneficiaries to choose high-quality, low-cost health care.

Title II of this legislation implements the President's medical liability reform agenda.

- The medical liability crisis has littered our courts with junk lawsuits. It has hindered patient care, resulting in 1500 counties lacking an Ob-Gyn. And it costs our health care system up to $100 billion per year.
- We need reform in order to have a rational medical liability system.

Finally, Title III reduces the Medicare premium subsidy for higher-income individuals in Part D.

- Income-relating the Part D premium was contained in the President's last two budget proposals.
- It will save over $900 million in 2013 and nearly $3.2 billion over five years.

Although this package responds to the funding warning identified in the 2007 report, more must be done to strengthen Medicare for the long-term.

I am eager to work with Congress to quickly pass this legislation – and the savings proposed in the President's Budget -- so we can get started on making Medicare a healthy program for current and future generations. But real solutions in Medicare will require genuine change in the way in which health care is conducted in America. And, if I can comment on that broader topic for a moment, let me say this:

There are two competing philosophies about the role government should play in health care. One is a Washington-run, government-owned plan, where government makes the choices, sets the prices, and then taxes people to pay the bill.

The other, supported by the Administration, is a private market where consumers choose, where insurance plans compete, and where innovation drives the quality of health care up and may drive the cost down.

The Administration believes every American needs access to health insurance at an affordable cost. In addition to its proposed tax reforms and health insurance market-based initiatives, the Administration believes the current health care system could operate more efficiently, without increasing federal spending on health care, if some portion of indirect public subsidies were redirected to make health insurance affordable for individuals with

poor health or limited incomes. The federal government would maintain its commitment to the neediest and most vulnerable populations, while giving the States, which are best situated to craft innovative solutions, the opportunity to move people into affordable insurance.

Before leaving Medicare, I want to make one more point.

I spoke earlier about the cherry blossom syndrome of entitlement warnings. Many may look at this budget and see the same old cherry blossom story – X billion of reductions here and Y billion there. But, as a Trustee of the Medicare Trust Fund, I ask that you concentrate on the condition of the Medicare Trust Fund. It is a story that needs to be told, and told, and told.

I have admired and appreciated David Walker, the Director of the Government Accountability Office (GAO) traveling the country sounding the warning. If my remarks today, describing the Department's budget, don't focus attention on this problem, then read his speech. Call the government actuary, or your favorite economist.

We are approaching an emergency. Real change in Medicare as a system is required, and soon. If you are 54 years old, and if Medicare is left on autopilot, when you turn 65 years old, Medicare will not be able to provide all the hospital insurance benefits promised under current law. We need a change in philosophy not just a change in the budget.

Now, on to other matters.

State Children's Insurance Program (SCHIP)

The President proposes to increase funding to states by $19.7 billion through 2013, with $450 million in outreach grants. Our proposal is consistent with the Administration's philosophy that SCHIP should be focused on uninsured, targeted, low income children first. It is also consistent with the position the President and the Administration

articulated last fall. Our legislative proposal calls on Congress to address the issue of "crowd-out." It outlines State responsibilities when they expand SCHIP programs, proposes enforcement mechanisms, and clarifies SCHIP eligibility by clearly defining income.

Medicaid

We are continuing our successful transformation of the Medicaid program. This budget request includes a series of proposed legislative and administrative changes. We propose legislative savings of more than $17 billion and assume administrative savings of approximately $800 million over the next five years while keeping Medicaid up-to-date and sustainable.

Food Protection

We have a good system of food protection in the United States, but as the global market matures, our systems have to change. Last year, we unveiled the Import Safety Action Plan and the Food Protection Plan which propose significant improvements in how we deal with imported products.

Our goals are to:

- Promote a common vision of import safety with our trading partners and foster a culture of collaboration;
- Focus on risks over the product life cycle rather than a snapshot at the border;
- Increase accountability, enforcement and deterrence with regard to imports;
- Build interoperable data systems and encourage data sharing; and,
- Promote technological innovation and develop new tools to enhance import safety.

The President's budget increases funding for food safety by $42.2 million or 7 percent, and the overall FDA budget by 5.7 percent. These increases for food safety will be used to continue implementing the prevention, intervention, and response measures of the Food Protection Plan.

Biomedical Research

We have proposed increases for each Institute and Center at NIH. The overall budget will support 38,000 research project grants, including more than 9,700 new and competing awards. Overall, the budget will be the same as FY 2008.

Emergency Preparedness

Our nation remains at risk of terrorist attack and war. HHS is responsible to prevent and detect attacks, and respond to mass casualty events. Our budget proposes $4.3 billion to:

- Increase bioterrorism readiness
- Double advanced development of medical countermeasures
- Establish new international quarantine stations
- Expand and train medical emergency teams

We are seeking the funds necessary to complete our Pandemic preparedness.

One rather interesting part of our preparedness budget deals with ventilators. In many emergencies, especially terrorist attacks or pandemics, ventilators are needed to help victims breathe. Currently, ventilators cost $8,000 to $10,000 each. They also require specially trained teams to operate them. The combination of those two factors makes having an adequate supply nearly impossible.

We are requesting $25 million to develop the next generation of ventilators that are portable, up to 90 percent less expensive and do not require special training to operate.

Health Information Technology

The President's budget proposes $66 million for the Office of the National Coordinator for Health Information Technology (ONC) to support activities coordinating federal, state and local government and private sector efforts to transition to an environment of electronic health information exchange. The budget will support ONC work to advance the President's goal for most Americans to have access to electronic health records (HER) by 2014 through:

- Establishing a successor to the American Health Information Community (AHIC) to an independent and sustainable public-private partnership;
- Determining, testing, and recognizing agreed upon health data standards;
- Working to remove barriers to create an environment that promotes the adoption and use of health IT;
- Investigating and supporting solutions for privacy and security challenges in electronic health information exchange;
- Implementing exchange of standardized test data among communities engaged in trial implementation activities to work towards the goal of the Nationwide Health Information Network.

Global Health

You will see a series of health diplomacy initiatives. Because threats to human health have become just as mobile as we are, our leadership in health around the world benefits Americans directly.

In addition to our work on HIV/AIDS, Malaria and Tuberculosis, we help other nations with disease monitoring and preparedness.

Conclusion

These are just some of the highlights of our budget proposal. Both the President and I believe that we have crafted a strong, fiscally responsible budget at a challenging time for the Federal government, with the need to further strengthen the economy and continue to protect the homeland.

We look forward to working with Congress, States, and all our other partners to carry out the initiatives President Bush is proposing to build a healthier, safer and more compassionate America.

Now, I will be happy to take a few questions.

Mr. DINGELL. Mr. Secretary, thank you. I am going to be asking most of these questions to get a yes or no answer simply because there is so little time here and we want to respect your time and the time of the other members. So Mr. Secretary, isn't it correct that the President's fiscal year 2009 budget targets traditional Medicare providers with cuts of $576 billion over 10 years?

Secretary LEAVITT. The 5-year number is the one I am more familiar with. It is $183 billion, so I don't have a 10-year number.

Mr. DINGELL. We will hold the record open so that if that statement is incorrect, you may correct me on that.

Secretary LEAVITT. Mr. Chairman, may I acknowledge that when we use the word "cuts," we both mean it is a reduction in the growth rate. We are reducing the growth from 7.2 % down to 5 %. Medicare will grow during that period by more than 5 % but we are in fact proposing a reduction in the growth rate.

Mr. DINGELL. Now, Mr. Secretary, the budget does absolutely nothing to reduce Medicare overpayments to Medicare Advantage insurance plans or the HMOs. That is true, is it not?

Secretary LEAVITT. Mr. Chairman, Medicare Advantage was designed to do three things. One was to establish the option and choice among people on a——

Mr. DINGELL. No, but it does nothing to cut back on those payments to that particular category of recipient?

Secretary LEAVITT. None of our reductions really focus on beneficiaries. They do focus on——

Mr. DINGELL. I am talking about Medicare Advantage plans. They continue to receive no cuts and they cut their payment at exactly the same level, yes or no?

Secretary LEAVITT. As we both understand, the design on Medicare Advantage is slightly different and——

Mr. DINGELL. Mr. Secretary, with all respect and great affection, I have got limited time.

Secretary LEAVITT. I always feel your affection, Mr. Chairman.

Mr. WAXMAN. In a limited way.

Mr. DINGELL. Mr. Secretary, the commission which is authorized by Congress to do an independent review of Medicare payment rates, MEDPAC, now tells us that we are paying these HMOs 113 % of traditional Medicare for every beneficiary who enrolls. Is that true or false?

Secretary LEAVITT. The Congress has in fact authorized a different reimbursement arrangement.

Mr. DINGELL. And in some instances, that average is exceeded by some of those being paid 130 % of costs. Is that correct?

Secretary LEAVITT. That is not a familiar number to me. I am aware that there is a differential in reimbursement but the number I have is less than that.

Mr. DINGELL. Now, the Congressional Budget Office advises us that these overpayments will cost Medicare over the next 5 years alone $54 billion. Is that correct?

Secretary LEAVITT. I have not seen that report. I read about it this morning but I have yet to receive a copy of it.

Mr. DINGELL. Now, today Mr. Secretary, we will be releasing a new report from the Government Accounting Office which sheds light on these HMOs and how they are spending these overpay-

ments. The title of the report is "Medicare Advantage: Increased spending relative to Medicare fee for service may not always reduce beneficiary out-of-pocket costs." I would note that according to GAO, nearly a third of the beneficiaries enrolled in these Medicare HMOs find that the plans spend more than 15 % of the Medicare payments on overhead, administration and profits. Is that true or false?

Secretary LEAVITT. Again, I have not seen that study.

Mr. DINGELL. Mr. Secretary, proponents of the excess spending at Medicare HMOs have said that these plans are important because they provide seniors with extra benefits. Now, are you aware that according to GAO, this report says that "relatively little of the overpayments are being spent on extra benefits."

Secretary LEAVITT. Again, I have not seen the report. Our information is that about 80 % of them are being spent on additional benefits.

Mr. DINGELL. And in point of fact, Mr. Secretary, the GAO found that the plans spent only 11 % of extra payments on extra benefits for seniors. The plans charge beneficiaries increased premiums to finance extra benefits so in spite of the fact that the plans are getting overpayments, they are still charging beneficiaries for extra benefits that Medicare has paid for. Is that true?

Secretary LEAVITT. Again, our information is that 80 % of it is being spent on extra benefits. I do have the view that there are things that can be done to Medicare Advantage that would expand the competitiveness of it and would I believe improve it, but I think it is a very good thing in general and it has been successful in the way that Congress designed it.

Mr. DINGELL. Now, Mr. Secretary, it is a fact, I believe, that according to GAO, one in five beneficiaries is in an HMO that charges more than Medicare fee for service for home health services and roughly one in six beneficiaries is in a plan that charges more than Medicare for hospital service. This means to me that beneficiaries who are in poor health find that the plans wind up costing them more than if they were in regular Medicare. Is that statement true or false?

Secretary LEAVITT. Well, it would be contrary to what we have found. It has been wildly popular among beneficiaries, particularly those in low-income areas and those in ethnic communities, ethnically diverse communities.

Mr. DINGELL. Mr. Secretary, are you aware also that according to GAO, the plans did reduce beneficiary cost sharing. One-third of that reduction was financed by additional beneficiary premiums. So essentially what these plans are doing is shifting costs, making more profits and seeing to it that the beneficiaries pay additional premiums for the benefits that they achieve. Is that statement true or false?

Secretary LEAVITT. I have not seen the study. As far as I know, it hasn't even been released. I have heard that it will be released today but I do not have a—I have not had a chance to review it. Therefore, it is difficult for me to respond.

Mr. DINGELL. Mr. Secretary, with all affection and all respect for you, and I think you are a fine public servant I grieve that you and I differ on this, I find that what we have been afflicted here with

is that our government is quite frankly paying fat cats in the HMO and insurance business excessive profits and benefits and quite frankly cutting back significantly on services and benefits to recipients of these programs. I think this is unconscionable. I regret that we have this disagreement on it. My time is expired.

The Chair recognizes now my good friend and colleague, Mr. Upton, for 5 minutes.

Mr. UPTON. Thank you, Mr. Chairman.

Again, Mr. Secretary, welcome to the Committee. As you know, in my opening statement I referenced the Medicare physician pay fix. As you know, it expires—the current temporary stopgap expires July 1, and if we fail to do anything, we are going to see a 10 % reduction, which as you must know is pretty unpalatable on both sides of the aisle, let alone in the physician community, as well as the patient community. We received quite a bit of letters from all sides on this. Where do we need to go? July 1 is not that far away. Pitchers and catchers are already reporting. The first preseason games are this week, and that will be about the All Star break in Major League Baseball so we are really pretty close. What should we be doing and where is the Administration? If we come up with just a temporary fix extended through the end of the fiscal year, stick something into a CR later on. What is the Administration's view as to the billions of dollars that will be in additional spending just to come up with a stopgap which takes us through the end of the year?

Secretary LEAVITT. I will give you my own view. The system in fact——

Mr. UPTON. OMB is not here. They are not watching.

Secretary LEAVITT. They are always watching. This system is a figment of a government-regulated price-controlled system that will always oversubsidize the wrong things and that will routinely underpay the right things, and until we wrestle with that fact, we are going to continue to have this dilemma. One option that many will advocate, particularly in the medical family, will be that Congress write a check for a couple of hundred billion dollars and just solve this. I would suggest to you that that would potentially be a short-run solution but it is a long-term disaster. We have to fix this system, and part of the solution needs to be a system that will begin to recognize value and not just volume. Whenever we begin to ratchet down the payments, whether it is 10 % or 1 %, miraculously what happens is, we end up seeing more procedures. So in a system like this where we reward volume, we are just going to get more volume and we need to begin looking at what I refer to as the four cornerstones of a value-based competition system where people have electronic medical records, where we can gather information, where we have quality measures, where people know what the quality of their care is, what the price of it is so that people can begin to deal with healthcare in a way that will give them a sense of what their value is, not just how much volume——

Mr. UPTON. We have had some incentives in past years as related to the IT industry. Is that not right, with electronic records? Wasn't that part of some of the solution?

Secretary LEAVITT. Well, we are making progress but we need to move even more aggressively as a Nation. In the 1 minute, 51 sec-

onds we have left, I would love to tell you a little bit about that but I recognize you may have other questions. Let me just suffice to say we are making serious progress and we need to make more.

Mr. UPTON. Well, thank you. It is an issue that I think this Committee and subcommittees need to deal with. I was pleased to see that the budget did include $66 million for the Office of National Coordinating for Health IT. Where are we in developing additional standards to give healthcare providers more confidence in implementing electronic health record systems and electronic prescribing systems probably along the lines of what the VA is already doing?

Secretary LEAVITT. Let me say that 3 years ago, there were no standards for electronic medical records that would make them interoperable so we could weave our healthcare sector into a system. I am happy to report to you, Congressman, that we now have 75 % of the medical records systems for practices that are being sold with what is known now as the CCHIT certification. It is a seal of approval that says if you buy a system like this, you are on a pathway to interoperability. The standards didn't exist 3 years ago. They now exist. We have a system in place and we are making progress.

As to e-prescribing, may I say the time has come. We need to begin to insist that physicians and their practices adopt e-prescribing. The money is—there is money savings. There are lives that will be saved by it. It is just time. I would suggest in June when we do deal with the SGR that we look at allowing Medicare the capacity to reimburse physicians at the highest possible rate when they use e-prescribing. It is when we begin to use that kind of incentive that we will see e-prescribing and its savings and its health benefits fully realized.

Mr. UPTON. I appreciate your being here, and my time is expired. I yield back.

Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes now the distinguished gentleman from New Jersey, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. Secretary, I have to say it is incredible to me—I want to talk about these Medicaid rules that are going into effect, and we had a Health Subcommittee hearing 2 days ago and we have governors here in the aftermath of the governors conference, both Democrat and Republican, and all we heard from those governors was that these Medicaid rules, in effect the cuts that would come out of them, you know, we have had several over the years and we have more that were just announced a couple weeks ago, that they are going to cause real and profound harm to covered services and access for the country's most vulnerable populations, whether it was the disabilities community or it was the graduate medical education or was the increased co-pays from one of the rules that we announced a couple weeks ago, how is it that—I mean, you were a governor. How is it that your former colleagues who run these programs are so concerned about these cuts that would come from the Medicaid rules but yet you and the Department dismisses them? I mean, I know you were a governor at one time. I think you supported—you know, you expressed some of those same concerns

with the cuts in the Medicaid program when you were governor. I mean, it just seems there is a total disconnect here and I just—if you would just explain that. I mean, it would seem to me you probably should get the governors together before you even put some of these rules out and talk to them about it and what the impact would be. Does the Department even do that?

Secretary LEAVITT. Mr. Pallone, I appreciate a chance to respond to this. As you point out, there is probably no one in this room who understands better the different perspectives that governors and the Federal Government might have on this, having served in that role myself for 11 years. Medicaid is a partnership between the Federal Government and the States. It is a partnership where both are expected to contribute, and if I could just characterize these in unvarnished terms, I think what we have right now is a dispute between partners.

Let me describe for you how I think that dispute comes about. There are seven ways in which we believe, I believe that the States are using ambiguities in our regulations to unfairly increase the amount of the share that the Federal Government is paying in our partnership.

Mr. PALLONE. But Governor, I don't want to stop you. I want you to continue, but, you know, one of the things that Chairman Dingell and I and other members of the subcommittee have advocated is increasing enhanced payments for Medicaid, you know, an FMAP proposal which was actually utilized the last time we had a recession or economic downturn, and the governors all said they were in favor of that and I believe you were in favor of that, you know, a few years ago when we had an economic downturn and we actually did an FMAP increase to the States. I mean, I understand there is this—you are the Federal Government, they are the States now, but I mean, you know, why not do something like that to help the States out?

Secretary LEAVITT. Well——

Mr. PALLONE. I mean, the Administration has been opposed to it. Do you oppose that?

Secretary LEAVITT. What we support and what I support is a partnership where both sides are putting out what they agreed to, and I would like to just acknowledge that I believe this is being driven primarily by the fact that there are contingent-fee consultants who go from State to State looking for any breadth of ambiguity and they have absolutely no incentive but to push and push and push and to drive and drive and drive on the basis that anything the Federal Government can pay is good.

Mr. PALLONE. But the problem is, we have an economic downturn now, Mr. Secretary, and, you know, in my own State the governor just announced a freeze on spending, literally a freeze, not even taking into account inflation. I mean, I understand what you are saying. I am not disagreeing that there may be some problems there but we are going in the exact—the Administration is going in the exact opposite direction of where the country is going. There is an economic downturn. There is more need for Medicaid, for SCHIP. We have talked as Democrats and Republicans with this bill that I mentioned about giving more enhanced match to the States and the Bush Administration wants to cut back. I mean,

even if what you are saying is true, that there are these ambiguities, the fact of the matter is that right now the States are hurting and people need the Medicaid program. So I would think that right now you would say okay, maybe there are these ambiguities but we have got a problem here that is just unique to the times and let us not make it even more difficult for States to operate.

Secretary LEAVITT. If that is the case, it is a decision that Congress ought to make. It is our view that this is—that they are exploiting in ways that are unfair ambiguities that in most cases don't exist, and I can give you lots of examples, and I believe it is my responsibility to maintain the integrity of this program to push back and to make certain that they are putting up their part of it. Now, again, I have been a governor, I understand, but when you get into this, we find out that there are—that many of the things we are trying to—most everything we are trying to close has no medical relevance. This is different programs like education and other parts of State government trying to put a tap into the vein of Medicaid in order to supplement State budgets, and if the Congress decides that they are going to assist States in this way, fine. However, I don't believe it ought to be done with contingent-fee consultants who exploit ambiguities and then benefit from it by pushing and pushing and pushing with no resistance. I believe this is good management, and it is important to the balance of the partnership that we have. If we are going to be partners, let us be partners. You put up your share, States, and we will put up ours. Now, again, I have been in this position.

Mr. PALLONE. Well, I know my time is expired. Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes now the gentleman from Nebraska, Mr. Terry, for 6 minutes.

Mr. TERRY. Thank you, Mr. Chairman. I appreciate it.

I just basically have two questions. The first one is going to be on our Medicare part D, an issue that has arisen in my district when I have suggested that people who are hitting the gap between the basic and catastrophic coverage, which is called the donut hole, that very limited number of opportunities of buying coverage in that it is basically all generic if you can even find one. Has there been any discussion in the agency about ways to provide incentives or what we can do to make sure that there is more, a wider variety of gap coverage opportunities?

Secretary LEAVITT. Congressman, others would likely be able to respond to that better than I at CMS but I will tell you that it is my impression that some kind of quote, donut hole or gap coverage, is available in nearly every State. It is more expensive if you want brand-name drugs but the fact that it exists in every State and that you can buy it I think is an important advance and I think one of the reasons that 86 % of the people who have a Medicare Advantage plan are happy with it. Now, we probably ought to get more detail on that——

Mr. TERRY. Yes, in Nebraska right now, there is not an opportunity to buy one that has name brand in it, and I have been hearing that that is occurring in other States now and that is—this is the first year that that has happened and so I just want to put it

on your radar screen because I think that is an issue that we may have to deal with, and if we can get your input.

Let me shift gears then to what you and I usually discuss, and that is electronic medical records. Your agency has developed a pilot program that I think is probably in about 1 year around the country and I just wanted to get an update from you how those are going, what we are learning in the pilot programs on electronic medical records. I know it is in its infancy but are there any initial lessons that we are learning from those?

Secretary LEAVITT. Let me give you a 2-minute report or less. First, we have made substantial progress on creating standards for interoperability, which is a fundamental basic requirement of a system of electronic medical records. We created what is known as CCHIT. It is a seal of approval. It is now driving the market. It is a 3-year certification but we update it every year and a number of providers decided they would wait until the third year. Well, the market suddenly started moving to those who were updating annually and now most everyone is beginning to update annually. In other words, we now have a process that is driving the market towards interoperability. I will tell you that I think our biggest challenge still is the fact that we have a mismatch in the market, particularly among small- and medium-size physician practices. The mismatch is, they make the investment. Most of the benefit comes from the—goes to consumers and/or the payers. We are looking to learn how we can manage that and the macroeconomics shift. We have just announced a Medicare pilot wherein 12 medical markets around the country, we will appoint up to 100 small- and medium-sized practices. It will cover 1,200 practices in total. We expect that we will see 3.6 million patients covered under it. In addition to that, we are working hard right now, and I will be myself in 40 different cities over the course of a 3-month period to meet with the medical family where we are asking them to take efforts that they are currently using to define quality and begin to standardize and harmonize the way we are measuring quality.

I like to point to four different things that have to happen for our medical system to emerge. The first is medical records. The second is measures of quality. The third is price groupings where people, ordinary people can have buckets of care, they can compare and make a judgment as to value. And then the last is finding ways to assure that everyone has a motivation to increase quality and cut costs, and that system is beginning to emerge, and the root of it of course has to be electronic medical records, and I am happy to report to you we are making substantial progress.

Mr. TERRY. The 12 cities, did you say, that you are doing a consortium——

Secretary LEAVITT. We refer to them as communities. It could be a State or it could be a city or it could be a metropolitan market. We have got some that are applying that we think will—and the way it works, it is very simple. The first year we are going to compensate them if they have a CCHIT system a little bit more on their Medicare payments. In the second year, we are going to compensate them more if they will use that system to report quality data. The third, fourth and fifth year, we will pay them more if they can demonstrate that they are in fact producing quality out-

comes for their patients. This is a means by which we can begin to demonstrate a way to share the benefit of electronic medical records among not just the payers and not just the consumers but with the physicians. Until we can see that macroeconomic shift occur, it is difficulty to persuade a small- or medium-sized physician practice that they ought to make that investment.

Now, another very important thing I have already spoken of, and that is the need for e-prescribing to become the standard. We have e-prescribing technology in most pharmacies. It is now the—we now need to get down to the hard business of just making the sociology shift. It is not the technology here that limits us, it is the sociology, and I believe it is time for Congress to say and allow Medicare to say if you want to be reimbursed at the highest level, you need to use e-prescribing. We have seen this happen in almost every other instance, and if someone would like to ask me another question, I have got some more to say about that.

Mr. TERRY. Thank you.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes now the distinguished gentleman from California, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman.

Secretary Leavitt, I want to follow up on these Medicaid proposals. You indicated that there are problems and that Congress ought to decide the issue but you haven't recommended to Congress to make changes. You haven't identified the problems and said make the appropriate programmatic changes in the statute. The Administration is proposing to put into effect these new rules without intervention from Congress.

Secondly, I want to indicate to you that when our Oversight Committee had a hearing on this issue, the gentleman from CMS could not tell us what the consequences would be if these changes were put into place for the States. Now, this is a partnership, a federal and State partnership, and as you indicated, both sides are supposed to put in their share to make the partnership work. Well, the Federal Government now is saying we are not going to put in the full amount that we put in in the past, and I might indicate that what we put in the past was put in to the States to use under Democratic and Republican administrations. The National Governors Association on a bipartisan basis has asked us to reject these Medicaid proposals. We at our committee are trying to find out what they cost, what the impact will be on the States since the Administration can't even give us those figures. I can't imagine a partnership where one side says we are going to put the burden on you at a time when there is a recession but we don't even know what the consequences are going to be. That isn't the integrity of the program. That is lack of integrity and concern about what the impact will be on the beneficiaries. So we sent out a letter to the individual Medicaid directors of the States and asked them to tell us what the financial impact will be on them. We are putting together a report. We are going to release it next Monday but I am going to get it to you in advance because I want you to look it over and evaluate what they are saying. I want you to see what the impact will be as they describe it, and if they are right, I hope you will reconsider these series of regulations.

The other thing I want to indicate to you is that California, for example, told us the regulations combined would result in a $10.7 billion loss of federal Medicaid funds over the next 5 years. That is just California. It is a big State. But when you look at it in Los Angeles, which is not only my district but one of the major cities in this country where millions of people come every year as tourists, people expect those who live there and those who visit that if there were a terroristic attack or some terrible accident that the healthcare system would be able to deal with an emergency. Well, I am going to give you a letter. I think we have already given you a letter from Bruce Chernoff, the chief medical officer of L.A. County, and he wrote that like many local governments that operate hospitals, L.A. County is facing serious financial pressures that are already destabilizing the emergency rooms. Emergency rooms have been closing. Hospitals have been closing. With these further cuts in the federal Medicaid budget, it is going to mean even a greater problem on a safety net to deal with any emergencies, so I want you to look at that as well.

In the few moments I have remaining, I do want to indicate to you my concern about the FDA cuts, in no small part due to your leadership in food safety. We are going to try to address these problems that are on the minds of our constituents about food safety, but as I look at it, the Administration is talking about a $42 million increase for overall food safety, but when you look at the FDA inflation rate of 5.8 % and with FDA's unique needs for maintaining high-caliber scientific staff and facilities, so 5.8 % and the $42 million you tout as an increase, there is not much left over. In fact, our people look at it and say there is only going to be $2 million left. How is the agency going to be able to do more in the area of food safety if—I know the cuts are on the increases for inflation but after that there is not much of an increase to do the additional work, and if they are pretty much using the same amount as last year, it didn't cut it last year and it is not going to cut it for next year. How do you respond to that?

Secretary LEAVITT. Congressman, as you indicate, I have made a substantial investment in this issue personally and feel deeply that FDA has a role to play. I will tell you that I worked hard for that $42 million and felt good about it in the context of a budget clearly intended to balance the budget by 2012. There are substantial demands on FDA. We have to think about this in a different way. We have got to be smarter. I believe the $42 million is an important step forward. May I say that we have added 1,000 people at FDA over the course of the last 2 years? There is a limit to the speed with which we can accomplish the mission that I am anxious to see accomplished. It never happens fast enough for me but I believe the budget is an important step forward.

Mr. WAXMAN. Thank you.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes now the distinguished gentleman from Texas, Mr. Barton, for 5 minutes.

Mr. BARTON. They may be 5 imperial minutes, you know, 5 Speaker minutes or something like that. No, I am just teasing. I apologize, Mr. Chairman, and I apologize, Mr. Secretary, for not being here at 9:30. For some reason I thought this started at 10:00

and if I got here by 10:15 I would be on time. So Mr. Dingell started apparently right at 9:30, which is to his benefit.

It is good to have you here. I know it is kind of contentious and I haven't listened to too many of the questions but my guess is, the Majority has been castigating you for various foul deeds or not doing as much as you should, and hopefully us in the Minority have been at least patting you on the back every now and then before we kick you in the pants.

My question to you, as you well know, under the current Medicare law, when the expenditures of the trust fund begin to exceed a certain percentage in terms of general revenue being spent on Medicare, it has a trigger that requires the President to report to the Congress that fact and to present a plan to get the general revenue share of Medicare back below, I believe it is 45 %. You sent us a letter last week or the week before last because the Medicare trigger has been triggered 2 years in a row. What part of that—the part of the program about health IT, I think Title I, would seem to me to be something that we could actually do. Would you care to elaborate on that?

Secretary LEAVITT. Thank you. I would be pleased to. First, let me say that I think this is a very important warning. While remedying the warning does not fix Medicare's problems, I fear that Medicare warnings have become like the blooming of the cherry blossoms in the spring. We just hear them and we don't pay much attention to them. We need to start paying attention. This is a serious problem and we need to focus on it. Title I essentially lays out a pathway where we could begin to reimburse on the basis of value, not volume, where we could begin to see some consumer and competition in Medicare that we believe would drive quality up and costs down. It essentially recognizes four needs we have in order to have our medical sector now become woven into a medical system, and that would be electronic medical records, the capacity to measure quality, the ability to compare practice and incentives where everybody gains if they increase quality and decrease cost. Title I of that trigger would essentially lay out benchmarks that would hasten the day when that market system could exist.

Mr. BARTON. On Medicaid, as part of Medicaid budget reconciliation several years ago, at the request of bipartisan taskforce of governors, we put more flexibility for States to use their Medicaid funds. There is apparently a move afoot to prevent that flexibility being utilized. Would you care to comment about that?

Secretary LEAVITT. Well, we had a brief conversation between Mr. Waxman and also Mr. Pallone and I about Medicaid. I was a governor for 11 years. I found the flexibility to be extraordinarily helpful. I think one thing you can count on—two things you can count on from the States. One is that they will use flexibility and innovation, and the second is, they will do everything they can to get the Federal Government to pay every bit of it.

Mr. BARTON. But Democrat governors want flexibility too. It is not just Republican governors.

Secretary LEAVITT. A very important point about this relationship, a very important point, is that the partnership and disputes that happen in the partnership are not between Republican and Democrat governors. They pretty well agree on two things: innova-

tion and flexibility are good, and the more you can get the Federal Government to pay is good. The dispute is between partners. The partners are the Federal Government and the State governments and we do have a series of ongoing disputes where we believe that the States are in fact using ambiguities to try and drive their ethic of getting—and no one can blame them for doing anything else. But somebody has got to stand up and say if we are going to have integrity in our partnership, we need to deal with this, and you asked me more about flexibility but I wanted to talk a little bit about who the partnership is between and where the disputes are.

Mr. BARTON. And finally, I want to compliment you and the President for funding the common fund at the NIH. The NIH reorganization reform bill that we passed last year or the year before last I think is one of the more significant reform packages that the Congress has done in the last 20 years, and a big part of that reform was a common fund where various NIH researchers would compete for funds across various departments, and that has been funded. I wish you all had funded NIH a little bit more but you did fund the common fund, so I appreciate that.

Last, Mr. Dingell and myself and Mr. Stupak and Mr. Shimkus have sent you a letter, and I would assume you have read it, about a request for information that so far you and the President have refused to give to the Committee. You are not claiming executive privilege or anything. I would certainly encourage you to look at the letter we sent you. We are trying—to his credit, Chairman Dingell, and Chairman Stupak, are trying to find a way to accommodate some of the concerns that you and the President have announced, but Mr. Shimkus and myself are just as committed as Mr. Dingell and Mr. Stupak to getting information that is important to the Committee and to the people for some ongoing investigations at the FDA, and I don't want to have to stand up on the Floor and support a contempt citation for you or the President. I don't want to do that, but if I have to, I will. So I would encourage you to get with your general counsel, read the letter. We have sent, I think, a good-faith effort to try to find a way to accommodate the legitimate needs of the Administration but also the legitimate needs of the Congress, and it is just not a fun thing when we start having to file contempt of Congress resolutions on the Floor of the House. So if you need to talk off camera about that to me any time, I would like you to do that, but I believe you have got until the end of this afternoon to comply with that letter.

Secretary LEAVITT. Mr. Barton, let me say that I share your view on how little fun is involved in anything related to such a citation, and I also want to acknowledge the important role of investigation and oversight, and we want to be both respectful and cooperative and I feel—I did receive the letter this morning and I have had a chance to review it briefly, and as I mentioned to Mr. Stupak, we will work with this and I feel optimistic we can resolve it. This is the type of dispute that existed for centuries in our government and we want to work cooperatively to resolve it.

Mr. BARTON. Okay. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

Mr. DINGELL. The time of the distinguished gentleman has expired. The Chair recognizes now the distinguished gentleman from Massachusetts, Mr. Markey, for 6 minutes.

Mr. MARKEY. Thank you, Mr. Chairman.

Welcome, Mr. Secretary.

Secretary LEAVITT. Thank you.

Mr. MARKEY. Mr. Secretary, the NIH budget in its capacity to actually purchase more research capacity has actually declined 13 % since 2003, and the President keeps talking about the National Institutes of Health and the research that they do in the most positive of terms. In order to keep the NIH spending just level with last year, it will require a 3.5 % increase in the NIH budget for the 2009 fiscal year. Do you support a 3.5 % increase in the NIH budget just to keep it even with this year's spending ability?

Secretary LEAVITT. Mr. Markey, I am going to tell you I feel very good about the fact that we did achieve level funding. I fought hard for that in a competitive budget. I would also just acknowledge one other thing. We all want more money for medical research. When you look at this budget, not just the Administration, when you look at the situation, the money for medical research is going one place and that is to healthcare costs. If we begin to focus on Medicare, making it sustainable and starting to turn that growth rate down, it is going to create more opportunity for medical research. So while I recognize that we would all be prepared to sign up for more if we had more, level funding was a good outcome in this budget and I am anxious to——

Mr. MARKEY. So you do support a 3.5 % increase?

Secretary LEAVITT. I support the President's budget, which brings it even with the 2008 budget. Now, would we like to have more? Of course we would, but we are focused on balancing the budget by 2012, and I am admitting to you I felt pretty good about the outcome because I fought hard for it.

Mr. MARKEY. Now, we are going to in this Committee be moving health IT legislation in the relatively near future. Chairman Dingell, Chairman Pallone, Mr. Barton and I, we feel very strongly about privacy issues and the role which they play in this new modern era as medical research are taken out of doctors' and nurses' cabinets and they are put online. So we are going to consider provisions here, protections which are central to the protection of the most intimate secrets of American families. So my first question to you is, would you support that individuals are notified if their personal information within a health IT system is or is believed to have been exposed to unauthorized users such as cases of a breach of the system's security?

Secretary LEAVITT. Mr. Markey, I believe that patients should control their medical records.

Mr. MARKEY. So if their information is compromised, do you think they should be notified that the information has been compromised?

Secretary LEAVITT. I want to be careful on commenting on specific provisions of bills that I have yet to see, but let me just—I think I can be responsive to your question in this way. I believe that the consumer, the patient ought to both have access to their medical data in a way that is convenient to them. I also believe

that no data should be shared with others if in fact it is not done with the permission of the patient.

Mr. MARKEY. Okay. So you agree then, if I may, that patients should be able to decide for themselves before their most personal information, their medical records are put into the electronic databases and health systems, that they should have to get—that their permission should be obtained before it is put into that database?

Secretary LEAVITT. I believe that medical practices have the right and the need to have electronic medical records for their own clinical uses. However——

Mr. MARKEY. Are you saying even without the permission of a patient, they should be able to put it into an electronic database?

Secretary LEAVITT. I do not believe a patient's information should be sharable with anyone without the patient's permission.

Mr. MARKEY. So you are saying that—just so I can follow, you are saying that their records should be able to be placed inside the electronic record even without the permission of the patient but that once it is inside the electronic record that no information can be disclosed for specific purposes once the patient is inside the system without getting the permission of the patient?

Secretary LEAVITT. Mr. Markey, you and I both understand, A, the importance of this, and B, the sensitivity of it, and I am reluctant to respond to a series of do-you-believes without understanding the context, and I am not being—I am not resisting the conversation. I just want to state in as clear a principle as I can what I believe. Now, I believe that there is a need for patients to control their data. Now, whether or not there is an opt-in or opt-out, I haven't given that enough thought to be responsive to it but I believe in the context that you are placing this, we are agreeing that consumers, patients should have control of their data and that no data should be shared with others without their permission.

Mr. MARKEY. And one final question. Despite the efforts by the—thank you for that answer. Despite the efforts by the CDC, the White House removed the following statement from a statement that Julie Gerbeting was making about climate change, and here is the statement: "The CDC considers climate change a serious threat." That was deleted from her testimony. Do you believe it is a serious threat, and if it is a serious threat, what is HHS doing in the public health sector in terms of climate change?

Secretary LEAVITT. As you know, I headed the Environmental Protection Agency prior to being here and I came to understand the importance and the sensitivity of this issue and I came to understand very clearly that the atmosphere of the Earth is in fact—the temperature is increasing and I think it is clear that man has had some impact on that and that we are now sorting through exactly how to respond to it. In the 36 seconds that we have left, I don't think I am going to be able to lay out a full policy position of the Administration but it is clear that anything that causes the spread of disease is of importance in the health community.

Mr. MARKEY. Thank you.

Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes—oh, before I do. Mr. Secretary, the sound system in this

place is not very good. Would you pull it closer to you, please, because your comments are very important and——

Secretary LEAVITT. Thank you. Oh, I can hear myself now and you can hear me too.

Mr. DINGELL. I think it is important for you to hear yourself but it is even more important we hear you.

Secretary LEAVITT. You never know when I might disagree with myself, so that is good.

Mr. DINGELL. I will you, Mr. Secretary, in the midst of a campaign, I get pretty tired of listening to myself.

The Chair recognizes now the distinguished gentleman from Illinois, Mr. Shimkus, for 6 minutes.

Mr. SHIMKUS. Thank you, Mr. Chairman, and thank you, Mr. Secretary, for being present. I am going to try to go through these pretty quick.

The welcome to Medicare physical exam—you know, I am a big believer in wellness, preventative care. I think it helps the livelihood of individuals. You identify illnesses early, plus it is a huge cost savings to be preventative versus dealing with catastrophic failures. The utilization of this program is low. What do you attribute this to and what can we do to up the utilization of the welcome to Medicare physical?

Secretary LEAVITT. I don't think people know about it. We have a campaign on right now to expand people's knowledge of the benefits that were offered under the Medicare Modernization Act. People tend to think about that as the prescription drug benefit but there were a whole series of screening and the welcome to Medicare physical. We have a bus tour that is going around the country. We have public service announcements. We have lots of different things that are going into correspondence with Medicare beneficiaries, and so I will just concur with you that there is great value and I hope people will hear and use them.

Mr. SHIMKUS. Let me follow up with two other issues that are similar. Gene Green and I worked on the AAA bill, the abdominal aortic aneurysm, the prescreening for this. Same premise, lower utilization. You know, what can you tell me about the utilization on that program, and it just kind of segues into the same point. What are we doing budgetarily as far as education for both these programs?

Secretary LEAVITT. I am not able to respond at that level of granularity on the budget or on the utilization factors. It is something I would be happy to respond to you in writing if you would like, but as you point out, it is the same principle. Part of the modernization of Medicare was to recognize that it is prevention, prevention, prevention, that every dollar we put into prevention we get a big payback in terms of less utilization and we get people who are healthier and that is after all the goal of Medicare and that is healthier Americans.

Mr. SHIMKUS. And I hesitate to move in this direction because we have had discussions before on the Medicaid AMP provisions. It is my contention along with a lot of my colleagues and some independent observers that we don't pay full costs or we don't pay costs to the physicians who are doing the Medicare, especially generic drugs, delivering that service to the seniors. You have before

disagreed with that assumption, I think, and I would just use this opportunity to give you another chance to disagree and then tell me why.

Secretary LEAVITT. Well, now that the microphone is fixed, I won't be disagreeing with myself. My position remains the same, Congressman. We think the plan is working. We think there are negotiations that take place between plans and pharmacies and physicians, and I mentioned earlier in a related area that I am very anxious to see us begin to use e-prescribing and that we could potentially begin to utilize that as a method of being able to change that equation if it isn't working for others, but I don't have the concern that you expressed.

Mr. SHIMKUS. Let me move forward to FDA extraterritorial jurisdiction. Can we get your assistance to work on legislation to kind of address this concern that is coming up through the Committee?

Secretary LEAVITT. I think this is a legitimate question and one that I would like to work on with you. We are seeing more and more of the goods we consume, particularly food and medicines, coming from outside the country, and if people violate the laws of our country or theirs, we obviously have the sovereignty issues that have to be dealt with but we can also move rapidly to cut off access to American consumers, and we should. This is a big concern to me. I recently returned from India where I had a chance to see as many as 80—I didn't see them but I was told that there were between 80 and 100 facilities that are generating vaccines and medicines for American consumption. We need to have a bigger presence there. We need to begin to recognize that that part of our world is changing and that we need a means of being able to rapidly respond when goods or medicines or devices come into this country that don't meet American standards. We need to send a very clear and unambiguous signal to the world that if you want to produce for American consumers, you have to meet our standards.

Mr. SHIMKUS. And I can't speak for the chairman or the Majority but I think your assistance in working through this on the health and safety and the welfare of our citizens would be well received and hopefully would allow us to move something in a compromised fashion that would help us reach those goals.

Let me also move quickly to, the Minority staff issued a report on debarred individuals and our concern that actions not be taken aggressively to keep debarred individuals from being involved in some of the processes. Would you consider posting each of these lists? There are two separate lists. We found, you know, one from HHS, one from—one on the FDA, one in the CMS. Marion Illinois is a veteran hospital in my district in which because of the lack of information they hire doctors who are having issues in other States, and it affected the health, welfare and safety of individuals being served in Marion. Our concern is if there is no clear transparency on the debarred aspect of these folks, we need to help clear that out. I think it was a great work by the Minority staff and we would like your help in doing that.

Secretary LEAVITT. Thank you. I can't respond on the specifics because frankly this is a new idea to me, but I will tell you at a principle level, I firmly believe in transparency and that people

ought to know if those who are producing drugs, those who are producing vaccines, those who are producing devices have done so in a way that does not meet our standards, people ought to know that. So on principle I am prepared to work on the specifics. I just need to have more information.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentleman has expired. The Chair thanks the gentleman. The Chair recognizes now the gentlewoman from California, Ms. Eshoo, for 6 minutes.

Ms. ESHOO. Thank you, Mr. Chairman, and welcome, Mr. Secretary, and thank you for being here.

I just would like to make an observation, having listened to members' questions and statements and your responses. It seems to me that we all love our history once it has been made. We celebrate it, say isn't it extraordinary that at a given time in our country we took steps that would not only place us and our country in a real leadership position but then celebrate the outcomes of that. But we seldom I think have a deep appreciation that we are making history, and I think that is where we are with this budget. I think we are writing the wrong history for our country. At the beginning of this century, the 21st century, where science, technology, biotechnology and all of that is merging and America is on the threshold of not only merging these disciplines but supporting them and investing in them. I think it is a sad statement that the budget is making and I don't think that is Republican or Democrat. I think that the opportunity to do that and seize the opportunity to do that is so critical, and the budget doesn't reflect that. It doesn't reflect that. And so I think that we stand to lose as a country in merging these disciplines and investing in them. In fact, FDA Commissioner von Eschenbach told the Wall Street Journal yesterday that he needs more funding for his agency than what the President has responded to. So with all due respect to you, when you say, you know, I support that and I am for it, but there aren't dollars in the budget and they actually reflect a decrease, I think that is a really serious issue for our country.

Now, having said that, you noted that there is a $66 million investment in the Office of the National Coordination for HIT. I support your commitment to it, the dollars for it. The Commonwealth Fund reported last year that the economy could save nearly $90 billion in healthcare costs over the next decade if in fact we have widespread adoption of HIT. As you know, several organizations are supporting this issue including AARP, the Business Roundtable, SEIU, and they are calling for enactment of HIT legislation this year. We have sent over, Congressman Mike Rogers and myself, the legislation, the bipartisan legislation that we have put together and you have heard that the Committee may soon consider legislating this area. We want you to look at that legislation. We want to work with you on it, and I am just going to assume that you will work with us on it.

On the issue of TB funding, tuberculosis funding, there is a real shortfall there. In Santa Clara County in my district, which is the whole Silicon Valley, there is unfortunately a real serious uptick of TB cases. They don't have the funds to address that so we want to work with you on what the Department can do. I am just point-

ing it out. But I think that is serious. I mean, how can it be that the home of Silicon Valley has more cases of TB reported and we don't have the funding for it? It just doesn't square off and it is serious.

Now, I want to ask you something about SCHIP. In what I think are impossible requirements that the Department has set down, it includes the requirement that States have to first enroll 95 % of their children with families earning less than 200 % of poverty in these programs. Does any State in the union currently meet these standards out of 50 States? Who does?

Secretary LEAVITT. Let me just—there are a couple of things you—let met just answer your first question and there a couple of things you talked about I would like to respond to.

Ms. ESHOO. Well, I would like you to answer this one first. I mean, the others are more observations.

Secretary LEAVITT. We believe there are several who can and CMS——

Ms. ESHOO. No, but are there any States——

Secretary LEAVITT. I don't know the answer——

Ms. ESHOO [continuing]. That meet the requirement?

Secretary LEAVITT [continuing]. To that. CMS would need to respond to that.

Ms. ESHOO. Okay. We will get the answer from you on that.

Of the States that have enacted or have considered programs, you know, to reduce the number of uninsured, has the Department assessed the impact the August 17th guidance has on those States?

Secretary LEAVITT. Well, we feel confident it has caused people to focus on those——

Ms. ESHOO. No, but I mean, have you actually assessed the impact on States? I mean, you have set down today that this is a partnership and while you are saying there are some ambiguities and have not requested anything from us, it seems to me that the Department has the responsibility in an unbiased way to study the impacts. That is why I am asking.

Secretary LEAVITT. Well, we think the ambiguities that we are speaking of are clearly defined in the law——

Ms. ESHOO. Ambiguities are clear?

Secretary LEAVITT. Let me be more specific. For example, many States receive an additional payment for public hospitals. They are now appointing a lot of hospitals as public hospitals that really aren't public hospitals and then they are taking that extra payment and they are putting it into the general fund——

Ms. ESHOO. Well, it seems to me, Mr. Secretary, that you having been a governor, now you are the Secretary, that before we get into the weeds with what is working, what isn't working, that there are some prior values in this, and that is the care of the people that are in your charge and my charge. That is the greatest and highest value of all. I think that these guidances that have been issued are really punitive. You know, I said, I think it was earlier this week, to whomever was here, if children were testifying on the next panel, they would say what did we do to you that you are doing this to us where, you know, children are going to be denied healthcare coverage, you know, for a year before they can enroll.

I mean, where does that come from? Does that spring out of an ambiguity?

Secretary LEAVITT. No. We are in the business, all of us collectively, of choosing priorities and we believe that those who are under 200 % should have our first priority, and the August 17th——

Ms. ESHOO. But you are forcing children who don't have insurance to wait a full year in order to get it. Is that an ambiguity? I mean, what does that come from?

Secretary LEAVITT. No child who doesn't have insurance who is under 200 % has to wait at all. We want to focus on those who are truly—who are in the lowest income categories before we start using money to help people cancel private insurance to have public insurance.

Ms. ESHOO. Well, I think we have a deep disagreement on this, but in these other areas I hope that you can work with us. I think that we can make progress on HIT. It will make a huge impact in our country, and thank you for being here today.

Secretary LEAVITT. Thank you.

Ms. DEGETTE [presiding]. The Chair recognizes the gentleman from Pennsylvania for 5 minutes.

Mr. MURPHY. Thank you, Madam Chairman.

Mr. Secretary, some of the issues you have been speaking out today are some reform issues and I am a believer that we need to fix the system, not just finance it, but starting off, I believe there was something in the news the other day about Medicare costs are going to continue to climb. They are at that point now where they are exceeding half of tax revenues. Is that generally close to where we are?

Secretary LEAVITT. In time as they continue to go up, they will consume all revenues. But Medicare now has exceeded 45 % of its budget coming from revenues for the second year in a row.

Mr. MURPHY. So it continues to climb. Now, let us take a couple of these points you talked about today, for example, the costs to Medicare alone for prescription drug errors. I am assuming what you believe is that some of that can be fixed if we use electronic prescribing where it can automatically check the physician's prescription for the right doses, the spelling, all those things, that would save some money. Do we have any idea how much money that would save if we had these programs using electronic prescribing?

Secretary LEAVITT. I have seen figures public. I do not have recall of those. But one thing we do know and I think we can unequivocally agree, it will save money and lives. The technology is there and it is time.

Mr. MURPHY. Probably in the billions?

Secretary LEAVITT. Oh, it is probably closer to the hundreds of billions over time.

Mr. MURPHY. Okay. And with regard to eliminating nosocomial infections in hospitals, I know there have been some moves to say hospitals will stop paying for those, but when you list all them out, MRSA being that superbug, the killer, but also pneumonia, which many times people don't even realize you may get that from being in a hospital too long, urinary tract infections from having cath-

eters in too long, do we have any idea of how much money is wasted in paying for these preventable illnesses and if we could stop that what we could save?

Secretary LEAVITT. Again, the number is not on the top of my head but we do know that it would save a lot and frankly it just violates common sense for hospitals to be paid for events that shouldn't have occurred.

Mr. MURPHY. Let me expand that also to disease management for chronic illnesses. I know some actions have taken place there, and the majority of healthcare dollars are spent on chronic illnesses and many of those for people with very complex cases, heart disease, diabetes, cancer, people don't live a long time but very complex, many doctors, many treatments. Are we moving forward in a direction here that is also saving money and do we anticipate we can continue to save money if we do this right?

Secretary LEAVITT. Well, this is the sweet spot because we know 75 % of all of expenditures come from chronic diseases which are both their nature both preventative and manageable, and this is the place where the use of quality measures, by the use of electronic medical records, eliminating medical mistakes that can come in the context of the treatment of chronic diseases clearly saves money, a lot of money, and I don't have the figure but this is exactly the kind of discussion we need to be having.

Mr. MURPHY. Well, then here is the trillion-dollar question, because we don't have that number here, because the way that Congress is designed, we can't get numbers on prevention and cost savings. Although CDC has told us it is $50 billion wasted on nosocomial diseases and 90 million lives, 2 million cases, and even though they said that probably $28 billion a year is wasted on prescription errors with Medicare and the 75 % with chronic illness, maybe you can have more luck with finding someone who can actually give us some numbers because the way I see this, as a government what we oftentimes try and do is say well, we are spending too much so let us pay people less. Now, we are told the cost of a loaf of bread is going to climb quite a bit not only because of the cost of wheat but also the cost of transporting it, energy costs. I can't imagine people being told as they go to the grocery store well, even though a loaf of bread is going to jump from a $1.50 to $3, we are just going to—we are not going to do anything about that. I mean, we find ways. We have to find ways. We have to find ways, and this too I just see, instead of us just saying let us pay doctors less and hospitals less, what can we do to make these fundamental changes and fix this system, not just finance it.

Secretary LEAVITT. Congressman, you have heard me say many times that I don't believe we have a healthcare system, what we have is a healthcare sector, and until we are able to organize it into a system, we won't be able to capture that, and the four things I mentioned a couple of times, electronic medical records, quality measures, price comparisons and structuring it so that everyone has a motivation to save money and to have higher quality, we won't see those. Now, as you said, there are many of those things that Congress doesn't choose to score. However, there are discernible savings and I am working right now on being able to deter-

mine what a reasonable person could expect or a reasonable society could expect over time once those are put into place.

Mr. MURPHY. Well, as we go back and forth on the budget that you are requesting, I hope that is something we can come together on that instead of necessarily making just cuts but looking at some real ways of saving lives and saving money so we don't have to be spending so much. It is out of control in the health sector and too many people are dying from it. Just in the 5 minutes that I have been speaking, another person has died from an infection they picked up from a hospital and it unconscionable to me that we are still not doing anything about it. But I thank you so much because I know you are really committed to transparency and a patient's right to know about these things, so thank you for that.

Secretary LEAVITT. Thank you.

Ms. DEGETTE. The Chair recognizes the gentleman from Michigan for 5 minutes.

Mr. STUPAK. I thank the gentlewoman.

Mr. Secretary, as Mr. Barton said, the concern we have over the subpoena, I did speak with you earlier. You indicated we would have this thing resolved and hopefully have it resolved by close of business tomorrow. That is what the letter says and we want to get this thing resolved. Both Democrats and Republicans want to see it resolved and hopefully our offices and work together and get this thing resolved.

Let me ask you this question. You mentioned one of four issues that you think we can improve and help balance budgets, especially your budget, is through electronic medical records. Last year when you were here, Mr. Whitfield asked you about the NASPR program, a program both him and I and Mr. Pallone and others have supported that would save us money, and you said, and I quote, "It is a program we support. It is a program we would gladly administer." However, you also said, "It is the decision that was made at OMB last year not to fund it." So this year did you make a recommendation to OMB to fund NASPR for the 2009 budget?

Secretary LEAVITT. The first part of my statement still stands. We do support the program. We would be happy to administer it. Last year I did in fact make a request. OMB decided otherwise. This year we did not based on their decision last year.

Mr. STUPAK. Because they didn't fund it last year, you felt they wouldn't fund it this year?

Secretary LEAVITT. Well, I think isn't this a program that is either between us or——

Mr. STUPAK. Well, you never funded it last year and this year and actually we had a hearing on October 7 in which your staff, Dr. Wesley Clark, indicated that you strongly support it, it would save money, it is electronic, it cuts down on prescription duplications and deaths. So if it is one of your four tenets, why don't you support the program?

Secretary LEAVITT. Well, as I understand it, it was funded or proposed to be funded through the Department of Justice's budget, not ours, and the issue is one of jurisdiction between committees and——

Mr. STUPAK. But it is authorized under HHS, not under the Department of Justice.

Secretary LEAVITT. I can't reconcile that.

Mr. STUPAK. The Department of Justice has a Bell Rogers program, not NASPR. NASPR is found strictly in your budget, in our appropriations authorization, I should say.

Secretary LEAVITT. Congressman, I can't reconcile this for you. All I can tell you is that yes, we would support it. Our impression was we were supporting—that the Administration was supporting something very similar in the Department of Justice's program, or budget——

Mr. STUPAK. Our hearing on October 7, 2007, showed that a completely different program. One is extensive, the other one is not. One is all-inclusive, the other one is not. You know, we keep hearing you support it but no one will ever ask for the money or fund it.

Secretary LEAVITT. We did last year but it was an issue we didn't revisit.

Mr. STUPAK. Well, since we are talking about budget, the Administration states in its budget, this year's budget, that it is providing a net level increase of $130 million. Is that correct?

Secretary LEAVITT. To?

Mr. STUPAK. A $130 million increase in your budget for FDA.

Secretary LEAVITT. Oh, for FDA?

Mr. STUPAK. Yes.

Secretary LEAVITT. Yes, that is true.

Mr. STUPAK. Okay. Of that $130 million though, $79 million is estimated to be collected through user fees. This is money that must go directly into dedicated programs such as the Prescription Drug User Fee Act and the Medical Device User Fee Act authorized by Congress and this Committee. Is that correct?

Secretary LEAVITT. I believe that is right.

Mr. STUPAK. So if you subtract the $79 million from the $130 million, you really only have $51 million of new money for FDA programs. Is that correct?

Secretary LEAVITT. Whether or not coming from user fees or appropriated funds, they are still available to the FDA.

Mr. STUPAK. No, if it is coming from user fees, it must go to those programs. It cannot be used for other purposes in the FDA. So the new money for the FDA is actually $51 million when you back out the user fee money.

Secretary LEAVITT. Well, I don't want to argue over definitions but I would say that user fees are a different source of funds but they clearly go to the FDA for an FDA purpose.

Mr. STUPAK. For Prescription Drug User Fee Act and Medical Device User Fee Act to approve drugs faster and to approve medical devices faster. It doesn't go towards——

Secretary LEAVITT. The FDA——

Mr. STUPAK. As you testified earlier, when you were in India, all these other drugs, active pharmaceutical ingredients coming from other areas because the Science Board just 2 days ago said $51 million isn't going to make it; in fact, the FDA budget should be $375 million increase, 7 times more than what you are recommending. So how do you account for this disparity, $51 million versus $375 million your Science Board says you need?

Secretary LEAVITT. Well, I don't—I am not here to defend the Science Board's suggestion of our budget. I am here to defend the President's budget. I will tell you that like the Congresswoman said, FDA requested more money. That would be true of almost any agency or department in the Federal Government but part of making budgets is the process of going through and determining where the priorities will be and how much will be given to each. Now, we have added at the FDA 1,000 people over the last 2 years. We have a strategic plan that will begin to change the way we think about things. I think we have had a chance to talk about that as I have with Mr. Waxman and also Mr. Dingell. Clearly, it is going to require more money, and I fought awfully hard to get the $42 million into food safety and the additional money for FDA and I felt good about it in the context of this budget.

Mr. STUPAK. But how do you do it when you said in your statement about India 80 different firms exporting active pharmaceutical ingredients here to the United States and you said they must meet our standards or they can't come in. We don't know where those 80 plants are. We don't know what they are exporting that we saw with heparin from China, and more and more are coming from overseas and we are inspecting those plants, according to our investigations and your own FDA, every 40 to 50 years but yet we inspect pharmaceutical plants here in the United States every 2 to 3 years. You are encouraging people to go offshore. They are not going to be inspected. They can send garbage in because we don't have the inspectors and people are dying as in the heparin. You can't even tell us if that plant that made the heparin was ever even inspected. The FDA says we think we had the wrong address. That is not an excuse. Four people died, hundreds or more injured because of this drug and we don't even know if we inspected it.

Secretary LEAVITT. Madam Chairman, do you mind if I just take 1 minute to respond to this?

Ms. DEGETTE. Mr. Secretary, please be brief.

Secretary LEAVITT. Okay. Our plan calls for us to start having U.S. presence in other countries. We started last year and moving forward to an office in China. We will get our first foothold here this year and I think expand next year. I am suggesting, I believe we need to start the same process in India and that needs to be contemplated in future budgets. Now, adding 1,000 people in 2 years, that is serious progress. Changing the nature of the way we look at these problems, that is—it doesn't happen fast enough for me but nevertheless, we are moving toward the right direction and we are going to take a very clear position that if people want to make products for American consumers, they need to meet our standards.

Mr. STUPAK. The Science Board says you need $375——

Ms. DEGETTE. No, I am sorry, Mr. Stupak.

Mr. STUPAK [continuing]. Million, you bring $51 million. It doesn't look like you are serious about addressing the problem. That is our concern.

Ms. DEGETTE. I am sorry. Your time is expired.

Mr. STUPAK. I realize that. Thank you.

Ms. DEGETTE. And the Chair will announce that there are three votes on the Floor and there are 8 minutes remaining in the vote

on the Floor. At the conclusion of the three votes, Mr. Secretary, we will reconvene for members who want to ask their questions. So I would ask members to come directly back from the Floor, and I will recognize the gentlelady from New Mexico for 6 minutes.

Ms. WILSON. Thank you, Madam Chair.

There are two issues that I would like to address before we break for questions. One is the Urban Indian Healthcare Program. Your budget has proposed to eliminate it for the past 2 years and this will be the third year in a row when you do so. The Congress has not gone along with that. It is a fairly small program, $35 million. The Indian Health Service only earmarks 1 % of its $3.5 billion budget for urban Indian programs and yet 75 % of Indians live in urban areas. In the city of Albuquerque, it is about 50,000 people. Your department continues to propose that those folks be cared for by community health centers and yet the community health centers say they do not have the capacity to be able to absorb the increase in patient loads in the communities where we have high numbers of urban Indians. Why do you continue to propose to close this program when there is no alternative for the Indians who are being served there?

Secretary LEAVITT. If there is not a suitable alternative at a community health center, then we need to bolster the effort of the community health center. It just doesn't make sense to us to have two separate systems in metropolitan areas to serve populations. It does make sense to us to have a separate system in Indian tribal nations and on reservations where there isn't an alternative but where we have the alternative we think we ought to consolidate those efforts. You are right, we proposed it 2 years ago and it wasn't accepted and last year and it wasn't but we do again this year because we just think it makes sense.

Ms. WILSON. Where do you see the efficiencies? Why do you want it shipped over to a community health center that—I mean, we have multiple community health centers in Albuquerque and two that are particular to Indian healthcare. Why do you think that it costs less money to shift them over to the community health centers and shift around these boxes?

Secretary LEAVITT. I think we ought to all recognize that when you have two systems, there is duplication, and we think the quality of both systems—I mean of the one system could be enhanced for both populations.

Ms. WILSON. That assumes that you have a system and what you have is multiple community health centers, but we are going to have to deal with this again. I think your people need to come up and talk to us and show us where you think you are going to save money and where you are going to serve the people who need to be served because I haven't seen a proposal from you on it that will work.

The second issue has to do with recovery audit contracts. They were supposed to go into effect. I understand they have done several States already and they are having problems. They are kind of set up as a bounty payment to go after possible overpayments. You talked about going after value and not volume, and I am very concerned that these kind of bounty hunter folks who are going out to look for audits and problems in billing are going to have a dis-

proportionate impact on small providers in rural areas where there is—people make mistakes. It is not as though this is a simple system to navigate through, and I wonder if you would comment on where we are on that.

Secretary LEAVITT. The private contractors were used in three States that included California. They recovered over $400 million, mostly from hospitals. California objected to the process. CMS is now negotiating with California. The program has been modified and Congress agreed to expand the recovery of audit to all 50 States. We think it is an effective way for us to recovery taxpayer funds when they have been improperly expended.

Ms. WILSON. It is supposed to start in March in New Mexico and the contractor hasn't been chosen. Do you have any update on what is going to happen?

Secretary LEAVITT. I do not.

Ms. WILSON. Thank you, Madam Chair. I yield back the balance of my time.

Ms. DEGETTE. The gentlelady yields back.

Mr. Secretary, we will recess until the conclusion of the third vote and then we will be back.

[Recess.]

Ms. DEGETTE. The Committee will come to order.

The Chair will recognize herself for 5 minutes.

Mr. Secretary, thank you for being with us this morning and for staying through these votes. I just want to ask you about a couple of issues and then one issue I would like to have your department get some more information because I know that you won't have the information at your fingertips. The Administration's budget cuts almost $1 billion for HRSA, which is the principle agency charged with increasing access to basic healthcare for the medically underserved. It eliminates funding for training physicians at children's hospitals, which my children's hospital is very concerned about, for $301 million. It cuts nursing workforce development including the Advanced Education Nursing Program and it also cuts the National Health Service Corps by $2.52 million. So my question to you is, if we have some kind of a bioterror incident or a pandemic or other kind of health emergency, I am quite concerned and other members of this Committee are that the public health workforce could be overwhelmed. But with these deep cuts to our training programs, I am wondering what this will do to the capacity of our public health workforce to respond to an emergency.

Secretary LEAVITT. One of the things that you mentioned that I want to make a specific reference to is the children's hospitals.

Ms. DEGETTE. Yes.

Secretary LEAVITT. Years ago children's hospitals were in very serious peril and the Congress appropriately stepped forward and gave them a special allocation of graduate medical education funds. Since that time hospitals have been righted. The task has been accomplished and we believe that those are now duplication of the normal graduate medical education process. Now, I will tell you that I think the entire graduate medical education system should be thought through but that is the reason behind our reduction.

Ms. DEGETTE. So I can—not to put words in your mouth. What you are saying about these specific cuts is that it is the view of the

Administration that either those areas are duplicitous or that they are no longer needed? Would that be a fair——

Secretary LEAVITT. The original purpose of that stream of funding has been accomplished. Now, of course what happens is that when——

Ms. DEGETTE. I have a couple of other questions. I am sorry. One of the things in the President's budget that you folks have done is eliminated some programs like the prevention block grant and health professions programs and as justification the President said the programs are not based on evidence-based practices and in another case the evaluation found those activities do not have a demonstrated impact. It kind of goes along with what you were just saying, and I agree with that. One of my pet peeves is government just layering on duplicitous program after duplicitous program, but as I think about that philosophy for budget, I am wondering why the President and the Department doesn't apply these same effectiveness standards to the abstinence-only sex education programs, because in the President's budget there is a proposed increase of $28 million to these programs but study after study including a 10-year study that just came out in April 2007 from you folks found there is no evidence that abstinence programs implemented in upper elementary and middle schools are effective in reducing the rate of teen sexual activity and the main objective of Title V, section 510, abstinence education programs, is to teach abstinence from sexual activity outside of marriage. The impact—I am quoting from the results—"The impact results from the four selected programs show no impact on the rates of sexual activity," and in fact last year for the first year in many years the rate of teen pregnancy did not go down in this country. So my question is, what is the rationale for cutting programs like the children's hospitals and the workforce development and all this but increasing abstinence-only sex education funding by $28 million?

Secretary LEAVITT. Madam Chair, it has been my observation, as I suspect it has yours, that when studies like that come out, everyone tends to interpret it according to whatever view they generally have, and I believe this is one of those. As we have reviewed that study, essentially what it says isn't that it doesn't work, it is that it is not distinguishable necessarily from the effect of other——

Ms. DEGETTE. Well, actually that is not true, Mr. Secretary, and if you look at all of the other independent studies, they haven't shown that abstinence-only sex education works.

Secretary LEAVITT. What this study and I believe others indicate is that in their mind they could not distinguish its effectiveness——

Ms. DEGETTE. So you think the abstinence—you have reviewed it and you think the abstinence-only sex education programs work about the same as the abstinence-based sex education?

Secretary LEAVITT. And we also believe there is something——

Ms. DEGETTE. Is that a yes?

Secretary LEAVITT. We believe as the study does that they can have effectiveness but there are things we can do to improve them.

Ms. DEGETTE. So that is what you are trying to do now is improve the abstinence-only?

Secretary LEAVITT. Well, we certainly believe that it is an important part of a sex education approach. We advocate it. We are budgeting more money for it and we also believe that——

Ms. DEGETTE. Not to interrupt you, I am sorry. I am out of time.

Secretary LEAVITT. Yes, you are.

Ms. DEGETTE. But I am wondering if there is someone from your office who you could have speak to my staff about the improvements that you guys think you can make to make these abstinence-only programs work.

Secretary LEAVITT. Yes, I think that is a fair statement. With the time constraint, that might be a more efficient way.

Ms. DEGETTE. Thank you very much. Just one last question. This is the one that I know you won't have an answer to but I really would like a response. As you know, I worked on the embryonic stem cell legislation and I kind of got involved in thinking about some of these programs, and I found out that the Department has appropriated $10 million for this snowflake baby or the frozen embryo adoption program since 2002. Now, 295 children have been born using this so-called embryo adoption, and I guess what I would like to know, if you think is a good use of money, if this fulfills the public health agenda, and how much money is in this year's budget for the embryo adoption and also how much money is in this year's budget for encouraging adoptions of, say, the 114,000 children in the United States who are already born who are waiting for adoption. Now, I don't want to get into an argument with you but this was one thing as sort of a budget hawk that really leapt out and struck me as well.

Secretary LEAVITT. Your assumption that I wouldn't have information today that would respond to your query is right but it is a legitimate question of importance and we will be responsive to you.

Ms. DEGETTE. Thank you. I would appreciate it, Mr. Secretary, if we could have a response from your agency, say, by March 15. Would that be agreeable?

Secretary LEAVITT. Why don't I reference it and I will put a priority on it? I am not in a position at this point to—I don't know the complexity of the research you are asking for. I would like to—I will certainly respond by the 15th. Whether or not we have everything that you ask for is something I need to look at.

Ms. DEGETTE. Thank you very much, and at this time I would like to recognize the gentlelady from North Carolina for 5 minutes.

Ms. MYRICK. Thank you. I appreciate it.

I wanted to ask you about the budget for mental health, and forgive me if while I was gone it was already asked. I know there is a reduction of, I think, $126 million for SAMSA this year in the President's budget, but my question is broader than that. Really what I am concerned about of course is access and really getting this right for the people who desperately need it, which is a lot of underserved population and, you know, it is kind of near and dear to my heart just from family issues that we have dealt with. So can you just give me a broader view of what the mission is and what you want to accomplish in the mental health area?

Secretary LEAVITT. It is very important first to acknowledge that the Federal Government pays in excess of 45 % of all mental health

funds. Second, I would just also acknowledge that there is a need for us to resolve the issues regarding mental health and health insurance and there is moving through Congress right now bills that the Administration has spoken in favor of on mental health parity. So between our efforts to resolve those issues and also our continued funding through Medicare and Medicaid and other places where we pay about 45 % of all funding, we continue to make an effort and know it is an important area. I have had a special education in the last year and the President asked that I take a very deep look at the Virginia Tech shootings, and I went to 13 different communities where these kind of tragic events have occurred.

Ms. MYRICK. Right.

Secretary LEAVITT. Last weekend I attended the memorial service at Northern Illinois University where again we have seen the manifestations of some of these dilemmas. So it is something we will obviously keep working on and have a high interest in.

Ms. MYRICK. What about the relationship with the States? Because I know naturally the States pretty much control what they do with programming but a lot of them are having big problems in getting it right and making sure the services are delivered. Do you have any way that you work with them or, I mean, are they pretty much on their own?

Secretary LEAVITT. The biggest way we work with them is of course through Medicaid where I mentioned but also through SAMSA. Most of what we—most of the funds that we receive in SAMSA are delegated to the States in the form of grants and other programs and we do have an ongoing dialog. In fact, two years ago we put forward a matrix approach to the management of mental health, which has become a centerpiece not just for Federal Government and States but across the mental health community and how we approach and manage it.

Ms. MYRICK. Is it something you work with the governors on as well? I mean, is that another issue that you work with them?

Secretary LEAVITT. Well, it is with the State of course——

Ms. MYRICK. That is what I mean.

Secretary LEAVITT [continuing]. Along a plethora of issues that I deal with the governors on, that is one.

Ms. MYRICK. Well, you know, we see over and over again, and this is not your fault in any way. I mean, my thing is to figure out what is going to work so the person who needs the help can get it, and yes, the mental health parity bill is a part of that. I happen to support the Senate bill and not the House bill because I don't like mandates but the bottom line is, something should pass which will be helpful to people but the access problem and the way the systems are working at most of the local levels and all, it seems to be a real challenge today in people getting the help that they need. There is a lot of confusion and misdiagnosis and all that kind of stuff out there.

Secretary LEAVITT. Could I just mention one lesson that I learned after going to as many communities as I did and sitting down with the mental health community and with the education community and the law enforcement community and asking the question what should we be learning from these kinds of incidents? One of the lessons that became evident to me was that 25 years

ago or 30 years ago we began to change our strategy based on the availability of new medications. Rather than have people in institutions, we began to deinstitutionalize and move people toward community care settings. We were very successful in deinstitutionalizing. We have not yet fully developed our community delivery system.

Ms. MYRICK. There is no question. They are on the street and good homes are a problem and you can't get them in communities and there is not money for them and all that kind of thing.

Secretary LEAVITT. If I were to look for an area of investment, from my own view, that would be it. Now, we supplement that through SAMSA but it is also a place, as you point out, that the States and local communities need to be focused, and one of the second lessons we learned is that we are very slow to share information that is perfectly appropriate to share. There are lots of places under HIPAA that information can and should be shared that people don't because they are afraid.

Ms. MYRICK. Well, with the shootings, that is part of the challenge you have there too because those people all had previous records and some way that could have gotten help maybe before if somebody had known about it. Anyway, I would be glad to work with you any way I can on that. Thank you for your answers.

Ms. DEGETTE. The Chair recognizes the gentleman from New York, Mr. Engel, for 5 minutes.

Ms. ENGEL. Thank you, Madam Chair.

Mr. Secretary, I want to talk to you a lot about 9/11 but since the gentlewoman from North Carolina, Ms. Myrick, just spoke, I just wanted to briefly call your attention to a bill that the gentlewoman and I are sponsoring, which is a very strong bipartisan bill. We are really troubled by a lot of the damaging Medicaid regulations put forward by CMS with regard to public and teaching hospitals and we are asking for—our bill puts a moratorium for a year on these regulations being implemented. We hope our bill passes but it could simply—if you simply rescinded some of these regulations, there would really be no need for our bill. The Congressional Joint Economic Committee issued a study finding that Medicaid and the State Children's Health Insurance Program enrollment and the number of uninsured will rise over the next several months as a result of the current economic downturn and so I would just appeal to you to consider rescinding or postponing some of these regulations. The Joint Economic Committee specifically called upon the Administration to delay or cancel these proposed regulations that shift Medicaid costs to the States, so I am wondering if you could briefly tell me that you would consider rescinding this. It is again bipartisan. It hurts the States and we really would ask you to consider postponing it or rescinding it.

Secretary LEAVITT. Congressman, I understand your view. I expressed earlier, and I know you have a question so I won't let it go too long except to say we feel that the regulations are appropriate for reasons if you would like to take more time I would be happy to respond to but we likely will not be withdrawing those and I want to be straightforward about that.

Mr. ENGEL. Then let me also say before I get to the 9/11 things that I am very troubled by the budget slashing Medicaid and Medi-

care funding, particularly for teaching hospitals. Representing New York, our teaching hospitals train one in seven doctors nationwide and it is very, very troubling. This budget is very harsh in its treatment of teaching hospitals. The budget also slashes Medicare and Medicaid funding by $200 billion over 5 years and we estimate in New York our hospitals and health systems will lose $1 billion in 2009 and $10 billion over the next 5 years. It is really very, very troubling, but I will follow up with you on these things.

September 11, I mentioned it in my opening statement. This budget proposal increases a 77 % funding cut for 9/11 healthcare programs from $108 million, which isn't adequate in itself, from fiscal year 2008, down to $25 million for fiscal year 2009. I would implore you to please consider at the very minimum restoring that to the level of the 2008 budget to $108 million. We are not talking about lots of money here, and September 11 obviously is a tragedy for the country, not only for New York. We have our first responders who ran there, people who went there day after day trying to save lives are now dying. Some have already died or are sick for the rest of their lives. We are told that this impacts virtually every district across the country and it is unconscionable that the Federal Government is slashing funding and doesn't have a better response. We have a bipartisan bill sponsored by the whole New York delegation, Mrs. Maloney, Mr. Natham, Mr. Fossella on the Republican side, and we really think that we really need to step up with this. So I am wondering if you could comment on that, if you would consider restoring the money?

Secretary LEAVITT. Congressman, lest you would interpret that $25 million addition as being a lessening in our commitment, I want to disabuse that point. We currently have $175 million in unused appropriation that is available for the treatment of those authorized under the law, and our budget was put forward on the basis that we want to make certain there is adequate money to meet the demand, and at the point that there is more demand, then we will obviously be open to more appropriation.

Mr. ENGEL. Mr. Secretary, would you agree to meet with some of us in the New York delegation to discuss this, to have a meeting to discuss this? I think it would be very helpful if we could go back and forth on this important issue of 9/11 first responders funding for health reasons.

Secretary LEAVITT. I am always available to have conversations that can lead to a positive conclusion. I do want to emphasize though that our commitment is there but we didn't feel the need to additional dollars, given the $175 million that currently resides in the funds that are available.

Mr. ENGEL. So you will meet with us where we can discuss these issues?

Secretary LEAVITT. If it becomes important to meet with the delegation, I am happy to.

Mr. ENGEL. Well, I think it is important. Will you give me a commitment to meet with us? I would appreciate it.

Secretary LEAVITT. I am very happy to meet with you.

Mr. ENGEL. Thank you, Mr. Secretary.

Ms. DEGETTE. The Chair recognizes the gentleman from New Jersey for 5 minutes.

Mr. FERGUSON. Thank you, Madam Chair.

Thank you, Secretary Leavitt, for being here today. We appreciate your service. You have a very tough job and you discharge your duties with great skill and dedication and we certainly appreciate that.

I have a couple of questions today, a third if I have time. The first two are on public safety programs, the National Strategy for Pandemic Influenza, we have talked about this many times, and the second is about the strategic national stockpile for anthrax vaccines.

First I want to commend you and the Department on the great steps that you have taken to put into place all the key elements for the national strategy for pandemic influenza, the NSPI. In your budget is a request for the third year of funding which would complete the plan. One of the key parts of the strategy is making sure that in addition to the federal stockpiles that the States are also doing what they need to do. My understanding is that to date our Federal Government has purchased 50 million courses, which is recommended under the NSPI, while the States really haven't kind of stepped up to the plate as much yet. Some States have done great. Other States are sort of in the middle and some States really haven't done anything at all. My State, for instance, is getting close to a million courses in the stockpile. It is better than 90 % of what New Jersey is supposed to be doing. But it has been really kind of a mishmash of activity on the States' parts. What can we be doing to move the States along? How can we address this? Is this addressed in the budget request for this year and what can the Federal Government do, what can the Department be doing to move States in the right direction?

Secretary LEAVITT. Our pandemic plan proceeds as it was laid out originally. We have not had a new appropriation applied to that plan since 1986 and that is of great concern to me. We need to be successful on this budget to keep it moving forward. We are making substantial progress in the area of vaccines, particularly in the adjuvant or dose-sparing area. We are continuing to build our stockpile of antivirals, Tamifu and others that are appropriate. We have seen a robust response from most States but there are some who just made very deliberate decisions not to do it. I think that is the wrong decision but it is in fact their decision. We did pandemic summits in all 50 States and most of the territories and this issue was very put very squarely on the table and was talked about and some have made a decision not to do it. I think it is an error. We will continue to encourage them to prepare not just in the context of antivirals but in all aspects of community preparedness.

Mr. FERGUSON. I would encourage you to continue those efforts whether it is a carrot or a stick, however we need to do that, because that is obviously crucial because the plan really won't be effective as it has been designed until the States are doing frankly what the Federal Government, what you and the Department have already done, which is really step up to the plate and do what is necessary.

Secretary LEAVITT. We are encouraging people all over the country, whether they are a State government or a local government and for that matter those in private sector, to begin to prepare.

One of the worries I will just express in one sentence is, I worry that while we are moving and working hard on this that sometimes our effort at the Federal level causes the State and local governments to not view this as a priority, and public health is fundamentally a local issue. We do a lot that they can't do but it is a local issue and they need to take responsibility and ownership for this.

Mr. FERGUSON. And if you ever have recommendations for us what we can be doing as representatives from all around the country and obviously we have a great deal of interest in what is going on in our individual States, we certainly would appreciate your advice and suggestions on that front.

Let me please turn to the anthrax vaccine strategic national stockpile. Back in 2001, the Department established the need for 75 million doses of the anthrax vaccine, which would protect about 25 million people. The past 6 years HHS has procured closing in on 29 million doses, as far as I am aware, still short of the number that we are trying to reach. My understanding is that HHS is trying to procure this second-generation anthrax vaccine called RPA, which it hasn't been approved yet. It is not going to be available I understand for at least a few years if not several years. It has a short lifespan, a year-, year-and-a-half shelf life. We have other vaccines, proven vaccines which we have begun to stockpile already, they have a longer shelf life, they are proven, they have been in use. Why not continue to purchase and stockpile what we have available to us, what we know works and which frankly will last us longer in terms of shelf life than perhaps waiting for this second-generation vaccine which frankly we aren't even sure of its effectiveness yet?

Secretary LEAVITT. Well, as you point out, there is no such thing at this moment as a second-generation vaccine so we do continue to stockpile the first generation and we are building according to our goal. However, it is necessary that we get to the second generation, and what we are doing now is essentially research and development and we are asking for people to help us solve those problems.

Mr. FERGUSON. Thank you very much.

Thank you, Madam Chair.

Ms. DEGETTE. The Chair recognizes the gentlelady from California for 5 minutes.

Mrs. CAPPS. Thank you, Madam Chair, and thank you, Mr. Secretary.

Earlier this morning my colleague, Heather Wilson, brought up her great concern with the recovery audit contractor program. Secretary Leavitt, you claim that you have recovered over $400 but your own report that was released today disputes that assertion. I have here a summary of that report. Due to the high error rate, especially in California, that figure is actually lower because of all the claims that providers are appealing, and finally when they get to the third appeal before an administrative judge, they are winning. Eighty-eight % of the supposed overpayments have been recouped from inpatient claims yet your own chief financial officer yesterday in a briefing for committee staff, which my staff person attended, admitted that the program was fatally flawed when it

came to inpatient rehab and said we shouldn't even bother using it as an example. With an error rate of over 40 % in California as proven by a third-party evaluation of the program, I don't believe we are ready to move forward with this program. I believe that evaluation is only the tip of the iceberg. Auditing is a critical part of safeguarding taxpayer dollars and none of the providers I have ever meet object to auditing but it must be done correctly, and all indications are that this program, the one we have experienced in California, does not meet the test. Here are three or four of my questions to which I hope brief responses will suffice.

Do the figures in your evaluation reflect all of the money you are now accountable for returning to the providers because they have been winning their appeals?

Secretary LEAVITT. Congresswoman, I don't know that I have seen the report that you are referencing and I am not sure that from what I have heard about it that it reflects the conclusions that you have drawn. We believe that this is an important part of the way we can maintain program integrity. We also believe that it can be refined and improved. As you point out, it is a relatively new program. We have tried it a few places. We will do our best to improve it. I understand why a hospital would not like—as you say, they are willing to be audited but they really don't want to be collected, and——

Mrs. CAPPS. Well, not if they are—they have to pay all along the way the costs of these appeals and then when they get to the end and it is overturned, they are still not recouping that money and that is——

Secretary LEAVITT. Sixty % of them aren't being overturned and 40 % we have got to get better at, if that is what the number is.

Mrs. CAPPS. Okay. Well, you didn't have the facts for the first one, and the report was released today and your CFO was talking about it yesterday. Can you tell me how much in taxpayer dollars CMS is spending on these appeals?

Secretary LEAVITT. I don't have that fact.

Mrs. CAPPS. Could we get these in writing? I understand if you haven't seen it but the first question I asked that you didn't know and this one that you don't have the information, I think it would be important for our records.

Secretary LEAVITT. I would be very happy to respond if you want to give me a question——

Mrs. CAPPS. We will put it in writing to you, and I appreciate that.

And finally I would like to know how much money of the recovered money has been paid to the private contractors which will never go back to the Medicare trust fund. In other words, they don't have to—if they are wrong at the end of the appeal process, there is no cost to them. They have already pocketed the money. That is how it was explained to us.

Secretary LEAVITT. Well, that would be one interpretation of it, but again, we view it as a program with a lot of potential that we can refine, but we will respond to your questions.

Mrs. CAPPS. Thank you. Finally though, I want to get one more on the record if I could. According to the status update, the tables regarding appeals data doesn't reflect claim determinations of ap-

peals filed on or before September 30, 2007. Many providers didn't receive the decisions in their favor until after September 30 and now it has been validated by administrative law judges that they were in fact denied incorrectly. They have been filing many more appeals. Wouldn't this mean, if this is the case and many had not filed until the saw that the results were coming the way they were coming even though they believed they were wrongly censured. Wouldn't this mean that we are going to see much more money paid back to the providers and much less money saved by this program if this trend continues?

Secretary LEAVITT. Well, these are questions that would be better directed to CMS, and I would be happy to make certain that——

Mrs. CAPPS. I am going to direct them to CMS, and I appreciate your hearing me out. We have had many concerns over many months that have not gotten answers that we wanted to. Therefore, I am happy to put them in writing to you and look forward to hearing back from you. Thank you very much.

Ms. DEGETTE. The gentlelady yields back. The Chair recognizes the gentleman from New York for 5 minutes.

Mr. FOSSELLA. Thank you, Madam Chair, and thank you, Mr. Secretary for your patience. Let us jump right into 9/11 and in a way follow up on Mr. Engel's comments. You know this is an issue that we care deeply about and love to have, you know, everybody at the federal level working with local and State and everybody being on the same page. Even to this day it doesn't appear that that is the case despite maybe your personal desire and efforts. You mentioned about the $175 million left unspent. I understand it is obligated more for research grant applications. One of the reasons I think it causes us concern, for example, is the cancellation of the business center, the treatment business center in December. If you recall, that was really an HHS directive to create or to establish this business center, and almost without notice that program or that effort was terminated and we haven't gotten really I think a sufficient response. The ones we got have been all over the place, to be candid. So I would like to know your position on that and what is happening and the status of that business center.

The other question, as you are probably aware, we have been told that as a result of that, within 2 weeks thousands of folks, responders, some suffering from mental trauma, will receive letters as required by HHS regulations that say the program is being terminated and that ultimately perhaps the care that they are receiving will be compromised. In addition, I know there is a $25 million placeholder in the budget but some of the services that are to be reduced, it is my understanding, would compromise the care to residents and children affected in the surrounding area that inhaled the toxins at the time.

And finally, NIOSH itself developed estimates that put costs for running the current program at $218 million a year. You say there is $175 million yet unused or obligated unused. Why only the $25 million? We are still asking the question in many different ways and we would just love for HHS to really be taking the lead. New York City and New York State have been shouldering this burden I think disproportionately. The problem is only going to get worse. Every month there are 500 new people who sign up to be mon-

itored. They are moving throughout the country, 2,000 zip codes in the country. This is really a federal responsibility to an attack on America. So those are several questions and I would love to hear your response, Mr. Secretary.

Secretary LEAVITT. Well, let me break them into two categories. First, with respect to the $175-plus million, that is not obligated for research, etc. It is there available for treatment and we want to be responsible in the treatment of those that the federal law allows us to be.

With respect to the business center, that is something I am afraid I can't add a lot to the conversation on right now. I don't have the details. It is something that I am happy to try to respond to you in a written way but I don't have details that I can offer you today.

Mr. FOSSELLA. Well, let me just say this, if they can do it a little more expeditiously than last year. Two weeks ago, I think from February 8 we received responses to questions I asked last year at this time on this subject. It took almost a year to get a written response. So inasmuch as time is of the essence, can you promise me it will take a little less than a year at this time?

Secretary LEAVITT. I am always embarrassed when I hear that happening, so yes, I think we will do better on this one.

Mr. FOSSELLA. Thank you. With respect to the letters that may have to go out to the responders, I mean it is sort of related to the business treatment center. I mean, it is only 2 weeks away. Is there any way you can ensure or guarantee that those letters will not go out? Can you envision being treated for mental trauma——

Secretary LEAVITT. It sounds like a matter with some urgency to it. I am not familiar with it, to be honest with you, and not because I don't care about it. It is just not an area that I manage directly, but I think we can get a response to you in the short term.

Mr. FOSSELLA. And finally, you know there has been legislation introduced. I would love for at least some comment as to maybe we can make it better if you don't support it in its current form. But if you recall, Dr. Ogwanobi promised a report on the data collected for the financial and health information needs of this program and we never saw the report, and that was last year.

Mr. FOSSELLA. That was never intended to be a report. It was a task group that was set aside to help me resolve some issues. The issues were resolved by Congress even before they finished their work and therefore a report was not required and won't be forthcoming because it was not the intention of putting the group together. The issues it was studying were resolved by Congress.

Mr. FOSSELLA. Thank you, Mr. Secretary.

Ms. DEGETTE. The Chair now recognizes the gentleman from Texas, Mr. Gonzalez, for 5 minutes.

Mr. GONZALEZ. Thank you very much, Madam Chair. I know that I waived my opening remarks. I don't know if I can get an extra minute or not.

Ms. DEGETTE. Yes, yes, 6 minutes.

Mr. GONZALEZ. I appreciate it.

Secretary Leavitt, welcome, and I thank you for your patience. I have about four different areas. I want to start on what I think might be a simple one. I want to follow up on what Congressman

Markey was making reference to regarding health information technology, electronic medical records or whatever we want to call it because I think we are all embracing the concept. We understand its benefits but we are very concerned about the privacy factor here. Would you agree with the statement that regardless of how medical records may be gathered, retained, stored, disseminated, that the principles of privacy that belong to that patient apply regardless of the technology that is being utilized?

Secretary LEAVITT. I believe that a patient has to right to assure that their medical information will not be transported to another party without their permission.

Mr. GONZALEZ. I am just saying, if we can all agree, because we have had this debate before regarding other methods of obviously keeping these records and sharing them, can we just not apply the same principles that have served us well to whatever technology we are utilizing?

Secretary LEAVITT. I actually have not found much difficulty in agreeing on the principles. I have found there to be some difference based on perspective on how those principles would be applied. There is a need for a position to be able to manage records that are important to the practice of that clinic or hospital in a way that is actionable on their part consistent with their procedure. It is very clear to me as well that a consumer, a patient ought to control the dissemination of that to any other party. Those are principles I believe we can agree upon and I look forward to a conversation on ways to advance it.

Mr. GONZALEZ. I am just saying that I think if we just start off with that basic proposition, we can get to trying to see how we can actually have with your pilot project and everything else. Otherwise if we start off from day one if there is a question about privacy, I assure you we are going to have a very difficult time so I think we need to be coming together real quick on those principles and then everybody that is involved with that technology can find a way to address them, I guarantee you, and it is not just medical records but it is everything else. Business models such as business technologies change doesn't mean that we forget about antitrust laws or anything. So I am just saying the concepts, principles, the very tenets of what we hold dear in this particular society carry over to any technology and I wish we would just come to an early agreement on that.

Prescription drug reimbursement rate, my understanding, again, this is just with my conversations with my pharmacist back in San Antonio, that your reimbursement rate is predicated on the average manufacturer price. Now, my local pharmacist, the little guy on the corner, is having a real hard time on that reimbursement rate. Even my grocery store-situated pharmacist is having a real hard time because in essence you are reimbursing them at the same rate that you would reimburse what we refer to a prescription benefit manager, that obviously the amounts, the quantities that are being purchased may be one thing for the prescription drug management entity as opposed to the grocery store pharmacy base or the local pharmacist. What even I think aggravates the situation is that my little pharmacist, let us say a pharmacy in the deep west side of San Antonio, I would venture to guess it is 70

% of their customers are going to be Medicaid and Medicare so they are really impacted. How do you reconcile that? And I know that this is being contested and it is out there right now waiting for a decision.

Secretary LEAVITT. On Medicare part D, those reimbursement rates are negotiated between the plan and the pharmacy. On Medicaid, the reimbursement rates are actually negotiated between the State and—or in the State, and so, you know, I would say that if those are the two primary areas of your pharmacist's practice, that he really ought to focus his attention on Medicaid on the State of Texas and then negotiating agreements that he can feel good about with the plan.

Mr. GONZALEZ. Well, maybe I don't understand it as well as I should, but what is this average manufacturer price, how is it derived, who determined it, who set this particular standard?

Secretary LEAVITT. Well, it has gone through a lengthy process and it has been long debated and these are questions that might best be responded to by CMS as opposed to me. I have been taken through the exercise a number of times and I understand it when I hear it but I am not certain I would be as good at explaining it to you. But it is essentially the price, the lowest price that people buy that drug at. The obvious effort is to make certain that we are able to——

Mr. GONZALEZ. But we all know, I mean, just that numbers generally—if you are purchasing a lot of anything, generally you are going to get a better price. Does that mean everybody that doesn't have that kind of market share then suffers? And you are right, maybe I should discuss this with CMS and we will, and I have 45 seconds. One member of this Committee viewed your $19 billion, whatever it is for SCHIP as an expansion. Another member, Mr. Pallone, who happens to be the chair of the subcommittee, indicated that it is inadequate just to keep up with present needs. Who is right? What you have now in your budget for SCHIP, is it an expansion of SCHIP as represented by someone on the other side, or is Mr. Pallone correct to simply say just to stay up with what you have now?

Secretary LEAVITT. It very clearly would cover more children going into the future. It would focus on those children who are 200 % of the poverty level. We believe that we should focus on those before we begin to expand Medicaid into populations where people, many people have insurance and would likely cancel it in order to get government insurance. Our position has been very consistent. We have tried to fund in our budget the policy that was put into the expansion or the extension, the 18-month extension. The number is different than it was before because of—I think our time is up.

Mr. GONZALEZ. And I appreciate it, but I think what you are arguing here probably plays right to what Mr. Pallone represented. Thank you very much, and I yield back.

Ms. DEGETTE. The Chair recognizes the gentleman from Washington State for 5 minutes.

Mr. INSLEE. Thank you, Mr. Secretary. You have said that your job is to defend the President's budget and I think that is a little bit like the job of a mob lawyer. It is difficult. It is busy, it is de-

manding and it is difficult, given this budget, and I want to ask you about it, because one of the things you said, I am not sure I agree with you. You said that you can always want more money, and I just want to point out, it is not a question of you wanting more money. It is a question of whether you have the money to do what you are charged to do, and it is very disturbing to see this letter from the scientific committee that says most of the programs are massively underfunded. If they are to carry out the public and Congressional expectations presented them, thus whether the subcommittee has reached a proposed number that is accurate to the dollar is not the issue. It is that the FDA needs a very substantial increase in resources if it is to protect us as the public expects and Congress demands, and I would suggest that the issue is what the public expects and what the law demands, not what you or I want.

I want to ask you in specific reference to one of the FDA's jobs, which is to protect the public from these machines that are used to fool desperate people into thinking they have got a cure and these hoax machines, and this article by a Seattle newspaper, the Seattle Times, was really pretty stunning that they found in use like 40,000 of these machines, 10,000 of these EPFX machines, hundreds or thousands of the pap ion machines, and they told these horrendous stories of people in desperate conditions being defrauded out of money and hope that they might otherwise have by people using these scam machines, and we sort of looked into what the response has been and it is relatively negligible by the agency to be able to deal with this flood tide. I mean, these things are like, you know, almost one every street corner, it seems, and they are operating in wide-open advertising and they are not being shut down. So I guess the question is, does this budget allow you to fulfill the agency's responsibility to fulfill the public's expectation that you are going to shut down these bogus, fraudulent medical devices.

Secretary LEAVITT. Let me deal with your first point and then go to your second. If we made the assumption that there was an unlimited amount of money available, we would never have to choose a priority. We would never have to have competing noble causes which compete. We would never have to resolve those. But that is not the world that we live in and it is not the world at least in the budget philosophy of the Administration. We believe we don't have an unlimited capacity to tax people and therefore we take what we have and do our best to allocate it. Now, I will tell you frankly in a budget is intended to be balanced by 2012, I fought very hard to get that additional money into the FDA budget and I feel good about it. When you look at what has gone on, what we have to deal with to balance the budget, it is a clear mark of our intent, and I have said a couple of times, we have added 1,000 people at FDA over the last 2 years. There is a rate limiting capacity to manage that and that expansion in a way that is productive, particularly when we are trying to change the philosophy of what we do.

Now, with respect to the medical device, FDA would be a better place to direct that. I don't know with any specificity on that device. Very clearly they have a role there. Their primary role, interesting enough, is to determine if a product is safe or not. There are both State and local responsibilities for people who are selling

products but your point is, we have a responsibility, we need to meet it.

Mr. INSLEE. Well, I am not sure you and I are tracking because what I would expect the Secretary to come forward and say we have a statutory obligation, we have a public expectation, this budget will not meet either of those, which I believe clearly is the case as your own scientific review board indicates, but there just isn't enough money available to fulfill those. Now, that is what I would expect because I think it is a clear situation here and offer a rationale that there are higher priorities or you didn't want to close the tax loopholes of millionaires or you didn't want to close the tax loopholes on oil companies making $100 million a day or, you know, whatever, but just to come up and tell us that it is not going to what the Congress expects you to do, and I think that is absolutely clear.

Secretary LEAVITT. Well, let me make a comment about any scientific advisory board, which there are many, and the people who devote service and we respect it and value it. They are there to advise and to inform our judgments, not as a substitution for them, and any advisory, whether it is this one or another, offers a very important perspective but we do not advocate our need to make judgments and to set priorities to advisory committees. We are informed by their judgments but they do not substitute for our judgments.

Mr. INSLEE. Thank you.

Ms. DEGETTE. The gentleman's time has expired.

Mr. Secretary, thank you so much for making the time to be with us this morning. We are honoring our commitment to get you out of here by 12:45.

Secretary LEAVITT. Thank you. It looks like I wore everybody out.

Ms. DEGETTE. Yes, you have worn us down to nubs. I would also look forward, I know both sides of the aisle would look forward to hearing the responses to the questions we have asked for follow-up on. Thank you very much.

The meeting adjourned.

[Whereupon, at 12:45 p.m., the Committee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. EDOLPHUS TOWNS

Thank you, Chairman Dingell and Ranking Member. Welcome Secretary Leavitt. As the Congressman from the 10th congressional district of New York, I am profoundly disappointed with the Administration's proposed fiscal year 2009 budget and CMS rules. They devastate kids, seniors, persons with disabilities, chronically ill individuals, students, research institutions, poison control centers, health care programs for 9/11 workers, and state budgets. It is with great sadness that I say this. Thank you Mr. Chairman, I yield back.

May 9, 2008

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

Thank you for appearing before the Committee on Energy and Commerce on Thursday, February 28, 2008, at the hearing entitled "A Review of the Department of Health and Human Services Fiscal Year 2009 Budget." We appreciate the time and effort you gave as a witness before the Committee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the question, including showing the Member's name, and include the text of the Member's question along with your response. The Committee apologizes for the delay to you in forwarding this request to you, however, we believe your responses to these questions are important and they will be included in the hearing record. Your assistance with the request is appreciated.

To facilitate the printing of the hearing record, we ask that we receive your responses to these questions by the close of business on **Friday, May 30, 2008**. Please have your written responses delivered to **2125 Rayburn House Office Building** and faxed to **202-225-2525** to the attention of Hasan Sarsour, Legislative Clerk. Please send, as well, an electronic version of your responses to Mr. Sarsour at **hasan.sarsour@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Mr. Sarsour at the Committee on Energy and Commerce at (202) 225-2927.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Edolphus Towns, Member
Subcommittee on Health

The Honorable Gene Green, Member
Subcommittee on Health

The Honorable Diana DeGette, Member
Subcommittee on Health

The Honorable Lois Capps, Member
Subcommittee on Health

The Honorable Mike Doyle, Member
Committee on Energy and Commerce

The Honorable Baron Hill, Member
Committee on Energy and Commerce

The Honorable Mike Rogers, Member
Subcommittee on Health

The Honorable John Sullivan, Member
Subcommittee on Health

The Honorable John D. Dingell

1) According to the Science Board report, over the past 35 years food inspections by the Food and Drug Administration (FDA) have been reduced by 78 percent because of dwindling agency resources. FDA estimates that, at most, it inspects food manufacturers once every 10 years and cosmetic manufacturers even less frequently. The Agency conducts no inspections of retail food establishments or of food-producing farms.

   a) Does the budget provide adequate resources to close these gaps?

   Response:
   The amended FY 2009 budget request provides additional resources for FDA's field operations to oversee the adequacy of industry prevention strategies through increased risk based inspections, audits of contamination controls, sampling, and surveillance.

   FDA developed a comprehensive Food Protection Plan (FPP) to address both food safety and food defense. The FPP focuses FDA's efforts on preventing problems first, using risk-based interventions to ensure that preventive approaches are as effective as possible, and instituting a rapid response as soon as contaminated food is detected. The FPP is integrated with the Administration's Import Safety Action Plan in the shared principles of prevention, intervention, and response.

   These initiatives reinforce the importance of safety measures to address risks throughout a product's life cycle and build upon FDA's risk-based approach to inspectional activities. By focusing on prevention, FDA is promoting increased corporate responsibility so that food problems do not occur in the first place. In addition, FDA's Beyond Our Borders Initiative will expand FDA's presence in other countries. We recognize that FDA cannot inspect its way to safety.

   To support this work, the Administration requested additional resources. The FY 2009 budget submitted to Congress in February 2009 and the FY 2009 budget amendment submitted in June 2008 recommend increased funding for food protection of $167.2 million

   Specifically, FDA will build the additional capacity to conduct the following field operations with the FY 2009 increases proposed in the amended budget request:

   - 1,857 additional domestic food safety inspections
   - 850 additional foreign food inspections
   - 90 additional imported and domestic cheese program inspections
   - 92 additional domestic low acid canned food inspections
   - 50 additional domestic fish and fishery Hazard Analysis and Critical Control Point (HACCP) inspections
   - 85 additional juice HACCP inspections
   - 40,000 additional import food field exams

The funding increases will allow FDA to build the capacity to achieve the foreign inspection increases by the end of FY 2010.

b) Do you think the Agency should conduct inspections of retail food establishments or of food producing farms?

Response:
Conducting regulatory inspections of retail food establishments has long been the responsibility of agencies at the state, local, and tribal level. Health Departments and Departments of Agriculture in the 56 states and territories work in conjunction with over 2,000 city and county health departments to conduct food safety inspections of restaurants, food stores, schools, hospitals, other institutions, and vending operations.

Federal resources are best directed at providing leadership in the science of retail food safety and in assisting state, local, and tribal agencies develop and implement inspection programs that result in improved industry practices. Leveraging the expertise and mutual resources of Federal, state, local, and tribal partners provides the best opportunity for maintaining regulatory oversight of an extremely varied and diverse industry of well over one million establishments in the United States.

FDA plays an active role in this "cooperative program" and devotes resources to promote more effective and uniform inspection programs. Among the numerous on-going FDA initiatives aimed at improving food safety at the retail level, are:

- Publishing the FDA Food Code, a science-led model code after which agencies throughout the United States model their state and local ordinances and that the retail industry recognizes as the authoritative resource for food safety practices at retail;
- Issuing guidance documents that elaborate on best practices on topics such as retail Hazard Analysis Critical Control Point (HACCP) programs, employee health and hygiene, and consumer advisories.
- Maintaining and promoting the use of the FDA Voluntary National Retail Food Regulatory Program Standards by state, local, and tribal agencies. Among others things, these Standards outline the optimal practices for training inspection staff, conducting inspections and enforcement activities, investigating illnesses, maintaining industry and community relations, and evaluating program effectiveness.
- Making FDA's State Training classroom and Web-based training on retail food safety-related topics available to approximately 27,000 state, local, and tribal regulators.
- Working with associations of state and local authorities and with industry associations to develop and implement strategies for improving food safety practices at retail.

Leveraging and collaboration of these cooperative programs, which include retail food and foodservice establishments, Grade A milk safety, and molluscan shellfish, is an effective use of the nation's food-safety resources.

With regard to inspections at food-producing farms, while FDA does not routinely conduct on-farm inspections, FDA has made significant efforts to improve food safety at the farm level. For example, FDA published the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," which recommends good agricultural practices and good manufacturing practices that growers, packers, and shippers can take to address common risk factors in their operations. FDA and the U.S. Department of Agriculture issued the Guide in several languages and have conducted significant outreach, both domestically and internationally, to encourage adoption of the recommendations. FDA continues to provide training in good agricultural practices.

In addition, FDA proactively engaged the produce industry to develop commodity-specific guidelines for those commodities that, according to the Centers for Disease Control and Prevention, have been associated with a larger proportion of foodborne illness outbreaks. FDA provided extensive technical input to industry, and we have provided links to these guidelines from our web site (http://www.foodsafety.gov/~dms/fs-toc.html#prod) to facilitate access by growers and packers of these commodities. So far, commodity-specific guidelines have been developed for lettuce and leafy greens, melons, and tomatoes.

FDA also has developed and conducted several training courses on farm investigations for FDA and state investigators to provide them with the necessary tools when farm investigations are conducted, for example, as a follow-up to an outbreak.

2) Please indicate whether you generally agree with the following primary findings in the Science Board report:

   a) "FDA does not have the capacity to ensure the safety of food for the nation." (page 21.)

Response:
The American food supply is safe, and FDA has adequate resources to ensure that the U.S. food supply is among the safest in the world. Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

However, changes in food production technology, industry practices, demographics, consumer preferences, and other factors have posed challenges that required us to adapt our current food protection strategies and to develop the Food Protection Plan. For

example, shifting population demographics mean that more of the U.S. population is, and increasingly will be, susceptible to foodborne illness. In addition, consumers are eating more foods that are prepared outside the home. Consumers are also eating a greater variety of food year-round due to the increasing volume and variety of imported food products. In addition, the variety of agents associated with foodborne illness has grown steadily over the last few decades. While consumers in the U.S. enjoy one of the safest food supplies in the world, growing challenges required a new approach to food protection with an increased emphasis on prevention.

FDA's Food Protection Plan is a critical first step in addressing these issues. The Food Protection Plan focuses on improving food safety through prevention, intervention and response. The prevention element means promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures with industry and other stakeholders, FDA can best address critical weaknesses. The intervention element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly. The response element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. It also includes the idea of better communication with other federal, state, and local government agencies and industry during and after emergencies.
Implementing the steps described in the Food Protection Plan, along with the resources needed to fund them as requested in the FY09 budget, are necessary to improve food safety in the United States.

Implementation of the Food Protection Plan is underway. FDA held a meeting with all 50 states to share information and develop strategies and future activities between Federal, state and local partners. FDA has begun the effort to increase its presence beyond our borders by setting up an office in China and possibly other countries. FDA has piloted the use of an advanced screening system to identify food safety threats at the border. In order to strengthen response efforts, FDA awarded grants to six states to establish Rapid Response Teams to enable rapid, localized response to foodborne illness outbreaks or other food-related emergencies. The six states receiving the funding are Michigan, California, North Carolina, Massachusetts, Florida, and Minnesota. FDA is also holding two public meetings this fall to further the discussion of best practices for product tracing. The purpose of the meetings is to stimulate and focus a discussion about mechanisms to enhance product tracing systems for fresh produce and to improve FDA's ability to use the information in such systems to identify the source of contamination associated with fresh produce-related outbreaks of foodborne illness.

We will continue to move forward to implement the Plan and work with all our stakeholders to enhance the safety of the food supply.

b) "The FDA IT infrastructure is obsolete, unstable, and lacks sufficient controls to ensure continuity of operations or to provide effective disaster recovery services." (page 50.)

Response:
While there are many Information Technology (IT) challenges that FDA faces, outlined below are some activities that FDA has taken to try to alleviate these challenges.

Starting in 2004 and revised in 2006, the FDA Business Framework drove the establishment and implementation of the Bioinformatics Board (BIB) to provide strategic direction and coordination of business process and information management (IM) harmonization initiatives. Additionally, five Business Review Boards were established to harmonize business processes across FDA strategic lines of business:

- Pre-Market
- Post Market Safety
- Product Quality and Compliance
- Administrative Services
- Scientific Computing/Computational Science

In 2007, the Chief Operating Officer (COO) position was established and the Chief Information Officer (CIO) position was elevated to respond to the importance and criticality of IT issues/concerns. Furthermore, the Business Review Boards identified five-year goals and strategic objectives for Information Management. As a result of these strategic goals and objectives five Agency-wide IT initiatives were established:

- Information and Computing Technologies for the 21st Century
- MedWatch Plus
    1. Adverse Event Portal
    2. FDA Adverse Event Reporting System
- Harmonized Inventory Project
- Common Electronic Document Room
- FDA Advanced Submission Tracking and Review: Information Bus Exchange

Outlined below are some of the Food and Drug Administration Amendments Act (FDAAA), Import Safety Action Plan (ISAP) and Food Protection Plan (FPP) initiatives and impact:

Information Management Initiative	**Impact**
Information & Computing Technologies for the 21st Century	Provide modernized servers & analysis mechanisms to meet Bioinformatics requirements.
MedWatch Plus	Provide single portal for adverse event reporting and consumer complaints.
Harmonized Inventory Project	Clean-up legacy data and provide one

Information Management Initiative	Impact
	source for registration and listing data.
Common Electronic Document Room	Provide an FDA-wide electronic document room to facilitate data sharing across all business lines.
FDA Advanced Submission Tracking and Review	Establish services that will move data across applications throughout the continuum of the Product Lifecycle from Pre-Approval through Consumption creating a closed loop system encompassing all FDA business lines.

Throughout 2007 and to the present, the FDA has realigned all IT resources, both project and personnel, to the CIO as well as restructured the decentralized IT components across FDA to the CIO. Timelines and dashboards for Agency initiatives have been developed and disciplined focus has been established on cost and standards, creating a foundation for long term savings.

Continuing in 2008 and beyond, the FDA will achieve business driven IT that is managed as a FDA IT investment portfolio, standardize approaches to systems development to increase interoperability, minimize redundancy by centralizing IT and obtain economies of scale across FDA through leveraging Indefinite Delivery/Indefinite Quantity Contracts to deliver the systems and functionality to implement the FDAAA, ISAP, and FPP.

These advancements at FDA have raised Information Technology to a corporate level resource that is being directed, governed and managed across the Agency by the Bioinformatics Board and the CIO. This approach enables business driven IT support and services that promote and protect public health.

On September 30, 2008, FDA announced the selection of ten contractors to receive up to a total of $2.5 billion for information technology (IT) and data center management services over the next ten years. The contract is the cornerstone of the FDA's Information Technology for the 21st Century (ICT21) bioinformatics initiative, an extensive IT modernization program encompassing data management, data warehousing, IT infrastructure and IT security.

c) "Recommendations of excellent FDA reviews are seldom followed." (page 56.)

Response:
Over the years, FDA has been the subject of many outside reviews. The recommendations and comments in these reviews are always carefully considered and evaluated. Often recommendations are implemented. Dr. von Eschenbach, Commissioner of Food and Drugs, asked for the Science Board review because he wanted the advice of outside experts to help the Agency in its efforts to modernize its

scientific capacity. FDA is committed to following up on the Science Board recommendations. The Report's recommendations dovetail with some of the Agency's new statutory responsibilities under the Food and Drug Administration Amendments Act of 2007. For example, both asked FDA to create a Chief Scientist Office. On April 9, 2008, FDA announced the appointment of Frank M. Torti, M.D., M.P.H. as FDA's Principal Deputy Commissioner and first Chief Scientist. As Chief Scientist, Dr. Torti supported the launch of FDA's Fellowship Program and will work to ensure the quality and regulatory focus of the intramural research programs of the Agency.

The Institute of Medicine (IOM) Report issued in July 2006 contained many recommendations that FDA has already implemented, or are in the process of implementing, in the areas of medication error prevention, patient education and label comprehension. In September 2006, the IOM released another report entitled, "Promoting and Protecting the Health of the Public: The Future of Drug Safety." The report recognized the progress and reform already initiated by the Agency and made a number of recommendations for additional improvements. Shortly thereafter, in January 2007, the Agency issued its response to the IOM recommendations, outlining a comprehensive implementation plan. FDA continues to work on a number of initiatives for improving drug safety that the Agency identified in that January 2007 response to the IOM recommendations, and has already made significant progress on several projects.

FDAAA requires FDA to develop a new active, post-market surveillance capacity for drugs and biologics; IOM and the Science Board made a similar recommendation. On May 22, 2008, FDA launched the Sentinel Initiative with the ultimate goal of creating and implementing the Sentinel System-a national, integrated, electronic system for monitoring medical product safety. The Sentinel system will enable FDA to query multiple, existing data sources, such as electronic health record systems and medical claims databases, for information about medical products. The system will enable FDA to query data sources at remote locations, consistent with strong privacy and security safeguards. Data sources will continue to be maintained by their owners.

The 2009 budget provides resources for FDA to respond to recommendations made by the Science Board, IOM, and GAO, in their various reports, including among other things, strengthening food protection, modernizing drug safety, speeding the approval of generic drugs, and improving the safety and review of medical devices.

d) "The FDA has substantial recruitment and retention challenges." (page 40.)

Response:
There always are challenges in recruiting and retaining a high quality scientific government workforce. In a highly competitive market place, recruiting and retaining scientific staff is a challenge as FDA is competing with other health-related organizations and institutions for the same pool of individuals. Additionally, some of our mission-critical positions require specialized education and experience making some of our key

positions the most difficult to fill, as oftentimes only a limited number of individuals possess these unique skills. However, FDA is committed to hiring and retaining the necessary personnel to ensure we accomplish our mission of protecting and promoting public health. FDA recently was granted direct-hire authority, which expedites the hiring of qualified candidates, for numerous mission-critical positions including medical officers, mathematical statisticians, consumer safety officers, microbiologists, chemists, epidemiologists, biologists, pharmacologists, pharmacists, and health/regulatory/general health scientists. We have expanded our recent recruitment efforts to include a broad range of events nationwide including those involving academia and professional associations as well as those targeted at attracting veterans, minorities and persons with disabilities. This effort resulted in FDA hiring an additional 1,300 exceptionally skilled experts including physicians, scientists, inspectors, and investigators.

In the fall of 2008, the FDA also launched a new two-year fellowship program, which provides an opportunity for health professionals and other scientists to receive training and experience at FDA and for the Agency to benefit from their knowledge and experience. In addition this program is aimed at attracting scientists, engineers and health professionals to the Agency and to provide participants with advanced training in the scientific analysis involved in the safety and regulatory decisions unique to the Agency's mission.

e) "The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak." (page 3.)

Response:
FDA is a science-based Agency. FDA continues to fulfill its public health mission. The Agency recognizes that it must be equipped with the expertise and infrastructure to meet emerging challenges, such as: foodborne disease outbreaks, whether intentional or unintentional; evaluation of complex drugs and biologics developed by emerging techniques in molecular and cell biology; the potential for pandemic influenza or other emerging infectious diseases; and miniaturized bioengineered medical devices, to name a few. The world is undergoing a rapid expansion of scientific knowledge and globalization that will have dramatic impacts on the industries and products that FDA regulates.

FDA has taken a number of steps to support their existing scientific regulatory base and to prepare for future challenges through designing and executing activities based on internal, proactive, strategic thinking. As noted above, on April 9, 2008, FDA announced the appointment of Frank M. Torti, M.D., M.P.H. as the FDA's Principal Deputy Commissioner and first Chief Scientist, who will, among other things, work to ensure the quality and regulatory focus of the intramural research programs of the Agency. Also, as noted above, FDA has hired an additional 1,300 exceptionally skilled experts including physicians, scientists, inspectors, and investigators, to enable FDA to further its mission.

Launched in March 2004, FDA's Critical Path Initiative is FDA's effort to stimulate and facilitate a national effort to modernize the sciences through which FDA-regulated products are developed, evaluated, and manufactured. In March 2006, HHS Secretary Leavitt and then Acting FDA Commissioner Andrew von Eschenbach announced the release of FDA's Critical Path Opportunities List, providing 76 concrete examples of how new scientific discoveries—in fields such as genomics and proteomics, imaging, and bioinformatics—could be applied during medical product development to improve the accuracy of the tests used to predict the safety and efficacy of investigational medical products. FDA is building on its unique position to work with other federal agencies, patient groups, academic researchers, industry, and other stakeholders to identify areas ripe for improvement and to coordinate, develop, and/or disseminate solutions to scientific hurdles that are impairing the efficiency of developing and evaluating FDA regulated products.

For example, on October 7, 2008, FDA announced a collaboration with the Program for Appropriate Technology in Health (PATH) Malaria Vaccine Initiative (MVI) to develop laboratory tests to better predict the level of safety and effectiveness of experimental malaria vaccines before they are used in human clinical trials. PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions to improve global health and well-being. PATH-MVI supports the development of malaria vaccines and is expected to spearhead the efforts to ensure their availability and accessibility in the developing world once a safe and effective vaccine becomes available. This collaboration with the PATH-MVI supports the overall mission of the FDA and specifically the Agency's work under our Critical Path Initiative.

Following are two other examples illustrating both FDA's application of state-of-the-art applied science and the Agency's commitment to request peer review and assessment of our work. As part of the Agency's response to the 2007 melamine contamination of animal food, FDA prepared a Multi-Center Melamine Safety Risk Assessment to describe the possible risk to human health associated with eating pork, chicken, fish and eggs from animals that had been inadvertently fed animal feed that may have been adulterated with melamine and its analogues (cyanuric acid, ammelide and ammeline). The FDA Science Board, an advisory board to the Commissioner, rapidly peer-reviewed the Agency's Melamine Safety Risk Assessment and unanimously concurred with the findings in the assessment.

In addition, in connection with the recent heparin investigation, FDA was able to establish a link between a contaminant found in heparin, oversulfated chondroitin sulfate, and the serious adverse events seen in patients given heparin after intensive inquiry and laboratory analysis. FDA worked closely with the manufacturer and experts in academia and private laboratories to carry out a thorough chemical analysis of the suspect products. Conventional laboratory testing did not initially identify the contaminant. FDA experts then developed new test methods using state-of-the-art technologies such as nuclear magnetic resonance, capillary electrophoresis, enzymatic kinetics, and bioassays. As a result of a disciplined systematic examination, FDA scientists identified the previously

unknown contaminant in the heparin. Specifically, some of the heparin product and heparin API manufactured by Baxter's supplier, SPL, was contaminated by oversulfated chondroitin sulfate, a heparin-like product derived from animal cartilage.

3) FDA is conducting physical inspections of less than 1 percent of food imports. Do you believe that the budget provides adequate resources to significantly increase physical inspections for food resources? Why or why not?

Response:
The FPP focuses on prevention as a means to promote improved food protection through measures ranging from general best practices for all foods to the possibility of additional measures for high-risk food. By focusing on prevention, FDA is promoting increased corporate responsibility so that food problems do not occur in the first place. By building safety in from the start, FDA will be better able to target its resources to achieve maximum risk reduction.

We recognize that FDA cannot inspect its way to safety. Therefore, the FPP and ISAP reinforce the importance of safety measures to address risks throughout a product's life cycle and build upon FDA's risk-based approach to inspectional activities.

In FY 2007, the percent of food import lines physically examined was 1.28 percent. For FY 2008, FDA estimates that it will examine 1.13 percent of food import lines, and in FY 2009, the estimate rises to 1.26 percent.

In FY 2009, FDA plans to increase it's capacity to perform an additional 40,000 import food field exams, 10,000 medical product field exams and an additional 375 food and medical import lab sample analyses by FY 2010. In addition, FDA electronically screens all FDA-regulated products offered for formal entry into the United States. FDA also performs security screening on 100 percent of the prior notices submitted for imported shipments of human food and animal feeds. Prior notice is required for all such shipments. In addition, risk-based security targeting results in tens of thousands of intensive prior notice reviews of the highest risk food shipments each year.

FDA will continue to focus resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. The benefit of Prior Notice Import Security Reviews comes from the quality and targeting of review activities, not from the volume of imports analyzed. The quality of import screening is a better measure of FDA's import strategy than simply focusing on the number of items physically examined.

We also note that the Office of Personnel Management granted FDA direct hiring authority in April 2008 under which FDA's Office of Regulatory Affairs (ORA) is executing the plan for increased food inspections. ORA will hire an additional 150 employees to conduct food field exams, inspections, and sample collections. These investigators will conduct critical

activities such as import food field exams. They will also assist senior investigators perform high risk food inspections.

4) Our investigations found that FDA can only inspect foreign drug makers once every 13 years. Experts tell us that inspections should be done once every two to three years. Do you agree?

Response:
A risk-based approach to using limited foreign inspection resources is most effective and pragmatic in terms of consumer protection. FDA will continue to apply a risk-based approach to identify drug production and distribution activities of greatest concern and focus resources on those activities. The two to three year inspection frequency that you propose generally could be appropriate for those facilities manufacturing high risk finished drugs or active phamarceutical ingredients (APIs), and products named in pending New Drug Applications (NDA) or Abbreviated New Drug Applications (ANDA). Some firms with questionable current good manufacturing practices compliance histories may need more frequent inspections. Some API manufacturers and low-risk over-the-counter drug product manufacturers and testing laboratories can be inspected less frequently. Even among facilities manufacturing sterile drugs, the risk of non-sterility (one criterion for assigning a risk-based inspection frequency) will differ for aseptically processed drugs and terminally sterilized drugs. For some products, even the type of technology used can affect the level of risk.

Regular inspections of some foreign facilities by other reliable government authorities should also influence the frequency of FDA inspections. FDA also believes resources available for surveillance inspections should be heavily directed for facilities in countries not known to have robust regulatory systems.

It is critical to note, however, that while inspections are an important component to ensuring the safety of imported medical products, we believe in a multi-pronged approach. The FDA Beyond Our Borders Initiative is one prong, designed to promote and verify compliance of imported food, cosmetics, and medical products with FDA requirements. This Initiative includes increased FDA presence overseas, increased FDA inspections, greater sharing and use of foreign competent authority inspection reports and other information, use of third party certification, and increased capacity building with countries that have less developed regulatory systems to ensure product safety. The Agency is currently working to establish FDA offices beyond our borders, in China, India, Latin America, Europe, and eventually, in the Middle East.

5) For China, more than 700 firms now make drug products and export them to the U.S., yet FDA is only able to inspect about 10 to 20 firms a year. This means it will take the agency more than 50 years to inspect each firm one time with present resources.

a) Is this calculation correct?

Response:
Using a simple average to make this calculation would have a number of limitations. Not all sites that register with FDA actually ship, or they may discontinue shipping after a given period of time. Our inspection program overseas is primarily driven by pre-approval inspections. This type of inspection brings us to sites that consistently file applications or that we have never inspected because they are new sites. To further facilitate using a risk-based approach, FDA's Operative and Administrative System for Import Support (OASIS) import data is factored in to determine the frequency or existence of shipping from any given site. After applying the site selection model to the registration data, FDA uses OASIS import data to generate the limited number of strictly surveillance inspections we conduct overseas. In addition, if we learn of specific, significant safety issues related to a facility, that facility would be inspected if analysis by FDA suggests an inspection would be beneficial. As discussed above, FDA believes that a risk based approach to using foreign inspection resources is most effective and pragmatic in terms of consumer protection. FDA will continue to apply a risk-based approach to identify drug production and distribution activities of greatest concern and focus resources on those activities.

In addition, as mentioned above, inspections are only one piece of a mulit-pronged approach. The Agency is currently working to establish FDA offices Beyond Our Borders, in China, India, Latin America, Europe, and eventually, in the Middle East. This initiative was developed to increase FDA presence overseas, increase FDA inspections, greater sharing and use of foreign competent authority inspection reports and other information, use of third party certification, and increase capacity building with countries that have less developed regulatory systems to ensure product safety.

b) Do you believe the FY2009 budget will adequately provide resources to deal with this issue?

Response:
The President's February FY 2009 budget request provided increases of $42.2 million which funded an additional 50 foreign food inspections, 20,000 additional food field import exams, as well as 1,057 additional domestic food safety inspections.

In June 2008, the Administration submitted an FY 2009 budget amendment to Congress for an additional $275 million for FDA. If Congress approves the FY 2009 budget amendment, FDA estimates that it will achieve 1,050 additional domestic inspections and 1,050 additional foreign inspections. Of the 1,050 additional domestic inspections, 250 are domestic medical product inspections. Of the 1,050 additional foreign inspections, 250 are foreign medical product inspections. These increased inspectional performance outputs will be realized in FY 2010 once new investigators are hired and fully trained.

The additional medical product inspections will be comprised of human drug, biologics, animal drug, and medical device inspections. The additional 250 domestic medical product inspections will include:

- 75 Human Drug inspections
- 137 Biologics inspections
- 13 Animal Drug inspections
- 25 Medical Device inspections

The additional 250 foreign medical product inspections will include:

- 143 Human Drug inspections
- 13 Biologics inspections
- 14 Animal Drug inspections
- 80 Medical Device inspections

Inspections are one important enforcement tool that FDA uses to ensure the quality of medical products, including drugs, from foreign and domestic sources. In addition, FDA's Beyond Our Borders Initiative is a cornerstone of the Action Plan for Import Safety, and includes establishing offices in China, India, and other locations. In addition to FDA foreign inspections and import exams, this initiative also relies on greater collaboration with foreign regulators, use of third parties to provide information about the compliance of regulated industry with FDA standards, and greater FDA direction to regulated industry to ensure that their global activities meet FDA standards.

Consistent with recommendations in the Action Plan for Import Safety, FDA must modernize its IT systems. Improving FDA's IT will help the Agency target inspections to foreign firms whose products pose the greatest risk. IT improvements will allow FDA to better predict the firms and products that pose the highest risk imports.

Under the Action Plan for Import Safety, FDA must also strengthen its capacity to conduct the science that supports risk-based inspections. FDA scientists must stay ahead of those who accidentally or intentionally defeat FDA oversight of imports. The Action Plan for Import Safety requires a strong FDA science-based program including laboratory support so that FDA can ensure the safety of imports for patients and consumers.

6) Class II and III medical device makers are inspected every two years domestically. Yet, overseas, FDA can only inspect class III makers once every 6 years and class II manufacturers every 27 years. Do you believe that this is a problem?

Response:
Each year, FDA performs foreign device pre-approval and Good Manufacturing Practice (GMP) inspections which assess data in applications and a firm's GMP compliance. These inspections are designed to evaluate the capability of manufacturing facilities to generate a safe and high-quality product and address manufacturing location, design, source and specifications of components, manufacturing controls, and product labeling and servicing, among other things. In FY 2007, FDA conducted 290 inspections of foreign device manufacturers which includes pre-approval, GMP, and post-market audit inspections), compared to 237 in FY 2005, and 220 FY 2006.

In FY 2009, FDA's Office of Regulatory Affairs (ORA) plans to conduct 334 pre-approval, GMP, and post-market audit inspections plus 58 additional device inspections in the Bioresearch Monitoring, Mammography, and Radiological Health program areas, for a total of 392 foreign device inspections. In addition, the FY 2009 amended budget request includes funds for 80 additional foreign device inspections. ORA will work with FDA's Center for Devices and Radiological Health to determine the specific program areas for these inspections. ORA is hiring, training, and building the capacity to perform these inspections by the end of FY 2010.

It is critical to note, however, that while inspections are an important component to ensuring the safety of imported medical products, simply calling for more inspections is not the solution. The FDA Beyond Our Borders Initiative is a multi-pronged approach to promote and verify compliance of imported food, cosmetics, and medical products with FDA requirements. This Initiative includes increased FDA presence overseas, increased FDA inspections, greater sharing and use of foreign competent authority inspection reports and other information, use of third party certification, and increased capacity building with countries that have less developed regulatory systems to ensure product safety.

7) The Administration's FY2009 Budget requests cuts of $136.7 million from funds for State and local bioterrorism and emergency public health preparedness and $61.9 million from hospital emergency preparedness programs. The Administration has cut these programs over the past five years, reducing the funding level by one-third. A recent report by the National Association of County and City Health Officials (NACCHO) found that these cuts have adversely affected local preparedness. Can you please explain why the President has continuously sought to decrease funding for these programs despite evidence that his cuts are hurting local preparedness capabilities?

Response:
The FY 2009 President's Budget proposes to shift the grant cycle for these programs to a 9 month, 3 week grant period, instead of the usual 12 months. The request maintains funding at the same level as in FY 2008 on a month-to-month basis. This shift is proposed to allow future grant periods to begin on June 1 instead of August 31, which better aligns with State budget cycles and other Federal grant programs, provides States more time to meet the matching and maintenance of effort requirements in the Pandemic and All-Hazards

Preparedness Act (PAHPA) that will be implemented in FY 2009, and makes it easier for ASPR and CDC to implement the performance and reporting requirements in PAHPA.

8) The Food and Drug Administration Amendments Act (FDAAA) signed into law last year authorized a new and separate user fee program for the advisory review of DTC prescription drug television advertisements. The DTC user fee program would have been available to companies interested in voluntarily submitting a DTC television advertisement to FDA for advisory review. The FDAAA, however, provided that in order for the DTC program to commence, it was required that FDA receive at least $11,250,000 in combined advisory review and operating reserve fees 120 days after the legislation was enacted. This did not occur. Can you explain why the Agency did not collect the required amount in user fees so that this much needed program could commence?

Response:
On September 27, 2007, the President signed into law FDAAA (Public Law 110-85). FDAAA provided that advisory review and operating reserve fees could be collected only to the extent and in the amount provided in advance in appropriations Acts.

On December 26, 2007, the President signed the Consolidated Appropriations Act, 2008 (Public Law 110-161). The law does not appropriate user fee funds for the voluntary review of Direct-To-Consumer (DTC) television advertisements. As a result, under FDAAA, FDA did not have the authority to collect and spend user fees for this purpose. Therefore, no invoices were sent and the Agency collected no user fees for DTC advertisements.

9) Consistent with the President's Budget for FY 2007 and FY 2008, the National Institutes of Health Office of the Director (NIH OD) budget does not continue the National Children's Study (NCS) in FY 2009. The FY 2009 President's budget requests no funds to continue implementation of the National Children's Study. To phase out this study, existing contracts for pilot studies and other activities will be allowed to expire when the FY 2008 funds provided for planning are exhausted and no additional contracts will be awarded.

   a) What is the Administration's rationale for not funding this study despite your acknowledgement that the study will be "one of the richest information resources available for answering questions related to children's health and development and will form the basis of child health guidance, interventions, and policy for generations to come?"

Response:
No funds are requested to continue the National Children's Study in FY 2009 as NIH is investing in higher priority areas. The Study's future price tag of at least $3.1 billion over 28 years to implement the data collection phases for a study as large as this one is more than NIH can commit to meeting. Financing this large study would require undesirable trade-offs in other NIH priorities, such as the number of investigator-initiated research grants that NIH could afford.

10) The President's budget proposes to zero-out funding for the Emergency Medical Services for Children program. For nearly 25 years, the Emergency Medical Services for Children program has improved the availability of child-appropriate equipment in ambulances and emergency departments and has supported hundreds of programs to prevent injuries, and has provided thousands of hours of training to EMTs, paramedics and other emergency medical care providers. Is this correct?

Response:
When the Emergency Medical Services for Children (EMSC) program was established in 1984, States did not have pediatric protocols integrated into their EMS systems. To date, considerable progress has been made and 44 states have implemented state-wide pediatric protocols for medical direction. Many States today are better equipped to handle occurrences of critical or traumatic injury in children. The President's FY 2009 budget supports funding the Maternal and Child Health (MCH) Block Grant. The activities previously funded under the EMSC program may be continued by States utilizing funds under the more flexible MCH Block Grant.

11) The President's budget proposes to zero-out funding for the Health Professions program, a program dedicated to addressing national shortages in the health professions. Since its inception, progress has been made in the areas of geographic distribution, but there are still areas in the country where health professions shortages exist, particularly in inner-city and rural areas. Is this correct?

Response:
The Health Professions program under Titles VII and VIII of the Public Health Service Act provides both policy leadership and support for health professions workforce enhancement and educational infrastructure development. The Administration requests $66.1 million in FY 2009 for Health Professions Training. While the budget eliminates funding for several programs, it directs resources to nursing programs that provide direct patient care in areas where nurses are critically needed. Additionally, the President's Budget focuses on activities that would directly address issues of health care access, namely, activities that place health care professionals in areas of greatest need.

In addition, an Office of Management and Budget (OMB) Program Assessment Rating Tool (PART) review of the Health Professions program was conducted in 2002 and the program received a rating of Ineffective. The PART review noted that there is a disagreement regarding the purpose of the program. A clear and focused purpose is not found in the authorizing legislation, external reviews, and program documents. While the program is managed well overall, it has not regularly used performance data to improve program outcomes.

12) The President's budget proposal eliminates funding for the Children's Hospital Graduate Medical Education Program, a program has been critical to our ability to fund the training of future pediatricians and meet the health care needs of children. Is this correct?

Response:
No funds are requested for the Children's Hospital Graduate Medical Education Payment Program (CHGME) in FY 2009. The FY 2009 budget focuses on activities that fund direct patient care by placing doctors, nurses, and other health care professions in regions of the country that face shortages. An Office of Management and Budget (OMB) Program Assessment Rating Tool (PART) review of the CHGME was conducted in 2006 and the program received a rating of Adequate. The PART review noted that the program makes timely payments to eligible hospitals and is achieving its long-term performance goals, but is fundamentally duplicative of other Federal, State, and private efforts. Also, the PART review determined that the CHGME does not address a specific need. Children's hospitals are more likely to have positive profit margins than other hospitals. In 2000, 74 percent of children's hospitals had positive margins, compared to 67 percent of all hospitals, and 59 percent of major teaching hospitals.

13) Please explain how the President's "high poverty areas" initiative for Health Centers is different from his "high poverty county" initiative? The President has committed $27 million toward the high poverty areas effort. Is this amount sufficient, given what we know about the lack of access to primary health care throughout the Nation?

Response:
The FY 2009 Request for the Health Center Program continues support for the President's High Poverty goal to place health centers in high poverty areas that currently lack a health center site. Under the President's High Poverty goal, the FY 2008 Request included $26 million to be directed to fund health centers in poor counties around the Nation that lacked a health center site. The continuation of the President's High Poverty goal is reflected in the current FY 2009 Request that includes another $26 million for the President's goal of placing health centers in high poverty areas. This Request will fund up to 40 new access point grants in high poverty areas around the Nation without a health center site. Priority points will be available for applicants demonstrating that they will serve areas (or populations) with a significant percent of the population at or below 200 percent of the Federal Poverty Level (FPL).

This approach would maintain the Administration's focus on highlighting the needs of the highest poverty areas, by creating an additional incentive to serve these areas where there is no existing health center. It also allows for open competition at a national level – and applicants would be eligible from all States. In addition, the $26 million request will fund up to 25 planning grants to community-based organizations for projects to plan and develop Health Centers in high poverty areas across the country. This support will enable community-based entities in areas without the benefit of a health center to enhance their readiness to implement a health services delivery grant, and in some cases provide an inducement for an organization to address the health care needs of the underserved in a high poverty area where there would otherwise be no expansion activity.

The Honorable Edolphus Towns

Poison Control Center Question:

1) Mr. Secretary, my question concerns the proposed funding for the Poison Control Centers. The Administration's budget proposal calls for $10 million. The 2008 funded amount was $30 million. HHS's FY 2009 justification estimates evaluating 2005 data said that "72.5 percent of all human exposure calls (2.4 million) to poison centers were able to be managed on-site, avoiding unnecessary visits to healthcare facilities. With an average emergency room visit costing $560 by 2007 figures, poison center calls saved nearly $1 billion in annual medical expenses. The Institute of Medicine study found that every dollar spent on Poison Control Centers saves $7 in healthcare costs. HHS has recognized the value on a cost-avoidance basis, therefore why wouldn't HHS fund the poison controls centers at the level accorded in 2008? It seems like a good return on our investment. The Administration's FY 2009 justification also said that these centers have been stabilized and accredited, but this justification ignores the fact that medical directors and toxicologists are needed to staff these centers and must be paid. Please respond.

Response:
The FY 2009 budget request represents the accomplishments of the Poison Control Center (PCC) grants. The original purpose of the financial stabilization grant program was to support efforts by PCCs to steady their funding structure and increase accessibility to poison prevention and control programs and services. These grants have largely accomplished their goal of stabilizing funding for the centers, and HHS funding now represents only 8 percent of total financing for PCC operations.

The remaining funding is provided through state funding, poison center host institutions (primarily hospitals and universities), contracts with hospitals to whom poison centers provide consultation, other grants, and donations. The certification grant program assists centers in achieving certain standards thereby enhancing the quality of poison control services available to the public. Fifty-eight of the 61 poison control centers (95 percent) are now certified. This is an increase from 78 percent in 2001. All grantees continue to implement financial stability activities, such as strategic planning, staff retention strategies and financial planning initiatives.

9/11 Question:

2) Mr. Secretary, I'd like to ask you about the health care programs for 9/11 workers. As you know, there are first responders throughout the country who worked at Ground Zero and are now suffering serious health problems from breathing the air there. There have been internal estimates from your own department (NIOSH) that the cost of maintaining existing health care programs, which don't even cover all the needs, is about $200 million next year. But the President's budget requests only $25 million. Can you explain that? Why wouldn't programs for 9/11 heroes be fully funded?

Response:
HHS has allocated $925 million for WTC-related efforts since September 11, 2001. A large portion of this amount has gone to support care, treatment and monitoring services for responders. CDC plans to carryover approximately $118 million to FY 2009 to support screening, monitoring and treatment of responders affected by the WTC attack. With these balances and the President's FY 2009 budget request of $25 million, CDC expects to have sufficient resources to support ongoing medical monitoring and treatment for responders (residing within and outside of the NYC-NJ metropolitan area) through FY 2009 and beyond.

Health Information Technology Question:

3) Mr. Secretary, you said at an HIT conference in Florida that consumer privacy of electronic data was essential. Yet, the Administration's budget only allocates $2 million for enforcement. If patient privacy is regarded as being so important why would the Administration allocate what seems like such a relatively low amount to enforcement and what has been the enforcement history thus far?

Response:
The Department's Office for Civil Rights (OCR), which administers the HIPAA Privacy Rule, does not budget separately for its civil rights and Privacy Rule enforcement activities because it has an integrated program. However, OCR estimates that approximately $17,200,000 of the $40,099,000 FY 2009 President's Budget request for OCR operations will be dedicated to Privacy Rule enforcement activities. The $17,200,000 in FY 2009 includes a request for an additional $2,051,000 and 13 FTE to increase OCR's ability to respond promptly to the more than 8,500 Privacy Rule complaints filed annually with OCR by the public.

With respect to enforcement history, OCR's investigations and demands for corrective action and compliance have resulted in changes in the privacy practices and procedures of covered entities in over 6,985 cases (67% of investigated cases) since the April 2003 compliance date. The change obtained from these covered entities has been systemic, benefiting all health care consumers served by the entities. In approximately 3,470 cases (the remaining 33% of investigated cases), OCR's investigations found no violation. In addition, OCR resolved 21,780 cases after intake and review due to jurisdictional or procedural issues, or lack of allegations that would constitute a failure to comply with the Privacy Rule.

OCR has referred 438 cases to the Department of Justice for criminal enforcement and 261 cases to the Centers for Medicare and Medicaid Services for HIPAA Security Rule enforcement.

In summary, OCR has received more than 38,800 complaints alleging violations of the Privacy Rule since the April 2003 compliance date. Of the complaints received, a total of

32,200 (83%) have been resolved as specified above as of the end of August 2008. Approximately 6,600 cases remain open.

CDC HIV Prevention:

4) The CDC is about to announce new HIV incidence numbers for the United States that report the number of new infections is perhaps as high as 55,000 to 60,000 a year rather than the 40,000 that has been previously reported in years past. While many have been complacent about HIV/AIDS in our country, AIDS is increasing in our nation, particularly in certain groups like gay men and African-Americans. Despite these alarming figures, you have proposed to cut CDC HIV funding by $1 million. Upon examining the budget further we see that the actual money proposed for prevention is being cut by roughly $40 million since you propose to transfer funds for increased testing programs. While we support testing, we also can't short change HIV prevention. Your Administration has had 7 years to cut HIV rates in our country, but you have failed miserly. This is not a very good legacy to leave the American people. Don't you think we should be increasing CDC's HIV prevention budget to decrease AIDS in our own country rather than cutting it?

Response:
In August 2008, CDC released estimates of HIV incidence in the United States based on new technology that allows researchers to distinguish recent from long-standing infections. Results from that new surveillance system indicate that approximately 56,300 new HIV infections occurred in the United States in 2006. This number is approximately 40% higher than CDC's previous estimate of 40,000 new infections per year, which was based on less precise methods. It is important to note that the 2006 estimate does not represent an actual increase in the annual number of new infections; rather, a separate CDC historical trend analysis published alongside the incidence estimate suggests that the number of new HIV infections was never as low as 40,000 and has been roughly stable since the early 2000s.

CDC continues to work to reduce new HIV infections, reduce behaviors associated with HIV transmission and acquisition, increase knowledge of HIV infection, and link infected persons to needed prevention, care and treatment services. Emphasis will continue to be placed on ensuring that those who are infected have an opportunity to learn of their infection and receive supportive prevention interventions.

CDC recently updated its estimates of the percentage of HIV-infected individuals who were unaware of their infection. The new analysis indicates that approximately 21 percent of persons living with HIV in 2006 were unaware of their infections. This represents a decline from an estimated 25 percent unaware in 2003. To identify persons infected with HIV and reduce their risk of transmitting the virus to others, CDC has consistently invested in HIV testing as a proven prevention strategy.

In September 2006, CDC published its *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.* Since that time, CDC has engaged in an intensive effort to assist stakeholders in deciding how to implement HIV screening in health-care settings, while at the same time assuring that other vital HIV prevention efforts and HIV testing in non-health-care settings continue.

In September 2007, CDC began the HIV Testing Initiative to increase testing in medical and community-based settings, make voluntary testing a routine part of medical care, and create new testing guidelines, models and best practices. Jurisdictions funded through the Initiative are expected to test more than one million Americans and yield more than 20,000 new HIV diagnoses. Twenty-three jurisdictions were initially funded; 2 more were added in FY 2008 for a total of 25 jurisdictions. The 23 grantees initially funded for this initiative have made considerable progress toward implementation of HIV screening in the most severely affected populations in the United States.

Of course, testing is only one component of CDC's comprehensive HIV prevention portfolio. In addition, CDC will continue to emphasize evidenced-based prevention interventions for those most affected by HIV/AIDS, especially racial and ethnic populations and men who have sex with men of all races. CDC will also continue to support efforts to integrate services for HIV, viral hepatitis, STD, and TB prevention Finally, CDC will continue to build the systems needed to monitor the epidemic, strengthen prevention programs and capacity of grantees to deliver effective prevention services, and rigorously evaluate prevention efforts.

Ryan White HIV/AIDS Program:

5) Your Administration has funded HIV testing initiatives, particularly in African American communities, that expect to find 20,000 new people who are HIV positive. Additionally you have issued recommendations that everyone from ages of 13 to 64 should receive routinely an HIV test when they encounter the healthcare system. This will result in finding even more people who are HIV positive and will require lifesaving care and treatment. Can you tell us how many new people will be requiring Ryan White HIV/AIDS programs due to all these new testing initiatives?

Response:
Several assumptions are used to estimate the increase in demand for Ryan White HIV/AIDS Program and other HIV/AIDS services among people without insurance. These assumptions include:

- An estimated two-thirds of HIV-positive persons who learn their serostatus in 2008 will enter care. At least 20,000 persons are expected to learn of their infection as a result of CDC's funded efforts to implement the *Revised Recommendations*. Thus, at least 13,334 of the newly identified HIV-positive persons will enter care.

- Of those entering care, an estimated 25 to 28 percent (3,333 – 3,733) will be uninsured and may seek one or more services from the Ryan White HIV/AIDS Program and/or other safety net programs.

6) Your budget proposes to increase Ryan White funding by a mere .004 percent or $1.1 million. Some parts of the program, like funding for hard hit cities and training, you propose to cut. How do you propose we pay for all the drugs and the healthcare that is required to keep these low-income, predominately from minority communities, alive? Your proposed budget doesn't keep up with inflation, let alone account for more people who will need Ryan White services. For example, we know that the AIDS Drug Assistance Program (ADAP) grows monthly by 386 people, but you propose to increase ADAP by only $6 million while the need is over $130 million. How are we going to provide the necessary healthcare and medications to all these people?

Response:
In FY 2009, the Ryan White HIV/AIDS Program continues to coordinate and collaborate with related Federal, State, local entities as well as national AIDS organizations in order to leverage and promote efforts to address unmet care and treatment needs of persons living with HIV/AIDS who are uninsured or underinsured. The President's Budget Request in FY 2009 for Ryan White is $2,167,912,000; an increase of $1,120,000 over the FY 2008 enacted level. This funding will continue to support over 2,300 providers that help half a million individuals living with HIV/AIDS obtain access to life-sustaining care and supportive services. In addition, the Program will continue to appropriately target resources to racial/ethnic minorities and women because these groups are disproportionately impacted by HIV/AIDS.

The FY 2009 Request also includes an increase of $14,239,000 to support current Part B program activities and includes an increase of $6,046,000 for the AIDS Drug Assistance Program (ADAP) to provide life-saving medications for people living with HIV. The Health Resources and Services Administration estimates that the number of clients served by ADAPs will be approximately 150,000 clients.

The Honorable Gene Green

1) Mr. Secretary, you know that I and others have deep concerns with the cuts in LIHEAP funding and believe we need to fully fund the program at its authorized level.

Not only do I have concerns with the funding level but also whether or not we are fairly protecting the safety and health of LIHEAP participants across the nation.

The National Weather Service, a government agency under the National Oceanic and Atmospheric Administration, compiled a ten year average of weather fatalities from 1997 – 2006.

It found that, on average, 18 people a year were killed due to extreme cold temperatures. Extreme heat, on the other hand, killed an average of 170 people, almost 10 times as many Americans.

More shocking than these facts is that only 3 percent of LIHEAP funding goes toward cooling homes in the summer, and 74 percent goes toward heating homes in the winter, despite the clear evidence that extreme heat is a greater health threat.

Based on these assessments, do you believe the LIHEAP program is effectively protecting the health and safety of those most vulnerable to extreme temperatures?

Response:
As a block grant, LIHEAP provides much flexibility to the States to design their energy assistance programs in the way that they believe best serves the health and safety needs of their low income populations. In addition to heating, a State may choose to establish a summer cooling component to its program and set aside as much funds as it believes necessary from its LIHEAP allocation to be used for cooling assistance. A State also may choose to use some of its funds for heating and cooling crises that may occur throughout the year. States may use both regular block grant funds and emergency contingency funds to address the home energy needs of low income households.

2) In 2005, Congress included a "Welcome to Medicare Physical Exam" for new beneficiaries in an effort to detect and prevent costly diseases and conditions. However, three years after the implementation of the "Welcome to Medicare Physical Exam", the utilization rate of this program is low. Why do you think the utilization rate is low and what is CMS doing to increase the utilization rate of this program?

Response:
The number of "Welcome to Medicare" physical exams administered has been increasing. In fact, it rose 76 percent from 2005 to 2006. Further, in calendar years 2005 and 2006, Medicare received bills for the "Welcome to Medicare" exam for 45,145 and 79,514 beneficiaries respectively. Data for calendar year 2007 are not yet available.

CMS has produced outreach materials for organizations to use in communicating with both beneficiaries and providers about Medicare preventive benefits, in general, as well as specific services, to increase awareness of these important benefits. For example, CMS developed "The ABCs of Providing the Initial Preventive Physical Examination," a quick reference checklist for providers to use in delivering the Welcome to Medicare exam. This checklist is available for downloading on the CMS website. CMS also promotes the physical exam, as well as other Medicare preventive benefits, in the initial enrollment package that is mailed to newly enrolled beneficiaries.

To date, CMS has spent $4.3 million on the "A Healthier US Starts Here" initiative including

$2.9 million to fund the Mobile Office Tour. The tour has helped educate people with Medicare, their friends, families, and advocates about the availability of Medicare's preventive services, including the "Welcome to Medicare" exam. The Mobile Office Tour focused on increasing awareness about Medicare's coverage of preventive services overall.

In addition, CMS has taken several steps to reach out to the Hispanic, Asian-American, and African-American communities and other minorities to increase awareness of covered preventive services. Many stops on the Mobile Office Tour visited communities with high concentrations of these populations. CMS used a variety of media outlets to reach the audiences including newspaper articles, radio interviews, and advertising to promote local community events.

We believe that these efforts will increase the utilization rate.

3) I am an original sponsor of the "Screening Abdominal Aortic Aneurysms Very Effectively Act." This legislation includes screenings for abdominal aortic aneurysms as part of the Welcome to Medicare Physical Exam. Can you tell me what has been the utilization rate of the AAA screening?

Response:
As the Abdominal Aortic Aneurysms (AAA) screening benefit began in January 2007, data on utilization rates of the AAA screening as well as the "Welcome to Medicare" exam for calendar year 2007 are not yet available. However, we would note that the number of "Welcome to Medicare" exams from which beneficiaries may receive referrals for AAA screenings rose 76 percent from 2005 to 2006.

Medicare pays for the one-time ultrasound AAA screening, which must receive physician referral as a result of the "Welcome to Medicare" exam. The additional time period to obtain the "Welcome to Medicare examination" may increase the number of beneficiaries referred for AAA. At-risk beneficiaries eligible for AAA screenings are 1) those with a family history of AAA; 2) men age 65 to 75 who have smoked at least 100 cigarettes in their lifetime; 3) those manifesting other risk factors in a beneficiary category recommended for AAA screening by the United States Preventive Services Task Force (USPSTF).

4) In an effort to detect costly and life-threatening conditions like abdominal aortic aneurysms in their early stages, how much money has CMS allocated for FY09 to educate and encourage physicians to provide and Medicare beneficiaries to take advantage of the "Welcome to Medicare Physical Exam" and the associated AAA screening benefit?

Response:
CMS uses various outreach strategies to educate Medicare beneficiaries and physicians about the "Welcome to Medicare" exam and the associated Abdominal Aortic Aneurysms (AAA) screening benefits. Educating beneficiaries about the exam and AAA screening is part of the

broader "A Healthier US Starts Here" initiative. To date, CMS has spent $4.3 million on this initiative, including $2.9 million to fund the Mobile Office Tour. The tour helped educate people with Medicare, their friends, families, and advocates about the availability of Medicare's preventive services including the "Welcome to Medicare" exam and AAA screening.

CMS has also developed a variety of national educational Medicare Learning Network (MLN) products specifically to inform the Fee-for-Service (FFS) provider community on Medicare-covered preventive services and screenings, including the AAA screening. The main focus of these products is to make providers aware of preventive services coverage and billing information for such services. MLN products are used on a national and local level by Medicare FFS contractors (carriers, fiscal intermediaries, and Medicare Administrative Contractors) and CMS regional office staff in their provider outreach and education efforts. MLN written products providing information on the AAA screening include a) "The Guide to Medicare Preventive Services for Physicians, Providers, Suppliers, and Other Health Care Professionals", b) "The Expanded Benefits Brochure", c) "Quick Reference Information Medicare Preventive Services, d) annual MLN Matters article which reminds providers about the preventive services covered by Medicare and the MLN educational products specific to preventive services. In addition, three web-based training courses for FFS providers focused on preventive benefits. In 2009, one of the courses will have a separate lesson on the AAA benefit.

Longstanding outreach materials used to communicate with both beneficiaries and providers about Medicare preventive benefits include "The ABCs of Providing the Initial Preventive Physical Examination," a quick reference checklist for providers to use in delivering the "Welcome to Medicare" exam. This checklist is available for downloading on the CMS website. CMS also promotes the physical exam, as well as other Medicare preventive benefits, in the initial enrollment package that is mailed to newly enrolled beneficiaries.

Preventive services education and outreach is a priority initiative. Key messages about the benefits and importance of preventive care and utilization of Medicare-covered services are also conveyed both nationally and locally through inclusion in public events, activities, and materials.

The Honorable Diana DeGette

1) Since 2002, the Department of Health and Human Services has spent approximately $10 million on awareness of frozen embryo adoption, also known as "snowflake babies." Approximately 295 children have been born using the so-called embryo adoption method. Do you think this is an appropriate use of federal funding? How does frozen embryo adoption fulfill the Department's public health agenda, using the traditional definition of public health as, "the science and practice of protecting and improving the health of a

community, as by preventive medicine, health education, control of communicable diseases, application of sanitary measures, and monitoring of environmental hazards?"

Response:
The frozen embryo donation and/or adoption public awareness program came into being when Congress appropriated $1,000,000 for this effort in FY2002 (Public Law 107-116). Senate Report 107-84 (page 244) accompanying the FY 2002 appropriations gives insight into the Congressional intent in funding this program:

> *During hearings devoted to Stem Cell research, the Committee became aware of approximately 100,000 spare frozen embryos stored in vitro fertilization (IVF) clinics throughout the United States. The Committee is also aware of many infertile couples who, if educated about the possibility, may chose to implant such embryos into the woman and potentially, bear children. The Committee therefore directs the Department to launch a public awareness campaign to educate Americans about the existence of these spare embryos and adoption options.*

As frozen embryo donation and adoption is a very new field, it does not fit easily into any traditional definition. Clearly, however, it is related to infertility, adoption, and health information, which are addressed by programs within the Department of Health and Human Services.

2) In communications with my office regarding how the frozen embryo adoption program fulfills a public health agenda, your staff said: "More than 400,000 frozen embryos in the United States face potential destruction—termination of human life at the earliest and most vulnerable stage. Embryo adoption offers opportunities for couples seeking children to do so, while preventing the potential destruction of innocent human life." Please indicate where federal law defines a frozen embryo as a human being.

Response:
In the Senate Report to Public Law 107-116, Congress evinced an interest in the embryos as the means by which infertile couples may "bear children."

3) How much money is in this year's budget for the frozen embryo adoption programs? And how much money is in this year's budget for encouraging adoptions of the 114,000 children who are already born and are waiting for adoption?

Response:
The Congress appropriated $3,930,000 for the frozen embryo program in Fiscal Year 2008. For that same year, the Administration for Children and Families (ACF), within HHS will spend $2,242,200,000 on programs that support the adoption of children already born. In fact, as more people have become aware of the availability of children in foster care through such efforts as AdoptUSKids.org, almost 10,000 children have had to have their listing removed because they have found permanent families.

See below for the sums from the various programs within ACF dedicated to adoption:

Adoption Assistance	$2.2 billion
Adoption Opportunities	25.4 million
Adoption Incentives	4.3 million
Infant Adoption Awareness	9.6 million
Special Needs Adoption	2.9 million

4) Do you think it is a better use of federal resources to fund frozen embryo adoption programs than for adoption of children who are in need of a loving family?

Response:
The Department does not see the two concepts as in competition with one another; just the opposite. Potential parents are encouraged to consider all forms of adoption available to them and choose the type of adoption that best suits their individual circumstances. Some potential parents are ideally suited to adopting a teenager out of foster care; others want to go overseas to adopt a girl from China who might otherwise perish; still others would like the opportunity to adopt an embryo who would otherwise remain frozen.

5) How much federal money has been spent on actual frozen embryo adoptions, as opposed to funding for public awareness campaigns?

Response:
Until FY2008, the law only allowed activities focused on raising public awareness. Therefore, to date, no Federal money has been spent on actual frozen embryo adoptions.

In FY2008, Congress increased funding for the program from the FY2007 level of $1,980,000 to $3,930,000 and included permissive authority to expend funds for medical and administrative services related to embryo adoption. In FY2008, the Office of Population Affairs announced a competitive contract to explore the questions associated with funding medical and administrative services related to embroyo donation/adoption. The contractor will also examine options for the design and development of objective performance measures for the entire frozen embroyo donation/adoption program. This process will help ensure that the funds are being targeted in the most efficient and effective manner possible.

6) During the hearing you said that "there are things we can do to improve [abstinence-only sex education programs]." What improvements can you make, or are you considering making, in order to make these programs effective?

Response:
The Department is working to strengthen abstinence education programs with a focus on heightened program oversight and strengthened expectations of our grantees. Following

are some of the steps being taken to improve these programs:

- Technical assistance to Community Bases Abstinence Education (CBAE) grantees is being provided in five key areas: sound business practices; program evaluation; medical and scientific accuracy; Congressional compliance; and communication.

- Data reporting in Section 510 Title V and CBAE is being strengthened. Grantees now are required to report the number of youth served, the hours of service per youth, and the proportion of youth that complete the program. This data is used to measure actual performance against grantee projections so we can better target technical assistance efforts.

Additionally, we will be implementing a new data collection instrument requiring grantees to survey youth before and after service delivery to provide actual behavioral outcomes measurement, including proportion of youth abstaining from sexual activity.

- Steps are being taken to ensure the accuracy of scientific and medical information given in ACF's abstinence education programs. Specifically, signed assurances by the applicants, special terms and conditions attached to grants, and a thorough review of curriculum materials by medical professionals have been implemented to ensure the accuracy of medical and scientific information.

- The CBAE program announcement has been fine-tuned to ensure that organizations have the capacity to implement these grants and that they do so with greater efficiency. These changes will result in applications that give us a clearer picture of each organization's accounting systems, policies, partnerships, and staff qualifications.

- The findings of relevant research and evaluation efforts are being integrated. For example, based on the findings of the Title V study conducted by Mathematica Policy Research, Inc., grant applicants are required to show that their programs include high school aged youth and include activities that create a supportive peer environment for young people choosing abstinence until marriage.

7) What is your rationale for cutting programs like children's hospitals graduate medical education and workforce development programs while at the same time increasing abstinence-only sex education funding by $28 million?

Response:
No funds are requested for the Children's Hospital Graduate Medical Education Payment Program (CHGME) in FY 2009. The FY 2009 budget focuses on activities that fund the placement of doctors, nurses, and other health care professions in regions of the country that face shortages. An Office of Management and Budget (OMB) Program Assessment Rating Tool (PART) review of the CHGME was conducted in 2006 and the program received a rating of Adequate. The PART review noted that the program makes timely

payments to eligible hospitals and is achieving its long-term performance goals, but is fundamentally duplicative of other Federal, State, and private efforts. Also, the PART review determined that the CHGME does not address a specific need. Children's hospitals are more likely to have positive profit margins than other hospitals. In 2000, 74 percent of children's hospitals had positive margins, compared to 67 percent of all hospitals, and 59 percent of major teaching hospitals.

Questions regarding physician administered drugs:

It is my understanding that interpretations by CMS of the recently released regulation regarding "physician administered drugs" under the Medicaid Drug Rebate program are causing widespread confusion and chaos among Medicaid agencies. I am concerned about the administrative burden on all hospitals which now have to collect and report drug-specific codes for each drug billed to Medicaid and on the impact on 340B Hospitals because it divert savings that safety-net hospitals currently rely on under the 340B Drug Discount Program to treat indigent patients.

When we enacted the Deficit Reduction Act our intent was to ensure rebates are taken for drugs administered in physician offices, based on the OIG report that recommended the same. We did not change the statutory exemption from the drug rebate program for most hospital outpatient clinics. Hospital clinics are exempt from rebate requirements if they dispense the drugs using a formulary and the drugs are billed to Medicaid at no more than a cost "determined under the Medicaid state plan." It is my understanding that CMS has made public pronouncements eliminating the state's authority to set the maximum reimbursement levels that will define when rebates apply to drugs administered in hospital clinics, and instead has announced a national standard for determining these reimbursement caps, that has no connection to the provisions of States' Medicaid plans.

Seven national groups representing hospitals and several members of Congress have written to you requesting clarification regarding CMS policy in applying the new NDC collection and reporting rule to outpatient drugs administered in hospital outpatient clinics. If you have not had the opportunity to personally read it, I strongly suggest that you do so. As they are anxiously awaiting a response, I want to ask you about it today.

8) How do you plan on addressing the chaos and uncertainty caused by the "physician administered drugs" rule and provide clarifications to the field?

Response:
As HHS and CMS have communicated to Congress and in other correspondence, we believe that the rule addressing physician-administered drugs correctly interprets the provision outlined in the Deficit Reduction Act of 2005 (DRA), Public Law 109-171, and clearly communicates the requirements. The timeframe for implementing this provision was set by statute. We understand that hospitals may have to change the way they bill for drugs to meet the statutory requirement.

The DRA did not exempt hospital outpatient departments, including those that participate in the 340B program, from the provision that requires Medicaid State agencies to collect NDCs on outpatient drug claims billed to Medicaid. The preamble to the final rule discusses how hospitals with drug formulary systems qualify for the exemption from the drug rebate program under 1927(j)(2) of the Social Security Act. Drugs dispensed to Medicaid beneficiaries by safety-net hospitals under the 340B Program are not subject to Medicaid rebates as long as those drugs are purchased under the 340B program. Because there are instances where hospitals do not purchase drugs provided to Medicaid beneficiaries through 340B contracts, States may still require that NDCs be placed on all claims submitted for payment. It is a State responsibility to determine which drugs are subject to rebate.

9) Will you consider extending for at least one year the effective date of this rule as it applies to drugs dispensed by hospital outpatient clinics until a clarification is made and sufficient time has passed to implement the regulation in an orderly, effective, and efficient fashion?

Response:
The DRA included a provision that allows States to request an extension to the implementation date of the provision. As of March 4, 2008, 24 States requested and were granted an extension for outpatient hospital departments. The majority of states requested a six month extension. Based on the fact that many States implemented this provision on time and the majority seeking an extension requested that it be for six months, we granted a six-month extension to all requesting States. We note that the provision in the DRA required that the collection of utilization data for physician-administered drugs be implemented by January 1, 2007; however, States could continue to receive matching funds for these drugs until January 2008.

10) Will you agree to provide a clarification of the statutory provision that exempts drugs from the Medicaid Rebate program that are administered in a hospital outpatient treatment setting provided that the hospital uses a formulary system and is not reimbursed more than the cost established under its Medicaid State Plan as the upper limit on payment to a hospital for such drug?

Response:
As discussed in the earlier response, the preamble to the final rule details when drugs administered in hospital outpatient departments, including those that participate in the 340B program, are subject to Medicaid rebates. As noted in those provisions, drugs dispensed to Medicaid beneficiaries by safety-net hospitals under the 340B Program are not subject to Medicaid rebates as long as those drugs are purchased under the 340B program. Because there are instances where hospitals do not purchase drugs provided to Medicaid beneficiaries through 340B contracts and do not bill Medicaid at acquisition cost for those drugs, States may still require that NDCs be placed on all claims submitted for payment. It is a State responsibility to determine which drugs are subject to rebate.

The Honorable Lois Capps

All questions are in regards to the Medicare Recovery Audit Contractor program.

1) Do the figures in the evaluation of the RAC program, released February 28, 2008, reflect all of the money CMS is now accountable for returning to the providers? According to the February 28th update, the tables regarding appeals data doesn't reflect claim determinations of appeals filed on or after September 30, 2007. We are aware of the fact that many providers didn't receive the decisions in their favor until after September 30 and have filed many more appeals since then.
    a. Can you provide the Committee with an estimate of funds that will be returned to the providers due to the number of appeals being overturned in the providers' favor?
    b. Can you please update your overall figures of savings to the Medicare program with the updated data due to the appeals that have been overturned since September 30, 2007?
    c. Please include the number of appeals that have been filed even if they haven't been decided on yet (at any level) as well as the number of appeals that are awaiting decisions specifically on the ALJ level.

Response:
No, the figures in the evaluation of the RAC program, released February 28, 2008, did not reflect all of the money CMS is now accountable for returning to the providers. The updated amount of underpayments refunded to providers is $37.8 million. With regard to appeals, as of March 27, 2008, $46.0 million in RAC collections were overturned on appeal.

As of March 27, 2008, the RACs returned $693.6 million to the Medicare Trust Funds after subtracting the amounts repaid to providers for underpayments, the amount overturned on appeal, and the costs of operating the RAC demonstration.

CMS is not able to determine the number of appeals pending at the first level. However, we estimate that as of May 1, 2008, there are 2,181 claims pending at the second level of appeal (QIC) and 828 claims pending at the third level of appeal (ALJ).

2) How much in taxpayer dollars is CMS spending to defend the contractors during the appeals process?

Response:
CMS does not have an estimate of the amount spent to defend the RACs during the appeals process. The funds paid to Medicare claims processing contractors to process the overpayment/underpayment adjustments, handle appeals of RAC-initiated denials, and other costs incurred to support the RAC demonstration totaled $8.7 million as of March 27, 2008.

3) What is the dollar amount that has been paid to the private contractors that will never go back to the Medicare Trust Fund?

Response:
The contingency fees paid to the RACs for detecting and collecting overpayments and detecting and refunding underpayments were $187.2 million. The funds paid to Medicare claims processing contractors to process the overpayment/underpayment adjustments, handle appeals of RAC-initiated denials, and other costs incurred to support the RAC demonstration were $8.7 million. The funds paid to the RAC Evaluation Contractor, the RAC Data Warehouse Contractor, the RAC Validation Contractor, and the federal employees who oversee the RAC demonstration were $5.4 million. As of March 27, 2008, the total cost of operating the RAC demonstration was $201.3 million. This equates to the RAC demonstration costing only 20 cents for each dollar collected.

The Honorable Mike Doyle

1) As you may know, I, Rep. Sessions and several of our colleagues from this committee were successful in enacting legislative language last fall that requires FDA to create a Unique Device Identification system for medical devices, which is crucial to improving patient safety, reducing medical errors, facilitating device recalls, improving device adverse event reporting and accurately populating electronic health records. We need FDA and HHS to move quickly on this proposed rule and I would like to know the timeline for publishing a proposed rule on UDI.

Response:
On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) was signed into law. FDAAA mandates the Secretary (and by delegation, FDA) to promulgate regulations establishing a UDI system that will require the label of a device to bear a unique identifier, unless FDA requires an alternative placement or unless FDA provides an exception for a particular device or type of device. The unique identifier is required to identify the device through distribution and use.

There are many issues that we must resolve before we can begin drafting regulations to implement these requirements. For example, the FDAAA expressly states that exceptions may be made for a particular device or type of device and we must consider what, if any, exceptions would be appropriate to consider. We have been working diligently on these issues since the enactment of the FDAAA and intend to initiate rulemaking activities in the near future.

The Honorable Baron Hill

In 2004, President Bush signed Project Bioshield into law. Project Bioshield authorized $5.6 billion over 10 years to stockpile vaccines and drugs to fight deadly biological agents such as anthrax. The need for a vast anthrax vaccine stockpile was made painfully evident in the 2001 anthrax mail attacks on Capitol Hill, and in New York and Florida.

As I understand, Health and Human Services (HHS) determined that 75 million doses of an anthrax vaccine would be necessary to vaccinate 25 million Americans. However, there are fewer than 30 million doses currently stockpiled.

1. Is this correct?

Response:
Antibiotics represent the first line of defense to protect the nation following an anthrax attack. The Food and Drug Administration (FDA) has approved antibiotics for both post-exposure prophylaxis and treatment for inhalational anthrax. The Strategic National Stockpile currently has enough 60-day oral antibiotic regimens on hand for more than 40 million individuals, and sufficient courses of intravenous antibiotics to treat hundreds of thousands of symptomatic patients.

Since 2005, HHS has executed contracts worth $691M for 28.75M doses of BioThrax®. At this time, HHS is procuring the maximum amount of vaccine available in the marketplace. It is worth noting that the second BioThrax® contract also stipulates several important improvements to the existing vaccine, including FDA approval for the use of BioThrax® in a post-exposure prophylaxis regimen, and for extended expiry dating for the vaccine.

In addition to BioThrax®, HHS is continuing to build a portfolio of anthrax vaccines that provides an incentive to industry to meet our goals of strengthening and diversifying the manufacturing base and supporting the development and acquisition of novel technologies and next-generation products. On February 28, 2008 BARDA released a Request for Proposals (RFP) for the acquisition of a next-generation recombinant Protective Antigen (rPA) Anthrax Vaccine. This RFP addresses the need for late-stage development and acquisition of an rPA-based anthrax vaccine and provides the potential to award more than one contract. HHS expects an award this year.

The development and acquisition of anthrax antitoxins are another important element of our preparedness. In 2006, HHS awarded two contracts for the development and acquisitions of 30,000 treatment courses of anthrax therapeutics, for treating the life-threatening toxemia associated with advanced anthrax infection.

2. If so, why has the 75 million dose stockpile not been fulfilled?

Response:
HHS and DoD together have procured and will continue to procure the production capacity of the only U.S.-licensed anthrax vaccine – BioThrax® - until there are other

anthrax vaccines available for consideration. The BARDA strategy to reach the 75 million dose requirement is based on supporting a broad base of manufacturers with multiple candidate vaccines. Our current strategy is to procure the maximum amount of licensed anthrax vaccine (BioThrax®) available in the world marketplace. Two contracts have been awarded totaling over 28.75M doses. Maximum capacity of BioThrax® will be procured until a second-generation vaccine is available. BARDA is also poised to award one or more new Project BioShield acquisition contracts for a recombinant protective antigen (rPA) vaccine in November/December 2008. Lastly, BARDA has used its Advanced Research and Development appropriations to ensure that earlier stage anthrax vaccines programs are appropriately funded. To date, BARDA has invested over $43.5M in anthrax vaccine advanced development programs.

Based on the current pipeline of products, projections provided by manufacturers and BARDA professional estimates, BARDA predicts that the 75M dose requirement of anthrax vaccine will be met in 2013. At that point, BARDA estimates that multiple manufacturers will be involved in either expanding manufacturing capacity and/or delivering licensed and pre-licensed products to the SNS.

It is also my understanding that a large percentage (upwards of 75 percent) of Bioshield vaccine contracts have actually gone to foreign-based manufacturers.

3. Is this correct?

Response:
This is not correct; BARDA has Project BioShield contracts with five US-based, two Canadian, and one Danish manufacturer.

4. If it is, can you please explain to me why HHS is making more of an effort to use domestic manufacturers, especially given the country's current economic situation?

Response:
HHS is using mostly domestic manufacturers. BARDA has Project BioShield contracts with five US-based, two Canadian, and one Danish manufacturer.

The Honorable Mike Rogers

General Procurement

1) It has now been over 5 years since the anthrax attacks on the U.S. homeland occurred. Is anthrax still the number 1 priority biological threat facing this nation?

Response:

Anthrax is a top priority public health emergency threat, as identified in the 2007 HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan.

2) Given the HHS 75 million doses anthrax vaccine stockpile requirement, the termination of the VaxGen contract, RFP delays, and years needed for the development of a new anthrax vaccine, what are the Department's immediate plans to maintain the stockpile and increase our nation's preparedness against a potential anthrax attack that could occur at any time?

Response:
HHS is pursuing a comprehensive approach to address the threat of anthrax, and has made substantial investments in the acquisition of a variety of medical countermeasures for the Strategic National Stockpile (SNS). This multifaceted effort includes the acquisition of antibiotics, vaccines, and therapeutics to meet urgent public health needs in the event of an attack.

Antibiotics represent the first line of defense to protect the nation following an anthrax attack. The Food and Drug Administration (FDA) has approved antibiotics for both post-exposure prophylaxis and treatment for inhalational anthrax. The Strategic National Stockpile currently has enough 60-day oral antibiotic regimens on hand for more than 40 million individuals, and sufficient courses of intravenous antibiotics to treat hundreds of thousands of symptomatic patients.

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In addition to BioThrax®, HHS is continuing to build a portfolio of anthrax vaccines that provides an incentive to industry to meet our goals of strengthening and diversifying the manufacturing base and supporting the development and acquisition of novel technologies and next-generation products. On February 28, 2008 BARDA released a Request for Proposals (RFP) for the acquisition of a next-generation recombinant Protective Antigen (rPA) Anthrax Vaccine. This RFP addresses the need for late-stage development and acquisition of an rPA-based anthrax vaccine and provides the potential to award more than one contract. HHS expects an award this year.

The development and acquisition of anthrax antitoxins are another important element of our preparedness. In 2006, HHS awarded two contracts for the development and acquisitions of 30,000 treatment courses of anthrax therapeutics, for treating the life-threatening toxemia associated with advanced anthrax infection.

3) I understand why HHS is focused on anthrax vaccine in light of the VaxGen contract failure. But we also know from 2001 that additional anthrax therapies are needed for people who contract inhalational anthrax. If anthrax is the number 1 priority, why is anthrax vaccine the only near-term (thru FY08) anthrax BioShield procurement priority? Does HHS also intend to focus on other non-antibiotic therapies?

Response:
In addition to antibiotics and vaccines, HHS has focused on the development of antibody-based anthrax antitoxins to treat toxemia. On June 20, 2006, HHS awarded a contract for 20,000 treatment courses of an anthrax therapeutic (ABthrax) to Human Genome Sciences (HGS) for $165,205,217. On July 28, 2006, HHS awarded a contract for 10,000 treatment courses of Anthrax Immune Globulin (AIG) to Cangene Corporation for $143,833,719. Both programs have met all milestones to-date and are on track to meet all delivery schedules stipulated in their contracts. Cangene initiated deliveries to the SNS in 2007 and HGS will begin in 2008.

BARDA has also used Advanced Research and Development appropriations to fund earlier stage programs. To date, BARDA has invested over $27M in three additional antibody-based anthrax antitoxin programs (Pharmathene, Elusys, and Emergent BioSolutions). All three programs are meeting milestones and are demonstrating promising results in non-human primate/anthrax challenge experiments.

Pending availability of funds, BARDA will also launch a new program in late 2009 to develop a next-generation antitoxin program based on small molecule technologies. Further BARDA will launch in FY09 development of antibiotics to address multidrug resistance that may occur among multiple bacterial biothreats.

In addition, as noted, antibiotics represent the first line of defense to protect the nation following an anthrax attack. The Food and Drug Administration (FDA) has approved antibiotics for both post-exposure prophylaxis and treatment for inhalational anthrax. The Strategic National Stockpile currently has enough 60-day oral antibiotic regimens on hand for more than 40 million individuals, and sufficient courses of intravenous antibiotics to treat hundreds of thousands of symptomatic patients.

4) Of the total $3.4 billion in BioShield funds available through FY 08, HHS has only obligated approximately $1.9 billion. The Implementation Plan only targets two additional purchases in the near-term – anthrax vaccine and acute radiation syndrome therapy. Does HHS anticipate that these acquisitions will account for the remaining $1.5 billion?

Response:
Yes, BARDA has targeted remaining funding available for FY08 for medical countermeasures for Acute Radiation Syndrome and Anthrax rPA. BARDA also expects to award one or more Acute Radiation MCM contracts for anthrax, an extension of 2 months has been granted on the open solicitation for rPA anthrax vaccine that will push the expected target date for contract award into the fourth quarter of CY2008.

5) HHS has also identified 8 items for mid-term acquisition, which are to occur in the FY 09-FY 13 timeframe (diagnostics, broad spectrum antibiotics, anthrax anti-toxins, filovirus countermeasures, smallpox antivirals, ARS countermeasures, bioassays, and radionuclide-specific agents). Does HHS anticipate that all of these acquisitions can be made with the $2.2 billion remaining in the BioShield budget?

Response:
In the FY09-FY13 timeframe, spend plan funding is targeted for Anthrax therapeutics, Anthrax rPA, smallpox antiviral, medical countermeasures for ARS and contract options such as clinical studies that will result in license indications for special populations.

6) The timeframe between RFP submission and award has taken several years in some instances (anthrax therapy – nearly two years, smallpox vaccine over one year, etc.). How do you plan to reduce these time lines in the future?

Response:
Acquisition decisions are complex and involve rigorous scientific, technical, and contractual evaluation. HHS has instituted greater internal oversight of the procurement process and begun to acquire additional highly skilled technical and contracting personnel to support the increase in procurement and contract management activities.

In order to maintain the engagement of industry, HHS is working towards making solicitations as transparent and as expeditious as possible. HHS is implementing best practices through an improved acquisition infrastructure. This infrastructure provides consistent program and project management and effective monitoring of contract performance. HHS now uses acquisition tools such as draft RFPs and pre-proposal conferences to increase transparency and expedite the RFP process. These tools allow clarification of the RFP requirements and engage potential Offerors in a more in-depth understanding of the RFP prior to submitting their proposal. Improved RFPs and corresponding improved proposals should allow for a more expeditious timeline to contract award.

Domestic Capacity

7) It is my understanding that only $882 million of HHS contracts for biodefense vaccines and therapeutics is to U.S. based manufacturing companies, compared to more than $2.7 billion in total potential contract awards to foreign-based manufacturing companies. Does it make sense to place such a high percentage of your biodefense countermeasure investment in foreign-based manufacturers?

Response:
This is not correct; HHS has Project BioShield contracts with five US-based, two Canadian, and one Danish manufacturer. But, the focus is on a product that best fulfills

USG requests. The USG carefully evaluates all product acquisition proposals from both domestic and foreign contractors.

8) If we experience a large scale anthrax attack and surge capacity is needed for production of additional doses in the US, how can we control production if it is located in a foreign country that may also want those products for their citizens?

Response:
Five of eight manufacturing contracts under HHS' Project BioShield are U.S. based, thus providing substantial surge capacity in the event it is needed.

Anthrax Therapy

9) According to the Implementation Plan, mid-term acquisitions are planned in the FY 09-13 timeframe. This is a long time period. Can you tell me when you expect to procure additional anthrax anti-toxins? Is this planned for early in the mid-term time frame?

Response:
HHS will continue to: 1) develop its two late-stage antibody-based antitoxin programs with Cangene and Human Genome Sciences under Project BioShield and 2) fully support its three new advanced development programs with Elusys, Pharmathene, and Emergent. It is our expectation that the three early stage products may be ready for Project BioShield acquisition in the 2010/2011 timeframe. In the interim, all three programs will continue to be fully funded by advanced research and development appropriations.

10) Given the historically lengthy time period between RFP and actual award, does HHS plan to issue an RFP, particularly in the anthrax anti-toxin area prior to FY 09 to allow for procurement immediately upon availability of funds?

Response:
HHS does not plan to issue an RFP for development of additional anthrax antitoxins in FY 2009. It currently fully supports three advanced research and development programs with FY 2007 and 2008 appropriations, and will continue to do so with the FY 2009 appropriation.

HHS is working to reduce risk to the USG and drug manufacturers by using advanced research and development funds to support programs through Phase II clinical development, a stage where programs could be considered ready for Project BioShield acquisition. Awarding Project BioShield contracts to early-stage programs such as Elusys, Pharmathene, or Emergent at this point places unnecessary risk on the USG and the developers.

11) What process is necessary to issue RFPs for mid-term acquisitions before FY 09? Is this an internal process or are multiple agencies involved? What needs to be done to enable this to occur? Can Congress help?

Response:
The requirement setting and procurement process are interagency and are in need of internal streamlining, as presented below. Use of the Special Reserve Funds authorized by the Project BioShield Act of 2004 is based on the HHS determination that critically needed medical countermeasures are advanced enough in development to warrant acquisition, and is also subject to six legislative requirements for interagency and Presidential approval.

In order to issue an RFP using the Special Reserve Fund (SRF), the following four steps are required by the Project BioShield legislation:

1. The Secretary of Homeland Security, in consultation with the HHS Secretary and other Federal agencies as appropriate, must determine that there is a material threat, which is communicated by issuing an Material Threat Determination;

2. The HHS Secretary must determine that additional medical countermeasures are necessary to protect the public health from this threat;

3. The HHS Secretary must determine that a particular security countermeasure is appropriate for acquisition for the Strategic National Stockpile using the Special Reserve Fund;

4. The Secretaries of HHS and DHS must jointly recommend use of the BioShield SRF for this acquisition to the Director of the Office of Management and Budget (OMB).

In order to expedite the acquisition process to the degree possible, once this joint HHS/DHS recommendation letter has been submitted to the OMB Director the RFP can be issued (contingent upon availability of funds). Release of the SRF that is required for any contract award also requires an additional two steps by the Project BioShield legislation:

5. The Director of OMB, under authority delegated from the President, must approve use of the SRF; and

6. The Secretaries of HHS and DHS must jointly notify Congress of the procurement.

To inform the determinations in which the Secretary of HHS is involved, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), acting through the deliberations and actions of the PHEMC Enterprise Governance Board, provides broad-based input. These determinations are based on knowledge of current medical countermeasures and the medical and public health consequences likely to result from the

threat, scientific data on prospective medical countermeasures; the quantities to be procured; and the feasibility of meeting FDA requirements for licensure (vaccines and biologics), approval (drugs), or clearances (devices and diagnostics) within eight years. As a result, products must be in advanced development to support release of an RFP, and award of an acquisition contract, under Project BioShield, using the SRF.

BARDA

12) What is the status of hiring a BARDA Director?

Response:
On April 14, 2008, The Department of Health and Human Services announced the selection of Robin Robinson, Ph.D., as the first director of BARDA.

13) How is the lack of having a BARDA Director affecting BARDA activities including the issuance of RFPs and the awarding of contracts for both advanced development and procurements?

Response:
BARDA was led by an Acting Director during this period. There was no lapse of leadership during the transition from the Office of Public Health Emergency Medical Countermeasures to BARDA. BARDA issued RFP's and awarded contracts during the period a BARDA Director was being recruited.

14) Although the HHS FY 08 budget is not yet complete, can you discuss BARDA's plans for FY08 BARDA funds (when funds are available) and the timing of RFPS?

Response:
The following summarizes BARDA's use of FY08 funds for Advanced Development:

Anthrax Therapeutics							
Monoclonal Antibody - ETI-204	7/11/2007	10/30/2007	9/2007	10/2007 to 9/2009	0.96	HHSN 272200700035C	Elusys
Monoclonal Antibody - Valortim	7/11/2007	10/30/2007	9/2007	10/2007 to 9/2010	0.93	HHSN 272200700033C	PharmAtl
Monoclonal Antibody - Valortim	7/11/2007	10/30/2007	9/2007	10/2007 to 9/2010	0.99	HHSN 272200700033C	PharmAtl
Antitoxin - Monoclonal Antibody	2/15/2008	6/4/2008	9/25/2008	TBD	5.31	HHSN272200800040C	Emergent

The Honorable John Sullivan

1) My first question deals with growing problems with the Medicare Aggregate hospice cap that hospice providers across Oklahoma and the nation are having.

Problems with the Aggregate Hospice Cap have resulted in 40% of Oklahoma hospices hitting or exceeding this cap. This threatens these hospices' ability to stay in business and provide quality end-of-life care. Consequently, hospices are being forced to choose between two unacceptable alternatives: withhold care from terminally ill Medicare beneficiaries or face bankruptcy, a choice that in my view is unacceptable. Additionally, qualified hospice patients are in danger of losing access to care.

I would like your comments on this issue to see if the Administration is aware of this growing problem. If so, if the Administration is planning on addressing this issue in a regulatory manner?

Response:
One of our top priorities is access to care for our Medicare beneficiaries, especially those who are terminally ill. The Medicare hospice benefit covers palliative and support services for beneficiaries who have a life expectancy of six months or less if the disease follows its normal course and who have elected to receive palliative care under the hospice benefit. This benefit has grown dramatically since its inception in 1983.

Medicare spending on hospice increased 130 percent to $6.7 billion between 2000 and 2004. Hospice expenditures in 2006 were $9.8 billion. Medicare's spending on hospice services is projected to increase at an average annual rate of 9.0 percent per year from 2004 to 2015. This growth outpaces the rates of spending growth for hospital, physician, skilled nursing facility, and home health services. The number of Medicare-certified hospices is also increasing, with a 26 percent increase in the number of hospice providers from 2001 to 2005.

In addition, the national average length of stay (ALOS) that remained unchanged from 1998 to 2000, increased by 40 percent from 2000 to 2005. The ALOS is the primary reason why so many hospices are exceeding the cap. The hospices in Oklahoma have an ALOS much higher than the national average of 108 days compared to 67 days for calendar year 2005.

We are working with hospice providers who are subject to the cap to help mitigate any hardship. Under the Medicare Modernization Act of 2003, Congress gave a provider of services or a supplier the right to an automatic repayment schedule of at least six months if repaying an overpayment within 30 days constitutes a "hardship," unless an exception applies. It also provided for longer installments if a provider met the definition of "extreme" hardship.

The CMS has approved repayment plans for many hospices, giving them up to 60 months (5 years) to repay the overpayments. In some instances, providers are struggling to repay the debt and have begun to default on these repayment arrangements. This is because several of the providers have overpayments from over a period of several years and the aggregate repayment

arrangements are putting the providers in financial distress. As a result, some providers are requesting that the debt be compromised. Compromise requests where the debt is over $100,000 must be reviewed and approved by the Department of Justice.

2) Another important issue which needs to be addressed is access to quality, affordable health care, especially within our nation's indigent population.

The price of treating the indigent at our hospital emergency rooms is astounding compared to the cost of treating someone in a primary care setting. We need to take a look at creating an innovative new grant program funded through unused Medicaid Disproportionate Share Hospital (DSH) funds to help states fund health access networks using unobligated Medicaid DSH funds. These networks will get low income and uninsured patients who need basic medical care out of emergency rooms and into integrated "health access networks" of community health centers, public hospitals, federally qualified health care centers and other safety net providers for high quality primary, outpatient, inpatient and specialty care.

We also need to take a look at providing our safety net hospitals in statutorily defined low DSH states with funding increases through these unobligated DSH funds to strengthen and augment the nation's health care safety net.

What is the Administration's view of using the Medicaid DSH program as a way to create health access networks to help reduce the costs of care for the indigent population? Also, what is the Administration's view of increasing DSH payments to low DSH states through unobligated DSH funds?

Response:
The statute governing DSH sets forth certain limits on Federal financial participation for State DSH payments, including State- and hospital-specific limits, so that the availability of DSH funding is limited and varies significantly between States. While some flexibility may exist under demonstration authority, to date, CMS has received no demonstration proposals to significantly re-direct unobligated DSH funds to support health access networks.

The Administration shares your concern of improper use of costly emergency rooms and supports helping states implement effective reforms to slow spending growth while maintaining access to coverage. In fact, the Centers for Medicare & Medicaid Services (CMS) recently announced $50 million in grants to 20 states to help improve access to primary medical care so that Medicaid beneficiaries could avoid improper use of costly hospital emergency rooms. Created under the Deficit Reduction Act of 2005 (DRA), these grants will help Medicaid programs fund initiatives primarily in rural and/or other underserved areas, as well as programs that work closely with community hospitals, to provide alternative health care settings for individuals with non-emergent medical needs. Additional details can be accessed on the CMS website at www.cms.hhs.gov/GrantsAlternaNonEmergServ/.

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