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PRESIDENT'S FISCAL YEAR 2009 BUDGET PROPOSAL FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

FEBRUARY 6, 2008

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WEDNESDAY, FEBRUARY 6, 2008

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:04 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Kerry, Lincoln, Wyden, Stabenow, Schumer, Stabenow, Grassley, Hatch, Snowe, Kyl, Smith, and Roberts.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The hearing will come to order.

President Franklin Roosevelt said, "Democracy cannot succeed unless those who express their choice are prepared to choose wisely." The President's budget request presents the President's choices. Once the President puts his proposals forward, it then becomes the Congress' job to scrutinize those choices. We must determine whether he has chosen wisely.

I am just as interested as the President in controlling health care spending, but his choices are not the best ones for the long-term health of our country, our Federal health care programs, seniors, people with disabilities, children, and the poor who rely on them.

Over the next 5 years, the President proposes cutting more than $180 billion out of Medicare, he proposes cutting more than $18 billion out of Medicaid, and he proposes meager funding for children's health. These numbers are truly staggering. They do not reflect the choices of America's seniors, people with disabilities, children, and less fortunate citizens.

The President's choices related to the Medicare program are particularly troubling. His budget proposes over $182 billion in Medicare cuts. A significant portion of these cuts come from drastic, across-the-board reductions of what Medicare pays health care providers, but the President proposes those cuts only in the traditional fee-for-service program.

The President chose to permanently cut payments to hospitals, to nursing homes, to rehabilitation facilities and hospices. He also proposed permanent reductions of Medicare payments for ambulances, outpatient hospital services, and home health services. But the President chose not to address the differential between tradi-

tional fee-for-service and private Medicare Advantage payments. MedPAC estimates this differential at 13 percent. MedPAC recommends that we eliminate the difference.

The committee held hearings on Medicare Advantage last week, and we will have another one tomorrow. With all of the problems that Americans are learning about Medicare Advantage, it is confounding, to say the least, that the President chose not to propose any changes in the program, despite the recommendations of CBO and the recommendations of MedPAC.

Why did the President choose to protect private health plans at the expense of hospitals and other providers that treat beneficiaries in the fee-for-service program? Why? This budget demonstrates where the President's priorities really lie. The only change that the President proposed for the Medicare prescription drug benefit is to increase premiums to beneficiaries with high incomes. No one supports the Medicare drug benefit more than I. After all, I helped create the benefit. But it is not perfect.

The most recent HHS survey revealed that 85 percent of beneficiaries are satisfied with the drug benefit. That is encouraging. But it means that we have to do more before all beneficiaries are satisfied. The President's choice appears to indicate he is more easily satisfied than this committee.

Medicaid is America's health care safety net. It provides access to health care for the most vulnerable among us. Tough economic times like these stretch Medicaid to its limits. Since the President's last budget, the administration has proposed a number of changes to Medicaid that decrease what the Federal Government will pay. This means that States have either to make up for lost dollars or to cut services.

Now, on top of that, the President wants to make over $18 billion in additional cuts to Medicaid. Cuts of this magnitude are too big for this critical program, and that is especially so when Medicaid is stretched so thin. The President also proposes to fund the State Children's Health Insurance Program at $19 billion above baseline over the next 5 years. This level of funding is far below what the Congress chose to provide last year, and it may not be enough to even cover projected State shortfalls.

Last year, the committee made reauthorization of the Children's Health Insurance Program, otherwise known as CHIP, its top health care priority. After months of hard work, Congress delivered a bipartisan reauthorization to the President. He vetoed it. A bipartisan group of Senators and Representatives resumed negotiations. We tried to craft a package that the President would sign. We spent more long days and nights hammering out an agreement that addressed a number of the President's concerns. We sent the President that second bipartisan reauthorization package. He vetoed that one as well.

Now the President has proposed funding far below the level for which Congress has twice demonstrated its support. The Children's Health Insurance Program provides access to health care for America's poorest kids. The President is choosing not to do all that he can to improve and expand health care for America's children.

So, Mr. Secretary, help us to understand the President's choices. Help us to understand how making his proposed cuts would actu-

ally affect beneficiaries. What will the effect be on beneficiaries under our Federal health care programs, and on our country? Help us to work together—and I mean that—to choose more wisely.

Senator Grassley?

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA

Senator GRASSLEY. Thank you, Secretary Leavitt, for coming. One area of great interest for me, as it is with Senator Baucus, is this provision of the budget dealing with the State Children's Health Insurance Program. Last year's budget included only about a $5-billion increase for SCHIP, which many experts deemed insufficient, and which I said at that time was insufficient to keep the current program then at its level.

Even though funding for outreach activities to enroll uninsured children had been provided in earlier budgets, last year's budget included no funding at all for those activities. Many members of Congress supported the administration's proposal for SCHIP during last year's reauthorization debate. As you know, we were not successful in reauthorizing. Instead, Congress passed, and the President signed, an extension of the program till March next year.

While I am hopeful that SCHIP can be revisited, it is more likely that the debate will resume in the 111th Congress. It is, therefore, a bit surprising to me that this year's budget proposal actually puts forward a more credible funding amount for SCHIP. Instead of about $4 billion to reauthorize SCHIP, this year's budget has about $20 billion, almost 5 times as much, and the additional funding for outreach and enrollment has also reappeared in this year's budget.

First of all, let me commend you for the proposal. It is a more thoughtful and a more realistic proposal than was offered last year. In fact, I will go so far as to say that, if the administration had offered this proposal a year ago, it would have made a real difference.

On Monday, I wrote a letter to you and to OMB Director Nussle about this issue. In that letter, I requested that you provide an explanation of how, and more importantly when, you came to the realization that last year's proposal was off base and that substantially more funding was required to reauthorize SCHIP. I, for one, would like some answers, and I would bet a lot of my colleagues would feel the same way. I would ask consent that a copy of that letter be put in the record.

The CHAIRMAN. Without objection.

[The letter appears in the appendix on page 41.]

Senator GRASSLEY. I hope that your testimony will answer the questions in my letter and detail why the administration has done such an about-face on SCHIP.

Now I would like to turn to Medicare, another issue that the chairman has addressed. When it comes to the situation we have in Medicare, we need to think long and hard about its long-term implications on the budget and how we can solve those problems.

One troubling area is physicians' payments. The Physician Payment Sustainable Growth Rate—we refer to that as the SGR formula—is fundamentally flawed. At the end of last year, Congress passed the Medicare and Medicaid and SCHIP Extension Act. It

temporarily eliminated the 10.1-percent scheduled cut in physician payment for Medicare. It provided a 6-month half-percent increase instead. It also extended the Physician Quality Reporting System and included the usual 1.5-percent bonus payment to physicians for reporting quality.

However, if Congress does not act by June, physicians face a severe payment cut in the second half of this year. Without further action, Medicare payments to physicians will plummet way down over the next several years. These continued payment cuts probably will threaten access for beneficiaries if physicians decline to participate in Medicare or to accept new Medicare patients. While the President's budget does not offer any ideas for addressing the physician payment dilemma, it is undoubtedly one of the biggest challenges that Congress faces.

On a broader level, the President's budget achieves a substantial portion of its savings from Medicare provider payments. Many of these recommendations go far further than what the Medicare Payment Advisory Commission has recommended, and even taking their advice and doing what they want done is often very difficult to get a majority in the Congress to do.

We must then look beyond payment updates to control Medicare spending. Instead, the way that this program pays providers is in need of comprehensive reform. Today, Medicare rewards poor-quality care. That is just plain wrong, and we need to address this problem of rewarding people based upon quality of care as opposed to quantity that they deliver right now.

The administration recently released a plan, required in the Deficit Reduction Act, to implement value-based purchasing for hospital services. I am pleased with the thought that was put into the development of that plan, and I look forward to working with Chairman Baucus and other members of the committee to transform how Medicare pays for hospital services.

I am also pleased to see proposals in the budget to improve Quality Improvement Organizations—we refer to them as QIOs. Last year, I introduced a bill with Chairman Baucus to comprehensively reform that program. I look forward to hearing more about your ideas on how to ensure that the hundreds of millions of taxpayers' dollars that go to QIOs each year are dollars that are put to good use, without detracting from the fact that we do need to have people observing quality and making judgments about quality being improved in the entire health care delivery system.

Also included in this year's budget is President Bush's plan to help more Americans get health insurance. About 47 million Americans do not have health insurance. As I noted last year, the President has proposed correcting a flaw, a very serious flaw, in the health care tax policy. The Joint Committee on Taxation estimates that over the next decade Americans will receive more than $1 trillion of tax benefits from health care under our current tax law.

Now, there is nothing wrong with that except the unfairness of it, and where it does not drive the market in the right direction, and then still provides for 47 million people not having health insurance. Whether a worker receives a tax benefit under this system depends on whether his employer chooses to provide health insurance. We want to help individuals as well as what corporations

might do. Those benefits then could be more fairly directed to help meet the needs of millions of Americans without health insurance. One of the leaders in that area is Senator Wyden.

President Bush would extend the tax incentives for purchasing health coverage to the self-employed and those who buy health coverage on their own. Such an approach would be more equitable and it would make health insurance portable. It is very important that a person's health insurance not be dependent on where they work. I hope that as we discuss how to insure more people we can consider some changes to the taxation of benefits that will both expand health insurance coverage and contain health care costs. I would encourage working with Senators Biden and Bennett on that approach.

Lastly, Mr. Chairman, I also request that a lengthy letter and attachment regarding an investigation into the Food & Drug Administration be inserted into the record, and it is dated for today.

The CHAIRMAN. Without objection.

[The letter appears in the appendix on p. 43.]

Senator GRASSLEY. Mr. Secretary, I strongly encourage you to read this letter. I would encourage you to do it personally. I am not going to ask you if you actually read it, but I hope you will. It describes a troubling series of events involving the FDA, Wyatt, and a safety officer at the FDA. It involves the hiring of private investigators by Wyatt to find dirt on a safety officer, an FDA investigator submitting a criminal referral to the U.S. Attorney's Office that was riddled with false information. Mr. Chairman, that is what I was submitting for the record.

Thank you again for being here.

The CHAIRMAN. Mr. Secretary, thank you for coming before this committee to address the President's budget as relevant to your department. As you know, your prepared statement will automatically be included in the record, and I would urge you to stay within the 5 minutes allotted.

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

Secretary LEAVITT. Thank you, Mr. Chairman. I will do so.

Why don't I jump directly to the question you raised with respect to Medicare? First of all, let me just express my appreciation for the chance to come and talk about the budget. Obviously, Medicare is 56 percent of the $737 billion that our department administers, so it is the biggest part, and a very important part.

You asked about the reasoning of our budget. May I just acknowledge that we view this budget as a stark warning on the current course? If it remains on auto-pilot, 11 years from now, Medicare will be broke. It is a very serious problem. I know you share the concern.

Let us acknowledge that Americans' sensitivity on entitlement warnings has become a little bit numbed over the course of the years. There is a repeated cycle of alarms and inaction. Dire warnings become kind of a seasonal occurrence. It is a lot like the cherry blossoms coming out. We drive by them, acknowledge them, and then keep going without doing anything.

This budget warns in a different way. It illuminates with specificity the hard decisions that policymakers, no matter what their party, will need to make in coming years unless we change the current course. We can keep our National commitment, and must, but in our judgment we need to change the way we manage Medicare. Currently, the fee-for-service Medicare is a centrally planned, government regulated system of price fixing. Price fixing systems are adjusted when the government makes decisions on what the priorities should be. Those are very blunt tools, and they are inexact: government decides who gets treated, government decides how much they get treated, government decides how much value should be allotted to each different procedure. It is an inefficient system, and it has contributed substantially, in my view, to the dilemma that we face today.

If consumers were allowed to make these decisions through an efficient market that the government would need to organize, their decisions would be far more precise and, in my judgment, wise. One need look no further than the prescription drug benefit that you mentioned. I agree it is not perfect, but it is a great success. It has been a success because we organized the marketplace and we let consumers decide. In addition to the good things that you referenced in terms of satisfaction, we are now seeing the savings. Recently we have announced a substantial savings over the next 10 years as a result of many factors, but high among them is the competition.

So we have prepared our Medicare approach with three goals in mind: the first is long-term sustainability; the second is affordable premiums for beneficiaries; and lastly, a balanced budget by 2012. I am sure we will have a chance to talk more about that, so I will skip to just mention a couple of other things that I mentioned in my statement.

First, I would like to acknowledge what you have said about SCHIP. We view SCHIP, of course, to be a very important part of the vision to make certain that every American has an affordable insurance policy. The President proposes to increase funding to the States by nearly $20 billion over the next 5 years, and we are adding $450 million as part of that to outreach grants to assure that we are reaching those who are in most need.

Our proposal is consistent with the philosophy that SCHIP should be focused on the low-income in our society. It is also consistent with the 18-month extension that was passed in December. I will be pleased to reconcile that with you.

With respect to Medicaid, we have made steps in this budget to assure that Medicaid is sustainable. You mentioned the fact that there is an additional $18 billion. Again, I want to emphasize that, as with Medicare, our budget continues to increase. The $18 billion is the amount that we would reduce the growth rate. It would continue to grow every year to serve Americans.

We believe that every American needs to have access to an affordable insurance policy, and for that reason the President has proposed, as Senator Grassley indicated, very important changes to the tax code. When coupled with making tools available to States, we feel confident we can, in fact, meet that obligation.

I would like to comment, briefly, on food safety and the important work of the Food and Drug Administration. The United States has a good system of food protection, but it is not adequate for the future. So you will see a major emphasis in this budget, including 7 percent additional funding going into the area of overall food protection and safety, and a 5.7-percent increase in the overall budget. One thing that gives me perspective here is, in the last 2 years, we will have added 1,000 people at FDA. We are taking this very seriously.

Biomedical research. We proposed increases in each institute and center at NIH. Overall, the budget is about the same as it was before. On emergency preparedness, we are still a Nation that remains at risk. HHS obviously has a big responsibility. You will see efforts on our part to meet that responsibility in this budget, as well as being able to complete our pandemic influenza plan.

You will also see a series of health diplomacy initiatives I hope we will have a chance to talk about. We see the United States having a very important part not only for our own protection, but as an important leader in the world.

In conclusion, the President and I both believe that we have crafted a strong and fiscally responsible budget at a challenging time. I want to acknowledge, Mr. Chairman, that some will not agree with the decisions that were made, and that is why we are here to talk about them. My job is to do my best to give you an understanding of our thinking, and I will do so.

Mr. Chairman, could I acknowledge one other thing? That is, I have become aware that a series of questions that were raised at the last hearing a year ago that I had understood had been responded to, apparently were not. I want to acknowledge that. I cannot defend it. They have now been answered, and I can assure you that, if in fact there are questions this year, they will be responded to in a much more timely way.

[The prepared statement of Secretary Leavitt appears in the appendix.]

Senator GRASSLEY. Can I ask in regard to that, are those questions that every member of the committee asked or just the ones that I have asked?

Secretary LEAVITT. I do not know the answer to that.

Senator GRASSLEY. All right.

Secretary LEAVITT. I assume it was everyone's.

Senator GRASSLEY. All right.

The CHAIRMAN. I would hope so.

Secretary LEAVITT. It was everyone, I understood.

The CHAIRMAN. Well, thank you, Mr. Secretary.

I guess I am asking you, how can we honestly engage in a good, solid discussion about health care priorities, especially Medicare, Medicaid, and CHIP spending? You have asked for huge, draconian cuts which this Congress is not going to enact.

I might say that your budget request also sounds very much like you are trying, to say it bluntly, to privatize Medicare and Medicaid, in two respects. One is the letters that you sent to States changing the CHIP program. It is very bothersome, frankly, to send a letter that is not regulation yet, for Congress to codify. It just feels like you are just trying to privatize that program.

But more importantly, with respect to Medicare, you proposed huge cuts in fee-for-service, but did not touch the private side. You want huge cuts in the government plan, but no cuts in the private plans, even though we get very strong recommendations by the Congressional Budget Office, bipartisan, very strong recommendations by MedPAC, the panel that advises the Congress on Medicare spending, that the differential between fee-for-service and Medicare Advantage plans should be eliminated.

So how can we have an honest-to-goodness discussion when your budget is based, it seems, more on ideology than it is on trying to find a meeting of the minds between the Congress and the administration? I say that in part because cuts of Medicare, $182 billion, smacks of a meat ax cut. I see no analysis of how it is going to actually affect providers, how it is actually going to affect hospitals and all the other providers. There is no analysis, you just say "cut."

The real problem, frankly—and you alluded to this in your statement—about Medicare trust fund expenditures going up so high is health care costs in this country generally. That is the problem. We are not going to solve a problem just by cutting down Medicare or Medicaid, or not giving benefits to CHIP. That is not going to get to the underlying problem with health care costs.

So I am asking you, the administration, to talk to us about how we legitimately get health care costs under control. There is virtually nothing in this budget in a solid way to get at health care costs. Nothing. You just want to whack Medicare, whack Medicaid, and do not touch Medicare Advantage, the private plans. So again, it sounds like you want to cut government, meat ax approaches, cut government, bolster and help the private plans, but not address the underlying problem, which is health care costs.

Secretary LEAVITT. Senator, there is the basis of a very good conversation here. First of all, let me just acknowledge, in terms of nomenclature, when we talk about cuts, we are talking about a reduction in the growth rate. We would have taken it from 7.2 percent down to 5, so we will see it increase over the next year, and that would be true of Medicare. I know you are aware of that.

The CHAIRMAN. Why not eliminate that differential?

Secretary LEAVITT. I would like to address that. Let me acknowledge that the tools that are available to a budget maker right now in Medicare are relatively limited because we are in a price-setting type mode. I believe that ought to change. I believe we have to get consumers involved, not only in Medicare but in health care generally. I would like to take up your offer to talk some about how we could reduce costs in health care generally.

The CHAIRMAN. And where do I see in your budget an honest-to-goodness effort to cut health care costs?

Secretary LEAVITT. We have introduced, with the tools we have available, given the nature of this budget, decisions that we think need to be made. I will tell you, I think there is a better way to do this. The better way to do it would be to get consumers involved in it. A better way to do that is—there are four cornerstones that you and I have talked about before: electronic medical records, beginning to define what quality is, giving consumers information about what quality is and price, and beginning to create incentives

so that we pay providers on the basis of the value they provide, not just the volume they provide.

That is the key to not only getting Medicare back under control, but also beginning to stem the tide of health care costs generally. Medicare Advantage is a good opportunity to do that. You mentioned the fact that there is a differential in what we pay. Over time, that needs to be remedied.

The CHAIRMAN. Why don't you begin with this budget?

Secretary LEAVITT. Let me suggest a better way than simply using price controls to do that. If we were to expand the areas of competition beyond one county where we could have broader ranges of competition, we would see those costs come down. That is what happened in Medicare Part D. We created regional competition and the competition from the high-cost areas and the low-cost areas.

The CHAIRMAN. It sounds like you want to privatize more.

Secretary LEAVITT. What I am saying is, I would like to see consumers involved because I think——

The CHAIRMAN. It sounds like, basically, Mr. Secretary, there is nothing in your budget that addresses the point you made in the last minute, that is, the general hope that we could get health care costs down. If your budget had a very large component and made very clear that we are trying to get health care costs down generally, whether it is private fee-for-service, whether it is Medicare Advantage, whether it is fee-for-service generally, whatever it is, that would be great. I see nothing there. Again, I just see ideology. You want health care privatized and you want to cut government. That is what I see here, and that is a non-starter in terms of discussion here.

Secretary LEAVITT. Given the nature of Medicare, which is a regulated, government price-setting organization, that is the way we have to construct budgets. You and I seem to be in agreement that, if we could begin to create more involvement by consumers and change that system, we could potentially see it. I would love to have that conversation with you, Senator.

The CHAIRMAN. Senator Grassley?

Senator GRASSLEY. In my letter to the FDA dated January 10, 2008, I requested that FDA make available the Executive Secretary Alleda Syndelar for an interview with my committee staff. The response that I received from the FDA on February 1 was that they did not think that the Executive Secretary could give me the information that I sought. Now, that is, of course, a novel response. Now, I appreciate that, but it is not a very helpful response. So, a very simple question. Could you make sure that the FDA produces the Executive Secretary, as I requested?

Secretary LEAVITT. I am not sure the title "Executive Secretary" is one that is familiar to me.

Senator GRASSLEY. All right. How about, could Alleda Syndelar be made available for answers to questions?

Secretary LEAVITT. Senator, this is a circumstance that I am a little unfamiliar with. As you know, we have been working to be cooperative with you in making certain that you had the investigator and so forth, and we would be happy to continue this dia-

logue. I want to be cooperative. I am not familiar with this situation. This is one I am going to have to respond later on.

Senator GRASSLEY. All right. I would only ask you—and I do not blame you, I blame the Justice Department—remember, it took us 2 years to be able to question Agent West, and I do not want to go through that again because you might not be around here a year from now. I hope you are, but you may not be. So I need to work quickly with you to get an answer, and get her.

Secretary LEAVITT. Thank you. I would like not to go through what we did before either.

Senator GRASSLEY. All right. Thank you.

I appreciate that the administration has moved in a constructive direction relative to SCHIP. Would you respond to the questions in my letter? Now, not today because you do not have enough time today to do that, so do that in writing. But I would like to have you, today, elaborate further on when the administration determined that additional funding for SCHIP was needed, and maybe, what was it, a statistical base or philosophical or something that got us to the point where we have this reality of what I said a year ago we needed to do, and the fact that the President said they only needed $5 billion.

I will tell you, it carried a great deal of credibility with about three-fourths of the people on the Republican side of the aisle, so we did not get the bipartisan compromise that the President could sign, and we would have been able to do that if this had been acknowledged a year ago. So that is why it is important for me to understand why this change now, which is a very positive change.

Secretary LEAVITT. Senator, I think I can do that, briefly. First of all, let me just be clear that our proposal was not $5 billion. We had 5 and then some left-over money from previous allocations, which made it just under 10. So the difference between where we started was 10.

Senator GRASSLEY. All right. And 20.

Secretary LEAVITT. Just under 20 now.

Senator GRASSLEY. Yes.

Secretary LEAVITT. It can basically be attributed to three things. First, we dropped off the 2008 year and added 2013. 2013 is substantially more expensive than was 2008.

Second, we funded this year rather than just fulfilling what the States had suggested they would have. As we did in our previous budget, we have basically created a growth scenario.

Third, we have added the funds that you indicated for outreach. Our effort has been simply to say, let us arrive at the policy and then cost it out. We have better estimates now. Last year when we had this conversation I indicated repeatedly that I was interested in being able to arrive at a policy and then cost the policy out, not arrive at a number and then come up with a policy. What we have done here is consistent with the extension that was offered through the Congress and signed by the President in December.

Senator GRASSLEY. My staff just gave me something here that I am not sure I understand. But there is something about some disagreements with the figures that I will ask somebody else if they can do when I am not able to be here.

As I mentioned earlier, for several years leading up to the reauthorization of SCHIP, the administration's budget proposal included outreach funding for grants to States, schools, and community organizations to enroll children. Yet last year, when the Congress was working on an SCHIP reauthorization, the President's budget included no funding. Would you elaborate on why the administration reversed course and included outreach in this budget?

Secretary LEAVITT. It was consistent with the spirit and letter of the extension, and we attempted to take that extension and create a budget that approximated the will of the Congress.

Senator GRASSLEY. All right. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Kerry? No, you are not next. Senator Wyden is next.

Senator WYDEN. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. I have long felt, if you are going to do anything important here, it has to be bipartisan. That is what we are trying to do with the Healthy Americans Act. We are anxious to work with you as well, Mr. Secretary.

Let me also say, we appreciate Senator Grassley, Senator Crapo, Senator Stabenow, all of whom have been part of this effort as well.

Mr. Secretary, I believe that you care about the poor and the less fortunate, but this budget does not care about the poor and less fortunate. You have to defend it, that is your job, but it seems to me that much of it is indefensible. I share your view, for example, that there is a way to find savings in these programs. But I think, for example, it makes more sense to start with ideas like helping people buy quality, for example, with respect to providers and technology.

So my first question to you is, with the American people understanding that the health care system is broken and they want Democrats and Republicans to work together to fix it, why can we not get the White House to say that they will be part of an effort to reform the system and go where six Republican U.S. Senators are going and say that, as part of that, you have to cover everybody?

Secretary LEAVITT. Senator, first of all, the President has made very clear that every American needs to have access to an affordable insurance policy. We are anxious to see government play a productive role in organizing a system where that can occur. You will know from the many hours we have spent together working to find a bipartisan solution to this that I believe it is possible.

A very important part of that would be what was referred to earlier and correcting the blatant discrimination that exists in this country's tax code against people who have to buy insurance outside their employment. That would be a giant step forward. There are proposals being put forward by a Republican President and proposals being made by various members of this body who support variations of that tool. That would be a substantial step forward. If we could take that proposal, debate it this year, and do something about it, we think it could add as many as 20 million people to the rolls of the insured.

Senator WYDEN. Mr. Secretary, I would only say that there is a big difference between access and coverage. What the six Repub-

lican U.S. Senators have said as part of a bipartisan effort is that there would actually have to be coverage in return for making the various marketplace changes. I look forward, through the year, to continue to have the discussion.

Now, it seems to me that, in terms of this budget, one area that is going to work a particular hardship is, there is an awful lot of shifting of the cost to the States. I would assume that there would be very strong opposition from the Governors Association to this proposal. Am I right in that? Have you run this by the Governors Association? Because I look, for example, at the provision that limits Federal matching funds for such things as case management. I have heard again, if we are going to keep this bipartisan, Democrats and Republicans at the State level are very concerned about the fact that this budget shifts costs to the States.

Secretary LEAVITT. Senator, as you know, I sat in one of those chairs for a time and feel like I am somewhat sensitive to the feelings of Governors and the States. For example, on case management, we support case management. We think it is very important and vital to the management of Medicaid. But what we found over time is that case management is being used as a means of being able to fund a lot of things that are not health-related. For example, in one State that I am aware of, Medicaid funds were being used for child protection, and for adults receiving protective services, and probation and parole. That was not the intent. So we are just trying to close that kind of thing.

Senator WYDEN. On the point of the Governors Association, do you think that there is going to be support in the Governors Association for this proposal?

Secretary LEAVITT. I doubt it. But I can tell you that it is the right thing to do. I have found over time in my experience as Governor that States are as anxious as anyone to have as much help as they can from the Federal Government, and they will optimize it and should not be expected, I suspect, to do much less than that. But that is the reason we have a Secretary of Health and Human Services: to make certain that the program is managed in a fair way, and I am doing my best to do that.

Senator WYDEN. On your watch we still have an opportunity to influence the debate. You have 12 U.S. Senators. If you can bring the White House over to saying everybody ought to actually have coverage, not just access, you are going to have 12 U.S. Senators, as Senator Grassley indicated, wanting to work with you in a bipartisan way. I hope we will go as far as we can in that direction through the remainder of the year.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Grassley would like to speak.

Senator GRASSLEY. Yes. I hope my colleagues will just give me 30 seconds. You do not have to respond to this. But this is what I did not understand that my staff quickly put in front of me. We have a CBO document. This is about the $10 billion that you said we were starting with last year. CBO says that that was $4.16 billion, and the Congressional Budget Office says that the actual cost was going to be $2.62 billion. This gets back to, when Al Hubbard was working with you on this issue, I kept telling him what CBO

said versus what you folks are saying. He said, we do not understand what CBO said.

Maybe I said this even to you, and maybe you said the same thing to me, that I would be glad to get you together with CBO so we can understand it. So we are right back where we were of not understanding it. But I want to make it clear that CBO does not agree with you that you started out with $10 billion. So, I just wanted to make that point. If you want to respond and, if the chairman will let you, it is all right with me.

Secretary LEAVITT. We had conversations with CBO. I think we basically concluded we were counting different ways. I would like to keep the conversation going. I would still like to see us be able to resolve this and get the numbers right. I think if we get the numbers right we can find the policy, or at least if we get the right policy we can find the right numbers.

Senator GRASSLEY. Since the chairman stepped out, Senator Schumer is next.

Senator SCHUMER. Thank you. I think I would be next even if he did not step out.

Senator GRASSLEY. Yes, you would. You would. I would not show any favoritism he would not show.

Senator SCHUMER. Well, thank you, Mr. Ranking Member, and in absentia, Mr. Chairman.

I want to thank you, Secretary Leavitt, for coming. My first questions are on generic biologics. I would like to focus on the proposals included in the President's budget, 2009, for FDA. The proposal is a new regulatory pathway for follow-on biologics. The budget states that such a pathway should "protect patient safety, promote innovation, and be financed by user fees."

As you know, Senator Clinton, Chairman Waxman, and I put in legislation in this regard. We got a good working group, Senator Enzi, Senator Kennedy, Senator Hatch. We came to an agreement, but could not move forward because of timing issues. So I was really pleased to see that the administration included a proposal in the budget. It really would create great savings for both our government and our citizens.

Biologic spending grew by 127 percent from 2001 to 2005. Eleven billion dollars was spent in 1994, $45 billion today, $60 billion estimated in 2010. The top five biologics marketed in the U.S. account for more than 30 percent of Medicare Part D spending, which is huge.

So I think it is imperative we make this marketplace competitive so the Medicare program gets the best possible deal. In that regard, I am very glad that you have come forward.

This morning, I spoke with Commissioner von Eschenbach, who yesterday came actually and visited with my staff. I was saluting the Giants in New York, I am sure something you will agree was very important and necessary.

But in any case, we sat down and said two things: one, that we wanted to work together, that basically, while there might be differences, there are no insurmountable obstacles in the way of the administration and some of us coming together on a proposal; and that, instead of the administration submitting a proposal, we would

sit down and try to do something jointly. Does he have your support in that general endeavor?

Secretary LEAVITT. Indeed. Senator, we believe that follow-on biologics are an important medical development, and we would like to see them expanded in their generic form, like we would all generics. We would very much like to see the market competitive. We are working through some pioneering here in trying to figure out how to do it well, and there are lots of issues that you are familiar with. I will not recount them. But we are anxious to see a bipartisan proposal that could be arrived at.

Senator SCHUMER. And the idea of not either of us putting down a proposal, but trying to come up with a joint one meets your approval?

Secretary LEAVITT. That seems to me to be a better approach. If we could reach agreement, we would get somewhere.

Senator SCHUMER. Good. All right. Great.

Now, just to get into some principles here, some important principles, but I think ones that are not going to be in the way. There are three principles that I have always felt, and many of my colleagues: we need a clean pathway approval that is driven by science and allows the FDA discretion based on that science. Second, we must allow for interchangeability and comparability that is critical to achieve the savings. A pathway without interchangeability does not really help either competition or scientific advancement. And three, we have to have a mechanism to resolve patent disputes efficiently that incentivizes the parties to come to the table to provide a reasonable period of exclusivity. Those are general principles.

Now, one principle you have put on the table is a user fee to pay for this, and that is something that I would certainly entertain, and think that as long as the proposal had these kinds of things, that a user fee would be well worth it. Do you agree with that basic outline, that those three principles are important and could be combined with no interference with the user fee to make it happen?

Secretary LEAVITT. That is a succinct outline of the principles in question. What we have to find is a way to apply those great principles.

Senator SCHUMER. All right. Good. That is terrific. We will get our sleeves rolled up and start working with the Commissioner right away.

My next is a less friendly subject, I guess, which is IME (Indirect Medical Education). We have a shortage of physicians all over this country. I go to Upstate New York. I have been interested in diabetes, and we have diabetes legislation, Senator Domenici and I, to try to change the way we fund it so it will do early——

Anyway, so I go and meet with endocrinologists. I have not met a single endocrinologist from Upstate New York who was either born or trained in the United States. I asked the hospital administrators, and they just cannot get them. This happens with doctors everywhere. I think if you go to any one of our States, the proportion of foreign-born, foreign-trained doctors is huge.

Yet, the budget proposes devastating cuts to IME. Obviously it affects New York, which is the center of medical education. About 1 out of every 8 doctors is trained in New York. People come from

all over the country. They go back home. They get great training. It is one of the best things we can do. Your cuts would mean about $4.3 billion over the next 5 years.

So my final question is, how do we ensure we are not making the physician shortage even worse when we are cutting funds to the teaching hospitals for the purpose of training physicians?

Secretary LEAVITT. We are in agreement that we need to have medical education. That is obviously what creates the viability of the system on a long-term basis. Time today will not allow for an extended conversation on this, but let me just say I think the system is illogical, and in some cases creates a double payment. We are just looking for ways to refine the system, not to eliminate it.

Senator SCHUMER. I think you have done a pretty good job of chopping it up pretty good, but we will talk about it later.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Next, Senator Kyl?

Senator KYL. Thank you, Mr. Chairman.

First, let me just comment that I find some of the discussion here a little distressing, and it comes from good friends on the committee. My good friend from Oregon always urges bipartisan discussions, but then the comment that this budget does not care about the poor. Of course, the budget is not an animate subject, it is inanimate.

But the people who put it together obviously care about the poor, so I think we want to start a conversation on the basis of recognizing that everybody is trying to do the right thing here. My colleagues talk about "huge draconian cuts." The chairman complained about "meat ax cuts," and then asked what we could do about trying to get costs under control.

What the Secretary has tried to say here, and I think it is worth repeating again—and I would like to ask you to tell me if I have this straight, Mr. Secretary—is that essentially what you are trying to do is to recognize that markets set prices. We do not have a single-payor, one-size-fits-all government program here. We rely upon private market forces to work, insurance companies, physicians, consumers making choices, that then can affect prices. What I take it you have said is that, in your budget, you are trying to create opportunities for consumers to affect prices, to influence them to go down as one of the ways to cut consumer costs.

Do I have that right, or would you like to expand on that?

Secretary LEAVITT. I would just say it in a slightly different way. I would say that I believe that, if consumers were informed about quality and cost, they would make decisions that would drive the quality up and the costs down. They are provided with very little, either in Medicare or anywhere else in our health care system.

The point that was made earlier, I agree with. In order to have a sustainable Medicare Program, we have to create a system of health care generally because Medicare is a big part of the market. Medicare can be a part of reforming the market, but it is subject to the foibles of what I think is market-insensitive to consumers.

Senator KYL. And politicians always talk about, we have to do something about runaway entitlement costs. I do not know of a colleague who has not made that comment at one time or another.

Yet, when the budget comes out trying to reduce the rate of growth, it is characterized as cuts, as I said, "huge draconian cuts," "meat ax cuts."

Now, as I understand it, with regard to Medicare there is no cut, but rather you are assuming with this budget a rate of growth of approximately 5 percent rather than a rate of growth of about 7 percent and, with respect to Medicaid, a rate of growth of about 7.1 percent as opposed to 7.4 percent. Is that roughly correct?

Secretary LEAVITT. That is precisely correct. I would add that, if we allowed it to continue to grow on auto-pilot, Medicare will essentially run out of money 11 years from now. If it is allowed to continue beyond that, within 30 years it would subsume every piece of the Federal budget. Everything we spend for defense, everything we spend for highways, everything that goes to education, everything that goes to R&D would be taken up by Medicare. This is an emergency, and it is not very long in coming. Eleven years will happen fast.

Senator KYL. And, in fact, slightly reducing the rate of growth to the rate of growth that you project in the budget is not even, in and of itself, enough to solve the problem that you just articulated. Would additional policy changes not have to be made in order to ensure that the rate of growth does not get to the point that you articulated?

Secretary LEAVITT. We need more than a change in budget, we need a change in philosophy. That philosophy could work to the benefit of consumers because it would give them choices, higher quality, lower costs. It would, in fact, make Medicare sustainable.

Senator KYL. So just to reiterate, is the net result of the budget that you have proposed here a cut in Medicare or a cut in Medicaid?

Secretary LEAVITT. Let me say without equivocation, there are no cuts in this budget. It will continue to grow at 5 percent a year over the next 5 years. Medicaid will grow as well. We are simply reducing the rate of growth.

Senator KYL. Thank you, Mr. Secretary.

The CHAIRMAN. Does that adjust sufficiently for inflation increases and population increases?

Secretary LEAVITT. Well, medical inflation is a function of exactly what we are talking about.

The CHAIRMAN. I am asking on this debate over whether this is a cut or not. I mean, does your budget accommodate inflation increases over the years? Does it also accommodate population increases over the years?

Secretary LEAVITT. The budget grows at 5 percent per year. You can apply that to whichever of those factors you would like.

The CHAIRMAN. All right. Well, I think net is going to be more than that.

Senator Roberts? You do not have to do it now. We can always go to somebody else.

Senator ROBERTS. I am getting my track shoes on.

The CHAIRMAN. All right. Let 'er rip.

Senator ROBERTS. I have not started yet. Put that back at 5. [Laughter.] Thank you. About 5.30, because that is what it is going to take.

Mr. Secretary, thank you for coming. Thanks to the Senator from Arizona for pointing out some things we all need to hear. Thank you for your comments on Medicaid Part D for the greater growth and the lower cost, and more savings on premiums, and 85 percent of the people agreeing that this is a better program. I know that the chairman indicated we need to get that 85 percent figure up. We cannot even get 85 percent of the Senators to come back and vote or decide when to adjourn around here, so I think 85 is pretty good.

Let me just say that I have the privilege of being the chairman of the World Healthcare Caucus, in view of the fact of the passing of our dear friend, Craig Thomas. He was a strong fiscal conservative. He wanted Medicare to be fiscally sound, but he also knew that funding for the rural health programs was absolutely critical.

The President's budget—and this is discretionary, not entitlement—does propose a $150-million cut in rural health programs, the Health Resources and Services Administration. Two programs, rural outreach grants and rural hospital flexibility grants, are proposed for elimination, yet they have been very vital to our success in Kansas and other States like Kansas. Several other rural programs are proposed for flat funding, yet the needs of the communities continue to grow.

The budget proposes to reduce funding for the National Health Service Corps and completely eliminate title VII of the Health Professionals Program. Yet, as has been pointed out, we have a health professional shortage all across the country, and more especially in our rural areas. As a matter of fact, the HELP Committee actually approved legislation to renew this program and to increase funding over the next 5 years.

As the chairman also pointed out, the President's budget also proposes to significantly reduce—I do not know whether you want to get into the business of "cut" or "reduce" or the "reduction in growth"—Medicare and Medicaid programs for hospitals, home health care providers, nursing homes, and others, more especially, the friendly hometown druggist who has to administer Medicare Part D, yet he cannot get reimbursed for the generic drugs to give to the senior.

I am not going to get into that, but that is part of the problem. We need to return to a policy of fiscal responsibility and transparency. I agree with that. We need to get a handle on it. We need to have a change of philosophy. But I do not want to be in the business of tying the hands of our health care providers, especially those in the rural areas, and ultimately harming our seniors and our low-income populations by restricting their access to care.

The largest reductions in your budget come from freezing hospital payments over the next 3 years. In Kansas, they have put this on paper. That would translate to a $653-million cut to our Kansas hospitals over the next 5 years. We cannot do that and stay in business. From 2000 to 2006 in Kansas, our hospitals State-wide have experienced losses treating Medicare patients. In fact, the State-wide Medicare margin in 2006 was a negative 2.2 percent, even though in the Kansas City area one was 13 percent, and the big regional hospital in the middle of our State, 8 percent.

MedPAC recently recommended a full update for hospitals in 2009 because of a similar negative Medicare margin. Given all this, I just do not see the President's proposed payment freezes as a sustainable option. We have a lot of hospitals that have passed bond issues. We are down to the marrow of the bone. That has been going on for some time.

Home health care. I have stated over, and over, and over, and over, and over again, because I strongly believe in the service that our home health care folks do provide for our seniors, I fear that further reductions in their Medicare payments will come close to devastating their ability to provide care.

Home oxygen payments. Patients and providers are already about to undergo tremendous change in the next 10 months due to the implementation of the competitive bidding program that has really created a lot of confusion and exasperation among our home health care providers. This was supposed to be announced in March with the metropolitan service area that is in Kansas City.

We have 428 home health care providers. The minimum that could get a bid from Medicare is five. What happens to the other 423? They do not know. I do not even know how many have entered the bidding program, which means you are going to have existing home health care providers who do not know if they are going to be in Medicare or not. They are waiting to hear from CMS on round one. CMS has announced plans to move to round two, and we have not had anything back. If you could get a hold of Mr. Weems over there at CMS, tell him we need the news.

January will bring the end of certain monthly oxygen provider payments and the transfer of equipment ownership to thousands of seniors. Think of a World War II veteran. He now has ownership of the oxygen tank. He says to his wife Mabel, "Mabel, how do I attach this oxygen so that it works?" She says, "Well, it would be a good idea, dear, if you would put out your cigar."

I just do not think that that is the right way to go. This is the perfect storm. I want to be on record stating we should not exacerbate this by further reducing the oxygen benefit or deepening home health care cuts before we know the full impact of existing cuts and policies on the Medicare beneficiaries.

Mr. Secretary, you said Medicare is going broke, and it is. Over a period of time, that is where we are. But the other side of it is, the providers cannot afford Medicare because they are not being reimbursed at cost. So you can fix Medicare all right, but if hospitals opt out, like a lot of doctors do now, and set up specialty hospitals, and we have the community hospital that is faced with even more cost, and we have a bifurcated health care system with one system not having Medicare and the other system having Medicare, you are sure going to reduce costs, but we are not going to have a program.

The same thing with druggists, the same thing with home health care providers, the same thing with ambulance drivers, the whole universe of health care. And I tend to really try to highlight the rural health care delivery system, but it is true everywhere. Sure, we will fix Medicare, we will get those costs down, but there are people who will not take part. Then what does the senior do? That is the question, it seems to me.

Now, I have not left any time for a response. I am sorry about that. Thank you for testifying. Thank you for your continuing to work with the committee.

Secretary LEAVITT. Thank you. In absence of the chairman, maybe I will respond. Senator?

Senator KERRY. Go ahead and do that for a little while.

Secretary LEAVITT. I think the Senator raises some very good points. Let us acknowledge that Medicare is a government-regulated price-setting body. The government sets the price. We decide what is important. We essentially decide who gets to be treated and how much they are treated. It is a blunt and insensitive system in many ways.

What we agree on, I think universally, is it has to be fixed. What we cannot ever agree on is what specifically ought to be fixed, because we are making these decisions in an atmosphere that creates different priorities. That is the reason I feel so strongly that the change of philosophy is, rather than having a price-fixing system, we ought to have a competitive marketplace where the invisible hand of the marketplace does its work in a way that is substantially more wise and efficient.

Now, competitive bidding is a very interesting example of all of this. The models and pilots we have done on this lead us to believe we will save more than 20 percent on the areas we are doing competitive bidding on. That is an efficiency that will not be unfelt, but it will likely be more fair than if we were using a regulatory process to do that. Now, it needs to be fair, and we will get better at it as we go. But I want to underscore that this is an effort to try to use the marketplace as opposed to regulatory setting where, frankly, there are always political influences and so forth that come into that.

Senator ROBERTS. Would my colleagues permit me just 30 seconds to respond? Thank you.

As I indicated, we have 428 home health care providers in the metropolitan service area of Kansas City. The minimum that is in statute says that you could have that bid go to five. Well, I hope to heck you do not just give the bid to five, because that is going to be 423 home health care providers that will not have Medicare. I do not know what is going to happen to the people they serve. If they get out of Medicare and there is just private industry, I do not know. I guess my point is, again, you have to look at the providers.

If you have a program but you have no providers—and they are in the same situation. They would agree with you, because we are not getting at the cause of these rising health care costs. We are rationing health care now in rural areas. Here we have home health care providers, 428 of them. Half of them, I do not even know if they have applied. To apply was like going through a briar patch. There was a 1–800 number, dial 1 for this, dial 2 for all sorts of gobbledy-gook, and you could not understand it. You had to hire somebody to figure out how you applied. Then you wait, and wait, and wait, and it is extended, and extended, and extended. We still have not heard, and yet we are now moving to phase two.

What worries me is that you are not going to have a majority, or even enough, home health care providers that will have Medi-

care. Then you know what will happen. We already have sharks in the waters, and that is the big operations. They come in and say to a small home health care provider, guess what, I will offer you X, and that person thought that their operation was worth XX, but they are getting out. Then you have just a very small group of home health care providers, and then your costs are really going to go up.

Secretary LEAVITT. If we were to exclude so many people that people could not gain access, or what you suggest happened, it would not be a success. But every likelihood, in my judgment, is we will see dramatic reductions in our costs, and Medicare beneficiaries will still have access to the supplies they need. That is the way we need to define success.

Senator ROBERTS. Well, we may have a lot of babies born in pickups if we are not careful.

Secretary LEAVITT. Probably not for Medicare beneficiaries. [Laughter.]

Senator ROBERTS. No. I am just talking about the hospital that may not exist any more.

Thank you.

Senator KERRY. Thank you very much, Senator. I appreciate it.

Mr. Secretary, thank you. I know you were hearing from my colleagues. I was here and I heard the opening statement of the chairman, and I agree with significant components of it.

But let me pick on something that we agree on first just for a moment if I can, because I want to at least get the record clear on how this might be helpful. That is on the issue of e-prescriptions. We have a bill, a bipartisan bill, that we put in which would require physicians to adopt e-prescriptions, and ask in return that every physician in Medicare adopt this practice by 2011. Every independent analysis indicates this saves lives, it saves money, and Medicare spending will be curbed if it is passed. I think it should be passed, and passed quickly. Do you agree with that? Do you agree with the judgment that it saves lives, prevents errors, and that Medicare ought to adopt this rapidly?

Secretary LEAVITT. It saves lives, it saves money, and it saves time. Two years ago, I do not believe I could have said we were ready, but we now have succeeded in developing technology and having standards. This is the moment we need to begin to create that expectation that, if you are going to be reimbursed at the highest rate, you need to provide it to us in the most efficient and safe way.

Senator KERRY. So the standards are in place and the technology is there and we could go forward, in your judgment?

Secretary LEAVITT. In my judgment, we could. We support it and hope very much at the first available opportunity we can do that.

Senator KERRY. Well, I hope we will also, and I thank you for that.

Now, let me come back to this budget for a minute. It is really hard not to draw the conclusion that this is—and I have always had a lot of respect for you, and I think you are one of the more articulate persons in the administration. I know your history in your State as a Governor, and I respect it, so I do not know com-

pletely whether this is of your design or someone else's. That is not a question.

But what concerns me is, there really is a big ideological statement in this budget. Rather than engage us in an effort to do what we all know we are going to have to do—I mean, I heard you mention in your opening statement the significant challenge to Medicare. It has always perplexed me that the President chose to try to fix Social Security for the future and protect it, when Medicare goes bankrupt way before Social Security and is a bigger problem in many ways. Social Security is easy to fix compared to some of the struggles we have here within health care.

Yet, here you come with a budget that presents massive cuts that almost bureaucratically seeks to deal with CHIP, the Children's Health Care Program, that we wanted to do in a constructive, broader way with about $35 billion, not the $20 billion, but you are doing it administratively here. It is hard to see the credibility in that kind of approach. It is hard to see how, when you are tackling Medicare, you come at this with these kinds of cuts. You kept talking, in your statement, about a government decision and a government-run this, and a government choice here or there. I do not think we are getting a lot of letters from Medicare beneficiaries telling us, scrap the system.

I do not think we are getting a lot of letters from them complaining about having health care. They certainly do not say, get the government out of my health care life. Surely they would love to have a system that works as effectively as possible, but here you present us with these massive cuts without tackling Medicare Advantage, without demanding anything from the pharmaceutical industry, without any of the sort of systemic proposals that we ought to be looking at to do this as a whole.

You come in here and you have cuts on the skilled nursing facilities this year and annually thereafter; hospice update annually thereafter; inpatient rehabilitation facilities, annually thereafter; long-term care hospital, annually thereafter; outpatient hospital, annually thereafter; ambulance, annually thereafter; ambulatory surgical care centers, annually thereafter; home health, annually thereafter. You just run through this, and it is just sort of gutting the concept without really looking systemically at the problems.

I rode down here this morning on a plane with a consultant to Human Resources who specializes in benefit plans in health care. We were talking about it, and there are sort of three things driving the rise of health care in his judgment. One, is knowledge. We have better knowledge about how to help people live longer and how to take care of people, and we want to apply that knowledge, and doctors do, and people want it and they know it is there. We have better technology. Technology keeps increasing, and it costs more. We have better pharmaceuticals, and they keep people alive, and people want them.

So it is driving it in an open-ended way. We all understand that. Senator Wyden and Senator Stabenow and others have been working at this long and hard. Why come in with a budget that just sort of says, boom, we are cutting, without any regard to all of those pieces that play in this? It just does not seem responsible. It does not seem constructive. As the chairman said, it is not going to hap-

pen that way. So why are we not engaged in a better discussion here as to how you fix this thing big-time and save some money and give the Americans the best health care system they could have?

Secretary LEAVITT. Senator, I would love to respond to this. This is the fourth time——

Senator KERRY. Well, whether you would love to or not, you have to, right? [Laughter.]

The CHAIRMAN. Also, Mr. Secretary, briefly.

Secretary LEAVITT. Lucky for me. Briefly, let me say this is the fourth time I have been privileged with presenting a budget. Each time I am required to go through a price-setting system where, in order to present a budget that can be scored under the current rules, I have to deal with the price-fixing system. If I could present a budget that would say, let us take a look at what would happen if beneficiaries of Medicare had quality measurements, if they had electronic medical records, if they had price comparisons, if they had choices, I believe that we would begin to see prices fall and quality go up.

But we cannot score that, so we are left with coming and making a group of presentations here that—I mean, you are talking about $186 billion. You could make those reductions. Do I expect you are going to? No. But it is very important that people understand, we have a serious problem and we have to deal with it. If we want to be able to put forward that kind of proposal, we ought to have that conversation because we——

Senator KERRY. I am not going to disagree. I will wind up, Mr. Chairman. But I am not going to disagree with you on the scoring issue. Mr. Chairman, we need to find a way. I have had this problem when I presented, in 2004, a health care plan. All kinds of savings were unscoreable. All kinds of reasonable things were unscoreable. It is just ridiculous.

We are locked into a system where we have to sort of deal with a fake budget because somehow things that people in the real world in business can go out and give you a value for cannot, by government, be scored. That is just crazy. I think we ought to dig at that so that we can kind of maybe have a better conversation. I know time is ticking on this administration, but maybe you could help us do that and we could have a better conversation about all of this.

Secretary LEAVITT. This is a subject that not only have I given a lot of thought to, we have done a lot of work on it. Time is up, but I would love, in a different round, to have you tee me up and let me break into song over this.

Senator KERRY. Well, we will work on it.

The CHAIRMAN. Thank you. Thank you, Senator.

Senator Smith?

Senator SMITH. Mr. Secretary, thank you for being here. I actually feel a lot of sympathy for you because you are constrained by budget rules, scoring rules, from presenting, from what I hear from you, a market incentive system that I suspect in the end the American people would find more satisfying than what is being offered on the campaign trail now, which are command-and-control sys-

tems. It sounds great as a theme: health care for all, and the government will make sure you get it.

I just know when they put flesh on those bones, the American people are going to hate that when they see what it means. With all respect to Senator Kerry, I hear a lot about Medicare and usually it is because it is so bureaucratic and so few physicians are willing to participate in it any more, that despite the benefit the government provides for them, they cannot find a physician to care for them.

When you add it all up and you come to the bottom line, basically these programs are government command-and-control systems so that all of America will be on Medicare. The assumption is that government can provide these services, displace the insurance industry, at a cost less than the current system. I just do not know that there is any evidence of that anywhere in history that that is the case. I know that there aren't even numbers. People say look at all the savings here, the profit centers there, but the government costs have never been factored in in an honest way as to what its costs would be, and then all of America would be on Medicare.

Now, maybe that is where we are going. But my friend the chairman talks about, the problem is not demographics, the problem is cost. Well, as a businessman, I know how you deal with cost. You cut things out, you ration things, you eliminate, you reduce investment, you figure out how to do what government does, and you are forced to do, in this budget, which is reduce numbers so that you can show a bottom line that gets you to some balance.

So I have real sympathy for you. I do not hear a lot of answers. I want to exempt from what I said the Wyden-Bennett idea, which at least makes some proposal for the private system to provide some competition. But I have sympathy for you. That is basically what I have to say.

Secretary LEAVITT. I like this round of questioning. [Laughter.] Senator, could I just—unless you want to——

Senator SMITH. Well, I do have a question which stands in stark contrast to what I just said. That is a concern that I have, and I have to ask it because we are stuck with these budget rules. You are stuck with these budget rules. But, as I have noted before in hearings like this, you have been one of my champions when it comes to mental health and when it comes to youth suicide prevention. The Congress, last year, plussed up the Garrett Lee Smith Memorial Act to $40 million. To be at a current service level, we are going to have to be at $48 million this year.

There are about 4,400 kids a year in America who take their own lives. It is an epidemic. It is a problem. I actually think that government, with the kinds of programs we have going throughout the country—I get letters every week from some parent whose child's life was saved through the intervention of those funds, those programs that now exist on college campuses, in States, and on Indian tribe reservations. I just think we need to do that. I mean, I just think that we have to live up to this very crying problem in our country. Your budget says the number is 27, not 40, not the 48 that it needs to be, because you are stuck with the budget rules, because we are watching a train wreck in slow motion here.

So obviously you are going to see me fight for full funding, and I hope the President will support it. Sometime, Congress is going to have to face up to whether we are going to have a command-and-control medical system or whether we are going to go to a market incentive system, somewhat like Medicare Part D—not perfect, but as you noted, it is very successful, as noted by all the senior polls that I have seen on that issue. But if you can respond.

Secretary LEAVITT. I can respond in two parts. First, with respect to mental health, since I last appeared before this committee, I was assigned by the President to go to 13 communities where they had tragedies that were rooted, in most cases, in mental health. This was triggered by the tragedy at Virginia Tech.

I became more and more aware, as I traveled, that we have gone through, in the last 25 or 35 years, a substantial change in the way we treat mental illness. We have gone from institutionalizing to more treatment in community settings. We very successfully deinstitutionalized. We have not done an adequate job yet of being able to build alternative resources, and hence I see that as a priority.

With respect to your first point, may I just say I see very little about health care in this country that you could call a system. We have a large, robust, rapidly growing health care sector, but none of the things that make an economic sector into a system are present. We have to change that or we will never solve this dilemma in Medicare, and we will not solve the dilemma that employers and the public in this country face over the next decade. There is a reason. There is a reason that we spend twice as much as any other industrial competitor of ours without substantially greater measures of success. It is because our system is saturated with inefficiencies that only the invisible hand of a well-organized market can find. We will not find that in a budget where we are using price fixing.

Senator SMITH. Mr. Secretary, my time is up. I just want to note for you the 1–800 Medicare Part D call system. You need more money in there if you are going to keep that system with the service levels that it needs to preserve a program that is successful, good, and getting better, as the call times take too long. I have talked to Kerry Weems about this and made suggestions, but it is not reflected in the budget.

Thank you.

The CHAIRMAN. Thank you. Adam Smith's "invisible hand" is basically referring to, everybody is out for himself to get the most he or she can get. That is what I am saying, it is partly consumers, but it is also providers. Today, providers, understandably, are trying to get what they can get. So when we talk about the "invisible hand" of Adam Smith, we have to be careful in remembering, we all are Americans. We are all together here. The main goal here is to get the best health care possible for the least cost. That is the real goal here. I know we agree on that and we do not have time, because other Senators need time to speak here. But competition is important, but the real goal is better health care for all Americans at the lowest possible cost. That is the real goal here.

Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. I want to ask a couple of questions, one regarding Medicaid and a rule that is upcoming in March that is having a significant impact on my State of Maine, and I think across the country, on targeted case management.

In the Deficit Reduction Act, it was scheduled to achieve $760 million in savings, and now it is up to $1.2 billion. It is going to affect a very vulnerable segment of our population, particularly in the foster care arena. It is inconsistent with the statutory requirements in the Deficit Reduction Act in terms of limiting the number of days that would be available for targeted case management and services that would be provided to a very vulnerable population that has complex physical and emotional problems, transitioning to the community, because they cannot get those services until they are in the community, and limiting the number of days in which they can receive them.

So in all combination, this is going to have a draconian impact on States that are serving these populations. I am sort of surprised that the rule went this far, and the timing of it. I would hope that we would have a moratorium. Senator Coleman has introduced legislation for a moratorium until April of 2009. I know the National Governors Association has written to the Director of CMS on this issue, that it is very inconsistent and really contrary to the money following the person initiative so that we can help these individuals to transition into the community.

Secretary LEAVITT. Senator, could I explain the problem I have as the person trying to administer this? As you know, I served as Governor, and I know that States look at these programs and say we need to optimize the value we get from Medicaid and we need to find as many ways as we possibly can to attract a Medicaid match.

Well, what I found is that there are many States that do things like buying school buses with Medicaid money. I see them creating recreation programs. I see them doing foster care. I see them doing all kinds of things that are not medical services. They try to wrap Medicaid around it so that we will match their dollars.

Medicaid has a very specific and important role that is not buying school buses, or building buildings, or creating other programs. We are just trying to find a way to bring that into a sense of good management. We are not doing it to be unkind, we are not doing it to be anything other than fostering the program as it was intended.

Senator SNOWE. Well, I think the essence of the National Governors Association's letter to the Director of CMS certainly indicated working out the issues, whether it is making sure it is consistent with the law, and those where the rule is inconsistent. Obviously you have gone far beyond; when the original projected savings was $750 million, now it is up to $1.2 billion. This is going to have a severe impact on some of the most needy.

You mentioned foster care. Absolutely. In our State, for example, for young people who have a lot of physical and emotional problems, these are the vulnerable out of our population, and they need to have these services. If you pull the rug out from underneath them, they cannot make that transition and cannot get the care that they need and the services they deserve. So I hope we can

work this out because it is going to have an impact. And discerning where there are some egregious problems, absolutely, we should address them.

Secretary LEAVITT. That is the cooperation I would like to seek from you. The reality is, there are abuses and cheating the system.

Senator SNOWE. Well, then can we work on it? Because this rule is scheduled to go into effect, I think it is, March 3. So, I think the timing of it makes it very difficult. I hope in some way we can work that out and go from there, because that is the problem with the deadline that is looming.

Secretary LEAVITT. The estimate you indicated of the savings was larger than projected. It is very possible there was more of this than we thought. That is the problem we have had, because there is a lot of money going out the door to things other than health care, and we just need to isolate it to health care.

Senator SNOWE. On the second part, on Medicare, I think we all understand that we have some challenges—significant challenges—for the present and for the long term. My concern is, you mentioned that it is a reduction in the rate of growth. But ultimately, it represents a broad-based cut because you have an increase in the number of people being served by the program, increased costs in the delivery of health care services.

I mean, the cut in Medicare, the $182 billion, is going to represent a 15-percent cut for physician payments. You are cutting long-term care, hospice, home health care, hospitals, across the board. Yet there are no savings, essentially speaking, from the Medicare Advantage subsidies, of which, over the next 5 years, are scheduled to be $50 billion. Now, the chairman of MedPAC, the Medicare Payment Advisory Commission, said in fact 50 cents of every one of those dollars goes to the beneficiary. All the rest goes for administration, overhead, and profit.

So why are we not making it far more equitable in drawing from those subsidies that go into the Medicare Advantage program? I mean, the Director of CBO, Peter Orszag, said to us recently, it is very difficult to get any information from CMS regarding the performance of Medicare Advantage programs. Why are we not demanding the same level of standards?

When you are talking about a program that is receiving $50 billion in subsidies, 12 percent above the traditional fee-for-service—if all the beneficiaries moved over to the subsidy in the Medicare Advantage program, it would cost us $250 billion more, given the level of subsidies and the costs. He said there is a paucity of data from CMS to measure this program, Medicare Advantage. I think we deserve more than that.

Also, they should be included in the cuts. Why are we providing such significant subsidies when we are now asking for tax increases, cutting benefits, and borrowing for the future, and the next generation having to pay for it?

Secretary LEAVITT. Senator, I just want to acknowledge that 80 percent of whatever difference goes to beneficiaries, which is an important point. But the fact that there is still a difference is what you are addressing, and I would like to comment on that. I believe Medicare Advantage is doing a very good thing. Beneficiaries like it. It is beginning to create opportunity for people to have service

who otherwise would not have had it. It has been particularly popular among low-income and minority populations. People who are on Medicare Advantage are having less trouble getting a physician, et cetera, et cetera.

But we do need, over time, to bring this into a place where the initial incentives we provided to make certain it was nationwide are rationalized. Now, the better way to do that is for us to begin to look at the way the competition takes place. I am troubled by the fact that I am required to conduct competitions on a county-by-county basis.

If I could spread that into a larger competitive atmosphere like we do Part D, we would see the same kinds of downward pressure, and I think they would not only come down to the level of the other fee-for-service plans, I believe they would go below. But we have not set off that competitive pressure because we have been required to do this in such a narrow way. We have to have the capacity to let this work, and it will.

Senator SNOWE. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator SNOWE. Thank you, Mr. Secretary.

The CHAIRMAN. Thank you.

Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman.

It is always good to see you, Mr. Secretary. I first want to say that I know in today's *Hill* magazine that you have a column linking e-prescribing and doctor reimbursements, and certainly Senator Kerry and I, and others—Senator Snowe has worked on this issue extensively—have been working very hard and with the chairman's support, the ranking member's support, moving in the direction of e-prescribing. I would just note that you do nothing in this budget to stop the doctors' payment cut, which is totally contrary to our ability to be able to get e-prescribing.

So I am actually, in the interest of time, not going to ask for a response for that. But the reality is, we have been talking about health information technology for as long as I have had the opportunity to hear you at budget meetings and finance meetings. It is time to get this done.

On the broader note, while I have enjoyed very much working with you personally, I have to say today I am stunned at our general conversation about Medicare. Again, this is not a question. I have questions, but I have to say for the record that Medicare is the only part of universal health insurance we have in this country if you are 65 or older, if you are disabled. Some, close to 45 million people, get health insurance. It has worked well for over 40 years.

The characterization which—I appreciate the buzz words. This goes to a general philosophical debate that frankly will carry on into the next year and the next administration about government-controlled price-fixing, all of these great buzz words meant to scare people. I have to say, as other colleagues have, I do not have anybody telling me that they wish we would do away with Medicare or break it up more and privatize it more.

Yes, there have been some positives from Medicare Advantage, but the reality is that what we have seen is a constant effort to unravel the universal nature of Medicare and that has, in fact, in-

creased costs through privatization. The head of the Congressional Budget Office said, even if we capped Medicare Advantage payments at 150 percent of the regular payment, we would save money. It is extraordinary. It is extraordinary, what is happening.

I would argue that the way we designed the Medicare prescription drug plan, without Medicare itself, the administration being able to negotiate the best price, just adds to it. So just for the record, I would suggest that the efforts over the last number of years in this administration have added to the cost and have undermined our ability, in fact, to provide health care to the 45 million people who happen to think Medicare is a pretty good system, not that it does not need some improvements. But I think there is a large philosophical issue that a former speaker talked about, not being able to get rid of Medicare directly so we will let it wither on the vine. There have been great efforts to try to have it wither.

Mr. Chairman, count me in the camp that says we want to stop this from happening, because I could not disagree more with the notion of Medicare as a universal system that has worked well. We could spend all of our time having a philosophical debate, and I am not going to do that at the moment. But that is for the record.

When we talk about CHIP, it is true, I certainly concede that the administration has included $19 billion more over 5 years. But our bipartisan proposal needed at least $15 billion over 5 years just to keep the status quo, so you have put $19 billion in. Our $15 billion was to cover status quo without cost increases or inflationary increases.

Then on the other hand, you have proposed $17 billion over 5 years in Medicaid cuts that go to the same people, the same kinds of people, the same structure, so that on the one hand children who are the poorest of the poor, poor families, $17 billion in cuts, and basically just enough to keep even. Maybe a little bit more, but pretty much just enough to keep even on Children's Health Insurance. Could you speak to that?

Secretary LEAVITT. Yes, I can. Senator, I am a little bit stuck on the previous conversation. There are a couple of things I would like to make certain we understand. First, I think Medicare is a commitment our country has made, and I want to make sure you understand I have no interest in seeing it "wither." I see Medicare being about healthier and better lives for seniors. I am deeply concerned about what the impact is of this system we currently have, because we are going to go broke in 11 years. We have trillions of dollars of unfunded liabilities, and there is nothing sustainable about a system in the future where that occurs.

I think we would have to ask ourselves, will a Senate, a House, a Congress ever deal with this so long as the system is as it is and we have to go through and figure out surgically what the reductions will be? I do not think that there is much optimism that they will, but if we can create a system where it can happen, then it becomes sustainable.

Senator STABENOW. Mr. Secretary, with all due respect, the policy decisions that have been made under this administration have, in large part, made it worse by adding to the cost, adding to administrative costs. Medicare itself has a 2- to 3-percent administrative cost. And what are we trading that for? Twelve to 15 percent by

this constant, unrelenting effort to do what I know in your view—and I respect that—is more choice.

I mean, my folks are asking for more doctors, not more insurance plans. They are asking that they be able to get their medicine, get their doctor, and be able to get home health care and so on. So we, with all due respect, have a very different view of health care and Medicare, and frankly how the majority of Americans view this universal health care system called Medicare.

Secretary LEAVITT. But it is——

The CHAIRMAN. Senator Lincoln? Thank you very much.

Senator STABENOW. Thank you.

The CHAIRMAN. Senator Lincoln?

Senator LINCOLN. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. We are glad you are here.

I would like to follow up on a couple of things—I know the chairman brought it up, and so did Senator Snowe—on Medicare Advantage. The Medicare Advantage program obviously was designed by us here to provide private plan options for beneficiaries, but it was based on the assumption that private market competition would result in plans being able to provide good-quality coverage and extra benefits, while costing the government less than what traditional Medicare did, or at least 95 percent of the regular Medicare fee-for-service program.

You have devoted an awful lot of time here, I think, talking about government price controls and concerns about that. But I only think that is a good argument if it is a completely private program. It is not. I mean, it is subsidized tremendously by taxpayers, certainly not counting beneficiaries, co-pays, and all of that. But more than regular Medicare, anyway, is subsidized, a tremendous amount. In some places, I do not know, it is much as 13 to 20 percent or greater.

I know in my State—you said that there were a lot of people who really liked Medicare Advantage. I am going to invite you to come to my State office and answer those phones, where we have people who are being coaxed into the program, not getting providers. Their provider is not in the system and then they are left without care.

So I know we all have a lot of work to do here, but it is just hard for me to believe that you are going to talk about cost containment, you are going to talk about cutting costs and putting it back on track, but you are going to continue to insist on subsidizing these plans, and a tremendous amount.

Secretary LEAVITT. Senator, the plans cannot be subsidized indefinitely. The subsidy was established so that a nationwide system could be developed. I have indicated earlier today that I believe there need to be improvements in the way we make that competitive so we get the benefit design.

Senator LINCOLN. And you are not making recommendations on that. You are just saying you think we need those changes?

Secretary LEAVITT. I am saying that we need to make those changes. I see no——

Senator LINCOLN. But you are not suggesting what those changes are?

Secretary LEAVITT. I am not today, but I certainly have a lot of ideas about it, and I will be putting them forward at some point.

May I also say that there is no reason why Medicare could not provide to beneficiaries information about the quality of the care they are getting, about the cost of the care that they are getting. There is no reason we could not provide them with incentives that would allow them choices and information about how they can get better quality at lower cost. If we did, Medicare would win. If we did, beneficiaries would win. We would be able to pay providers on the basis of value, not volume.

Senator LINCOLN. But you are talking about transparency and assistance in terms of decision making, and yet Senator Smith brought out the issue of not adequately funding the call lines. I mean, when we made the transition, I have to say, I got in there in the trenches with your bunch because I had a tremendous amount of dual eligibles who were just left high and dry. So that is going to cost money too in terms of what you are talking about, because you are not dealing with people who are savvy about health care issues and the technical parts of health care, not just delivery, but the essence of health care.

So saying that that is going to be the magic wand that we wave and it is going to provide these Medicare Advantage plans the ability to cut their costs down 20 percent, which is what we are subsidizing, most of them in my area, I just think it is—I do not know. It seems a little bit unrealistic in terms of thinking there is this magic bullet.

But nonetheless, I am certainly willing to look at ways that those things can happen. I do agree that information is an important tool for everybody, but I hope that we will be realistic about whom we are dealing with, what kind of information, and what it is going to cost to get that information and to educate those people, particularly in terms of States like ours where we have a tremendous amount of dual eligibles and low-income seniors. That is growing because people are living longer, technology is getting more sophisticated. I just think we are going to have a lot more on our plate to deal with there than you are leading most people to believe.

But the other thing I wanted to make sure of in terms of clarifying—you talk about growth, that you are trying to limit or put a reduction on growth. You are trying to say that it is not a cut. But in many instances you have eliminated programs to do that, so you are just looking at the bigger picture as opposed to looking at what is happening.

I mean, I referenced your elimination of the Area Health Education Centers, the AHEC program. They have been tremendous in States like ours, tremendously helpful in training medical professionals who are not going into these rural areas where we need people to provide services and to have providers.

I would just say, I think you need to look at places or facilities like that that provide a tremendous service, and others that you are eliminating. The cuts in rural ambulance providers—those people are providing a service in a rural area and they are meeting the same standards with one ambulance covering three counties, compared to what you have ambulances doing in major metropolitan areas on 20 or 25 reimbursements in 1 day compared to somebody who is providing the same services for 3 reimbursements in 1 day.

Senator GRASSLEY. Can you give a short answer? Both I and Senator Wyden have a couple of questions apiece, and I know you have to go at noon.

Secretary LEAVITT. Yes. Senator, I would just say, with respect to Medicare Advantage, one nice thing about the Part D program that you reference is that, if people in your district and your State are unhappy, they do have a different place they can go. One thing about Medicare Advantage is that, if people are unhappy with traditional Medicare, they can at least choose that. We like to have that as an option because it gives people who are being poorly served an alternative.

Senator LINCOLN. But when they are given false information and they take that choice, then it takes us 6 to 8 months to get them back into Medicare fee-for-service.

Secretary LEAVITT. Well, if that is the case, we have a problem and we have to——

Senator LINCOLN. We do have a problem.

Secretary LEAVITT. But it does not mean that we should eliminate choice because one person had a bad experience, or two or three.

Senator GRASSLEY. Mr. Secretary, I just have two questions, and then whatever time Senator Wyden wants.

Senator LINCOLN. I would like to ask another question.

Senator GRASSLEY. I am sorry, I thought we were done. Yes.

Senator Wyden, if it runs past 12 o'clock, I am going to have to go. Will you finish up then?

Senator WYDEN. Yes.

Senator GRASSLEY. Since the Deficit Reduction Act, the administration has issued some regulations that have stirred up controversy. It seems to me there are bills out there to put moratoriums on just about every Medicaid regulation that CMS has issued. I have been willing to give you the benefit of the doubt and have generally opposed moratoriums on CMS regulations; however, recently the judicial branch has gotten involved in the reading of CMS regulations.

Then we had a court case, a Federal court case, striking down the Average Manufactured Price regulation, saying CMS "violated the APA and acted contrary to law and/or acted arbitrarily and capriciously in creating its Average Manufactured Price rule." It is a pretty serious charge, Mr. Secretary. We can only get so specific when we write laws. We have to depend upon people like you in the executive branch to fill in the details consistent with our intent.

Clearly, one court thinks that CMS has failed miserably on AMP. Should we be concerned that the court may think similarly about some of the other controversial rules, and can you tell me what you are doing to ensure that CMS regulations are consistent with statute and intent of Congress?

Secretary LEAVITT. Senator, most of the rules we have talked about today have been in the area of targeted case management, as a good example. I just want to assure you and other members that our purpose is eliminating only things that are not medical services, and we are doing our best to be protectors of the integrity of the program. There will always be disagreement, and that is

why we have courts. There will always be a need for people to interpret, and that is why we have a regulatory process.

I can assure you that no regulation goes out of our Department that is not reviewed in detail by our general counsel from whom we have a firm and strong opinion that we are acting within the law. I recognize that there will be times when there are disagreements, but there are processes to resolve those.

Senator GRASSLEY. Yes. Well, it is quite obvious you are going to have to follow the court's opinion as you go back through this on this specific rule, at least, right?

Secretary LEAVITT. Indeed, we will. We will follow the law.

Senator GRASSLEY. Yes.

In that case, I would suggest the law, as modified by the court decision, or at least the way they have interpreted it, you did not follow the law. Right?

Secretary LEAVITT. I am not sure.

Senator GRASSLEY. I am not a lawyer, so maybe I should not try to finesse things.

Secretary LEAVITT. I will follow the law. Write that down.

Senator GRASSLEY. All right.

This is another question. To be eligible for Medicaid, a person has to be a citizen or qualified agency. The DRA included a provision that would cause States to more thoroughly document the citizenship of Medicaid recipients and applicants. This provision was developed in response to the July, 2005 Inspector General's report that showed States were not doing a very good job of documenting the citizenship of Medicaid applicants.

In the Tax Relief and Health Care Act that we passed in December of 2006, we included provisions to improve upon what we passed in DRA. Specifically, the change gives States flexibility so that a person who had established citizenship for one Federal program would not have to do so again in Medicaid. In 2007, we saw Medicaid enrollments fall for the first time in nearly a decade. Some experts blame the decline in Medicaid enrollment on citizenship documentation rules, keeping American citizens off the rolls. Do you think that documentation enforcement in Medicaid is working properly or are there areas that can be improved?

Secretary LEAVITT. I feel confident there are ways we can improve. One thing we have had a problem with, however, is, in cases where States have delegated Medicaid eligibility to other programs, we have found that there have been abuses. We are interested in being able to maintain some level of control on that judgment. It is a very expensive thing when States do it in a way that causes enrollments to go outside the parameters of the law.

Senator GRASSLEY. Thank you very much.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman. Thank you again for your kind comments on our efforts to be able to work this session in a bipartisan fashion.

I have one other area I want to explore with the Secretary, and I think Senator Grassley and Senator Lincoln, all of us who want to work in a bipartisan way, may have some opportunities this session, and I want to explore that with you.

Mr. Secretary, as we all know, the physician payment update issue is upon us again. Of course, hearing the debate about what is known as the Medicare 45-percent trigger is going to be discussed as well. Some will of course say it is gimmick, but both of these are opportunities, it seems to me, for Democrats and Republicans to work together in a thoughtful kind of fashion to try to find some common ground on key issues like buying quality and comparative effectiveness, where Dr. Orszag has spoken, and in other areas.

Tell me what you think the possibilities might be this session, in the remaining 10 months, for a bipartisan group of us to look at some of these areas where we can make sensible policy, find savings, for example, and do it in a way that does not hurt people, that makes sense.

I wonder if you have some thoughts on those two areas, physician payment update and the 45-percent Medicare trigger, areas where we can make sensible reforms and start in motion what Senator Bennett and I, Senator Grassley, our group wants to do for the long term.

Secretary LEAVITT. Senator, I would like to acknowledge those two potential vehicles, and I would like to concentrate my response on what I think the potential policy changes that we could agree on might be.

I would focus on two areas. The first is in areas that would advance access. There is a great debate right now about how best to make certain that every American has health insurance that is affordable to them. Some would have a system that is more controlled by the government, others would have a different system that would be more private.

The areas of agreement between them, I think, are two. One, it would not matter which of those systems you have. Unless we are able to inject some level of market force or sensitivity to consumers into that system, neither will be sustainable in the long run. So the idea of electronic medical records, I think there is a substantial amount of agreement in that area. Quality measures. How do we create quality measures, how do we create cost comparisons, how do we use incentives to let everyone have a reason and a motivation to increase quality and decrease cost? I would say that is one.

The second area I would suggest is the whole area of the tax code. Your proposal has used tools eliminating the discrimination between those who purchase through their employer and those who purchase on their own. The President has made proposals in that way. I think working on ways to give fairness to the tax code and ways to bring value judgment and comparisons to health care are the two areas we could make progress on this year.

Senator WYDEN. I would encourage you to look for ways, and to the extent that Democrats and Republicans on this committee could be involved in this, we could help shape the debate in the U.S. Senate, both for the short term and for the long term, and there are two vehicles that we have coming up in the next few months for trying to drive the message, for example, about buying quality and comparative effectiveness. I hope that you will give us your thoughts quickly about how to use those two vehicles.

One last question I had dealt with something that we are working on for the purposes of the Healthy Americans Act, again, more generally. That is that providers still in this country are incredibly frustrated about how complicated the billing process is, that we still do not have what was pledged to them it seems like eons ago, a uniform billing system. Of course, that was also pledged in the HIPAA bill, the Health Insurance Portability and Accountability Act.

What progress is being made now, again for purposes of this year, to get simplification in medical billing for the extraordinary number of providers around this country who gnash their teeth about how it works today?

Secretary LEAVITT. Senator, I wish I could tell you there is a lot of progress on that. It is a very obvious problem. Anyone who has been to the doctor sees it. It is a reflection of the fact that we do not have a system. I think what we have is a sector that needs to be systemized. That would go a long way just to bringing consumers into a sense of involvement; if they understood their bill, that would be a great start.

Senator WYDEN. I know Senator Lincoln has a question.

Senator LINCOLN. I do. Just a couple more.

Thank you, Mr. Secretary. Just two or three more questions, if I may. In May of 2007, the GAO produced a report that determined that Medicare reimbursements for ambulance service providers, on average, were 6 percent below their cost of providing those services, and 17 percent for providers in super-rural areas. Again, I know for us, in a State like Arkansas, that is tremendously rural, it is virtually impossible for them to stay in business. We had a hospital administrator the other day testifying about losing several of their ambulance operators in rural Mississippi.

I guess my question is, what is your reason for the cut that you have in this budget? You are going to reduce payments roughly by $60 million in 2009, and nearly $1.3 billion over 5 years when you reduce the ambulance fee schedule. My concern is that you are going to have sick people in rural America and they are just not going to be able to get to health care providers.

Secretary LEAVITT. Senator, I think I would be better off responding on that specific line item in a letter or some other way to you.

Senator LINCOLN. However you would like to respond. I just need to know why you did it.

Secretary LEAVITT. It is a level of granularity that I am not able to respond to now.

Senator LINCOLN. Sure. I appreciate that.

The other is the Geriatric Health Professions program. We have had a lot of discussion here today about our growing elderly population. We know out of all of the medical schools in this country, every one of them has a good department of pediatrics, but only about six or seven have departments of geriatrics. If we do not maintain some of our efforts in training both the geriatricians that need to be out there, but also the other health care professionals in particular geriatric needs—the program supports the geriatric training at levels through our GEC centers, the Geriatric Education Centers, fellowship programs, small grants.

The programs are certainly critical, because we have such a high percentage of seniors who need that quality care. When you poll those individuals or they are interviewed, they say that the programs that they go through in these facilities are enormously helpful in their ability to better provide quality care, and certainly cost-effective care, to the aging population.

So I guess I am concerned that the administration eliminates the Federal funding for this year after year. If we just put them out of business, there is no longer going to be the kind of training programs that are training not only academic geriatricians, geriatricians, and physicians, but also providing the additional geriatric training for nurses, and a whole host of other things.

I guess my question is to you, with the growing population that we have in the aging sector, what is the justification for just eliminating the program year after year?

Secretary LEAVITT. We went through all of the programs and tried to make an evaluation of those that, first of all, were providing services and not necessarily infrastructure. The budget was intended to balance the budget by 2012. This is a decision we made based on the fact that we want to provide services as a priority to infrastructure. In many cases, these are about providing basic infrastructure.

Senator LINCOLN. But you cannot provide the services if they are not trained.

Secretary LEAVITT. I am quite concerned generally about the way we are conducting training for medical workers, and particularly for professionals. The demands in the future are going to be so high that, if we were to fill up all of the nursing schools, for example, and even expand them, we still would not be meeting what our needs are in the future.

There are some systemic changes that time will not allow us to talk about today, but that I believe can, in fact, begin to help us meet that demand, ideas such as beginning to measure competency as opposed to measuring the time people spend in their seat being trained. We can use existing facilities for workers, et cetera. So that is not exactly on point to your question, but I did want to be on the record as saying I am deeply concerned about our incapacity to meet the demands using the current system.

Senator LINCOLN. Well, that sounds good, I suppose, but it does not help us solve the problem. I would say, if your concern is about where we are spending time or money in these programs and whether or not we are getting the biggest bang for the buck, that maybe perhaps we need to look or revisit some of the metrics by which we are measuring these programs. I mean, our program in Arkansas received 100 percent, a perfect score.

So, there is a good way to do this, and it is very necessary. As you said, we are not only not training those who are going to practice. We are not training the ones who are going to train or teach the future practitioners. We do not have the academics, whether it is in our nursing schools or whether it is in our geriatric centers, or our medical schools, or anywhere else that are training health care providers.

My husband is a physician. He spent 12 years training. It is not something that, all of a sudden when we hit that brick wall, we are

going to be able to remedy it quickly, because we are not going to have the people in the pipeline. So, I would just encourage you to look, if we need to change the metrics and how we evaluate these, but we need to do something. I wholeheartedly agree. I am always working in a bipartisan way.

As I said, I got in the trenches with your bunch after the prescription drug piece. But we should think about that before we institute the law, before we put together the packages and create the cuts, because trying to do it after the fact is enormously devastating to the lives of some people who are really the fabric of our country. So, I hope you will not wait until we get there to meet those serious concerns.

Senator Hatch is here, and I know he had some questions.

Senator HATCH. Well, thank you so much, Madam Chairman.

I apologize. I was on the floor. But I was here a little earlier. I just want to personally express my appreciation for you. We have been friends for a long time. But your approach towards bringing consumers into the health care field is really the answer. Everybody, I think, with brains knows that. But it is so hard politically to get people to really do some of these things, because some want government to do everything. That, to me, is the absolute worst way of doing things.

But I wanted to tell you, you are not failing to gain some support up here, in a bipartisan way, to get consumers involved. Also, your work on health IT has been nothing short of spectacular. One of the highest priorities of this administration is to get greater value from our health care system, and you have articulated that as well as anybody, through disclosure of price, quality, and health information technology. As you know, I introduced the Wired for Health Care Act with Senators Kennedy, Enzi, and Clinton. Our bill encourages the development of interoperability for health information technology. I know you have been a leader in this field as well.

I just want to get your opinion on uniform standards for the secure transmission of health information. Do you believe that this should be spearheaded by the Department of Health and Human Services or should it be spearheaded by Congress, or should both the administration and Congress work together to develop these standards? If so, how can we accomplish this important goal? Give us your advice on how you think we can ultimately get this done.

Secretary LEAVITT. Senator, you have used the word "standards," which is in my mind the cornerstone of being able to measure and gather information about value through electronic medical records. I am very happy to report a lot of progress on standards-making over the last 3 years.

There are only three ways to arrive at standards. The first is, you can have government step up and just set the standard. It has been my experience that when that occurs, we do not always get it right. The second way is with what I call the last vendor standing, which is, you just let people compete until they try to eliminate one another. That will not happen. That will not work in health IT, for example, because there are just too many ways to get to the same place in a rational fashion.

The third way is through old-fashioned collaboration, where we bring all the players together and say, we are going to establish a

standard, we would like to ask you to help us do that. We have employed that the last 2½ years now in what we call the American Health Information Community. It is a place where we are able to arrive at standards and have them recommended to the Secretary of Health and Human Services for implementation across the Federal Government.

I am pleased to tell you, Senator, that we now not only have standards developing, but we also have an accreditation process where those systems that are produced by developers who employ them receive a certification that gives a physician confidence that they are buying a system that will meet the standards.

We now have 75 percent of the systems that are being sold in this country certified as being on a pathway to interoperability. That is a huge step forward, and we need to build on it, working together. But it is through this collaborative process that these standards need to be set. It is a mistake, in my judgment, for government to be the absolute standard-setter. We need to be a facilitator, an organizer, and a major player because we are a big payor of health care.

Senator HATCH. Well, I think you deserve a lot of credit for the work that you have done in that area.

I do not mean to keep you. I know you have been here a long time. But let me just ask this question. When reviewing the HHS fiscal year 2009 budget, I do have to admit that I was deeply concerned with the magnitude of the Medicare provider cuts and that market basket freezes make up 63 percent of the Medicare savings. I think that is correct, is it not?

Secretary LEAVITT. It is 56 percent. No, you are right on the savings.

Senator HATCH. Sixty-three percent.

Secretary LEAVITT. Yes.

Senator HATCH. Could you explain to me why market basket freezes are the primary area of savings for the Medicare program? And I would like to know the thinking behind that particular policy.

Secretary LEAVITT. Let me just mention to you that we had a discussion about this earlier, where I indicated that there is some frustration with a scoring system where we are not able to look at some of the things we have talked about getting consumers involved on, as to how that would be helpful in being able to drive these costs down. So we have ended up using this sort of price-fixing model that is currently part of Medicare to create a budget that would begin to move us toward sustainability.

We desired not to have an impact on beneficiaries, and so we looked hard at the providers and concluded that there was room within the operation of those providers to accommodate those reductions in growth. Again, it needs to be stated, we will continue to grow Medicare, it will continue to grow at 5 percent a year, but we believed there was some margin that we could capture.

Senator HATCH. Let me ask just one more question. I am deeply concerned about the impact that the Graduate Medical Education portion of this Medicaid rule on Inter-Governmental Transfers, the IGT, will have on universities. Let me just bring it home. At the University of Utah, it is no secret that the university would stand

to lose millions of dollars if this rule goes into effect at the end of May.

I just cannot allow that to happen because they have worked very hard to try to get where they—and I think they do a very efficient job. But I would like to have the opportunity to continue the dialogue with you and the university, and other universities as well—I think I can speak for others as well—to help us to come up with some sort of solution that really would work. There are very good parts of this rule, but the GME portion, in my opinion, was unworkable. I hope that you will work with us, because it has caused such angst, that it is unbelievable.

Secretary LEAVITT. Well, particularly the academic medical centers find themselves in a place where they have come to rely on this money. It has become basically a foundation piece from the Federal Government that is not part of the economics of their hospital generally. There are parts of that that are——

Senator HATCH. They would love that.

Secretary LEAVITT. My guess is, they would not disagree with the fact that it has become an integral part of their funding.

Senator HATCH. Yes, I think they would agree.

Secretary LEAVITT. However, there are parts of this that are duplicates where we are paying twice, frankly. That is what we are trying to avoid.

Senator HATCH. I do not disagree.

Secretary LEAVITT. So let me just finish by saying this. Graduate medical education is a vital part of the system, but the system we have right now lacks logic, in my judgment. Some big-picture thought ought to be given here. It is illogical, in my mind, for graduate medical education to be funded almost entirely by Medicare and Medicaid. We ought to have a more broad-based approach to that. There are many hospitals in this country and many medical-providing communities that benefit from graduate medical education that do not share in any of the cost. So this is not a matter that will be easily remedied, but it is a big-picture strategic issue that ought to be thought about.

Senator HATCH. I have heard the same worry from the administrator of Primary Children's Hospital in Salt Lake, Joe Mott, about the President's budget and its proposal to eliminate GME payments to children's hospitals. Of course, I have been a great supporter of providing GME payments to children's hospitals and was interested in the thinking that went behind developing the policy.

So all I can ask is that you would work with us to see if we can find some solutions that make sense both ways. In other words, I think what you are trying to do is noble and considerate of taxpayers, and yet we have a system here that has worked in some areas and maybe not as well in others, I do not know.

But I just want to personally tell you that I have been here 31 years and I have seen a lot of Secretaries of Health and Human Services, and I do not know one—and there have been some great ones—who has mastered that impossible-to-master task of running that outfit as well as you have. I just want to compliment you for it. I think you have done it in a bipartisan way.

You have had to carry administration positions, no question about that, and sometimes that irritates people up here on both

sides. But that is part of your job. But as far as working with people, holding out your hand to grasp theirs and trying to find solutions that we can mutually work on, I have never seen a better one.

So I just want to personally pay that tribute to you. I know it is a very, very tough job. It is very demanding. You are traveling all over the country all the time, trying to help people in every way. You worry as much about these things as we do—in fact, I think more.

I just want to personally express my high regard for you, and hope the people up here will work with you on some of these things that you really know, and we all know, need to be done. So, thanks so much.

I have been informed that I can shut this down and let you go, and I will bet that will be one of the happiest days of your life. [Laughter.] All right.

So with that, we will recess until further notice.

[Whereupon, at 12:14 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

SUBMITTED BY SENATOR GRASSLEY

February 4, 2008

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

The Honorable Jim Nussle
Director
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Dear Mr. Secretary and Director Nussle:

The United States Senate Finance Committee (Committee) has jurisdiction over the Medicare, Medicaid and SCHIP programs and is responsible for overseeing the proper administration of these programs. Last year, the committee considered legislation to reauthorize the State Children's Health Insurance Program (SCHIP). That legislation passed the full Senate on August 2, 2007 by a vote of 68 to 31. Members from the House and Senate met and produced a compromise SCHIP reauthorization bill, which was passed twice by Congress and vetoed twice by the President.

In the Administration's FY 2009 budget released today, the Administration's current proposal for extending SCHIP is a net of $19.7 billion over five years. Last year, the President's budget requested a net of $4.2 billion over five years for SCHIP reauthorization. The Congressional Budget Office (CBO) estimated that the President's budget request would result in net spending of $2.4 billion over six years (2007-2012).

The surprising 400% plus difference between the Administration's budget request from last year to reauthorize SCHIP and this year's budget request raises a number of questions. Numerous Members of Congress who relied on the Administration's assertions last year that SCHIP required only $3-5 billion will be understandably perplexed at the revelation that, as evidenced by this year's budget, SCHIP seemingly requires considerably more than projected by the Administration just months ago.

In order to better understand this unexpected turn of events, I request the following information:

(1) What were the assumptions that the FY 2008 budget request was based upon?

(2) What are the assumptions that the FY 2009 budget request is based upon?

(3) When did the Department of Health and Human Services first project that the cost of reauthorizing SCHIP would be substantially higher than what was proposed in the President's FY 2008 budget?

(4) When did the Office of Management and Budget first learn of a potentially higher cost for reauthorizing SCHIP?

(5) Knowing that months of work goes into the preparation of the President's budget, at what point in time did the Administration first become aware that the funding required for SCHIP reauthorization would likely need to be revised substantially upward in the FY 2009 budget?

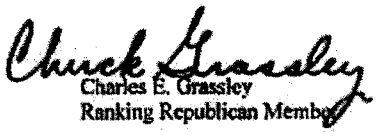
(6) What actions, if any, did the Department, the Office of Management and Budget or anyone in the Administration take to inform Congress that a substantially higher cost for SCHIP reauthorization had been determined and to share this revised cost estimate with Congress?

In addition to answering to these questions, the Department and the Office of Management and Budget is requested to provide copies of all analyses and estimates of the cost of SCHIP reauthorization prepared last year, particularly the analyses and estimates that led to the request in this year's budget.

In light of the approaching hearings this week on the President's budget, it is important for the Department and the Office of Management and Budget to respond promptly to this request for information. Accordingly, please provide a response no later that Tuesday, February 5, 2008.

I look forward to receiving this information.

Sincerely,



Charles E. Grassley
Ranking Republican Member

CC: Senator Max Baucus, Chairman, Senate Finance Committee

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

February 6, 2008

Via Electronic Transmission

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

The Honorable Andrew C. von Eschenbach M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Leavitt and Commissioner von Eschenbach:

As a senior member of the United States Senate and as Ranking Member of the Committee on Finance (Committee), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities at the Food and Drug Administration (FDA/Agency), a part of the Department of Health and Human Services (HHS). Previously, I wrote to Dr. von Eshenbach and his predecessor, Dr. Lester Crawford, regarding troubling allegations that a pharmaceutical company attempted to discredit the findings of Dr. Victoria Hampshire, an Agency employee and commissioned officer in the Public Health Service (PHS).

This Letter is based upon a comprehensive review of thousands of pages of documents obtained by my Committee staff. Portions of these documents were received by the Committee in response to letter requests to FDA, Wyeth Pharmaceuticals (Wyeth), its subsidiary division Fort Dodge Animal Health (FDAH), and Germinder and Associates, Inc. (GAI)—a public relations firm.[1] Wyeth hired GAI to handle public relations regarding its canine drug ProHeart 6. ProHeart 6 is a Wyeth Pharmaceuticals product designed to prevent canine heartworm and to treat both the larval and adult stages of the canine hookworm.[2] Additionally, this Letter contains information obtained by my Committee staff through interviews conducted with, among others, representatives of the aforementioned parties.

I. Background

On April 11, 2005, Committee staff received allegations from Dr. Victoria Hampshire that on January 7, 2005, she was wrongfully removed from her post at the Food and Drug

[1] Documents marked with Bates numbers beginning with the letters "FTDO" are documents obtained from Wyeth. Documents marked with Bates numbers beginning with letters "GA" came from Germinder and Associates. Please see the attached Appendix for descriptions of the cited documents.
[2] ProHeart 6 (moxidectin) background document, Fort Dodge Animal Health Presentation, January 2005, *available at* http://www.fda.gov/cvm/Documents/FINALVMACProHeart6.pdf (Attachment (Att.) 3).

Administration's Center for Veterinary Medicine (CVM) and was reassigned to another position.[3]

Dr. Hampshire informed Committee staff that she believed that she was removed and reassigned because of her work cataloging negative adverse drug events (ADEs) in conjunction with ProHeart 6. Her work demonstrated that the ProHeart 6 ADEs were increasing in frequency and in severity of associated safety signals. The ADE reports were sent to FDA from Fort Dodge Animal Health under the sponsor's mandatory reporting requirement and referred by Dr. Hampshire to her supervisors.[4] Dr. Hampshire believes that she was removed at the behest of Wyeth in an effort to minimize the impact of a presentation she was going to make at a Veterinary Medicine Advisory Committee (VMAC) meeting regarding her findings.[5] In 2005, I opened an inquiry into these allegations regarding ProHeart 6, issued document requests, and my staff began conducting interviews.

My staff has uncovered evidence supporting Dr. Hampshire's allegations, bringing into question the processes that FDA uses in response to industry allegations of wrongdoing by FDA employees. Their findings, as set out below, indicate that an industry sponsor may have used its resources to have the Adverse Events Coordinator removed in hopes of having its veterinary drug, ProHeart 6, returned to the market. Dr. Hampshire has offered credible evidence that the allegations Wyeth made against her to the FDA were misleading and easily refuted. Nonetheless, the FDA accepted Wyeth's allegations at face value and took actions against Dr. Hampshire that may have adversely affected the drug approval and recall processes. I offer the following findings and set forth a number of questions for the FDA.

A. <u>Dr. Victoria Hampshire</u>

The Committee obtained the following information about Dr. Hampshire through interviews, an April 11, 2005, letter she submitted to my staff, and documentation provided by various sources.

Dr. Victoria Hampshire, VMD, is a veterinarian and a Commander in the United States Public Health Service (PHS). In November 2003, Dr. Hampshire was promoted to Adverse Event Coordinator for CVM. This position required Dr. Hampshire to interact with pet owners whose animals were harmed and/or injured by products that are regulated by FDA through CVM. Among her major duties was the collection and analysis of thousands of adverse drug event reports. Dr. Hampshire's exemplary work at the FDA earned her a PHS Achievement Medal in June 2005 for her "significant achievements in post marketing veterinary drug surveillance."[6] Moreover, she was named Veterinarian of the Year in 2006 by the PHS.[7]

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[3] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005, with redactions (Att. 1).

[4] 21 CFR 514.80 requires companies to report veterinary or owner reports of suspect adverse drug experiences and product/manufacturing defects on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report."

[5] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).

[6] Nomination for US PHS Achievement Medal CDR Victoria Hampshire (Att. 51).

Prior to joining the FDA in May 2001 as a Safety Reviewer, Dr. Hampshire worked at the National Institutes of Health (NIH) until 1999 and worked independently as a veterinarian for one year. During Dr. Hampshire's time as an independent veterinarian in 2000, she formed a company called Advanced Veterinary Applications (AVA). AVA operated through an internet website as a vehicle for providing veterinary services limited to to friends, family, and former clients. The website accommodated house calls, relief work, and/or the prescribing of veterinary medications for a limited number of clients including friends, relatives, and colleagues. AVA was not an internet pharmacy. The website had an affiliation with VetCentric, an independent third party prescription fulfillment house that fills orders generated by the website. This method is commonly used by veterinarians who have few clients or practice on a limited basis.

VetCentric prescribing accounts allow veterinarians to save on overhead and generate income by marking up prescriptions with a margin. In Dr. Hampshire's case, her margin was a maximum of $5.00 to cover her time spent. In many instances, she charged nothing at all. Thus, her website generated minimal income and was not designed to solicit general internet clients.[8] Over a period of three years, from 2003 until 2005, Dr. Hampshire told Committee investigators that she received approximately $200 as a result of the AVA website (but see fn. 154, below). Dr. Hampshire viewed this site as one of three outside activities she was allowed to undertake while employed at FDA.

Dr. Hampshire filed disclosures for AVA during her employment with FDA.[9] In addition to AVA, Dr. Hampshire also disclosed two other outside activities, including limited employment at an emergency animal clinic and consultation work with the Humane Society of the United States. Dr. Hampshire also filed disclosures for other outside interests including speeches and talks that she gave outside of the Agency. All of these activities occurred outside of the scope of her government work and did not involve the use of FDA resources.

B. ProHeart 6 and Wyeth Pharmaceuticals

ProHeart 6, also known as moxidectin, is a Wyeth Pharmaceuticals product designed to treat both the larval and adult stages of the canine hookworm.[10] It is administered bi-annually with an injection at a veterinarian's office. ProHeart 6 was developed in part as a convenience to pet owners who want to protect their pets without using monthly pills or external creams and lotions. Further, the bi-annual injection was marketed as providing continuous protection against parasites.

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[7] See http://www.washingtonpost.com/wp-dyn/content/article/2006/05/11/AR2006051101883_2.html (Att. 52).

[8] Dr. Hampshire informed us that she received so little income from VetCentric and so much "junk mail" that she often threw away the VetCentric correspondence, including checks from time to time.

[9] See Att. 56 (Disclosure forms filed by Dr. Hampshire). Dr. Hampshire had no ownership interest in VetCentric, so filed no disclosures regarding that company.

[10] ProHeart 6 (moxidectin) background document, Fort Dodge Animal Health Presentation, January 2005, *available at* http://www.fda.gov/cvm/Documents/FINALVMACProHeart6.pdf (Att. 3).

ProHeart 6 was approved for use in the United States by the FDA in June 2001, based on laboratory studies that revealed no serious adverse drug events in healthy dogs.[11] ProHeart 6 is approved in several other countries, and a newer twelve-month version known as ProHeart SR12 has been approved for use in Australia since 2000.

Beginning in 2001, CVM and FDAH began receiving ADE reports from pet owners and veterinarians across the country. Initially, it appeared that many of the ADEs involved allergic-type reactions after administration of the drug.[12] The reactions that were cataloged as allergic reactions were attributed by FDAH to a manufacturing issue. FDAH allegedly resolved and "continu[ed] to optimize the manufacturing process."[13]

In the months following its approval, other problems plagued ProHeart 6. As a result, the label for ProHeart 6 was amended three separate times. The first amendment in June 2002 added anaphylaxis/anaphylactoid reactions, depression, lethargy, hives, and head and facial edema.[14] The label was amended a second time in November 2002 to include cardiopulmonary issues associated with dogs that were heartworm-positive.[15] Finally, the phrase "and rare reports of death" was added to the label in July 2003.[16] In addition to the label changes, the FDA required FDAH to send out two "Dear Doctor" letters noting the new information on the labels—one in July 2002, the second in June 2003.[17] As 2003 drew to a close, concerns began to arise among FDA safety reviewers about the increasing number of ADEs being reported by veterinarians and pet owners to both FDAH and CVM.

C. Removal of ProHeart 6 from the Market

In November 2003, Dr. Hampshire began noticing an increasing trend in ADEs being reported to CVM by FDAH, veterinarians, and pet owners across the country.[18] She alerted both the project manager and the team leader about this trend and suggested that the FDA should take some action to control the adverse impact that ProHeart 6 appeared to have on dogs in the United States.[19] Dr. Hampshire's initial outreach to her colleagues was heard, but no action was taken; in fact, Dr. Hampshire recalls that one of her colleagues stated, "The drug [ProHeart 6] will go away on its own after enough animals die."[20] However, this sentiment at the FDA changed in the spring of 2004 when consumer advocacy groups began to contact CVM en masse, lodging complaints about ProHeart 6.

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[11] FDA Veterinary Medicine Advisory Committee (VMAC) Meeting, January 31, 2005, Testimony of Dr. Lynn Post (Att. 4).
[12] ProHeart 6 (moxidectin) background document (Att. 3).
[13] *Id.* at p. 48.
[14] FDA VMAC Meeting, January 31, 2005 (Att. 4).
[15] *Id.*
[16] *Id.* Testimony of Dr. Margarita Brown (Att. 4).
[17] http://www.fda.gov/cvm/Documents/proheart6.pdf (Att. 47); http://www.fda.gov/cvm/Documents/Proheart6-062703.doc (Att. 48).
[18] Letter from Dr. Victoria Hampshire to Senate Finance Committee, dated April 11, 2005 (Att.1).
[19] *Id.*
[20] *Id.*

Consumer groups continued to press the FDA through the spring of 2004 and ultimately generated over 20 national news stories regarding the various adverse reactions pets had with ProHeart 6.[21] In response, FDA officials, including the head of the Office of New Drug Evaluation, began to ask when the FDA was going to act. FDA senior management, including the then-Director at CVM (Dr. Stephen F. Sundlof),[22] then-Deputy Director at CVM (Dr. Linda Tollefson), and the head of the Office of Surveillance and Compliance (OSC) (Dr. Dan McChesney), agreed to hear a presentation provided by Dr. Hampshire about the safety issues associated with the adverse drug event reports that CVM received. Dr. Hampshire made her presentation in July 2004. According to Dr. Hampshire, the CVM senior management staff unanimously agreed that ProHeart 6 was problematic and that it should be removed from the market, and that Wyeth should be asked to conduct additional studies.[23] In making this decision, Agency staff relied upon the nearly 5,000 ADE reports that were relayed to the FDA and the fact that there were large numbers of reports on relatively young, healthy dogs.[24]

Dr. Sundlof took the concerns that the management team raised and notified then-FDA Commissioner, Dr. Lester Crawford, who is also a veterinarian. According to Dr. Hampshire, Dr. Crawford asked Dr. Sundlof to speed up the process on ProHeart 6 in anticipation of the upcoming heartworm season and the potential increase in utilization. FDA officials at CVM scheduled a meeting with Wyeth officials to discuss concerns surrounding ProHeart 6. On August 11, 2004, FDA officials from CVM met with representatives of FDAH, a Wyeth subsidiary, to review the same presentation Dr. Hampshire gave to CVM management in July. Dr. Hampshire told Committee staff that she was unable to attend the August meeting. A follow-up meeting was set for September 1.

Dr. Hampshire stated that she represented CVM at the September 1 meeting and presented the findings, which were supported by seven safety reviewers, as well as CVM management.[25] By the end of the meeting, CVM decided that it would ask FDAH to remove ProHeart 6 from the market.

Following the September 1, 2004, meeting, FDAH continued to appeal the decision of CVM senior management to FDA's then-Commissioner Crawford.[26] The appeal included arguments that the data was inconclusive and that other competitor heartworm products had similar adverse events.[27] CVM staff, including Dr. Hampshire, advised the FDA Commissioner that this comparison had been addressed previously by changes to dosage and new warnings on other competitor drugs.[28] The then-FDA Commissioner Crawford ultimately concluded that CVM's decision was fair and accurate and the FDA proceeded with the recall.[29] FDAH made one last appeal to the FDA Chief Counsel who

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[21] See, *e.g.*, http://www.dogsadversereactions.com (moxidectin link).
[22] Dr. Sundlof is now the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN).
[23] Letter from Dr. Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[24] See FDA VMAC Meeting, January 31, 2005, Testimony of Dr. Margarita Brown, pp. 16 and 34-52. Dr. Brown was one of four veterinarians who initially reviewed adverse drug events for CVM. She synopsized why the adverse reports were serious (Att. 4).
[25] Letter from Dr. Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*

also rejected the appeal and upheld the recall.[30] Finally, on September 3, 2004, FDAH voluntarily recalled ProHeart 6 from the market,[31] provided that CVM would convene an outside panel of experts to reevaluate the data.

II. Findings

Set forth below are my Committee staff's findings with regard to ProHeart 6 and Dr. Hampshire.

A. Wyeth Pharmaceuticals' Investigation of Dr. Victoria Hampshire

1. Initial Disputes with FDA and Dr. Hampshire

Internal emails from FDAH following the September 3, 2004, recall of ProHeart 6, show that it requested a copy of the September 2004 slide presentation prepared by Dr. Hampshire.[32] Dr. Hampshire and CVM officials initially withheld the slide presentation because of particular concerns regarding the confidentiality of outside consultants that the FDA utilized in preparing the data. Dr. Hampshire believed the FDA needed the approval of the outside consultants before divulging their names to a drug sponsor because the use of the consultants was "pre-decisional."

On September 20, 2004, the President of FDAH, Dr. Thomas Corcoran, asked that Dr. Sundlof provide FDAH with the September 1 slide presentation.[33] Three days later, on September 23, 2004, Dr. Corcoran wrote a formal letter to Dr. Sundlof in which he continued to request the September slide presentation, asked for a narrative to accompany the slide presentation, and requested "the list of academics Dr. Hampshire consulted with in evaluating ProHeart 6."[34] On September 24, 2004, Dr. Sundlof responded to the Dr. Corcoran and provided a redacted copy of the September 1 slide presentation prepared by Dr. Hampshire. In the response, Dr. Sundlof stated, "[i]n considering your request for the names of the experts outside the Agency which Dr. Hampshire referred to during her presentation, CVM has determined that the information is pre-decisional and therefore considered confidential, thus we are declining to provide their names."[35]

Internal FDAH emails indicate that Dr. Corcoran sought internal guidance from FDAH Corporate Counsel regarding the ability of CVM to withhold this information as "pre-decisional."[36] Based on these internal discussions, Dr. Corcoran continued to ask the then-CVM director for the unredacted slides. In an email dated October 4, 2004, Dr. Corcoran stated, "In going through the presenttion [sic] slides were omitted. Would you look into this and let me know if the missing slides were omitted for a specific reason?"[37] Dr. Corcoran continued, "I need to understand the context of the 'predecisional' [sic]

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[30] *Id.*
[31] http://www.fda.gov/cvm/PH6QA.htm (Att. 49).
[32] FTDO 001391 (Att. 5).
[33] FTDO 000845 (Att. 6).
[34] FTDO 000846-848, at 847 (Att. 7).
[35] FTDO 00929 (Att. 7a).
[36] *See* FTDO 0000845 (Att. 6).
[37] FTDO 001075 (Att. 10).

statement that guides you to withhold the information from whom in the academic world you received advice on ProHeart 6. Obviously the nature of the advice is also key."[38] Finally, Dr. Corcoran commented on conversations with CVM, "The confrontational tone exhibited by some of the CVM personnel at the September 1 meeting seems to be continuing. Why?"[39]

As a follow-up to the October 4 email, Dr. Corcoran called Dr. Sundlof the following day to discuss the September 1 slide presentation. Contemporaneous notes of the conversation prepared by Dr. Corcoran provide a narrative of the call. Specifically, Dr. Corcoran wrote:

> On the issue of the "missing" slides from Dr. Hampshire's September 1 presentation, Dr. Sundlof stated he was told we were given all slides with data. Slides with commentary and conclusions were omitted. I told him this was totally unacceptable. If CVM presented this information as factual and it was the basis of their decision to demand we voluntarily recall ProHeart 6, we had an absolute right to see the complete presentation and they had an obligation to provide. ***I further told him that unless we received the entire presentation, I was going to make a big issue of initially withholding the presentation and then submitting only a portion of the presentation. I assured him this would be carried to the highest levels, and I wasn't speaking of FDA. He stated, "Message received."***[40] (emphasis added).

Following this conversation with FDAH's president, Dr. Sundlof emailed an un-redacted version of the complete September 1 slide presentation to FDAH on October 7, 2004.[41] In transmitting the slides, Dr. Sundlof noted, "The set I sent previously mostly omitted the conclusion slides because I thought, and still do think, that it is more important for FDAH to draw their own conclusion from the data in the reports FDAH sent to CVM rather than focusing on what FDAH considers problems with CVM's conclusions."[42]

2. Initial Complaints about Dr. Hampshire

One week following the September 3, 2004, removal of ProHeart 6 from the market, evidence suggests that individuals at FDAH received concerns regarding the possibility that Dr. Hampshire had a "vendetta" against FDAH and ProHeart 6. On September 10, 2004, Dr. Rocky Bigbie, Director of Field Veterinary Services at FDAH, received an email from M. Gatz Riddell, Jr., then-professor at Auburn University, who stated, "I have also heard that Tori Hampshire might have been on a mission with some type of ax to grind or a vendetta to carry out."[43]

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[38] *Id.*
[39] *Id.*
[40] FTDO 001654 (Att. 11).
[41] FTDO 001803 (Att. 12).
[42] *Id.*
[43] FTDO 000878 (Att. 13). Dr. Riddell was a source of information to FDAH that Dr. Hampshire may have a personal "vendetta" against ProHeart 6, and he was also an "Invited, Voting Consultant" to the VMAC

Further, that same day, a representative of the American Veterinary Medical Association forwarded an email from Larry Glickman, VMD, a professor at Purdue University, which discussed Dr. Hampshire.[44] The email concluded that Dr. Hampshire's actions were important because they "reflect[] a deliberate attempt by Victoria Hampshire to exclude veterinarians in the decision making process."[45]

3. Hiring Consultants to Investigate Dr. Hampshire

During September 2004, FDAH began an effort to get ProHeart 6 back on the market. Disclosures made to Committee staff indicate that on September 5, 2004, FDAH Director of Marketing Craig Wallace contacted Lea Ann Germinder of Germinder & Associates, Inc. (GAI),[46] an independent public relations specialist affiliated with FDAH since 1998. FDAH contacted GAI in an effort to begin a "communications outreach plan to respond to the recall."[47] This outreach effort included contact with "veterinarians, veterinary medical associations and key contacts in the animal health community and members of Congress and others believed to have influence at FDA and to continue to monitor and provide online coverage of the recall."[48]

Ms. Germinder informed Committee staff that she recalled receiving instructions from Craig Wallace "sometime between September 6, 2004 and October 12, 2004,"[49] to google Victoria Hampshire."[50] GAI began forwarding internet research on Dr. Hampshire to Mr. Wallace on September 16, 2004.[51] In response to the information on Dr. Hampshire, the Vice President of

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meeting held on January 31, 2005, to examine the voluntary recall of ProHeart 6. See FDA Veterinary Medicine Advisory Committee (VMAC) Meeting, January 31, 2005, Committee Deliberations on Question 1 (Att. 4). Further, Dr. Riddell voted "YES" to the question "is ProHeart 6 safe for use in dogs?" *Id.* Whether or not the contacts that Dr. Riddell had with FDAH were disclosed to the FDA prior to his voting on the January 31, 2005, VMAC meeting is unknown. However, it appears that the contact he had with FDAH representatives was a component in FDAH's investigation of Dr. Hampshire.

[44] FTDO 001849 (Att. 14).

[45] Dr. Glickman was introduced by FDAH at the September 1, 2004, meeting as a consultant for FDAH. In addition, Dr. Glickman presented FDAH's study data at the January 31, 2005, VMAC meeting. See, VMAC January 31, 2005 Meeting Transcript (Att. 4). Dr. Glickman had gathered data used by FDAH to support the position that Pro Heart 6 was safe. It is unknown whether Wyeth informed FDA that FDAH had these contacts with Dr. Glickman.

[46] According to disclosures made by Ms. Germinder, FDAH has "utilized the services of Germinder & Associates, Inc. in a wide variety of projects since approximately 1998." Further, GAI has also contracted some projects with Wyeth Animal Health since 2004. However, GAI has "never had a general written contract with either of Wyeth's animal health divisions governing their relationship" and serves as "an independent contractor and executes projects with Fort Dodge Animal Health according to signed estimates which set forth a scope of work as directed by the Vice President of Marketing, Craig Wallace." *See* Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, to Senator Charles E. Grassley, May 16, 2006, at 5 (Att.15).

[47] *Id.* at 11.

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] FTDO 000879-881, 879 (Att. 16).

Pharmaceutical Research (Rami Cobb) for FDAH concluded that the information "helps to point towards there being a personal agenda on her part."[52]

Based on the information made available to my staff, FDAH hired more than one person to look into Dr. Hampshire's activities. In fact, the Senior Vice President of North American Marketing at FDAH wrote to the Vice President of North American Marketing regarding the GAI research and said, "I had already hired an investigator to do the same."[53] Ms. Germinder then sought further help and entered into a written contract with her nephew, Dan O'Hare, for independent consulting.[54]

4. Failed Attempts to Purchase Competitors' Prescription Products from AVA

The key portion of the investigation into Dr. Hampshire occurred in early October 2004 and revolved around Dr. Hampshire's affiliation with a website she operated known as Advanced Veterinary Applications (AVA), http://www.advancedvet.com. As stated earlier, this was the website portal that Dr. Hampshire had created in 2000, prior to joining FDA. GAI and FDAH researchers came across AVA after Mr. Wallace asked for a google search of Dr. Hampshire.[55]

Ms. Germinder stated that, once directed to the AVA website, she saw that it offered Heartguard, a competitor drug to ProHeart 6.[56] According to Ms. Germinder, once he became aware of this, Mr. Wallace instructed her to research this matter further and directed Ms. Germinder to attempt to make a purchase from the AVA website. In response, Ms. Germinder assigned one of her direct staff members, Catherine Couch, to "mystery shop" the AVA website.[57] Ms. Couch determined that the website was live and operational. Ms. Germinder noted that she then instructed her nephew Dan O'Hare, an independent consultant hired by GAI, to conduct internet research and attempt to make a purchase.[58]

Mr. O'Hare made his first purchase of products from the AVA website on October 8, 2004. Mr. O'Hare placed an initial order for a product, Bitter Apple Spray—a non-prescription product—and paid $6.08 for the product plus shipping cost. He used the business name XC Direct, billed the purchase to his father's credit card and shipped it to his father's home.[59] This order was shipped to Mr. O'Hare from VetCentric on October 11, 2004.[60]

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[52] FTDO 000882-887 (Att. 17).
[53] FTDO 000888-893 (Att. 18).
[54] GA-9-00001-03 (Att. 19).
[55] *See* Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 11 (Att. 15).
[56] *Id.*
[57] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 11 (Att. 15).
[58] *Id.* at 11.
[59] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15)
[60] FTDO 000045-000049 (Att. 21).

Ms. Germinder's employees then attempted to purchase prescription products from AVA website that were direct competitors to ProHeart 6. Ms. Germinder asked Mr. O'Hare to purchase Heartguard, a competitor product to ProHeart 6. Mr. O'Hare was unable to purchase the product through the AVA website.[61] After being denied the product because he did not have a prescription for Heartguard and was not a friend, family member or former client that Dr. Hampshire worked with on the AVA website,. O'Hare instead purchased $1,197.65 worth of non-prescription pet products through the product link on the AVA website, including shampoos and pet treats.[62]

Later, GAI enlisted the help of Dr. Steven A. Levy, a veterinarian at Durham Veterinary Hospital in Durham, Connecticut.[63] Since 1990, Dr. Levy has been a canine-lyme disease consultant for FDAH.[64] Dr. Levy, according to the information presented to the Committee, worked with Ms. Germinder in the past and agreed to attempt to purchase Heartguard from the AVA website. However, Dr. Levy was unsuccessful in purchasing Heartguard from AVA.[65] Documents produced to my staff show that Dr. Levy then requested assistance from a person named "Kelly." Kelly was to obtain Heartguard using a prescription issued by Dr. Levy on October 18 and October 19, 2004.[66] According to GAI's documents, Kelly had a prescription from Dr. Levy and also requested a prescription through AVA.[67] Kelly had problems accessing the VetCentric ordering site, so she called VetCentric.[68] She told VetCentric that she "had a prescription from [Dr. Levy] and a request for a prescription through Advanced Vet [AVA]"but that she wanted a prescription from AVA.[69] She told VetCentric that AVA was her.[70] This statement was false; according to Dr. Hampshire, neither "Kelly" nor Dr. Levy were clients of AVA. Ultimately, VetCentric did not fill any prescription through AVA.[71] VetCentric personnel told Kelly that she could, however, purchase the Heartguard product using Dr. Levy's prescription.[72] Therefore, both of Dr. Levy's attempts to purchase Heartguard through AVA without an AVA prescription were unsuccessful.

In addition to the attempts by Mr. O'Hare and Dr. Levy, Ms. Germinder initiated an attempt to purchase Heartguard from AVA by enlisting the help of a pet owner in Maine. That individual was also unsuccessful.[73] Ultimately, GAI failed in its attempts to purchase products competitive with ProHeart 6 from Dr. Hampshire's AVA website.

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[61] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15).
[62] FTDO 000799-0000801 (Att. 22). According to Dr. Hampshire, the friends, family and former clients who used the AVA website to obtain prescription medication seldom, if ever, purchased non-prescription products.
[63] FTDO 000050-000053 (Att. 23).
[64] Resume of Dr. Steven Levy, found at http://www.durhamveterinary.com/cv.html (Att. 20).
[65] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12. (Att.. 15).
[66] FTDO 000054-55 (Att. 24).
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.* The letter from Kelly to Dr. Levy states that "I'm not sure about identifying Advanced Vet as my vet, but this seemed the only way to proceed with the order."
[71] *Id.*
[72] *Id.*
[73] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15)..

5. Interim Report Provided to Wyeth by Germinder & Associates

GAI produced its first report to Wyeth regarding Dr. Hampshire on October, 12, 2004.[74] This interim report consisted of information and research conducted, "in accordance with standard public relations research practices for background use only to determine the stakeholders who are conducting a negative communications campaign against ProHeart 6."[75] The report was designed with the "hope that understanding who these stakeholders are, what motivates them, the tactics they use, and the key messages they wish to convey will assist you in executing your business strategy regarding this matter."[76]

The interim report produced by GAI contains (1) screen prints of internet searches of the terms "Victoria Hampshire" and "Tori Hampshire;"[77] (2) various scholarly articles authored and/or peer reviewed by Dr. Hampshire;[78] (3) screen prints of the AVA website operated by Dr. Hampshire and information about VetCentric;[79] and (4) information on the "Dogs Adverse Reactions" website and other websites that appeared critical of ProHeart 6.[80]

6. Hiring a Private Investigator to Research Dr. Hampshire

In the days following the transmittal of the GAI interim report to FDAH, Ms. Germinder was in contact with Mr. Wallace on a daily basis.[81] However, she realized that she needed some experienced assistance in furthering the investigation. Consequently, Ms. Germinder contacted a longtime acquaintance, Ms. Donna Dauite, a licensed private investigator.[82] Ms. Dauite was tasked with tracking down proper legal ownership of the AVA website and was contracted by GAI to conduct this work.[83] During interviews with Committee staff, Ms. Germinder recalled that the decision to hire and contract with Ms. Dauite was discussed with Mr. Wallace and representatives of Wyeth prior to signing the contract. Specifically, Ms. Germinder told Committee staff on March 12, 2007, that she advised Mr. Wallace that further research would be done by a researcher who had credentials as a private investigator.

Ultimately, the GAI investigators, including Ms. Dauite, created a substantial investigative file on Dr. Hampshire. This file included property records for Dr. Hampshire's personal residence,[84] business search records related to AVA,[85] taxation

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[74] GA-4-00009 (Att. 25); GA-4-00134-231 (Att. 26).
[75] GA-4-00009 (Att. 25).
[76] *Id.*
[77] *See* GA-4-00135-00138 (Att. 26).
[78] GA-4-00159-00184 (Att. 26).
[79] *Id.*
[80] *Id.*
[81] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15).
[82] *Id.*
[83] *Id.*
[84] GA-4-00041 (Att. 27).
[85] GA-4-00043 (Att. 28); 00045 (Att. 29).

records related to both Dr. Hampshire and AVA,[86] as well as records related to the VetCentric Prescription fulfillment site.[87]

This information and over $1,000 in over-the-counter, non-prescription animal products that Mr. O'Hare purchased from the VetCentric component linked to the AVA website and provided to GAI were given to Wyeth in two separate packages. The first package was delivered by Ms. Germinder on October 20, 2004,[88] and included "the latest correspondence and documentation in attempting to order Heartguard from Advanced Veterinary Applications"[89] as well as two boxes of "product and paperwork." GAI delivered the remaining information to Wyeth on October 27, 2004.[90]

7. Meeting between Wyeth and Former FDA Commissioner

Emails produced to my staff detail at least two phone calls between Wyeth and senior FDA officials following Wyeth's receipt of GAI's October 27 production.[91] Specifically, internal Wyeth documents show that Geoffrey Levitt, Vice President & Chief Counsel, Regulatory and Research at Wyeth, spoke with then-FDA Chief Counsel Dan Troy on November 5, 2004, in an effort to follow up on a call made to then-FDA Commissioner Crawford by Wyeth Chairman, Robert Essner.[92] Based upon documents provided by FDA, it appears that the topic of conversation for both calls was "the apparent conflict of interest issue."[93] Further, emails obtained from FDA show that Wyeth prepared company-wide talking points on the issue, and that Wyeth believed they had "information to show not only that there was a strong appearance of conflict and bias, but also that these issues had influenced the data and analysis on which FDA's position was based."[94] The emails also show that Wyeth requested a meeting to discuss the issues with then-FDA Commissioner Crawford.

Wyeth created a 29-page slide presentation titled, "ProHeart 6: Apparent Conflict of Interest" and a 10-page appendix slide presentation with supporting documentation.[95] Both slide presentations appear to have been created based upon information obtained from the GAI investigation and Wyeth's own investigation of Dr. Hampshire.[96] Wyeth offered the slide presentations to FDA at a meeting on November 19, 2004.[97] This

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[86] GA-4-00044 (Att. 30); 00047-52 (Att. 31); 00055-57 (Att. 32).
[87] GA-4-00053 (Att. 33).
[88] GA-4-00031 (Att. 34).
[89] *Id.*
[90] GA-4-00058 (Att. 35).
[91] *See* FTDO 002613 (Att. 36).
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] See Wyeth's November 19, 2004 slide presentation (Att. 8).
[96] Similar web searches and document searches on Dr. Hampshire were conducted concurrently to the investigation conducted by GAI. One noteworthy portion of this Wyeth investigation is the involvement of FDAH Senior Vice President & Chief Counsel C.T. Newsum, as many documents related to Mr. Newsum were withheld from the Committee by Wyeth under Attorney Client Privilege related to Mr. Newsum's capacity as FDAH's Chief Counsel. The Committee is not subject to such common law privilege, but took no action to force production.
[97] *See* Letter from Douglas Dworkin, Wyeth Pharmaceuticals, to Senator Charles Grassley, December 16, 2005, at 3 (Att. 37).

meeting took place at the FDA. Representing Wyeth were "Bob Essner, Chairman, President, and Chief Executive Officer; Jeff [sic] Levitt, V.P. and Chief Counsel Regulatory and Research; Gerald Fisher, Senior V.P., Drug Safety and Metabolism."[98] The FDA was represented by then-FDA Commissioner Crawford, then-Chief Counsel Dan Troy, and Policy Analyst Dana Delman.[99] The topic of conversation was "issues surrounding the September 3, 2004, withdrawal from the market of ProHeart 6" and included discussion of "a potential conflict of interest issue."[100] This portion of the meeting included Wyeth's slide presentation regarding Dr. Hampshire.[101] The presentation alleged, among other things, that (1) public records revealed that AVA was an "active internet veterinary pharmacy" selling products competing with ProHeart 6, which raised the appearance of a conflict of interest; (2) Dr. Hampshire was biased because she had been in contact with anti-ProHeart6 activists; and (3) Dr. Hampshire presented adverse events data in a biased fashion."[102]

8. FDA Investigation of Dr. Hampshire

Following the meeting between representatives from Wyeth and FDAH, then-FDA Commissioner Crawford and then-Chief Counsel Troy provided Wyeth's slide presentation to Dr. Steven Sundlof, then-Director of CVM. Dr. Sundlof relayed the contents of the presentation via telephone to a Special Agent within the FDA's Office of Internal Affairs (OIA) Office of Criminal Investigations (OCI) on November 22, 2004. According to the FDA, OIA "is a subordinate office within OCI which conducts administrative and criminal investigations of alleged employee misconduct."[103] Based on this referral phone call, Special Agents within OIA opened an initial investigation into Dr. Hampshire on November 24, 2004, alleging that Dr. Hampshire was operating an internet pharmacy.[104]

In the meantime, Dr. Hampshire continued to work with CVM staff on ProHeart 6 and began preparing for a January VMAC meeting.[105] She was unaware of Wyeth's allegations and the FDA/OIA investigation. However, Dr. Hampshire informed Committee staff that her colleagues began to give her "a cold shoulder treatment," but she did not know why.[106]

Throughout December 2004, Dr. Hampshire continued to help select candidates for the January 2005 VMAC meeting. However, Dr. Hampshire was kept away from preparing the CVM presentation that would be given to the VMAC, despite her long history of working on ProHeart 6. During this same time, Mr. C.T. Newsum, Senior Vice President and Chief Counsel for FDAH, was working closely with the OIA agents.

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[98] FDA Memorandum of Meeting prepared by Dana Delman, Policy Analyst, November 19, 2004 (Att. 38).
[99] *See id.*
[100] *Id.*
[101] *See* Letter from Douglas Dworkin, Wyeth Pharmaceuticals, at 3 (Att. 37).
[102] Wyeth's November 19, 2004 slide presentation (Att. 8).
[103] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, at 1 (Att. 39).
[104] FDA Office of Internal Affairs, Case Initiation and Fact Sheet, November 24, 2004 (Att. 42E).
[105] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[106] *Id.*

Documents and information show that Mr. Newsum reached out to FDA agents on December 9, 2004, and was interviewed by OIA agents on December 16, 2004.[107] According to one of the FDA agents interviewed by Committee staff, Mr. Newsum called frequently regarding this matter. In fact, one written investigative report stated that Mr. Newsum spoke to an agent on "numerous occasions over the course of this investigation."[108] Eventually, OIA agents pulled Dr. Hampshire's ethics filings from the Office of Ethics at FDA where they learned that she filed three separate outside activity reports (OAR), including one for AVA Consulting.[109]

The FDA/OIA investigation into Dr. Hampshire included (1) pulling Dr. Hampshire's ethics forms; (2) reviewing the materials prepared by Wyeth; (3) interviewing the Chief Counsel for FDAH, (4) pulling all emails and internet activity from Dr. Hampshire at FDA; and (5) requesting the Department of Health and Human Services, Office of the Inspector General (HHS/OIG)[110] to issue a subpoena to VetCentric for records related to AVA.[111] Based on this information, the OIA presented investigative facts relating to Dr. Hampshire's alleged conflicts to officials at CVM on January 6, 2005.[112]

On January 7, 2005, Dr. Hampshire was called into a meeting with then-CVM Deputy Director Tollefson and OSC Director McChesney.[113] Dr. Hampshire informed my staff that, during this meeting, Dr. Tollefson told her that Wyeth had "pulled all plugs" at the level of the Commissioner and that Dr. Hampshire was being reassigned.[114] Dr. Hampshire agreed that if the industry sponsor had questions about her involvement that it was ultimately better to leave the role of lead reviewer for ProHeart 6 and let the data speak for itself. Accordingly, Dr. Hampshire then asked if she could be reassigned within CVM instead of being transferred out of the Center.[115] Dr. Hampshire was granted a move within CVM, but was no longer a lead reviewer on ProHeart 6. She

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[107] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab C (Att. 40).
[108] OIA Investigative Report January 31, 2005, at 3 (Att. 42B).
[109] *Id.*
[110] It is important to note that during the time-frame discussed in this Letter, FDA held a distinction within the Department of Health and Human Services (HHS) not afforded to other subordinate agencies. The FDA had a written memorandum of understanding (MOU) with HHS/OIG regarding the investigation of internal misconduct by FDA employees. Att. 41. This MOU was executed in July 1998 and allowed FDA to continue to have Criminal Investigators, Federal Series 1811 employees, on staff in the Office of Internal Affairs to conduct investigations into employee misconduct. *Id.* Further, the MOU provided that both FDA/OIA and HHS/OIG would hold concurrent responsibility for investigating employee misconduct at FDA with FDA/OIA taking a lead role unless it was preempted by the HHS/OIG's right in all cases to pursue a case jointly with OIA or after consultation replace OIA as the primary Agency. *Id.* Because of this right of preemption retained by HHS/OIG, FDA/OIA utilized the services of HHS/OIG whenever it needed to issue a subpoena duces tecum, as was the case here. The MOU was, however, withdrawn as of November 30, 2007, and the function of criminal investigation of FDA employees was returned to HHS/OIG "[t]o ensure integrity in the process of conducting sensitive employee misconduct investigations." Att. 53. According to HHS/OIG, "this function is more appropriately placed in an investigative office with statutory independence." *Id.*
[111] OIA Investigative Report, January 31, 2005, at 4 (Att. 42B).
[112] *Id.*
[113] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[114] *Id.*
[115] *Id.*

continued, however, to provide advice to CVM to keep continuity in CVM as they moved toward the advisory committee hearing.

During the next few weeks, CVM prepared for the January 31, 2005,VMAC to discuss the safety of ProHeart 6. One of Dr. Hampshire's colleagues was selected to make the presentation in place of Dr. Hampshire. On January 30, 2005, the Director of OSC called Dr. Hampshire at home and asked her to help prepare a statement for the VMAC in the event that questions arose about why Dr. Hampshire was not presenting.[116] In response to this request, she helped prepare a statement that said she was on vacation and had been reassigned within FDA to different projects.[117]

On January 31, 2005, the VMAC met to discuss the safety of ProHeart 6 and the earlier recall. The panel heard data from both FDA and Wyeth. The presentation by FDA included testimony from CVM employees who relayed the same concerns that were presented by Dr. Hampshire at the September 1, 2004, meeting with Wyeth. The panel, by an 8-7 vote, ultimately concluded that safety concerns based on serious adverse events warranted the continued recall of ProHeart 6.[118]

With the VMAC complete, and following her reassignment to another division within CVM, Dr. Hampshire was still unaware of the investigation into her activities. However, on February 8, 2005, she was contacted by the FDA Office of Ethics regarding her outside activities reports.[119] The Ethics staff asked Dr. Hampshire why she did not include her AVA website on her December 14, 2004, HHS Form 520-1 "Request for Approval of Outside Activity,"or OAR.[120]

Dr. Hampshire told my staff that she informed the ethics staff that the AVA website account was not included on her OAR because, even though it was still open, she had not been using it over the past year. She believed that she did not have to disclose an activity that was not producing income.[121] This belief was wrong, and the Director of Ethics informed Dr. Hampshire that "receipt of income" was not the standard for filing an approved outside activity request. Dr. Hampshire was also told that because she had not ended the AVA activity, she also needed to file a new OAR in order to close the 2004 file.[122] Dr. Hampshire agreed to file a new OAR report.[123] Dr. Hampshire did not know

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[116] *Id.*
[117] *Id.*
[118] VMAC meeting minutes, January 31, 2005 (Att. 50).
[119] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab A – Email from Office of Ethics to Dr. Hampshire Feb. 8, 2005 (Att. 42).
[120] *Id.* at p. 14 (Att. 42).
[121] *Id.* Because Dr. Hampshire seldom checked the website, she had no idea that GAI had ordered thousands of dollars of non-prescription supplies from the website, which gave it the appearance of being active. See Letter from Dr.Victoria Hampshire to the Senate Finance Committee dated April 11, 2005 (Att. 1).
[122] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab A – Email from Office of Ethics to Dr. Hampshire Feb. 8, 2005 (Att. 42, Exh. 6).
[123] *Id.*

that the request from the Office of Ethics was not initiated by that office, but was requested as part of the investigation being conducted by OIA.[124]

a. Re-Submission of Dr. Hampshire's Ethics Filings

Dr. Hampshire submitted her updated OAR on February 8, 2005 pursuant to the Office of Ethics request.[125] She continued to correspond with the Director of Ethics and other officials within the Office of Ethics and CVM regarding her disclosures.[126] On the morning of February 11, 2005, Dr. Hampshire was still unaware of the ongoing investigation into her activities. Later that day, Dr. Hampshire had lunch with a friend who was also employed at the CVM, who informed her that there was an investigation ongoing and that she should consider other employment.[127] This colleague informed Dr. Hampshire that representatives from Wyeth had obtained information about AVA and that they were looking into her outside activity.[128]

Dr. Hampshire told Committee staff that, upon hearing this, she began to fear that she did not adequately detail the AVA website on her disclosure forms.[129] As a result of this, Dr. Hampshire said that she returned to her office and called Dr. Sundlof's assistant to ask if it was too late to attach a new comment sheet to her OAR.[130] She was informed that Dr. Sundlof had not reviewed the OAR yet.[131] Dr. Hampshire then retrieved the disclosures she had prepared and given to Dr. Sundlof as a result of the February 8th conversations from the pile of OARs that were waiting to be signed by CVM Director Sundlof.[132] Dr. Hampshire told Committee staff that she thought that, in responding to questions by Office of Ethics staff, she should add a new comments page indicating that AVA website contained an internet pharmacy component.[133] Dr. Hampshire placed a pink note on the documents noting the new detailed version of the OAR.[134] According to Dr. Hampshire, she was under the mistaken impression that her supervisors and officials in the Office of Ethics had not yet read the form and that submitting it as amended was insignificant.

On Monday, February 14, 2005, after receiving the copy of Dr. Hampshire's amended outside activities form, the OIA agent called the Office of Ethics that had reviewed Dr.

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[124] Specifically, one of the Agents wrote in the OIA investigative report that he asked Ethics to request an update from Dr. Hampshire on her outside activities. OIA Investigative Report January 31, 2005, at p. 3 (Att. 42B). This request initiated the exchange on February 8, and all documents obtained and communications with Dr. Hampshire were transmitted by Ethics to OIA. Individuals within the Office of Ethics were prohibited from replying to Dr. Hampshire's inquiries until Ethics personnel consulted with OIA Agents investigating Dr. Hampshire. (Letter from David Boyer, Documents at Tab A—Email from Office of Ethics to Dr. Hampshire Feb. 8, 2005) (Att. 42).

[125] Dr. Hampshire's OAR form (Att. 42A).

[126] Letter from David Boyer, Documents at Tab A—Emails between Dr. Hampshire and various FDA personnel. (Att. 42).

[127] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).

[128] *Id.* This friend was later disciplined for advising Dr. Hampshire of the on-going investigation.

[129] Dr. Hampshire's OIA statement (Att. 42A).

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).

[134] *Id;*, Dr. Hampshire's OIA statement (Att. 42A)

Hampshire's OAR and asked "why four members in the chain of command would sign off on that document."[135] Dr. Wardrop, CVM's Chief Executive Officer, replied that he had not seen an OAR with such language and pulled a copy from his personal safe that did not include the additional language that Dr. Hampshire included in her amended form.[136] These originals without the additional language were sent to OIA on February 17, 2005, by the Office of Ethics.[137]

b. Criminal Referral to the United States Attorney's Office for the District of Maryland

At this point the OIA Agents still had not spoken with Dr. Hampshire. Aside from the information her colleague provided to her at lunch, Dr. Hampshire said she had no knowledge of the ongoing criminal investigation, and that she changed the OAR because of her concern over her co-worker's warning.[138] She erroneously believed that amending the form was innocuous.[139]

OIA agents prepared and submitted a referral letter to the United States Attorney for the District of Maryland (USAO).[140] This referral recommended prosecution of Dr. Hampshire for criminal violations of conflict of interest statutes, as well as for false statements to government officials.[141] The language of the referral letter indicates that OIA was unaware of some of the facts, however. For instance, the referral letter stated, "Through the web portal of Advanced Veterinary Applications (AVA), the subject [Dr. Hampshire] also advertises heartworm medications which compete with Pro Heart 6. An agent acting on behalf of Fort Dodge Animal Health had two orders filled through AVA."[142] This statement is inaccurate. FDAH had failed to get any orders for heartworm medication filled through AVA.

The referral letter also notes that, of the $774.55 received from 2002 through 2005 for VetCentric orders, $472.57 was paid to Dr. Hampshire from the orders placed by the agent for Fort Dodge Animal Health "to cement their Conflict of Interest Allegation. In this regard it is the opinion of the investigating agent that although the dollar amount may seem minimal, as an employee of the FDA, the subject has a grave and continuing conflict of interest."[143] This statement is also inaccurate.

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[135] OIA Investigative Report, March 7, 2005, at 3 (Att. 42A).
[136] *Id.*
[137] *Id.*
[138] *Id.*
[139] *Id.* (Dr. Hampshire's OIA statement); Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1)
[140] Referral Letter from FDA Office of Internal Affairs to Assistant United States Attorney Dunne dated Feb. 23, 2005 (Att. 2).
[141] *Id.*
[142] *Id.*
[143] *Id.* The items ordered from the website were ordinary items not requiring a prescription. Moreover, Dr. Hampshire informed Committee staff that she was never paid for the VetCentric order, because she apparently threw away the check for that order, thinking it was junk mail. See Dr. Hampshire's Letter to Senate Finance Committee (Att. 1).

OIA told the USAO that "When an order is placed through [Dr. Hampshire's] web site it is actually filled by a firm named VetCentric which fills and ships the order," and that there was "no evidence of a Nexus between Dr. Hampshire ... and VetCentric."[144] The letter nonetheless indicates that Dr. Hampshire's 2003, 2004, and 2005 Confidential Financial Disclosure Reports were deficient because she does not mention that AVA had an internet pharmacy component.[145] While the letter recommended consideration of potential violations, it also noted that the investigation found, "no evidence to suggest the subject committed any fraud when compiling Adverse Event Reports for ProHeart 6."[146] By letter dated February 24, 2005, the USAO declined criminal prosecution of Dr. Hampshire.[147]

c. The Administrative Case against Dr. Hampshire

OIA continued to build an administrative case against Dr. Hampshire. On February 24, the same day the United States Attorney declined prosecution, OIA Agents notified Dr. Hampshire that they needed to speak with her.[148] Dr. Hampshire advised the Committee that she met with two OIA agents that afternoon. According to Dr. Hampshire, the FDA agents informed her that there had been an ongoing inquiry into her conduct and that this was no longer a criminal matter. More importantly, Dr. Hampshire was advised that the investigation had originated from information generated by Wyeth, including attempts to see if she would dispense heartworm prescription products without a valid veterinary client relationship.[149] OIA also informed Dr. Hampshire that OIA had attempted to obtain prescription products from the AVA website, downloaded all of her emails and internet usage, and had determined that most of her clients were friends and neighbors.[150] Next, OIA agents pressed Dr. Hampshire regarding the changes she made to her outside activities form and stated that the changes raised integrity issues.[151]

The OIA agents questioned Dr. Hampshire on various topics during the February 24, 2005, interview, including details of her amendment to the OAR on February 11. One of the agents told Dr. Hampshire that he had been one of the people attempting to order heartworm medication to see if she would dispense the product without a prescription or a valid veterinary client relationship.[152] Further, according to Dr. Hampshire, the OIA agents referred to contacts she made with Congressman Van Hollen, who had asked FDA about her reassignment, and asked her if she had "called off the congressman."[153] Dr.

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[144] Referral Letter from OIA to the United Sates Attorney's Office dated Feb. 23, 2005 (Att. 2).
[145] *Id.* Ironically, Dr. Hampshire's retrieval of her 2005 Confidential Financial Disclosure Report was for the purpose of clarifying that AVA had a link to an internet pharmacy—a clarification for which she was referred for criminal prosecution.
[146] *Id.*
[147] Letter from Asst. United States Attorney Dunne to FDA Office of Internal Affairs, February 24, 2005 (Att. 43).
[148] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[149] *Id.*
[150] OIA Investigative Report, March 7, 2005, at 3 (Att. 42A).
[151] *Id.*
[152] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[153] *Id*; see also OIA Investigative Report, March 7, 2005 (Att. 42A); Dr. Hampshire informed my Committee staff that the OIA Agents specifically questioned her during their interview about the confidential communications between Dr. Hampshire and a member of Congress. While it appears this line

Hampshire provided OIA a sworn statement regarding the events surrounding her OAR amendment.[154] Finally, she informed OIA that other veterinarians at CVM utilized VetCentric prescribing accounts as part of their outside activities, in addition to other third party prescription filling houses.[155]

d. Remark by a Wyeth Sales Representative about Dr. Hampshire

The investigation into Dr. Hampshire remained open into the summer of 2005. The next entry into her OIA case file indicates that, during the summer, FDA received a letter from a veterinarian who was outraged by disparaging remarks a Wyeth field representative made about Dr. Hampshire.[156] This veterinarian wrote that a Wyeth field representative told her that Dr. Hampshire, "had generated $70,000.00 in one year from competitor product sales."[157] Further, this veterinarian reported that the Wyeth representative said that Wyeth had Dr. Hampshire "investigated by private detectives." This Wyeth representative went on to say that information about Dr. Hampshire's financial interests "had all been verified."[158] Finally, the Wyeth representative stated that once Dr. Hampshire was "taken care of," the adverse event reports would drop off and that the product would return to the market.[159]

Upon receiving this letter and determining that the letter contained "egregious claims," OIA decided that the matter was "best handled with a formal response to Fort Dodge Animal Health [Wyeth] by FDA legal counsel."[160] No formal correspondence from FDA Legal Counsel to Wyeth regarding this referral from OIA was ever produced to my staff. Mr. Secretary and Commissioner von Eschenbach, I reiterate my official request for a copy of that correspondence, if it exists.

Ultimately, OIA reported its findings of the investigation to then-CVM Director Sundlof via the CVM Executive Officer.[161] The Executive Officer for CVM reported back to the OIA agents on July 19, 2005, that Dr. Hampshire and the colleague who tipped her to the ongoing OIA investigation were both provided "a verbal reprimand and counseling by their supervisors and a memo documenting these actions was completed and retained by their respective supervisors."[162] The OIA case against Dr. Hampshire

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of questioning was only cursory, it must be noted that retaliation by federal agencies for contacting Congress is not new and could be construed as intimidation for protected whistleblowing in violation of the Whistleblower Protection Act, among other federal statutes.

[154] Although OIA alleged to the United States Attorney's Office in its referral letter (Att. 2) that Dr. Hampshire received $774.55 from Oct. 21, 2003 through February 23, 2005, Dr. Hampshire has informed Committee staff that she only received around $200, because she accidentally threw away a check for $472.57, thinking it was junk mail. Letter from Dr. Hampshire, April 11, 2005 (Att. 1). Technically, however, the website generated $774.55 over that time period.

[155] OIA Investigative Report, March 7, 2005, at 4 (Att. 42A).

[156] Letter dated 2005 (redacted by Committee Staff) (Att. 55); OIA Investigative Report, September 2005, at 2 (Att. 42D).

[157] *Id.*

[158] *Id.*

[159] *Id.*

[160] OIA Investigative Report, Sept. 23, 2005, at 2 (Att. 42D).

[161] OIA Investigative Report, June 8, 2005, at 2 (Att. 42C).

[162] OIA Investigative Report, Sept. 23, 2005, at 2 (Att. 42D). Dr. Hampshire informed Committee staff that the OIA agent told her he was going to recommend that she be reprimanded for changing her OAR without

was closed by report dated September 23, 2005.[163] Despite the completion of the investigation and the determination by OIA that Dr. Hampshire committed no fraud in the adverse event report collection for ProHeart 6,[164] Dr. Hampshire was not provided an opportunity to return to her previous position.

III. Conclusions and Recommendations

The series of events set forth in this Letter describe the removal of the lead adverse drug coordinator on ProHeart 6 issues from her position, ostensibly at the request of an industry sponsor, without sufficient proof of wrong-doing. Although a conflict-of-interest allegation deserves serious attention, this investigation, which includes information readily available to the FDA (particularly FDA agents) at the time of the events described, has shown that the allegations presented by Wyeth in its November 19, 2004, slide presentation were misleading.

For instance, Wyeth informed FDA that Dr. Hampshire was operating an internet pharmacy.[165] The AVA website, however, was a portal from which customers could order products from VetCentric, which was an independent pharmacy. A customer ordering products had to click on a "store" button that would take the customer to the VetCentric link.[166] Wyeth was fully aware that orders for products were sent to VetCentric for processing, shipping, and invoicing, because it so informed FDA during its November 19, 2005, slide presentation.[167]

Wyeth also told FDA that, because Dr. Hampshire's AVA website offered access to one or more products sold by VetCentric that were competitive with Wyeth's ProHeart 6, this demonstrated a conflict of interest. VetCentric, however, also offered ProHeart 6 (tablet form) and other Wyeth products.[168] Moreover, Dr, Hampshire informed the OIA agents that it is not uncommon at CVM for veterinarians to have similar arrangements with third-party fulfillment houses such as VetCentric.[169] The only significant activity on Dr. Hampshire's AVA site was, coincidentally, created by Wyeth itself. This may have resulted in the OIA agents' mistaking this activity as evidence of a "conflict of interest."[170] It appears that FDA agents failed to conduct a thorough investigation into the Dr. Hampshire matter prior to making a referral to the USAO.

In addition, Wyeth indicated to the FDA that Dr. Hampshire had inappropriate contacts with anti-ProHeart 6 activists.[171] Although several activists did contact Dr.

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getting permission from Dr. McChesney. She said that she was supposed to receive a written reprimand from Dr. McChesney, but that she did not receive one, nor has she seen one in her personnel file.

[163] *Id.* The report synopsized the issues, but did not set forth any findings.

[164] Referral letter from FDA-OIA to USAO dated Feb. 23, 2005 (Att. 2).

[165] See Wyeth's November 19, 2005 slide presentation (Att. 8).

[166] GAI's Interim Research Report, Oct. 12, 2004, Bates GA-4-00202 (Att. 26).

[167] Wyeth's November 19, 2005 slide presentation at p. 8.

[168] Dr. Hampshire's Rebuttal to Wyeth's slide presentation (Att. 44).

[169] OIA Investigative Report, March 7, 2005, at 4 (Att. 42A).

[170] See Letter of Referral from FDA Office of Internal Affairs to Assistant United States Attorney Dunne (Att. 2).

[171] See Wyeth Nov. 19, 2004 slide presentation (Att. 8).

Hampshire, such contacts were to report adverse events and her responses to these contacts were well within her job description.[172] Finally, the two emails offered by Wyeth to demonstrate that Dr. Hampshire's peers feared that she was on a vendetta came from two veterinarians with ties to FDAH (see footnotes 43, 45). That information, however, was not revealed by Wyeth to the FDA.

The allegations regarding Dr. Hampshire's bias against ProHeart 6, as pointed out above, were eventually rejected by FDA. Significant resources, however, were devoted to investigating Dr. Hampshire.[173] These resources may have been saved had the former FDA Commissioner, former Chief Counsel, and/or Director of CVM approached Dr. Hampshire and inquired about the information presented by FDAH. Instead, resources were expended by (1) two FDA/OIA Special Agents, (2) HHS/OIG, and (3) the USAO, not to mention (4) other offices within FDA. Further, the only violation that Dr. Hampshire committed and that was proven by FDA—amending her OAR forms—apparently happened because she learned of an investigation into her outside activities and panicked. Thus, it appears that Dr. Hampshire was verbally reprimanded as a result of the investigation conducted by the OIA agents and not as a result of any proactive campaign against an industry sponsor. By mishandling an investigation and submitting material to law enforcement that was rife with error, FDA not only wasted resources, it created serious doubts about the integrity of its processes.

Based upon these findings, I offer the following recommendations to the FDA and would appreciate your comments.

A. Require Formal Disclosure and Full Documentation of All Meetings Held by FDA Staff with Regulated Sponsors

At present, FDA regulations allow and encourage the FDA to accept requests for private meetings with every person outside the Federal Government.[174] These requests can be made by industry sponsors, as was the case with former FDA Commissioner Crawford agreeing to meet with Wyeth and FDAH representatives. The regulations state "An official transcript, recording, or memorandum summarizing the substance of any meeting described in this section will be prepared by a representative of FDA when the Agency determines that such documentation will be useful."[175]

Because the standard for documenting meetings is discretionary, it could potentially allow meetings with senior FDA employees to go unrecorded. In the case of the November 19, 2004, meeting that then-FDA Commissioner Crawford and then-Chief Counsel Troy had with FDAH and Wyeth representatives, FDA officials made a

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[172] Dr. Hampshire's Rebuttal to Wyeth's slide presentation (Att. 44).
[173] GAI, the firm that investigated Dr. Hampshire, estimated that its investigation cost about $20,000. Letter from Pamela Stuart, Attorney for Lea Ann Germinder, to Sen. Grassley, May 16, 2006 (Att. 15). We have no estimates from FDA regarding its expenditure of investigative man-hours, duplication of resources required to get Dr. Hampshire's replacement for the VMAC meeting up to speed, and time spent by supervisors and others on this matter.
[174] 21 C.F.R. § 10.65(c) (2006).
[175] 21 C.F.R. § 10.65 (e) (2006) (emphasis provided).

determination that documentation of the meeting was necessary.[176] The documentation of the meeting on November 19th is sparse and unhelpful, however.

Regarding Dr. Hampshire, the memorandum notes that, "Wyeth representatives conveyed their concerns with the FDA assessment of adverse reaction data, and a potential conflict of interest issue."[177] This is the only statement about the conflict of interest issue. This one sentence does not begin to describe Wyeth's production and delivery to the FDA of more than 25 slides of information challenging Dr. Hampshire's credibility. Further, the memorandum does not mention that this information was to be referred to the CVM Director for appropriate action. The bare-bones memorandum, which does not fully describe the events that transpired or the follow-up action that was recommended, thus effectively failed to disclose the real substance of the meeting. This is the sort of double standard that highlights the problem with transparency at the FDA: the transparency is there; you just can't see it.

My Committee staff received no further documentation from the FDA regarding any of the other contacts or meetings that then-FDA Commissioner Crawford or other FDA officials had with Wyeth/FDAH. However, OIA agents informed Committee staff about numerous contacts between them and FDAH's Chief Counsel.[178] The flow of information between OIA agents and FDAH's Chief Counsel is of great interest to me. It appears that all the industry sponsor's Chief Counsel had to do was to pick up the phone in order to contact an OIA agent. In order for me to converse with OIA, I have had to resort to obtaining a subpoena.

In addition, notes provided by Wyeth regarding a conversation between Dr. Corcoran of FDAH and Dr. Sundlof of the FDA, provide evidence of FDA's release of pre-decisional information to the company. Clearly, documentation of these meetings and discussions would provide much-needed insight into the interactions between the FDA and industry sponsors, and whether such interactions are appropriate. Accordingly, I recommend that new policies and procedures be put in place that require formal disclosure and full documentation of all meetings held by FDA staff with regulated sponsors.

FDA's failure to document has been brought to the FDA's attention on numerous occasions. I am now seeking your assurance, Mr. Secretary and Commissioner von Eschenbach, that this issue will be promptly resolved.

B. Improved Management of Internal Investigations

This case represents, among other things, a breakdown in FDA's internal investigation processes. Regarding the initial inquiry into Dr. Hampshire, then-CVM Director Sundlof chose not to discuss Wyeth's allegations with Dr. Hampshire and instead referred the matter to OIA Special Agents. This led to a poorly handled investigation involving significant resources and created an environment of fear that

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[176] See, Memorandum of Meeting between Wyeth and FDA Officials, November 19, 2004 (Att. 38).
[177] *Id.*
[178] See, FTDO 001654 (Att. 11).

apparently encouraged Dr. Hampshire to engage in the activity for which she was ultimately reprimanded—altering her ethics form.

I am not suggesting that all internal investigations of FDA employees be brought to the employees' attention. This case required a more thorough analysis of the facts and issues by the FDA to determine if the circumstances presented were merely a misunderstanding, or something else that required further action by law enforcement. In this instance, which may have been a unique situation, one question to Dr. Hampshire could have quickly resolved the matter. Asking Dr. Hampshire about her AVA website would, in all likelihood, not have compromised the investigation, nor would it have been anything other than a question that should—and could—be asked in a normal business setting.[179] Moreover, FDA should have independently examined the information Wyeth presented at the November 19, 2004 meeting.[180]

Yet another example of questionable management involves the letter sent to the FDA from a veterinarian who was outraged by a Wyeth field representative's disparaging remarks regarding Dr. Hampshire.[181] OIA apparently forwarded the letter to FDA Legal Counsel for appropriate action.[182] No evidence of any follow-up by FDA, however, was provided to my staff. If there was any follow-up by FDA, I request that I be informed immediately.

Regarding the February 23, 2005, referral letter sent by OIA to the United States Attorney's Office for the District of Maryland, I request that both the HHS and FDA describe in detail any policies and procedures that will be put into place to ensure that future referrals to the USAO will not be riddled with inaccuracies. I would also like to know (1) whether the referral to the USAO was reviewed by FDA/HHS counsel and, if so, who reviewed it; (2) whether the referral was reviewed by any individual(s) other than

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[179] Apparently, the practice of CVM veterinarians of using independent pharmacies, which Dr. Hampshire informed us was widely used at CVM, was not understood by FDA management or the OIA. After Dr. Hampshire explained the practice to management, CVM Ethics instated a clarification regarding the "Private Practice of Veterinarians," effective July 20, 2005, which states that "writing valid prescriptions to be filled by an independent pharmacy is entirely within the scope of veterinary practice" and "clearly acceptable as an outside activity for CVM employed veterinarians." See, "Outside Activity Process-Private Practice of Veterinarians." (Att. 54).

[180] One additional example of mismanagement occurred after the Committee's investigation was made public. On November 18, 2005, FDA spokesperson Susan Bro, who has since left the FDA, notified *Reuters* news service that the investigation into Dr. Hampshire was done with "Dr. Hampshire's knowledge." Letter from Senator Charles Grassley to Dr. Andrew von Eschenbach, Acting Commissioner, FDA, Nov. 30, 2005 (Att. 46). Further, Ms. Bro stated that the FDA investigation of Dr. Hampshire was not criminal, in direct contravention of the facts (*i.e.*, that a criminal referral had been made by OIA agents earlier that year in February 2005). Whether or not this was an intentional misstatement is unknown. However, it is difficult to understand why Ms. Bro made these statements, in light of the fact that Dr. Hampshire's attorney pointed out these inaccuracies to Ms. Bro's staff prior to the release of the statement. *Id.* This inaccurate statement to *Reuters* represents an instance where effective internal communication could have resulted in a correct response to the media. Further, despite un-contradicted evidence of this inaccuracy made to the press, FDA failed to set the record straight and correct the inaccurate statements made by Ms. Bro.

[181] Letter dated summer, 2005 (redacted) (Att. 55).

[182] OIA Investigative Report, Sept. 2005 (Att. 42D).

the signatory and, if so, who were the individual(s); and (3) who will be held accountable for this misleading letter.

C. New Procedures for Suspension of Advisory Panels when Sponsor Raises Allegations against FDA Employees

The FDA has guidance regarding conflicts of interest and advisory panel members, and conflict-of-interest reporting by FDA employees.[183] The case involving Dr. Hampshire raises questions, however, about yet another type of conflict of interest: a potential for targeted removal of FDA employees or panel participants who may not fully support the sponsor's views.

As part of this investigation, my Committee staff requested a list of all known OIA investigations since 1996 that were based on the complaints of industry sponsors.[184] There were several identifiable instances of such investigations. Although various reasons motivated these investigations, one common thread exists among all of the industry-initiated complaints to the FDA: there are no procedures at FDA to postpone advisory committee meetings when industry sponsors raise serious allegations against a panel participant and/or an FDA presenter. This potential loophole could allow industry sponsors to attempt to affect the votes of an advisory committee by removing individuals who possess information contrary to the sponsor's position. Therefore, I recommend that HHS and FDA create a list of requirements for those situations where industry sponsors seek to exclude an FDA employee from participating in an advisory committee meeting. The FDA should have the ability to potentially delay the proceeding until the allegations are substantiated or some other reasonable action is taken (a person with similar skills, qualifications, and understanding of the topic of the advisory committee meeting is up to speed with the presentation.) Although allegations of misconduct should always be taken seriously, they should not be acted upon without first conducting due diligence.

I look forward to hearing from both of you on how HHS and FDA intend to deal with these issues.

IV. Closing

Throughout my investigation, internal FDA sources revealed concerns and disagreements held by and between CVM scientists who are involved in the ongoing scientific review of ProHeart 6. In particular, my Committee staff has received

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[183] The FDA has new draft guidance procedures for removing and recusing members from FDA advisory committees, such as the VMAC, when there are conflicts of interest posed by participation of certain members. *See* http://www.fda.gov/oc/guidance/advisorycommittee.html. The FDA code of conduct requires that employees disclose potential conflicts of interest, such as the form 450 OAR that Dr. Hampshire filed in this case. The code of conduct also requires these individuals to recuse themselves from any advisory committee should they have a real or apparent conflict of interest. Further, any FDA employees who are Commissioned Officers in the Public Health Service are bound by a similar code of conduct and ethics as part of their oath to the PHS. Therefore, supervisors should be aware of the need to recuse and police FDA employees accordingly.

[184] *See* Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab E (Att. 45).

information which suggests that internal disagreement exists over whether or not old and new studies substantively address all historically reported major adverse events associated with ProHeart 6 use in dogs. By this Letter I am advising both of you that I am concerned that the scientific process is being compromised internally. In light of the findings presented in this Letter and the fact that FDA sources to this day continue to bring concerns about ProHeart 6 to my attention, I believe that involvement by FDA management at the highest levels may be necessary to ensure the integrity of FDA's processes. However, if it is decided that this matter does not need to be elevated to the highest levels, please advise me of that decision immediately.

While the details of this Letter are aimed at reforms at the FDA and the missteps made in investigating Dr. Hampshire both criminally and administratively, culpability does not lie with the FDA alone. It is uncontroverted that industry representatives ought to have a good working relationship with the FDA, but under no conditions should the scientific process be compromised by industry pressure.[185]

Moreover, I would appreciate a personal assurance from both of you that no retaliation will be taken against any person who contributed, either directly or indirectly, regarding this Letter, or who may contribute to any future investigation of ProHeart 6 that I might undertake.

In closing, please provide a response to the concerns, findings and recommendations contained in this Letter by no later than February 25, 2008. Should you have any questions please feel free to contact Angela Choy or Elizabeth Rinaldo of my staff at (202) 224-4515. All formal correspondence should be sent via electronic transmission in PDF format or via facsimile to (202) 228-2131 and original by U.S. mail.

Sincerely,

Charles E. Grassley
Ranking Member

Attachments

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[185] Additionally, the actions of Lea Ann Germinder were also problematic. Ms. Germinder's recollection of the events appears to be supported by the extensive documentation provided by GAI, including a contract with a private investigator. It appears that once the Committee inquiry into Wyeth's involvement in investigating Dr. Hampshire began, however, Ms. Germinder attempted to reduce her involvement, telling Committee Investigators that she did not understand why Wyeth had her do this investigation and that in hindsight it made her uneasy. These post-hoc sentiments aside, Ms. Germinder acted as the intermediary and coordinator for the private inquiry into Dr. Hampshire that led to the internal FDA investigation. While it was only one piece in the equation, her assistance to Wyeth, including hiring the private investigator, cannot be denied. Nonetheless, we appreciate Ms. Germinder's help and cooperation with our investigation.

Statement of Michael O. Leavitt
Secretary, U.S. Department of Health and Human Services
FY 2009 Budget Request for the
Department of Health & Human Services
Wednesday, February 6, 2008

Chairman Baucus, Senator Grassley, 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 week 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 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 gives 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 requests the President propose legislation that will change the trajectory enough to bring general revenues back below 45 percent. We will formally respond to the

trigger in coming days, 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 how to achieve the widely held aspiration that all Americans have access to an affordable, basic health insurance policy. 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.

A transformed health care system will provide the opportunity to avoid costly and unnecessary medical visits, and emphasizes upfront, affordable private health insurance options. 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.

As I noted, this is broad, systemic change. However, Medicare can be a significant force in shaping such a change.

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 nearly $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 above 200 percent of the Federal Poverty Level, 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 a new Food Protection Plan and proposed significant improvements in how we deal with imported products.

The President's budget increases funding for food safety by 7 percent, and the overall FDA budget by 5.7 percent. Eighty percent of the FDA budget pays for people. In two years, we will have added more than a thousand people at FDA. I mention that as an indication of how seriously we take the need to prepare aggressively for the future.

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.

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.

United States Senate Committee on Finance
Public Hearing
"The President's Fiscal Year 2009 Budget Proposal for the Department of Health and Human Services"
February 6, 2008

Questions Submitted for the Record

Senator Baucus:

1. *SCHIP*

Question

Mr. Secretary, last August, CMS sent a letter to state health officials announcing significant changes to the Children's Health Insurance Program, or CHIP. There was a great deal of controversy surrounding that letter. Many of us who were working on CHIP reauthorization thought that the restrictive nature of the changes was misguided. We also thought that a letter was not the legal and proper way for an agency to make such changes.

Now, you come before us with a budget request that contains a legislative proposal to codify the August 17th directive. You are asking Congress to help you make the changes CMS already made.

I wonder why. Does this mean that you agree with those of us who believe that CMS lacks the authority to impose these new policies through a letter?

The legislative proposal goes one step further. It would reduce the threshold from 250 percent of poverty to 200 percent. Nineteen states cover kids at 200 of poverty and another 26 states cover kids above 200 percent of poverty. So, your proposed change would make it harder for most states to cover poor kids.

The majority of Americans, and the majority of the members of Congress, support a different approach. We want a robust program. We want to cover more kids. You and the president say you want to cover kids, but this proposal would accomplish just the opposite. Can you explain why you are trying to narrow CHIP rather than expand it?

Response: Continuing efforts to prevent the substitution of the State Children's Health Insurance Program (SCHIP) for private insurance is one component of the President's larger legislative proposal on SCHIP reauthorization. The August 17th State Health Official letter reminds the States of their existing statutory obligations to targeted low-income children, including obligations to find and enroll such children "in an effective and efficient manner that is coordinated with other sources of health benefits coverage" before States consider expanding to higher income levels. Statutory authority for the August 17th guidance is found

in Section 2101(a) and Section 2102(b)(3)(C) of the Social Security Act, and implementing regulations at 42 C.F.R. 457.805.

The President's FY 2009 Budget proposal actually contains several important elements to reauthorize SCHIP and to re-focus the program on uninsured, targeted low-income children, including this policy to put poor children first. The Administration strongly supports this important program and is committed to securing the necessary legislative changes so that SCHIP can be responsibly reauthorized. We look forward to working with all Members of Congress to achieve the goal of reauthorization through 2013.

2. *Medicare*

Question

Your budget is very helpful in at least one sense: it makes the ideological preferences of the Bush Administration crystal clear to the American public. By proposing staggering cuts to traditional Medicare providers – hospitals, nursing homes, hospice facilities – while protecting generous payments to insurance companies, your budget would have catastrophic consequences for the fee-for-service benefit. This is the benefit that, for over 40 years, has guaranteed health care for our nation's seniors.

I should note that I have welcomed, and continue to call for, meaningful dialogue regarding our nation's rising health care costs. But by replacing constructive discussion with ideological fervor, your budget ignores that challenge.

Question

a) Mr. Secretary, in the effort to restrain health care spending, can you explain the rationale behind exclusively targeting health care providers while completely ignoring payments to private insurance plans?

Response: The savings as proposed in the President's FY 2009 budget do not come solely from Medicare Parts A & B, but the President's budget proposals will also result in significant cuts to Medicare Advantage (MA) plans. The reductions in payments to Original Medicare would result in $44 billion in payment cuts to MA plans, an amount that is roughly one quarter of the total provider outlay savings.

Question

b) Mr. Secretary, most economists agree that Medicare Advantage plans will merely transfer these cuts to providers. Given MedPAC's findings that Medicare Advantage plans are paid more per beneficiary than is spent in traditional Medicare, shouldn't we at least consider reforming that program as well?

Response: I am aware that, per the payment structure established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, MA plans on average are paid higher than traditional Medicare. However, it is important to remember that MA plans are not identical to traditional Medicare. MA plans

provide an important choice for beneficiaries, and most offer additional benefits beyond what traditional Medicare would cover. While it is true that MA plans in most regions are being paid more than the FFS rates, the vast proportion of the extra amounts are required to go directly to beneficiaries in the form of reduced cost sharing or extra benefits. The Administration continues to support policies that will ensure all beneficiaries across the country have access to these plans.

Question

c) The President's budget misses the point. We cannot simply ratchet down payments across the board and say this improves 'efficiency' and 'competition.' Let's be real. Payment cuts of this magnitude could jeopardize access to Medicare providers. Did the President's budget contemplate the number of providers who would simply drop out of the Medicare program if they had to endure sustained cuts and freezes of this magnitude? If so, how many doctors, hospitals, etc. would leave? Or does President's budget presume all providers would stay in the game and be 'more competitive' with sustained payment cuts?

Response: Without reductions in payment increases, Medicare costs will almost double by 2018. Even a payment freeze won't keep overall payments to providers constant as increased use of services will continue to drive up overall provider payments. The proposed payment freezes help preserve access for Medicare beneficiaries. Without them, Medicare spending is expected to increase by 7.0 percent over the next 10 years (FY 2009-2018), and Medicare beneficiaries will face increases in their premiums and co-payments. We believe that providers will continue to participate in Medicare. Private markets adapt to produce efficiencies and improve productivity; the payment freeze encourages efficiencies in the delivery of health care services.

Question

d) The President's budget really hits hospitals hard. It proposes four or five different spending cuts that are indefinite. How do you envision that hospitals would respond to these proposals? What specifically do you think hospitals can do to absorb cuts of this magnitude? Do you think hospitals would reduce nursing staff ratios?

Response: Despite average negative profit margins, hospitals continue to have significant access to capital to expand their services. Hospital construction spending has grown 191 percent between 1999 and 2007, with $32.6 billion spent on construction in 2007 alone. In addition, the Medicare Payment Advisory Commission (MedPAC) has noted that all indicators of payment adequacy were positive for hospitals. MedPAC has also noted that the rate of cost growth has been high for the hospital industry when there has been low financial pressure. Hospitals historically have demonstrated that they can reduce costs without hindering access.

The Administration has been working on improving the accuracy of payments to hospitals and improving the quality of care provided. Medicare Severity-Diagnosis Related Groups (MS-DRGs), value-based purchasing, elimination of payments for never events, and the efforts of Medicare Quality Improvement Organizations all encourage hospitals to improve the quality and efficiency of the services they provide. It is only appropriate that some of the benefits from these efforts result in savings for the Medicare program.

3. *Medicaid regulations*

Question

Mr. Secretary, CMS has issued a slew of rules that will cut federal payments for Medicaid. This will result in increased costs to the states, which are already in tough fiscal situations.

Many of us in Congress are concerned about states' ability to absorb the cost shift. Indeed, a few of the rules are currently being delayed because Congress imposed moratoria. I am, however, disappointed that Congress cannot focus on Medicaid as a whole because we are trying to keep up with the regulations.

Mr. Secretary, when the Finance Committee held its hearing on your nomination, you vowed to work with us on issues of shared concern. However, I am not sure you consulted any of us as your department issued one regulation after another. We have written you letters of concern. We have talked publicly and privately with you about our concerns. But still the rules keep coming.

Secretary Leavitt, I will do all I can to protect Medicaid because America needs a health care safety net.

a) Can you help me understand why CMS appears to be able to work its will on the Medicaid program regardless of what the law says?

Response: We strongly believe that all of our work and these regulations in particular are consistent with our obligations under Title XIX of the Social Security Act. We believe they will bring greater transparency and accountability to the program. The law, in fact, places great responsibility on us to ensure that the States are meeting their obligations to appropriately finance their share of the Federal partnership.

I share your concern in protecting the Medicaid program so that it is available for those who need it. Each of these rules is vitally important to ensure the integrity of the Medicaid program; that Medicaid beneficiaries are receiving the services for which Medicaid is paying; that those services are effective in improving the health outcomes of individuals with Medicaid; and that taxpayers are receiving the full value of their dollars that are spent through Medicaid.

These recently issued regulations are part of our oversight responsibility to ensure that Medicaid payments are consistent with statutory requirements. Some regulations were issued at the express direction of Congress and other regulations interpret and implement statutory provisions enacted by Congress. The absence of legislation mandating the current approach did not eliminate the Secretary's authority or responsibility to ensure compliance with existing statutory provisions. The Department has exercised that authority through the rulemaking process, as required under the Administrative Procedure Act.

Question

b) Will you promise me that you and your department will work with this Committee and other members of Congress, on both sides of the aisle, moving forward?

Response: I appreciate that Medicaid is a vitally important program that serves very vulnerable populations. As such, I believe it is my duty to be a responsible steward for the Medicaid program. These regulatory actions have been taken to promote transparency and accountability in financing and to support efforts to maintain the integrity of the program. I remain committed to working with Congress in helping to advance the Administration's agenda.

4. *Medicaid drug pricing*

Question

Mr. Secretary, I am concerned about America's pharmacists. They have been dealing with major changes in both Medicare and Medicaid. In many communities around this country, the pharmacy is the cornerstone of the health care system. Beneficiaries often have more regular contact with their pharmacists than any other health care professional.

I have introduced two bills to help America's pharmacists. One related to the Medicare drug benefit and one for the Medicaid program. I am going to continue to push for enactment of these bills. I am proud to say that both of these bills enjoy strong bipartisan support.

I am troubled, though, by the administration's position. The president's budget proposes reducing Medicaid payments to pharmacies by $1.1 billion.

I would like you to explain why you think a billion dollars should come out of pharmacies' cash registers. Especially in light of the 8 billion dollars the CMS AMP rule would already take.

I would also like you to help me understand how the HHS OIG and the GAO were wrong when they predicted low reimbursement. I would like you to tell me how the US District Court was wrong when it found that the AMP rule posed irreparable harm to the pharmacy industry.

Please tell me why our concerns for America's pharmacies are unfounded.

Response: The President's FY 2009 Budget seeks to rationalize pharmacy reimbursement by building on changes to pharmacy reimbursement in the Deficit Reduction Act of 2005 (DRA), Public Law 109-171, which set the Federal Upper Limit (FUL) for all multiple-source drugs at 250 percent of the average manufacturer price (AMP). The FUL encourages states to pay pharmacies more appropriately for the estimated acquisition costs of generic drugs.

By lowering the FUL reimbursement for multiple source drugs to 150 percent of AMP, this proposal would result in significant savings for both State and Federal governments. The FUL would be set at one and one-half times the average price paid to manufacturers. We believe that this mark up will be sufficient to cover the wholesaler's fees and retail pharmacy costs. While states must not exceed the FUL for drugs in the aggregate, they retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists. CMS encourages states to set fees they pay pharmacies that are adequate and reasonable to compensate them for their costs in dispensing these prescriptions in accordance with 42 CFR §447.

As CMS noted in its response to the GAO draft report "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs" (GAO-07-239R), we believe the report to be based on incomplete and misleading information, as well as nondisclosed pricing data. CMS also emphasized the expected changes in utilization and cost data after implementation of the related DRA provisions, and we continue to believe that accurate data and valid calculations will only be attainable after these provisions have been fully implemented.

Finally, as noted in the CMS response to the OIG draft report "Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit," we find the OIG analysis to be deficient in data and methodology, and believe that an accurate analysis of the impact of this rule can only be conducted once the provisions of the DRA have been implemented.

5. *Case Management*

Question

Case Management has been the primary vehicle that states have used to develop plans of care, monitor the services provided to beneficiaries, and assure the overall health and welfare of recipients of Home and Community Based Services through the 1915c waiver. While the Department demands that States assure waiver participant health and welfare, it has emphasized in the new Targeted Case Management rules that participants in the waiver can reject case management as a service, can have only one case manager, and that States cannot deliver case management through Medicaid administration. How are states to assure the overall health and welfare of waiver participants given these new regulations?

Response: Section 6052 of the Deficit Reduction Act of 2005 (Public Law 109-171) redefined the scope of allowable case management services, strengthened state accountability, and required that CMS issue regulations. Therefore, CMS issued a rule that clarifies the definition of covered case management services. Case management consists of services which help beneficiaries gain access to needed medical, social, educational, and other services. "Targeted" case management services are those aimed specifically at special groups of enrollees such as those with developmental disabilities or chronic mental illness. The rule includes measures to address concerns about improper billing of non-Medicaid services to the Medicaid program by some States.

Under DRA law and this rule, services such as a comprehensive assessment of an eligible individual; development of a specific care plan; referral to services; and monitoring and follow-up activities are allowable case management services. This rule does not impact medically necessary services. Overall, the rule includes significant beneficiary protections that ensure comprehensive and coordinated services to meet the needs of beneficiaries. It is important to remember that the point of case management is to ensure a coordinated approach to medical and other supportive services. To achieve this objective, a single case manager must be accountable for all case management activities in accordance with a written care plan, so that beneficiaries will not "fall through the cracks" of a piecemeal case management approach.

Senator Grassley:

1.Question:
Last week, I wrote to Commissioner von Eschenbach about FDA's foreign inspections program. One of the issues of interest to me is the establishment of FDA facilities abroad. An important step to improving FDA's ability to inspect foreign pharmaceutical plants would be the establishment of offices in Asia, where pharmaceutical manufacturing is rising dramatically. When FDA officials briefed my staff in December, they indicated that no firm plan was in place for such an office. Commissioner von Eschenbach recently said that he wanted FDA presence abroad to be "ongoing and continuous" rather than "episodic and periodic," and that he planned to put "boots on the ground" in countries such as India and China. I'm interested in knowing more about the Department's role in this process.

a) Is HHS currently working with the FDA to establish offices in Asia?

b) If so, what efforts are underway, and in which countries?

c) What do you believe needs to be done to make FDA offices in India as well as in Asia a reality?

Response: This is a key priority of mine and over the next two years, we plan to station eight full-time FDA staff along with five locally-employed staff at the United States embassy in Beijing and the United States Consulates General in Shanghai and Guangzhou.

These experts will fulfill the first step in our Beyond our Borders initiative to locate FDA staff overseas to facilitate inspections and build capacity among foreign regulators.

We are looking forward to the Chinese government's expected agreement to this plan, and the granting of the necessary diplomatic visas and other credentials for our staff.

We are also hoping to open similar offices in India and in several other countries in the future. More remains to be done, and I look forward to working with the Committee toward this.

2.Question:
When FDA officials last briefed my staff on FDA's foreign inspections program, they reported disappointing numbers of inspections that were conducted over the last several years. In China, the world's largest producer of active pharmaceutical ingredients, and where export safety seems to be a growing problem, only 11 inspections were conducted during fiscal year 2007. I find that number very troubling, especially when compared to the number of inspections that were conducted in countries with robust internal controls—14 in Switzerland, 18 in Germany, and 24 in France for the same year. Is the Department of Health and Human Services satisfied with the current allocation of inspection resources?

Response: First we have to make clear that simply increasing inspections is not the solution. Similarly, comparing the number of inspections conducted in different countries is not a useful measure of relative health risk of drugs imported from those countries. In each of the recent years, FDA has increased the numbers of foreign drug inspections and the agency continues to allocate and prioritize inspection resources in the different countries according to the highest risk to the public health. It is the case that foreign inspection resources should be increased. However, foreign inspections are only one tool to address the risk associated with imported drugs. The Action Plan for Import Safety outlines a number of steps that will increase the safety of drugs and drug ingredients imported from China and elsewhere.

Collaboration with foreign governments and regulatory bodies, providing technical assistance, and other capacity enhancing activities are particularly important. In the case of China, we have held numerous meetings with Chinese officials on the topic of import safety, and in December 2007 signed two carefully crafted MOUs with China to enhance cooperation on U.S.- imported foods and medical products. We have already seen the fruits of these efforts in our ability to obtain visas for FDA inspection teams. In addition, plans are well underway to

establish an FDA office in China which will increase collaboration and information sharing and enable rapid response to potential problems with Chinese exports.

FDA now has confidentiality arrangements with 19 agencies in 18 countries (including the EU) that permit FDA to share and obtain non-public inspectional information concerning foreign drug manufacturing firms. These relationships offer FDA substantial opportunities to leverage the inspectional resources of other countries' competent regulators in order to obtain important information on the CGMP and other compliance status of foreign drug firms. Further, they provide for the exchange of timely information about products that have known and suspected safety problems.

The Action Plan also recommends a third party inspection programs as a way of leveraging inspection resources and providing more useful information to the FDA on the risk profiles of foreign drug firms. In addition, we are proposing to develop good import practice guidances, best practices for track and trace technologies, and continue to work on import safety priorities through our diplomatic relationships.

3. **Question**

I continue to be concerned about improper payments in the Medicaid and Medicare programs. GAO has reported for more than a decade on varied financing arrangements that inappropriately increase federal Medicaid matching payments. Further, GAO found that thousands of medical providers abuse the federal tax system.

a) What steps are the Centers for Medicare & Medicaid Services (CMS) taking to improve its oversight to limit abuse and what results are expected by the end of fiscal year 2009?

Question

b) How will you rein in Medicare costs while improving services? What approaches do you support to ensure that payments to doctors are for necessary services and are accurate?

Response: I share your concern with improper payments in the Medicaid and Medicare programs. CMS continues to enhance its program integrity efforts to improve oversight and limit abuse of these two critical programs.

First, let me respond to the two GAO study areas you have cited:

Medicaid Financing: There is, unfortunately, a long and complicated history that is marked by States seeking to inappropriately shift the State share of funding for the Medicaid program to the Federal government; Federal recognition of this practice predates 1991 when Congress enacted prohibitions on provider taxes and

donations designed for this purpose. Most recently, CMS has pursued administrative actions to identify and prevent the spread of loopholes used by States to inappropriately shift costs to the Federal government. The philosophical underpinning of these regulations is that Medicaid is a financial partnership between the States and the Federal Government, and that it is inappropriate for States to shift their matching responsibilities to either the Federal government or to providers.

Federal Tax Liabilities of Providers: The President's FY 2009 Budget includes a proposal that allows Medicare provider payments to be included in the Federal Payment Levy Program (FPLP), which would help the Treasury Department to collect outstanding tax debt of Medicare providers. In addition, HHS and CMS are continuing to provide assistance in exploring the legal and practical challenges of expanding the FPLP to Medicaid.

Overall, CMS continues to work diligently to improve its oversight and limit abuses in the Medicaid system and has several ongoing initiatives. As you are aware, the Deficit Reduction Act established the Medicaid Integrity Program and dramatically increased resources for CMS to combat Medicaid fraud and abuse. CMS has made significant progress towards developing a strong, effective, and sustainable program to combat, fraud, waste, and abuse in Medicaid and The Comprehensive Medicaid Integrity Plan covering FY 2007 to FY 2011 can be accessed on the CMS website at: http://www.cms.hhs.gov/DeficitReductionAct/02_CMIP.asp#TopOfPageCMS.

With regard to Medicare program integrity efforts, CMS has required that all existing Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) suppliers be accredited to meet quality standards by September 30, 2009. As of March 1, new DMEPOS suppliers are required to be accredited in order to get a Medicare billing number. We are also expanding a demonstration we implemented last year to prevent fraud in the home health benefit from two cities to nine additional cities. This demonstration requires home health agencies to re-enroll in the Medicare program. CMS is also conducting more stringent review of wheelchair claims and has instituted a demonstration in certain metropolitan areas that will validate enrollment of independent diagnostic testing facilities (IDTFs) in the Medicare program.

Further, CMS continues to work with our new Medicare Administrative Contractors (MACs) and Fiscal Intermediaries (FIs) to ensure that payments for all providers are accurate and for medically necessary services and items. The MACs and FIs do this by preventing future improper payments and their efforts include developing Local Coverage Determinations and local coding and billing articles; educating providers as a group and individually; and reviewing claims before they are paid either through "automated" reviews (conducted when no medical records are required to make a determination), or "complex" reviews (conducted when medical records must be evaluated to make a determination). In

addition to processing claims and preventing improper payments, MACs and FIs also detect past improper payments, recover overpayments, and refund underpayments.

We recognize the importance of provider education as part of the effort in ensuring that Medicare pays accurately and only for medically necessary services and items. CMS and its contractors have implemented Medicare educational programs that entail both broad-based efforts and more focused communications with specific providers or provider groups concerning specific billing problems. These efforts include the use of a wide array of CMS-developed educational products on coverage, payment, and billing. In addition to these products, CMS also offers national and local provider forums to assist providers in understanding Medicare program requirements. CMS also has dedicated provider contact centers that answer millions of provider calls annually.

With regard to your specific question about the accuracy of provider payments, Medicare is rapidly transforming from a passive payer into an active purchaser of high quality care by linking payment to the value of care provided. This transformation will shift from paying providers solely based on volume of services and create appropriate incentives to reward providers for providing high quality care. We have taken a number of steps in the various Medicare payment systems toward establishing a value-based purchasing program that is consistent with the four cornerstones identified in the President's Executive Order on value driven health care which include (1) health IT standards; (2) quality standards; (3) price standards; and (4) incentives.

Specifically, we have established the Physician Quality Reporting Initiative (PQRI) program that is a quality reporting system based on measures for physicians and other eligible professionals. We have also issued a report in November 2007 that lays out a plan towards implementing a Medicare hospital value-based purchasing program building from the existing quality data reporting model. Finally, we are conducting a number of demonstrations on pay-for-performance with hospitals, home health agencies, and physicians. We are awaiting the results of these demonstrations to inform us on further steps towards development and establishment of a value-based purchasing program in these payment systems.

4. **Question**

I am also concerned about abuse of nursing home residents and other vulnerable populations. GAO has reported that continued attention is needed to improve quality of care. Greater demands on resources continue to be an issue, and key CMS initiatives for improvement have experienced delays. How does CMS intend to maintain momentum in its oversight of this vulnerable population during fiscal year 2009 and the years ahead?

Response: Individuals in nursing homes are a particularly vulnerable population, consequently CMS places considerable importance on ensuring nursing home quality. The FY 2009 Survey and Certification budget request is $293 million. This program works to ensure the safety of beneficiaries and the quality of care provided in health facilities – two critical CMS responsibilities.

To ensure survey frequency levels are sufficient to safeguard patient safety and quality, the Budget requests an increase of $12 million, or 4 percent, over FY 2008. This request will allow States to inspect long-term care facilities and home health agencies at their legislatively mandated frequencies and to nearly maintain FY 2008 survey frequencies for all other facility types. This funding is essential to continue to improve the quality of care in nursing homes through rigorous survey and enforcement processes. CMS expects States to complete over 23,000 certifications and over 44,000 complaint visits in FY 2009, an increase of approximately 2,700 visits over the FY 2008 level.

Funding for the Survey and Certification Nursing Home Oversight Improvement Program (NHOIP) activities is included in direct survey costs, as these activities have become a standard part of nursing home survey procedures. NHOIP activities are intended to improve survey processes through targeted mechanisms such as, investigating complaints which allege actual harm within 10 days, imposing immediate sanctions for facilities found to have care deficiencies that involve actual patient harm, and staggering inspection times to include a set amount begun on weekends and evenings.

CMS has two performance measures related to the quality of care in nursing homes to assess the effectiveness of these and other survey and certification activities in nursing homes: reduction in the prevalence of restraints and pressure ulcers. Progress on these performance measures is due to the new and intense collaboration between survey and certification and the Quality Improvement Organizations, as well as careful work between CMS and nursing homes in the new national campaign entitled *Advancing Excellence in Nursing Homes*. In addition, CMS is working to improve surveyor training so that surveyors will be better able to detect inappropriate restraint use.

5. Question:

Given that you personally led the Pandemic flu summits around the country, what do you think should be done to continue to focus national preparedness—especially given that federal funding for infectious disease control has been cut at the federal level and funding for state and local governments is set to expire?

Response: Emergency preparedness planning since 9/11 has stressed preparing for all hazards. Pandemic planning presents a unique leadership role for the public health sector including strong collaborations with external partners including the private sector. Because of the overarching elements (economic, educational, and security) that cross all aspects of the community, pandemic planning, using many

of the elements from seasonal influenza planning, should be a continual element to be measured, evaluated and refined by federal, state and local partners. Funding is crucial to support the infrastructure for an all hazards approach to preparedness.

The FY 2006 pandemic influenza emergency supplemental funding included $600 million for state and local preparedness. Pandemic preparedness is a shared responsibility and must involve every level of government.

As of February 1, 2008, HHS has obligated $576 million (96 percent) of the $600 million:

On August 30, 2007, ASPR awarded $75 million to State and local grantees to increase medical surge capacity, establish stockpiles of critical medical equipment and supplies, support planning and development of alternative care sites, and conduct medical surge exercises for pandemic influenza.

On July 17, 2007, CDC awarded $175 million to assist public health departments in their pandemic influenza planning efforts.

In 2006, HHS awarded a total of $325 million for State and local preparedness and conducted over 50 State pandemic influenza summits.

HHS provided $1 million to the National Governor's Association (NGA) to assist States in upgrading their pandemic influenza preparedness capabilities.

The remaining $24 million appropriated for State and local preparedness will be awarded to States on a competitive basis this fiscal year.

In addition, the FY 2009 budget includes $971 million for State and local preparedness capacity building through the two preparedness cooperative agreements.

States are able to use these funds to support State and local preparedness.

6. **Question**
We have made significant progress in implementing Pay for Performance in Medicare, and I appreciate the collaboration we have had with you and your Department. In the budget, there is a proposal to require states to report on Medicaid performance measures and that Medicaid payment would be linked to performance. This is the second year in a row we have seen this proposal. Could you describe for us how the President's proposals would work and what progress you have made forwarding the proposal since last year?

Response: I am pleased that you share the Administration's interest in helping to improve the quality, efficiency, and delivery of medical care in the Medicaid

program. The President's FY 2008 Budget included a legislative proposal to implement Medicaid pay-for-performance. Through the Administration's FY2009 budget development process, this proposal was re-visited. The features of this proposal remain the same – requiring States to report on Medicaid performance measures and linking performance to Federal Medicaid grant awards – except the President's FY 2009 Budget proposes administrative action to implement the State reporting requirement. Specifically, the President's FY 2009 Budget proposes legislative action to link State performance on specific measures to Federal Medical Assistance Percentage (FMAP) reductions. We look forward to working with you and other Members of Congress to advance this proposal.

7. **Question**
The budget proposes eliminating the indirect medical education payment for Medicare Advantage enrollees that goes directly to the teaching hospital from CMS. Despite repeated requests, I have seen no evidence that the Medicare Advantage plans are actually passing the amount in their payment attributable to IME along to the teaching hospitals. Do you have any such evidence and if not, then why take the IME out of the hospitals instead of out of the plans?

Response: A teaching hospital negotiates its rates directly with a Medicare Advantage plan including an amount to be paid for the costs of using the teaching hospital. Medicare makes a payment that includes indirect medical education (IME) payments to the Medicare Advantage plans for each beneficiary. The budget proposal would eliminate duplicative IME payments paid by Medicare to the teaching hospital for these beneficiaries.

8. **Question**
Under current law the government contribution to Part D premiums does not take a beneficiary's income into account. What would be the impact of income-relating the Medicare Part D premiums just as under Medicare Part B premiums, as the President proposes?

Response: Income-relating the Part D premium in a manner similar to that under Part B serves to increase higher income beneficiaries' responsibility for health-care costs. In addition, implementing an income-related Part D premium would lower government costs by an estimated $3.2 billion over the next 5 years (2009-2013). Finally, the income-related premium proposal is expected to affect 5.6% of Part D enrollees in 2009 and 9% of enrollees by 2017.

9. **Question**
Mr. Secretary, like beneficiaries from the home states of my colleagues, Iowans who are in need of Medicare assistance are having great difficulty getting through on 1-800-Medicare to speak with a live person. Furthermore I have heard from many Iowans that after they have gone to great trouble to get a hold of a representative for Medicare, they have been sent the wrong forms, have found that previously submitted forms have been misplaced, have had to go through lengthy appeals processes and

have generally found that Medicare has given them incorrect and oftentimes unhelpful information. In light of this, how do you intend to improve the accuracy of information, service, and response time with respect to beneficiaries' inquiries?

Response: CMS strives to provide callers with an unbiased and trusted source for information about their health care decisions and to ensure our call centers disseminate information that is timely, accurate, and understandable As a result, we welcome feedback that helps us to identify improvement opportunities for any aspect of our call center operations.

In response to your particular concern about wait times, the 1-800-MEDICARE call center is staffed to meet an 8-minute average speed of answer (ASA). Most days, the ASA is under 8 minutes. While the budget only allows for an 8-minute ASA, we continue to work aggressively to keep call wait times lower than the contractual agreement. Regarding your concerns about the accuracy of information provided by 1-800-Medicare, where inaccurate information was provided, the call center contractor has discussed the calls with the appropriate customer service representatives (CSRs) and provided them with coaching and training. In addition, we have reviewed and revised a number of call center scripts to clarify them and make it easier for the CSRs to locate them. We have also developed a side-by-side chart in order to give CSRs an effective way to distinguish between the unique characteristics of Original Medicare, Prescription Drug and Medicare Advantage plans. We continue to reinforce the accuracy of information provided by CSRs, specific to Part D and more general information, through call center activities such as refresher training and staff meetings, *The Question of the Day* Quizzes. As an additional step, CMS recently awarded an Independent Quality Assurance contract, designed to support the development and implementation of quality, content, and training initiatives at the 1-800-MEDICARE call centers.

10. **Question**

Mr. Secretary, you wrote Chairman Baucus and me in December 2007 and asked that we avoid physician payment cuts by "adjusting" payments to other fee-for-service providers. The President's budget proposes reducing other provider payments by $113 billion over five years but does not address physician payment. How do you envision reforming physician payment and the SGR, taking the Administration's FY 2009 budget proposals into account?

Response: Creating some stability in Medicare physician payment levels is important in order to ensure beneficiary access to care. But at the same time, we need to ensure that we are getting the most appropriate value for our expenditures, that quality of care is of the highest levels, and that the fee-for-service payment system doesn't create incentives to generate excess volume and intensity of services.

We do not have a magic bullet to deal with the Medicare physician payment issue, but we look forward to working with Congress to address the issue. In addition we are working on some important elements that could be building blocks that ultimately are part of a revised Medicare physician payment system. We have been implementing the Physician Quality Reporting Initiative (PQRI), which creates payment incentives for physicians who report quality measures. We are very interested in building on the success of our Physician Group Practice demonstration and incorporating a mechanism for physician group practices to report and perform on quality measures. We are implementing the medical home demonstration project and are interested in the potential for the model to change how care is furnished to and coordinated for Medicare beneficiaries. We are very interested in creating financial incentives to encourage physicians to implement an electronic health records system and we have begun implementing an electronic health records demonstration project. We have been working to develop meaningful, actionable, and fair measures of physician resource use to initially be used for confidential feedback reporting to physicians about the comparative costs of their care. As in other payment systems, value-based purchasing and transparency initiatives give consumers access to data that can improve their healthcare choices. We are evaluating the possibility of posting the names of physicians who successfully report PQRI measures on the CMS website.

Senator Rockefeller:

1. *Overall Budget Cuts*
   Question
   a) President Bush released the fiscal year 2009 budget request that includes large reductions in Medicare spending growth and decreases in Medicaid spending. Medicare spending is reduced by $6 billion in FY 2009 and by $182.7 billion over five years. In addition, the request will seek to reduce Medicaid spending by $1.2 billion in FY 2009 and by $18.2 billion over five years.

   Most reductions in Medicare spending would result from decreases in annual updates in reimbursement payments to hospitals, nursing homes, hospices, ambulances and home care agencies. However, the budget request would not reduce Medicare overpayments to Medicare Advantage plans.

   Secretary Leavitt, we are threatened with a recession and the needs of our most vulnerable women, children, elderly and disabled continue to increase. These cuts to Medicare and Medicaid will add to an already burdened safety net of health systems and providers. In light of these massive cuts to programs that serve a large portion of our population, how can health care providers ensure that access and quality of care are maintained for our most vulnerable communities?

   Response: While this Budget proposes a total of $182.7 billion in savings to the Medicare program over five years, it is important to recognize these numbers in context. Over the next five years, Medicare benefits spending will total $2.8

trillion. The budget proposals only slightly reduce average annual growth in Medicare spending; under this budget Medicare spending will still grow an average of 5 % annually from FY 2009 to FY 2013, which is a higher growth rate than both the average medical inflation and CPI projections for this time period. In addition, encouraging providers to be more efficient saves beneficiary out-of-pocket costs of $6.2 billion over five years.

The proposed $18.2 billion in savings for Medicaid programs are also a fraction of the $1.3 trillion in total outlays from FY 2009 to FY 2013. Under this budget, Medicaid spending will still grow by 7.1 % during the next five years.

Question

b) As a former Governor who had to cope with a serious recession in West Virginia in the 1980s, I am very troubled by this budget and its hits on States. States have real balanced budget requirements, and too often in a downturn States are forced to cut Medicaid and other programs that help vulnerable families.

This budget makes it worse. Under the President's budget, grants to state and local government for all programs other than Medicaid would decline by $18.9 billion or 7.4 percent from fiscal year 2008 to 2009, after adjusting for inflation. How can the Administration justify such cuts?

Response: The FY 2009 President's Budget works to enhance access and continuity of coverage by improving program integrity, increasing State flexibility, and promoting cost-effective management of Medicaid dollars. Many reforms build on past efforts by Congress and the Administration to restrain growth rates and promote long-term viability of the Medicaid entitlement program, which together, will save $17.4 billion over five years in Medicaid legislative changes and $800 million in administrative changes over five years. Through these efforts, we can restrain the five-year annual average growth rate of Medicaid from 7.4 percent to 7.1 percent.

Question

c)For many years, I have worked to try and improve our programs to care for abused and neglected children. I am disturbed that this budget cuts programs that invest in prevention for such vulnerable children.

Discretionary funding for the Promoting Safe and Stable Families is cut to just $63 million – it should be $100 million. And there is a 30 percent reduction in the Social Services Block Grant which helps pay for services that protect children from neglect and abuse, foster care, adoption, and related services for children and families.

In addition, the budget assumes cuts in payments to states for children and families services programs. These cuts would come as weak economic conditions create increased need for these types programs; if the federal government cuts funding, the burden of supporting these programs is likely to fall to states and

local governments. Why is this Administration ignoring the needs of our most vulnerable children?

Response:
The President's FY 2009 budget maintains significant investments in programs that provide critical services to children and families while at the same time taking a responsible approach to deficit reduction.

In fact, the budget request includes increases in funding for key investments in programs serving children and families, such as the Adoption Incentives Program (request of $19.7 million is over $15 million more than the FY 2008 enacted level), the Mentoring Children of Prisoners program (request of $50 million is $1.4 million more than the FY 2008 enacted level), and Head Start (request of $7 billion is $149 million more than the FY 2008 enacted level).

The President's budget also maintains funding at the FY 2008 enacted level for important programs that protect vulnerable children from neglect and abuse. These programs include: the Promoting Safe and Stable Families (PSSF) program; the Community-Based Child Abuse Prevention program; Child Abuse Discretionary Grants; CAPTA State Grants; Child Welfare Services; and, Adoption Opportunities grants.

The Administration is committed to deficit reduction and consequently the budget targets resources to those programs with measurable outcomes and reduces funding to programs that fail to demonstrate results, like the Social Services Block Grant.

Question
d) Child care funding is flat – not even covering inflation. Child care is one of the most expensive costs for a young family. According to a national survey, child care costs for licensed centers can reach up to $10,920 a year for 4-year-old children and up to $14,647 a year for infants. In fact, in 9 states including West Virginia, child care for 2 children costs more than the average mortgage. Child care funding is flat in the President's budget, but inflation for child care is over 6 percent, more than general inflation. How do you expect families to cope with rising costs?

Response:
The Administration recognizes the importance of child care – Child care is both a critical work support for many low-income families, and an important opportunity to advance school readiness, particularly for at-risk children. States have numerous funding streams that can be used for child care, and they have maximum flexibility to maintain coverage for needy families.

Child care funding is at a historically high level. Federal and State funding for child care is at an all time high and has increased more than threefold between

1996 and 2008 1996 and 2008,from approximately $3.6 billion to $12 billion. This amount includes TANF spending (either through transfers or direct spending), SSBG spending on child care, and State investments in child care. This amount also includes the increase in Federal child care funding enacted by the Deficit Reduction Act of 2005 (DRA), which totals $1.8 billion in new funding through FY 2010 when factoring in State matching funds.

Other programs help meet the need for child care. There are a number of other programs including Head Start, State funded Pre-K, and 21st Century Community Learning Centers, that provide quality care for children whose parents might need child care services.

States can prioritize resources for child care. By design, the CCDF block grant is not the only source of Federal support for child care. For instance, States may transfer up to 30 percent of their TANF funds to CCDF, or spend TANF funds directly on child care without limit. In FY 2006, States transferred almost $2 billion in TANF funds to the child care program, and spent an additional $1.2 billion in TANF funds directly on child care. The significant decline in the welfare caseload has freed up resources that can now be used for child care and other work supports.

Families can choose from a range of quality child care settings. Providing access to quality child care does not necessarily mean that all parents will choose licensed, center-based care. Research[1] shows that many parents choose child care based on specific characteristics of that type of care, such as relationship with provider, convenience of location, extended family networks, and trust. These components of quality care can be found in family child care homes and informal care settings, such as with relatives, and in-home providers – not just centers. Parents may choose from a range of child care settings, and cost of care can vary substantially depending on these choices.

2. *CHIP*

Question

a) Do you believe the August 17th guidance has the force of law or is it interpretive?

Response: The State Health Official (SHO) letter sets forth a review strategy for the Centers for Medicare & Medicaid Services (CMS) to ensure compliance with existing requirements under the State Children's Health Insurance Program (SCHIP) for the effective and efficient provision of child health assistance coordinated with other sources of health benefits coverage. The SHO letter is

[1] [ACF issued a press release in January 2007 titled, "Family Child Care Meets Needs of Working Parents," which highlighted a summary report of research funded through ACF. The research found that family child care, including care provided by relatives, is an option that works best for many families. Parents using family child care cited safety for their children, convenience of location, relationship with provider and trust as the most compelling reasons for choosing that type of care. You can find a link to this report on the ACF website (http://www.acf.hhs.gov/news/press/2007/Care_in_the_Home.htm).

currently the subject of ongoing litigation and it would not be appropriate to comment on legal issues outside of those proceedings. The Department's overall position in these actions was summarized in a January 10, 2008 letter from the Department of Justice to the United States District Court for the Southern District of New York. In that letter, the Department of Justice indicated the view that the SHO letter is a general statement of policy that announces the course which the agency intends to follow in adjudications concerning compliance with requirements already set forth in regulations.

Question

b) Why was this comprehensive policy change handled through a letter to states and not through the formal rulemaking process with proper notice and public comment?

Response: As the Centers for Medicare & Medicaid Services (CMS) has developed more experience and information from the operation of SCHIP programs, it has become clear that the potential for crowd-out is greater for higher income beneficiaries. The August 17th State Health Official letter reminds the States of their existing statutory obligations to targeted low-income children, including obligations to find and enroll such children "in an effective and efficient manner that is coordinated with other sources of health benefits coverage" before States consider expanding to higher income levels. Statutory authority for the August 17th guidance is found in Section 2101(a) and Section 2102(b)(3)(C) of the Social Security Act, and implementing regulations at 42 C.F.R. 457.805. Also, as noted above, the SHO letter sets forth a review strategy and is a general statement of policy. Therefore, we do not believe it requires the engagement of formal rulemaking procedures

Question

c) How many children currently enrolled in CHIP today will lose coverage because of the August 17 directive? Please include in your analysis the following:

- The number of children in families above 250% of poverty in Wisconsin, Ohio, and any other state who were previously enrolled in CHIP before application of the August 17th policy, but who are now enrolled in state-only programs or not otherwise insured.

- The number of children who will lose CHIP coverage forever because they were on the rolls when this August 17th policy went into effect, but went off the rolls for a short time to enroll in their parents' employer-sponsored coverage, and at some point in the future will need to re-enroll in CHIP because their parents loss their job during the economic downturn.

- The number of children in states, like West Virginia, that have passed eligibility expansions beyond 250% of poverty that will not be allowed to ever enroll in CHIP because of this new policy.

Response: In general, we expect states to apply any programmatic changes based on the strategies set forth in the SHO only to new applicants so there should be no impact on current enrollees.

Bullet 1: The Centers for Medicare & Medicaid Services (CMS) does not possess SCHIP enrollment data by income level and data on enrollment in state-only programs.

Bullet 2: Children that continue to meet the eligibility requirements under a SCHIP program will remain eligible and should not lose coverage as a result of the SHO. However, children that have changes in circumstances (e.g., access to and enrollment in employer sponsored health insurance), and discontinue SCHIP coverage for a period of time as a result of these changes, will subsequently be considered new applicants and may be subject to programmatic changes implemented by the State consistent with the SHO.

Bullet 3: In accordance with the applicable requirements, CMS formally reviews the State plan and any requested amendments on a case-by-case basis for compliance with applicable requirements. This review would reflect compliance the review strategy outlined in the August 17, 2007 SHO letter. We cannot speculate on the outcome of the review of CMS review of any particular State program or proposal. Further, the Centers for Medicare & Medicaid Services (CMS) does not possess SCHIP enrollment data by income level and data for separate (non-Medicaid) programs.

Question

d) The August 17 directive purports to clarify how CMS applies existing statutory and regulatory requirements under CHIP. However, Dennis Smith, Director of the CMS Center for Medicaid and State Operations, has made public statements suggesting that the directive should also be applied to Medicaid programs. Is it the intention of HHS that the directive be applied to both separate CHIP programs and Medicaid expansions?

Response: There is clearly an interaction between Medicaid and SCHIP and the implication for Medicaid needs to be considered.

From a policy perspective, it should be clear that the focus of the SCHIP and Medicaid programs should be on targeted low income populations. Thus, it would be consistent to apply the policy of serving the poorest children first, where a state chooses to expand its programs through Medicaid or separate SCHIP program funding. Thus, we continue to review this issue.

Question

e) The President's budget proposal includes $450 million over five years for outreach grants to states, localities, schools, and community-based organizations

to enroll low-income uninsured children in Medicaid and CHIP. What will be in the impact of this proposal on spending and enrollment in Medicaid?

Response: The President's FY2009 Budget proposes to provide resources to find and enroll eligible but uninsured, low-income children into Medicaid and SCHIP. The proposed outreach funding is estimated to lead to increases in average monthly Medicaid enrollment of approximately 500,000 to 600,000 children throughout FY 2009 to FY 2013 as well as increases in Medicaid expenditures of $5 billion over the same five year period.

3. *Medicaid*

Question

a) At least 9 million children are without health care in this country. The actions taken by your agency and the President in the last two years will increase the number of uninsured. Several proposed rules will result in deep cuts to state funding of Medicaid (which covers poor children) and last year the President twice vetoed legislation to provide health insurance to 10 million low-income children. Is the goal of the Administration to increase the number of uninsured children? If so, why?

Response: I am deeply troubled that you view the Administration as seeking to increase the number of uninsured children. The Administration shares your concern in protecting the Medicaid program so that it is available for those who need it. Each of the rules we issued is vitally important to ensure: the integrity of the Medicaid program; that Medicaid beneficiaries are receiving the services for which Medicaid is paying; that those services are effective in improving the health outcomes of individuals with Medicaid; and that taxpayers are receiving the full value of their dollars that are spent through Medicaid. Further, the Administration supports a responsible reauthorization of the State Children's Health Insurance Program (SCHIIP) that re-focuses the program on uninsured, targeted low-income children.

Question

b) CMS issued the final rule on a regulation limiting Medicaid reimbursement for school based services on December 28, 2007, which eliminates federal funding for school-based administrative activities such as enrolling children in Medicaid and SCHIP. At the same time, the Administration's FY2009 budget proposes to spend $450 million on outreach grants for states to fund and enroll eligible children. Why does the Administration favor these grants over existing, successful school-based outreach?

Response: The Administration's rule on school-based administration and transportation services addresses long-standing concerns about improper billing under the Medicaid program by school districts for administrative costs and transportation services. Both HHS' Office of the Inspector General (OIG) and the Government Accountability Office (GAO) have identified these categories of

expenses as susceptible to fraud and abuse. Congress has also expressed concern over the dramatic increase in Medicaid claims for school-based administrative costs and transportation services.

We acknowledge the importance of outreach and referral activities, and in no way preclude State or local Medicaid agencies from engaging in such activities. Nor do we preclude school employees from conducting activities that inform individuals of the availability of Medicaid services. This regulation is an important step in protecting the fiscal integrity of the Medicaid program by preventing improper claiming and cost-shifting identified by many OIG and GAO audits.

The Administration also remains committed to covering eligible but uninsured low-income children in the Medicaid and the State Children's Health Insurance Program (SCHIP). The outreach grants you describe provide targeted resources for States, localities, schools, and community based organizations, and is part of a larger effort to responsibly reauthorize SCHIP.

4. *Medicare*

Question

a) Secretary Leavitt, you have on numerous occasions stated you do not believe that the government should negotiate prescription drug prices because it would impede competition and reduce convenience for beneficiaries without providing much cost savings.

Just last week, I received a letter from a fellow West Virginian who listed in painstaking detail the drugs she takes and the costs associated with these drugs. She asked me to look over the list and tell her which prescriptions she should not fill because she couldn't afford all the medications she needed to live. This country can and should do all it can to make medications affordable.

Medicare premiums continue to rise and millions of Americans will once again fall into the doughnut hole this year. How does this Administration intend to address rising prescription drug costs considering your absolute refusal to negotiate with drug companies for lower prescription drug prices, as the VA currently does?

Response: In their review of recent Part D legislative proposals calling for government Part D price negotiation, CBO and CMS' independent Office of the Actuary concluded that requiring the government to negotiate drug prices would not yield savings beyond what Part D plans are already achieving. Drug prices for all payers in all programs do change periodically in response to market factors such as inflation. Competition between Part D plans to offer quality low cost prescription drug coverage has lead to effective promotion of generics and drug price negotiation.

Our experience with the Part D program has shown that our subcontractors, the Part D sponsors have been successful at providing affordable quality prescription drug coverage to Medicare beneficiaries. The average beneficiary premium for the standard benefit in 2008 was estimated to be $25. This is nearly 40 percent lower than originally projected when the benefit was established in 2003 and also lower than projected earlier this year. Eighty seven percent of beneficiaries have access to a Part D plan with a premium that is lower than their 2007 plan.

We share your concern regarding the beneficiary that you described in your letter and are committed to ensuring that beneficiaries understand their plan choices and utilize all of the sources of extra help that may be available to them. Our low income subsidy program and other state initiatives such as the State Pharmaceutical Assistance Program (SPAP) provide drastically reduced prescription drug costs for millions of low income individuals. We also provide all beneficiaries with the tools necessary to assess their plan options and determine the plan that best meets their needs. The Plan Finder website provides individually-tailored information that beneficiaries can use to assess the cost, coverage, and convenience of different plans. Beneficiaries can also receive this same information through 1-800-Medicare or through our partners such as the SHIPs.

Question

b) MedPAC has said repeatedly that the government overpays Medicare Advantage plans by 12% - 19% and should eliminate these overpayments so that traditional Medicare and private plans are paid the same – a recommendation that was noticeably absent from the President's FY 2009 budget request. In 2006, Medicare paid MA plans $64 billion. According to the Congressional Budget Office (CBO), making MA plan payment rates equal to traditional Medicare payment rates would save $65 billion over five years and $160 billion over ten years.

During this time of fiscal uncertainty, how can HHS justify continuing these gross overpayments to MA plans rather than forcing them to compete with traditional Medicare for customers? Wouldn't the elimination of these overpayments reduce the size of government and save American taxpayers money?

Response: The savings as proposed in the President's FY 2009 budget do not come solely from Medicare Parts A & B, but the President's budget proposals will also result in significant cuts to Medicare Advantage (MA) plans. Over five years, the reductions in payments to Original Medicare would result in $44 billion in payment cuts to MA plans, an amount that is roughly one quarter of the total provider outlay savings, over five years.

Regarding the payment rates, Congress established current payment levels to ensure that the MA option was available all across the country, including in rural areas. While it is true that MA plans in most regions are being paid more than the

FFS rates, the vast proportion of the extra amounts are required to go directly to beneficiaries in the form of reduced cost sharing or extra benefits. Because of these policies, beneficiaries in all parts of the country have access to at least one Medicare Advantage plan. The Administration continues to support policies that will ensure all beneficiaries across the country have access to these plans.

c) **Question:**
When it was created in 2003, the Medicare Advantage was touted as a cost-effective program. How can Medicare Advantage be cost effective if it actually requires beneficiaries and taxpayers to invest more?

Response: Congress established current payment levels to ensure that the MA option was available all across the country, including in rural areas. While it is true that MA plans in most regions are being paid more than the FFS rates, the vast proportion of the extra amounts are required to go directly to beneficiaries in the form of reduced cost sharing or extra benefits. Because of these policies, beneficiaries in all parts of the country have access to at least one Medicare Advantage plan. The Administration continues to support policies that will ensure all beneficiaries across the country have access to these plans.

5. *Long Term Care*

Question

a) The Deficit Reduction Act of 2005 included language allowing the expansion of the Long-Term Care Partnership program nationwide. Can you tell us how many states are currently participating in the Partnership program?

Response:
The following list shows the status of the Partnership program to date. In addition to the states listed below, another 10 have passed the necessary state enabling legislation and are in the process of writing regulations and developing program infrastructure, but have yet to file Medicaid State Plan Amendments.

- ◊ **Partnership Policies Currently for Sale (12):**
  - o Demonstration States: CA, CT, IN, NY
  - o New DRA States: FL, ID, KS, MN, SD, NE, OH, VA
- ◊ **Medicaid State Plan Amendment Approved (10):**
  - o IA, CO, GA, MO, ND, NJ, NV, OK, OR, PA
- ◊ **State Plan Amendment Pending (5):**
  - o AR, MI, NH, TX, WI

Question

b) The Deficit Reduction Act also included a requirement for the Department of Health and Human Services to establish reciprocity standards for Partnership policies within a year of enactment. It has been two years sine the DRA was

passed. When will HHS issue a proposed rule on reciprocity standards for states with Partnership policies?

Response:
The Department conducted consultations, as required in the Deficit Reduction Act, and the reciprocity standards are currently under development.

Question

c.) The DRA also included a provision I championed to create a National Clearinghouse for Long-Term Care information and provided $3 million in funding for the Clearinghouse for fiscal years 2006, 2007, and 2008. Can you describe for this Committee the activities that the Clearinghouse has undertaken in the last two years? How many beneficiaries are currently using the Clearinghouse website each year? Do you believe $3 million per year is adequate funding for the Clearinghouse going forward?

Response:
The Clearinghouse engages in two major complementary activities; conducting a direct mail campaign with states to raise awareness about the need to plan ahead for long term care and publishing a consumer website with a wide variety of information on long term care. Each of these activities is described below:

Own Your Future Direct Mail Campaign

The goal of the Own Your Future Campaign (Campaign) is to make persons aged 45 to 65 aware of the need to plan ahead for long term care. The Campaign is operated in cooperation with governors. States are selected for participation on a competitive basis. HHS sends a letter from the governor to every household in the participating state with a resident between the ages of 45 to 65. Included with the letter is a tri-fold brochure that offers a state/federal long term care planning kit. The letter is also a key method for informing consumers about the Clearinghouse website.

The planning kits can be ordered from the Clearinghouse website, with a postage paid postcard, and, over the phone (24/7). The kit contains three items:

◊ a 28 page booklet developed by HHS that outlines the risk of needing long term care and includes information on a variety of planning activities including home modification, advance care directives, long term care insurance, coverage from public programs, and exploring community services.

◊ a 12 page state booklet that outlines state resources that are available to assist in planning including area agencies on aging, SHIP programs and Medicaid agency information.

◊ a compact disc with 10 tracks featuring interviews with a variety of experts and persons who have planned ahead for long term care. The topics covered on the CD include talking to family members about long term care, long term care insurance, home modifications and the need for clear legal directions.

Over the last two years the following 8 states have conducted Campaigns. The response rate (percentage of households in initial mailing that request a planning kit) varies by state but generally runs between 6.5% and 7.5%. Approximately 400,000 people in the eight states have requested planning kits as a result of the mailings. Ohio and Pennsylvania are scheduled to kick off their campaigns at the end of March and beginning of April.

State	Target Population
Michigan	1,635,171
South Dakota	105,736
Texas	802,827
Nebraska	237,170
Georgia	1,069,814
Tennessee	804,053
Missouri	787,446
Virginia	210,000
Total	**5,652,217**

States often conduct complementary activities such as holding town hall meetings, emailing to state employees and contacting major employers. These activities are designed to take advantage of unique messaging opportunities in states. In addition, the Department has a public service announcement that is made available to television stations.

National Clearinghouse for Long-Term Care Information Website Statistics (www.longtermcare.gov)

The National Clearinghouse for Long-Term Care Information was launched at the end of Dec 2006. Initial tracking software was only able to track hits and could not isolate visits. New tracking software was implemented in April 07 allowing specific visit information collection starting in May 07. Statistics on visits for that 9 month period (May 07 to Jan. 08) show that:
- Total number of unique visitors for the 9 month period was 97,472
- Average number of visits per month was 10,830
- Average number of visits per day ranged from a high of 2,193 to a low of 982

Applying the average number of unique visitors per month to the first 4 months of website activity (January through April 2007) gives an **estimated total of 140,792** unique visitors since the Clearinghouse became operational. In addition, almost

every day there are more than 1,000 visitors to the site, and in the 13 months of operation there have been an overall total of 368,480 visits to the site.

Website Visit Statistics May 07-Jan. 08

Month	Visits	Unique Visitors	Avg. visits per day	Avg. visit duration
May 07	70,164	13,605	2,193	2:17 min
June 07	28,484	8,340	982	2:41 min
July 07	35,658	11,536	1,114	2:52 min.
Aug. 07	48,634	11,742	1,520	2:47 min.
Sept. 07	33,521	8,977	1,117	3:06 min.
Oct. 07	36,801	10,227	1,150	3:01 min.
Nov. 07	32,904	9,566	1,061	3:10 min
Dec. 07	35,691	9,595	1,082	2:45 min
Jan. 08	46,623	13,884	1,457	2:59 min

- Visits: Total number of visits to the site. This includes people who visit more than once.
- Unique visitors: Unduplicated number of individuals using site.

To date, the Campaign has sent a direct mail piece to approximately 13 million households (includes pre-DRA states and OH and PA) that have a resident in the 45 to 70 age bracket. Campaign costs usually run around $1 per household (includes website, administration, fulfillment, initial letter and other complementary activities) The DRA provided $3 million in funding for the period of FYs 2006 through 2010 for the establishment of the National Clearinghouse for Long-Term Care information. Over FYs 2009 and 2010, we estimate that these resources will enable us to reach an additional 6 million households. We estimate that by the end of the DRA funding we will have reached approximately 19 million households or about half of the U.S. population between the ages of 45 and 65.

6. Health through the tax code

Question:

a) The President claims that his standard deduction proposal – a $105 billion investment over five years – will insure 8 million additional people. That is a cost of $13,125 per person over 5 years, which equals $2,625 per year or $218.75 a month for each person. Is this really the most efficient use of tax dollars?

The Congressional Budget Office (CBO) assumes in their baseline that the Children's Health Insurance Program (CHIP) costs $1,220 in 2007 per child and $1,600 in 2012. Wouldn't you agree that CHIP is a more efficient and effective use of tax dollars based on the numbers? Why, then, did the Administration consistently oppose a bipartisan proposal to invest greater federal resources to cover more low-income uninsured children in CHIP when doing so would have

been much more cost-effective than the President's tax proposals for the uninsured?

Response:
The State Children's Health Insurance Program (SCHIP) has been a successful program in providing health insurance coverage to millions of vulnerable, poor children. In fact, the program has expanded to cover almost 7 million children since its enactment. The Administration is committed to ensuring SCHIP's continued success as a safety-net program through a reauthorization proposal that focuses on covering low-income, uninsured children that are eligible for SCHIP but not enrolled in the program.

For higher income children and families, the Administration has proposed a standard deduction for health insurance premiums (SDHI). This proposal would provide a standard tax deduction of $7,500 for individual coverage and $15,000 for family coverage, regardless of whether the insurance is purchased though an employer or the individual market. Rather than an expansion of a government-run health care program, the SDHI proposal equalizes the tax treatment of the group and non-group health insurance markets allowing for greater competition, affordability, and consumer choice.

The Joint Committee estimates that over 8 million tax returns would claim the health deduction for newly-purchased health insurance (i.e. insurance that would not have been purchased in the absence of the deduction). These newly-purchased insurance policies would cover 11 million individuals for all of part of the year.

Question:

b) According to CBO, 1.5 million people who would have employment based coverage under current law would become uninsured under the President's tax proposals, and about 6.3 million would switch from employment-based to non-group coverage. What is your analysis of the number of individuals who would lose coverage under the President's tax proposals due to employers dropping coverage? The President seemed particularly concerned about so-called "crowd-out" in the context of the CHIP debate, so I would like to know if he has similar concerns in this context.

Response:
The Department of Treasury has estimated that about 3 to 5 million more people would have health insurance under the proposal.

This is consistent with the most recent analysis from the Joint Committee on Taxation (JCX17-07), which estimates that the Administration's proposal may reduce the number of individuals with ESI by about 6 million. However, the majority of these

individuals would purchase non-group (individual) coverage and fewer than 500,000 of these individuals would become uninsured.

In fact, these individuals are included in the Joint Committee's estimate that over 8 million tax returns would claim the health deduction for newly-purchased health insurance (i.e. insurance that would not have been purchased in the absence of the deduction). These newly-purchased insurance policies would cover 11 million individuals for all of part of the year. Considering the change in coverage from ESI to non-group, these estimates are in line with the Treasury Department's estimates.

7. Child Support Enforcement

Question:

a) Child Support Enforcement is an effective program, and every dollar invested helps to collect over $4. We have an incentive program to inspire States to improve, but the DRA prohibits State reinvestment as a match. Why should we discourage States that have succeeded, especially now when States are predicting budget shortfalls?

Response:

Taken as a whole, the child support enforcement provisions in the DRA create opportunities for State child support enforcement agencies to improve outcomes for children and families while improving efficiency.

These provisions help children and families by:

- Providing States with the option to pass through more collected child support to both TANF and former TANF families;
- Decreasing the trigger for passport denial from $5,000 to $2,500
- Imposing mandatory review and adjustment of child support orders for families receiving TANF, and
- Providing matching of insurance settlement data through the Federal Parent Locator Services (FPLS).

In addition States continue to receive incentive payments from the Child Support Performance and Incentive Act of 1998, providing additional funds for carrying out or improving their child support enforcement programs. As mandated by the DRA, State expenditures using these Federal payments are not subject to Federal matching. In FY 2008, States will receive $483M in incentive payments.

Senator Hatch:

1. *Medicare*

Question

In your budget, there are reductions which appear to target teaching hospitals and safety net hospitals– the Indirect Medical Education (IME) reduction and the reduction in hospital Disproportionate Share Payments are particularly hard on these hospitals. Could you please give me the rationale on why the budget appears to target hospitals that care for the low-income? It seems to me that we should be giving these types of hospitals more federal dollars since they care for a large number of the poor.

Response:

Safety-net hospitals are a vital source of care for the uninsured in our country. For too long they have had to bear the burden of providing care to the uninsured. The Administration would reduce the number of uninsured by providing tax breaks that encourage the purchasing of health insurance, which will support safety-net hospitals, not hurt them.

Our proposal to switch to a value-based purchasing system for hospitals with incentives for both improvements in care as well as meeting specific quality of care measures makes it possible for safety-net hospitals to actually increase their payments in comparison to other hospitals.

2. *Medicare Hospitals*

Question

It is my understanding that there is a great deal of interest—among the members of this Committee, in the hospital industry, and in the administration—in the adoption of a value-based purchasing payment system for hospital care. If we are going to move forward on this, don't you believe it will be difficult to convince hospitals to partner with the Federal government in a collaborative way to design a system that works if there are savings of over $1.5 billion dollars (possibly coming from the hospitals) from implementing a value-based purchasing system?

Response:

For too long Medicare payments have been based on the volume of services furnished, not the quality of care provided to the beneficiary. The hospital value-based purchasing proposal will shift the focus to the quality of care and make "smarter" payments. Under such a system, hospitals can earn bonus payments by improving the quality of care provided to beneficiaries, which can help offset other reductions proposed in the budget.

3. *Medicare Competitive Bidding*

Question

Mr. Secretary, I want to raise the issue of competitive bidding with you. As you know, the second phase of the program which was authorized by the Medicare Modernization Act of 2003 was recently announced and Salt Lake is one of the cities included. Let me tell you, SL providers don't know what to expect and they are very concerned about the impact this will have on their Medicare patients if they are not awarded a bid. What do we tell these providers and their patients? I know Sen. Roberts also raised this issue to you.

Response: First and foremost, CMS is committed to protecting beneficiary access and quality of care. The final rule for the durable medical equipment, prosthetics, and orthotics (DMEPOS) competitive bidding program established numerous beneficiary protections. For example:

- Competitive bidding will reduce the amount Medicare pays for DMEPOS and will bring the payment amounts more in line with that of a competitive market. Also, contract suppliers must submit claims for competitive bidding items on an assignment basis. These factors will help limit the burden on beneficiaries by reducing their out-of-pocket expenses.

- Contract suppliers must meet the newly established DMEPOS quality standards and accreditation requirements, as well as meet other program requirements (such as meeting financial standards). The independent accrediting organizations play a key role in ongoing monitoring of supplier quality.

- A sufficient number of contract suppliers will be selected to meet beneficiary demand.

- The performance of contract suppliers will be monitored through beneficiary satisfaction surveys that measure beneficiaries' level of satisfaction with the services they receive under the competitive bidding program.

- Beneficiaries are protected from financial liability under certain circumstances when a non-contract supplier furnishes them with a competitively bid item.

- When a physician specifically prescribes a particular brand name product or mode of delivery to avoid an adverse medical outcome, contract suppliers are required either to furnish that item or mode of delivery, to assist the beneficiary in finding another contract supplier in the competitive bidding area that can provide that item or service, or to consult with the physician to find a suitable alternative product or mode of delivery for the beneficiary.

- Beneficiaries will be able to obtain repairs of equipment they own from either a contract or non-contract supplier.

- Replacement parts needed to repair beneficiary owned equipment may also be obtained by a beneficiary from either a contract or non-contract supplier, even if the parts are competitively bid items.

- Contract suppliers are required to make available the same range of products to beneficiaries that they make available to non-Medicare customers. For transparency, we will post on our web site a list of brands furnished by each contract supplier.

- Under the grandfathering rules, some beneficiaries will have the opportunity to make arrangements with a non-contract supplier that will allow the beneficiary to continue to receive a rented item from the same supplier (grandfathered supplier) that had been furnishing the item to the beneficiary before the implementation of a competitive bidding program, provided the supplier is willing. If a supplier agrees to furnish "grandfathered" items to one beneficiary, it must furnish those items to all similarly situated beneficiaries.

- Beneficiaries will be allowed to use an Advance Beneficiary Notice (ABN) to make informed consumer choices regarding whether to agree to be financially liable for special deluxe features that Medicare does not consider medically necessary.

CMS has also created numerous provisions to protect small suppliers and ensure that they have an opportunity to participate in the program. The final rule for the DMEPOS competitive bidding program established numerous small supplier protections, such as:

- The adoption of a new definition for small suppliers reflective of the healthcare industry, working in collaboration with the Small Business Administration,

- A 30 percent target for contract awards to small suppliers for each product category,

- Flexibility for suppliers in not requiring them to submit bids for all product categories because it may be difficult for small suppliers to furnish all of the product categories in the competitive bidding program, and

- Authorization for small suppliers to form networks if they cannot independently service an entire competitive bid area.

Furthermore, CMS conducted an aggressive education campaign for this program. The proposed regulation was published on May 1, 2006, giving stakeholders an opportunity to see how the program would be implemented and allowing their comments to help shape the program. Quality standards and the accreditation processes were released in August 2006, and CMS informed those who would participate in the competitive bidding program to start preparing by getting accredited.

Preliminary education began months before the final regulation was issued, and the formal education campaign began on April 2, 2007, the day the final regulation was released. Prior to opening the supplier bid window on May 15, 2007, CMS established a dedicated Web site, www.dmecompetitivebid.com, with a comprehensive array of important information for suppliers, including a tool kit, fact sheets, Web casts, and questions and answers. CMS also held Open Door

Forums and sent listserv announcements in order to disseminate key information about the program.

After opening the Round 1 bidding window, CMS held six bidders' conferences, during which various parts of the bidding process were explained. All of the bidders' conferences were held via teleconference to ensure maximum opportunities for suppliers to participate. CMS provided extensive education and support to suppliers with the on-line bidding system, answered supplier questions and posted them on the competitive bid Web site. CMS also provided a toll-free helpline to assist bidders with all of their questions and concerns. Every bidder received a letter explaining the accreditation requirements. Every bidder also received e-mail reminders to check its bids and submit the required financial documents.

CMS is also planning an aggressive education campaign for beneficiaries once the Round 1 bid evaluation process is completed and contracts are sent to suppliers. We will have Round 1 area-specific fact sheets and beneficiary tip sheets that explain the bid evaluation process and the single payment amounts for the competitive bid items. CMS will be working with its Regional Offices, State Health Insurance Programs (SHIPs), and other partners to educate beneficiaries in Round 1 of the upcoming changes from the DMEPOS competitive bidding program. There will also be an online web tool available on www.medicare.gov that will help beneficiaries locate suppliers that are Medicare contract suppliers in the competitive bid areas. In addition, beneficiaries can always call 1-800 MEDICARE for help in locating a Medicare contract supplier.

As mentioned earlier, we plan to do a similar and more aggressive education campaign for those areas in Round 2. CMS is taking into account its experiences from Round 1 of the DMEPOS competitive bidding program, as well as the success of the demonstration projects several years ago, and is using this information as we move forward to implement Round 2. We have already announced the Metropolitan Statistical Areas (MSAs) where Round 2 will be implemented to give suppliers time to get accredited by our independent accrediting organizations. In the spring, we plan to announce the zip codes in the MSAs and product categories where the DMEPOS competitive bidding program will take place. We plan to open the supplier bid window in the summer after providing education opportunities for suppliers about the bidding process. We have already made refinements on the supplier bidding process for Round 2 based on our experiences in Round 1. For example, for Round 2, we have upgraded the supplier bidding submission system and streamlined the required financial documentation to make it easier for suppliers.

4. *Medicare Quality Improvement Organizations (QIOs)*
Question
Sen. Rockefeller and I have introduced a bill to restructure the Medicare QIO program. This bill has the support of many members of the Finance Committee.

Could you talk about the Administration's QIO proposal and how it is different from the proposals introduced in the Senate -- specifically, the Hatch-Rockefeller bill and the Grassley-Baucus bill?

Response: The Medicare Quality Improvement Organization (QIO) program has labored under outdated and restrictive contracting requirements. The Administration has a package of 5 QIO reform proposals that will ensure CMS hires the right contractors for the job and enhance competition for QIO contracts. The five proposals are:

- **Authorize the Secretary to Set the Geographic Scope of a QIO contract:** Current law generally limits the Secretary to issue a single contract for each State, the District of Columbia, and territories.

- **Authorize Early Termination of QIO Contracts without Panel Review:** Make QIO contracts consistent with Federal Acquisition Regulations (FAR) by allowing the Secretary to terminate a QIO contract for default or poor performance, eliminating the existing right of panel review under the QIO statute.

- **Expand the Pool of Eligible QIO Contractors:** Broaden the scope of contractors eligible to conduct the review of health care quality, and the improvement of quality in care in the Medicare program. This would allow qualified non-QIO contractors to review quality of care complaints so long as they employ qualified physician reviewers.

- **Eliminate Conflicts of Interest in QIO Contracts:** Prevent QIO contractors from simultaneously holding contracts to improve the quality of care provided to beneficiaries and to review complaints about the quality of care provided to beneficiaries in a designated area. The proposal would also allow non-QIOs to obtain contracts to review beneficiaries' complaints.

- **Make QIO Quality Activities More Explicit:** Clarify in the statute that QIOs and other qualified organizations have the explicit authority to conduct activities specifically designed to improve the quality of care.

  Like both the Hatch-Rockefeller bill and the Grassley-Baucus bill, the Administration's QIO proposals make the quality improvement activities of the QIOs more explicit. Our proposals clarify that the statute authorizing the QIO program has been and can continue to accommodate the QIOs performing proactive initiatives to promote the effective, efficient and economic delivery of health care services. The Administration's proposals also eliminate conflicts of interest between beneficiary protection and clinical quality improvement activities by establishing stricter contractor standards in reviewing beneficiary complaints.

  While the Administration's proposals would eliminate the conflicts of interest in QIO contracts, the Grassley-Baucus bill requires the QIOs to only perform

technical assistance functions and transfers all other functions, such as beneficiary complaint investigations, to Medicare provider review organizations. Further, while the Administration's proposals provide for on-going performance management reviews, mid-contract checks on performance, and financial consequences if contractors do not maintain pre-specified performance levels, the Hatch-Rockefeller bill contains different proposals designed to improve the QIO program administration, including requirements for additional reports on the management of the QIO program, and specific standards of organizational integrity.

5. *Medicare Compendia*

Question

In 1993, Congress established a system that uses compendia to establish coverage under Medicare Part B for certain off-label uses for certain prescription drugs. Section 1861(t)(2)(B) of the statute lists the following publications as officially recognized compendia:

- The AMA Drug Evaluations Compendium (AMA-DE);
- The American Hospital Formulary Service Drug Information Compendium (AHFS-DI);
- The US Pharmacopoeia Drug Information Compendium (USP-DI)

Unfortunately, this list the Congress named in 1993 is no longer current. Specifically, the AMA-DE is no longer published, and the USP-DI has been bought by Thompson Micromedix and will be published under a new name. CMS has not updated the compendia, leaving coverage decisions to local carriers and patients with uncertain access to therapies.

In the Medicare Physician Fee Schedule for 2008, CMS outlined a process to evaluate applications for compendia to become approved. This process began on January 15, 2008 and will conclude on July 15, 2008. Unfortunately, the CMS framework could yield a situation where CMS determines that no compendia are approved for 2008. This would leave patients waiting for access until sometime in 2009. It is essential that CMS act quickly and affirmatively to update the list of compendia recognized under section 1861(t)(2)(B) of the Social Security Act. Cancer patients don't have the luxury of waiting any longer.

Response:

We understand the importance of recognizing additional Part B drug compendia along with the need to establish a regular, timely, and transparent process for consideration of additional compendia. Therefore, in the November 2007 physician fee schedule final rule, CMS established a sub-regulatory annual process for making changes to the list of compendia for Part B drugs. That process involves:

- The annually acceptance of requests to revise the list of compendia. This period would begin on January 15 of a year. Requests would be submitted within 30 days (i.e., by February 15).

- CMS publishing a listing of the timely, complete requests received (by March 15) and allowing the public 30 days to submit comments on the requests (by April 15).

- A complete request would have to contain specific information identified in the final rule.

- CMS will evaluate how well a compendium achieves desirable characteristics of compendia that were recommended by a special advisory panel.

- CMS will publish a decision within 90 days after the close of the public comment period (i.e., by July 15).

The process for 2008 is occurring ahead of schedule because of: (1) proactive CMS interactions with the stakeholder community during the period leading up to January 15; (2) timely submission of requests; (3) CMS' prompt initial review of requests for completeness; and (4) CMS' posting the requests for the 30-day public comment period as soon as our initial review was complete. CMS has posted four requests for public comments on February 6, 9, 13, and 20. The comment periods for these requests close on March 7, 9, 13, and 20, respectively. The requests can be found on the CMS website at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcd_6. CMS also received a fifth request after the 30-day period, but has decided to review it in light of the public interest on this topic. The fifth request was posted on March 4 and the comment period closes on April 3.

After the comment periods end, CMS will publish decisions as soon as the evaluation process has been completed but no later than 90 days after the close of the comment periods (which occur in June 2008 for four requests and July 2008 for the fifth). CMS could announce decisions earlier if the evaluation is completed earlier than the end of the 90-day period.

Once CMS publishes the decisions, we expect that contractors who pay Medicare claims would immediately utilize the newly approved compendia. The use of newly-approved compendia will not be delayed until 2009.

6. *State Children's Health Insurance Program (CHIP)*

Question

I know that you already been asked numerous questions about the dramatic difference in the Administration's request for the CHIP program. Mr. Secretary, I want to congratulate you and your staff for recognizing the need to significantly increase federal dollars necessary for this program. Could you please talk with me about why

these numbers changed so dramatically from the President's request in FY 2008 to the request in the President's FY 2009?

Response: As the President and I mentioned last fall, the Administration is committed to responsibly reauthorizing the SCHIP program with a policy that is focused on enrolling eligible uninsured, targeted low-income children. And, if enrolling these children requires more than the funding increase proposed by the President, we expressed our willingness to work with Congress to find the necessary money. The funding level included in the President's FY 2009 Budget proposal for SCHIP reauthorization is higher than in the FY 2008 Budget for variety of reasons including the substitution of a more expensive year (2013) for a less expensive year (2008); increased spending projections from the states; additional funds to sustain higher enrollment levels in SCHIP; the need to add new dollars to replace lower amount of unexpended allotments available for redistribution; and specifically increased funding for growth.

7. *Medicaid 340B program*

Question

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 diverts 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 hope that you will be able do so. I am hopeful that you will be able to respond to them and I also wanted to ask several questions myself.

a.) 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 we have, correctly interpreted the provision outlined in the Deficit Reduction Act of 2005 (DRA), Public Law 109-171, and clearly communicated the statutory 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 National Drug Codes (NDCs) on outpatient drug claims billed to Medicaid. 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 and they are billed to Medicaid at the acquisition cost. Because the 340B prices afforded the safety-net hospitals are much lower than what Medicaid would otherwise pay, the law provides that drug manufacturers are not liable for Medicaid rebates when Medicaid pays for theses drugs. Rebates are not required where such hospitals bill Medicaid no more than their acquisition cost for the drugs, as determined under the State plan. Were this not the case, Medicaid would be paying hospitals the full Medicaid reimbursement for the drugs but would not be able to collect the Medicaid rebate. 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.

Question
b.) 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.

Question

c.) 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, in accordance with the statute, 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 and they are billed to Medicaid at the acquisition cost. Because the 340B prices afforded the safety-net hospitals are much lower than what Medicaid would otherwise pay, the law provides that drug manufacturers are not liable for Medicaid rebates when Medicaid pays for theses drugs. Rebates are not required where such hospitals must bill Medicaid no more than their acquisition cost for the drugs. Were this not the case, Medicaid would be paying hospitals the full Medicaid reimbursement for the drugs but would not be able to collect the Medicaid rebate. 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.

Senator Bingaman:

1. **Question**

The Congressional Joint Economic Committee issued a study this month [http://www.jec.senate.gov/Documents/Reports/01.18.08%20CHIP%20Medicare%20Report.pdf] finding that both Medicaid and the State Children's Health Insurance Program enrollment and the numbers of uninsured will rise over the next several months as a result of the current economic downturn. In addition to urging the President to expand SCHIP, the Joint Economic Committee specifically called upon the Administration to delay or cancel proposed regulations that shift Medicaid costs to states. Given the significant economic downturn, would the Administration consider rescinding the pending Medicaid regulations and/or guidances which add significant economic burden to the states?

Response: As a former Governor, I can appreciate that Medicaid is one of the largest programs in State budgets. As Medicaid competes for resources at the State level against all the other demands that are present, an erosion of confidence in the integrity of the Medicaid program ultimately is not good for Medicaid nor for the people who rely on it. These rules will provide greater stability in the program and equity among the States. Each of these rules is vitally important to ensure the integrity of the Medicaid program; that Medicaid beneficiaries are receiving the services for which Medicaid is paying; that those services are effective in improving the health outcomes of individuals with Medicaid; and that taxpayers are receiving the full value of their dollars that are spent through Medicaid.

It is important to also put these savings into context. These rules represent only about 1 percent of federal spending on Medicaid.

2. **Question**
The Budget proposes approximately $200 billion worth of payment cuts to many different Medicare and Medicaid providers. However, the budget does not propose any direct cuts to private plans providing Medicare coverage (Medicare Advantage (MA) plans). Although cuts to Medicare fee-for-service payments will reduce benchmarks to these private plans no direct cuts are made to these plans and nothing is done to address the very significant differential in payments between traditional Medicare and MA plans (on average MedPAC/CBO estimate of 112 percent of traditional Medicare) and private-fee-for-service MA (on average MedPAC/CBO estimate of 119 percent of traditional Medicare plans). When support for MA plans was debated in 2003 proponents argued these plans would lead to significant savings and efficiencies for the Medicare program. Given this is the primary justification for MA and that MedPAC has strongly recommended equalizing these payments, how does the Administration justify making very significant cuts to most Medicare providers but allowing MA to continue to receive payments far in excess of traditional Medicare?

Response: You are correct that the savings as proposed in the President's FY 2009 budget do not come solely from Medicare Parts A & B, but the President's budget proposals will also result in significant cuts to Medicare Advantage (MA) plans. The reductions in payments to Original Medicare would result in $44 billion in payment cuts to MA plans, an amount that is roughly one quarter of the total provider outlay savings over five years.

Regarding the payment rates, current payment levels ensure that the MA option is available all across the country, including in rural areas. While it is true that MA plans in most regions are being paid more than the FFS rates, the vast proportion of the extra amounts are required to go directly to beneficiaries in the form of reduced cost sharing or extra benefits. Because of these policies, beneficiaries in all parts of the country have access to at least one Medicare Advantage plan. The Administration continues to support policies that will ensure all beneficiaries across the country have access to these plans.

3. **Question**
During Secretary Leavitt's testimony before the Finance Committee on Wednesday, February 2nd Senator Grassley asked the Secretary about problems with citizenship documentation requirements in Medicaid. Secretary Leavitt reported that the US Department of Health and Human Services had uncovered "several instances" of Medicaid recipients without proper citizenship documentation being determined eligible for Medicaid when "states had delegated Medicaid enrollment to entities other than state Medicaid programs." Please provide a complete list of these instances and detailed information about each instance including but not limited to:

the state in which each instance occurred, the non-Medicaid entity that determined Medicaid eligibility, the problem with citizenship documentation that was discovered, and, if available, a contact at the State Medicaid agency that would be best suited to respond to follow-up questions.

Response: The Deficit Reduction Act of 2005 (DRA) required States to obtain documentation of citizenship from citizens and U.S. nationals as part of the eligibility determination process for Medicaid coverage. The Department of Health and Human Services is taking steps to evaluate the implementation of the citizenship provision and work with States to help improve their implementation efforts. To date, the Department has provided on site technical assistance in response to State concerns that the new requirements have impacted eligibility determinations for otherwise eligible individuals. Additionally, we are working to identify implementation best practices and those which are inconsistent with the new documentation requirements. At the conclusion of the technical assistance reviews the Department will conduct targeted compliance reviews to help identify practices inconsistent with the law. These reviews should be completed over the summer months and when completed the Department will be glad to share the findings. At that time we will be in a better position to provide more specific information.

4. **Question**

For 11 years, states have been given the option to implement mandatory Medicaid managed care, but the elderly and disabled have always been exempted from this requirement. A new legislative proposal in the budget would eliminate the exemption for duals and kids with special needs from mandatory managed care by repealing the exemption in 1932(a)(2). What explains this reversal of longstanding practice?

Response: As in the past, we believe success in waivers should inform policymakers about changes in the Medicaid program. Although Section 1932(a)(2) lists special rules that exempt children with special health care needs, beneficiaries dually eligible for Medicare/Medicaid, and American Indians from managed care options, States can rely on seek waiver authority to require enrollment of these populations in managed care arrangements.

A number of states have successfully used waiver authority to require exempt populations to participate in managed care. Among these states are California, Connecticut, Florida, Indiana, Minnesota, Missouri, North Carolina, New Jersey, Pennsylvania, Texas, Virginia, Wisconsin, and West Virginia. In general, populations with complex medical needs are the ones who can gain the most from a managed care environment.

The FY 2009 President's Budget proposes to repeal Section 1932(a)(2) to permit States to mandate their enrollment into managed care without seeking waiver authority. We believe that permitting States to enroll these groups in Medicaid managed care programs will greatly enhance beneficiaries access to quality health

services in part through improved care coordination, tracking mechanisms, simplified billing, enlarged provider networks, management of chronic illness, and better screening. The Medicaid program will also benefit from reduced costs, increased emphasis on preventive care, and minimization of unnecessary services.

5. **Question**
The Budget would appear to extend QI-1 for one year but then cut the matching rate from 100% to a state's regular FMAP, thus almost halving the cost of the QI-1 extension. Can you confirm? What is the justification for removing full federal support for states providing QI-1 coverage for low-income seniors and disabled individuals?

Response: The Qualified Individual (QI) program was created to pay the Medicare Part B premiums of low-income Medicare beneficiaries with incomes between 120 and 135 percent of the Federal poverty level. In addition, QIs are deemed eligible for the Medicare Part D low-income subsidy program. States currently receive 100 percent Federal funding for the QI program. The FY 2009 Budget proposes to extend the QI program through September 30, 2009. The FY 2009 President's Budget also includes a proposal to align the federal reimbursement for the QI program from 100 percent to the State's FMAP rate. By aligning the federal reimbursement to the State's FMAP rate, this proposal promotes consistency in the matching structure across the Medicaid program.

6. **Question**
Does the Budget's baseline anticipate any administrative or regulatory changes that HHS expects to put forward later this year? If so, which policies do you anticipate to put forward? In what fashion (e.g., regulation, State Medicaid Director Letter, etc...). Irrespective of the baseline are there any other administrative or regulatory changes to Medicaid or SCHIP that you anticipate making this year that have not been described in the budget?

Response: Many assumptions must be made in order to calculate the baseline estimates. These include assumptions about the timing and substance of regulations that will be issued over the projection period, the use of the administrative discretion provided under current law, and other assumptions about the way programs operate. As a matter of general practice, administrative actions articulated in the President's Budget are included in the baseline estimates. In the Mid-Session Review, progress made on these administrative actions is evaluated and baseline estimates are modified as necessary.

The President's Budget announces plans for several initiatives that the Administration will implement through either regulatory or sub-regulatory guidance, including: (1) clarification of the inflation protection requirement in the long-term care partnership programs; (2) issuance of a regulation defining Section 1915(b)(3) services, and (3) issuance of a regulation codifying the longstanding

Medicaid "free care" policy. The specific details on these administrative proposals are still being developed at this time.

To the extent possible, anticipated administrative actions are announced in the President's Budget; however, Federal administration of the Medicaid and the State Children's Health Insurance Program (SCHIP) is a dynamic process and in being a responsible steward of the programs, we will take the necessary administrative actions within the confines of the law.

7. **Question**
On page 67 of the HHS Budget in Brief what is meant by statement that your SCHIP reauthorization proposal "clarifies eligibility for SCHIP by clearly defining income" ? Please provide specific elements of this proposal including which populations would be impacted and how income definitions would be clarified? How does this proposal differ from the August 17 "State Health Official Letter" also described on page 67?

Response: The Administration believes that it is necessary to clarify the application of income disregards to ensure that SCHIP serves the population originally intended: low-income, uninsured children. Through income disregards, States effectively raise the income eligibility threshold and increase eligibility beyond the statutory definition of "targeted low-income child." Additional details about this specific proposal are still under development.

The August 17th State Health Official Letter shares the goal of putting poor children first and achieves this by strengthening efforts to prevent the substitution of SCHIP for private insurance.

8. **Question**
In testimony last year, Dennis Smith of CMS stated that HHS was considering administrative or regulatory action to limit Medicaid eligibility through limitations on income disregards. Such a proposal is not mentioned in the President's budget. Is HHS still developing or considering such a regulation or administrative action? If so, when do you anticipate implementing such action? In what manner will it be implemented (e.g., promulgation of a regulation, a State Medicaid Director Letter, etc...)?

Response: As part of the larger SCHIP reauthorization proposal, the President's FY 2009 Budget proposes to clarify the use of income disregards. Further details on this proposal are under discussion; however, there is clearly an interaction between SCHIP and Medicaid and the implication for Medicaid needs to be considered.

From a policy perspective, it should be clear that the focus of the SCHIP and Medicaid programs should be on targeted low income populations. Thus, it would be consistent to apply the policy of serving the poorest children first, where a

State chooses to expand its programs through Medicaid or separate SCHIP program funding. Thus, we continue to review this issue.

We have presented a legislative proposal on SCHIP and believe both SCHIP and Medicaid should be addressed. We will continue to exercise our obligations under current law and reserve the option to take further regulatory action if deemed necessary.

9. **Question**
On page 24 of the Budget, what is meant by the statement that you will strengthen Medicaid program integrity and accountability by "giv[ing] States more flexibility to tailor acute care benefits in a manner that better meets the needs of higher-income LTC populations"?

Response: The President's FY09 Budget, includes a Medicaid legislative proposal to redesign acute care benefits for optional long-term care groups

The Deficit Reduction Act of 2005 (DRA) provided States with more flexibility to offer private sector-type coverage to certain adults and children. This proposal would expand the benefit flexibility option established by Section 6044 of the DRA to certain optional aged, blind and disabled groups. The benefit flexibility would be applied to acute care services only, long term care services would be exempt.

10. **Question**
The Budget proposes to significantly reduce Medicare Disproportionate Share Hospital (DSH) payments. During the Monday February 4, 2008 briefing by HHS and OMB staff of Senate health staff, this payment reduction was justified by the decrease in uninsured Americans that the Administration claims is attendant to the Affordable Choices proposal. Such an assertion would appear to assume that Medicare DSH payments are primarily intended to reimburse uncompensated care cost experienced by Medicare providers. Please confirm that this is the Administrations position or provide an explanation of how the statement made during the briefing is consistent with some other perspective on the purpose of Medicare DSH.

Response: Disproportionate Share Hospital (DSH) payments help compensate hospitals for the care they provide to uninsured individuals. The President's budget includes a comprehensive tax proposal to provide credits for the cost of health care. These tax credits will help reduce uncompensated care, and thus, make it possible for us to reduce the size of Medicare DSH subsidies.

11. **Question**
Throughout the last year, the Administration has issued a series of new regulations and guidances that significantly alter the structure and focus of Medicaid program and the State Children' Health Insurance Program (SCHIP). The Administration

describes these proposals on pages 62 through 64 and page 67 of the HHS Budget in Brief. The Administration has argued that several of these proposals are premised on efficiency. Please provide all the efficiency studies utilized by the Administration to support these policies.

Response: The statute confers upon the Secretary the responsibility to assure "proper and efficient operation" of State Medicaid programs and that Medicaid payments are "consistent with efficiency, economy, and quality of care." It is within the Secretary's discretion to make such determinations and conduct the appropriate Federal oversight. Moreover, SCHIP programs are required to provide benefits "in an effective and efficient manner that is coordinated with other sources of health benefits."

Recent regulations and guidance all fall within the Secretarial Federal oversight responsibility to ensure that Medicaid and SCHIP are operating within statutory requirements.

12. Question

The President's budget contains funds for the continued work of the American Health Information Community (AHIC) to advise the US Department of Health and Human Services. There is a lot of support for continuing the effort to establish national interoperable Health Information Technology standards. Many of us support the bipartisan Wired for Health Care Act. Will you work with us to get this passed and signed into law?

Response:I appreciate your dedication to health information technology (health IT), and share your commitment to this important issue. As you know, one of my highest priorities as Secretary has been to advance the availability of interoperable health IT across the Nation improving the quality and cost-effectiveness of health care.

HHS has issued a contract for the establishment of a collaborative health IT and health information exchange governance entity, with multi-stakeholder functions related to interoperability and standards, in the private sector (the successor to the AHIC [American Health Information Community], or "AHIC 2.0"). The team of LMI Government Consulting and The Engelberg Center for Health Care Reform at the Brookings Institution, working under a cooperative agreement with HHS, is convening stakeholders to establish a nationwide focal point for health information interoperability in the private sector as a public-private organization. The existing AHIC will continue to receive HHS funding and to function as an advisory committee under the Federal Advisory Committee Act until December 2008, when we anticipate that the successor will be fully established. It is important to ensure that all interested stakeholders are able to have a voice in this very complex undertaking and the AHIC 2.0 will provide a sustainable venue.

I hope to work with you and your colleagues in Congress to ensure that any health IT legislation complements steps already taken towards what I believe is our

shared goal of ensuring that most Americans have access to secure and interoperable electronic health records by 2014. However, I am concerned that the legislation you mention, as presently drafted, could create barriers to continued progress already underway. Several milestones have been met to meet the President's call for mostAmericans to have access to electronic health records by 2014. Our achievements and continured work in the areas of governance, interoperability, networking, adoption, privacy, and secuirtyis on a forward path and I hope to work with you to ensure any health IT legislation will not slow this progress.

13. **Question**

Given the challenges that many of my constituents confront in accessing healthcare, I am particularly interested in flexible solutions that facilitate access to healthcare for patients who have difficulty reaching traditional healthcare settings. For these patients, remote monitoring can play critical role in their ability to receive important continuity of care.

The drug warfarin can be very effective at reducing the rate of stroke and blood clots. However, dosing with warfarin must be monitored carefully to ensure therapeutic benefit and protect patient safety. Medicare has covered home monitoring of warfarin dosing in limited circumstances since 2002. On December 20, 2007, the Centers for Medicare & Medicaid Services proposed to expand coverage of home monitoring for patients on chronic warfarin anticoagulation therapy. If finalized as proposed, Medicare coverage would be significantly expanded.

However, it is my understanding that if finalized as proposed, Medicare coverage for home monitoring still would be limited to patients with certain specified indications (i.e., mechanical heart valves, atrial fibrillation and deep venous thrombosis), and that 20 to 30 percent of patients on chronic warfarin therapy, who otherwise might be good candidates and benefit from home monitoring, might still be ineligible for home monitoring. For example, patients often are prescribed warfarin to treat cardiovascular prophylaxis, cerebrovascular prophylaxis, dilated cardiomyopathy, etc... In all of these conditions, chronic warfarin therapy requires careful monitoring to reduce the risk of serious bleeding while maintaining sufficient anticoagulation to reduce the risk of clotting. Yet, if finalized as proposed, Medicare's coverage policy would not cover home monitoring for persons taking warfarin on the basis of these indications.

Please explain why CMS is recommending limited coverage for home monitoring generally. Also, please explain why the agency is not recommending coverage for all patients on chronic warfarin therapy who otherwise are suitable candidates for home monitoring.

Response: Under Medicare's former national coverage determination (NCD), effective July 1, 2002, coverage of home prothrombin time/international normalized ratio (PT/INR) monitoring was limited to patients with mechanical

heart valves who were receiving the anticoagulation drug warfarin. In June 2007, CMS received a formal request for reconsideration of this NCD from International Technidyne Corporation, HemoSense, Inc., and Roche Diagnostics Corporation on behalf of the Prothrombin-Time Self-Testing Coalition. The requestors asked CMS to expand coverage of home PT/INR monitoring to patients using warfarin for any reason, or in the alternative, to include patients with atrial fibrillation and deep vein thrombosis (as well as continuing existing coverage for those with mechanical heart valves).

As you have noted, CMS published a proposed decision in December of 2007 for purposes of receiving public comments as required by statute. After considering additional evidence and public comments, we issued our final decision on March 19, 2008, and expanded Medicare coverage nationally for two additional types of patients. Our evidence review determined that the evidence to support home monitoring for patients with atrial fibrillation and deep vein thrombosis was considerably stronger than the evidence for other indications.

We found that the current evidence does not support broad national coverage for all indications for warfarin use or more frequent testing. We remain concerned about the limited generalizability of existing studies to broader populations. In particular, the ability of the investigators to enroll only a very small percentage of eligible subjects leads us to determine that home testing should only be covered in patients who demonstrate the capability and motivation to accurately perform home testing as part of the management of their anticoagulation therapy. This includes prompt communication of the test results to their physician and adherence to the prescribed treatment regimen. We believe that any benefits attributable to home testing are negated if the testing is not integrated into a comprehensive therapeutic strategy.

While we have expanded coverage nationally for two additional groups of patients, our decision is flexible in allowing local Medicare contractors to make coverage determinations for beneficiaries with indications that are not addressed by this NCD. We believe that the final decision balances the desire for broader access against the concerns that some patients will not be able to manage or benefit from home testing. The policy provides flexibility for other beneficiaries who may be suitable candidates for home monitoring.

We would be happy to reconsider this decision if new evidence supported broader coverage.

Senator Kerry:

1. *Medicaid Cuts – Impact on Stimulus*
   Question
   According to a report from the Center on Budget and Policy Priorities, more than half of the states in the nation will face budget trouble in 2008. Yet, the Medicaid budget

cuts proposed by the Administration are blind to this economic reality and work counter to the efforts of this body and the administration to pass an economic stimulus package. How does the Administration reconcile these conflicting policy proposals?

Response: The Administration supports economic growth packages that are broad-based, large enough to make a difference and rely more on tax-relief rather than creating new government spending programs or expanding existing programs.

Similarly, the FY 2009 President's Budget supports efforts to slow the growth rate in the Medicaid entitlement program. The proposals would restrain the five-year annual average growth rate from 7.4 percent to 7.1 percent. Additionally, it would enhance access and continuity of coverage by improving program integrity, increasing State flexibility, and promoting cost-effective management of Medicaid dollars. Many of these reforms build on past efforts by Congress and the Administration to restrain grow rates and promote long-term viability of the Medicaid entitlement program, which together, will save $17.4 billion over five years in Medicaid legislative changes and $800 million in administrative changes over five years.

2. *Recent Termination of the Medicare Health Support Demonstration Project:*
Question
When it comes to the rising cost of care, we all agree that more needs to be done to better manage chronic disease – in the health system at large and in the Medicare program in particular. Medicare has been attempting to modernize its disease management capabilities through a number of programs, including the Medicare Health Support pilot. Yet CMS recently decided to terminate Phase I of the pilot while we wait for up to 3 years for an evaluation. Many observers around Washington feel that CMS's narrow interpretation of the statute (Section 721 of the MMA) essentially terminates the MHS program. This means that 35 million Medicare FFS beneficiaries will not have the opportunity to benefit from care management services in the near future, as intended by Congress in the MMA. My office has reviewed and we have concluded that the flaws were not in the legislation but in the design and implementation of the pilot – particularly with respect to determining whether the pilot programs achieve budgetary savings.

Mr. Secretary, the impact of care management has been demonstrated in commercial health plans and self insured businesses, in both published and unpublished studies. Given that the pilot design and implementation were flawed, I would like to know if you are willing to rethink your understanding of the legislation and act upon the latitude provided in the legislation to move forward immediately to Phase II with a design that is more reflective of current standards in the industry?

Response: CMS agrees that managing chronic diseases is an important aspect of any health care regimen. We also believe it is important to find the right tools to

do this job. To that end, CMS has tested and continues to test a variety of disease management models to determine what works for the Medicare fee-for-service population.

CMS has not terminated the Medicare Health Support (MHS) program. Phase I of the pilot program is being allowed to run its course and will be fully evaluated prior to making any decisions regarding expansion to Phase II. Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Chronic Care Improvement Program, now called MHS, as a two phase program. The statute called for a 3-year Phase I to develop, test and evaluate programs using randomized controlled trials, and authorized the Secretary to expand the program under a Phase II only if specified criteria were met. Those criteria required each program (or components of a program) to (1) improve the clinical quality of care, (2) improve beneficiary satisfaction, and (3) achieve savings targets specified by the Secretary (at a minimum, budget neutrality). We believe these statutory parameters are clear and provide no authority for an extension of Phase I beyond the 3-year point, or for initiation of a Phase II absent achievement of all of the specified criteria.

The independent evaluator for MHS will continue its review until each of the Phase I programs has been evaluated for its complete 3-year pilot period (or the operational period for the three programs that chose to terminate before the end of their 3-year period). No decision on Phase II will be made until that evaluation is complete. This full evaluation of Phase I will give us maximum opportunity to determine whether or not any program or program component meets the statutory requirements for expansion. Should such evidence be found, we then would have the authority to expand MHS to Phase II.

However, our experience to date suggests that the Phase I programs have not met the statutory requirements for the initiation of a Phase II and are unlikely to meet them in the future. The programs' impact to date on quality and beneficiary satisfaction has been small and inconsistent. In addition, to reach budget neutrality, the five MHS organizations still in operation would need to reduce their Medicare claims costs by between $300 and $800 per participant per month for the remaining months of the pilot (Phase I) program. This represents a 20 to 40 percent reduction in claims costs from current billing levels. If a program is unable to save enough money to at least cover the cost of its MHS fees, it will be liable under the statute for repayment of those fees to Medicare.

Program-wide fees paid to the MHS programs to date equal about $360 million – an increase of 5 to 11 percent in Medicare costs for participating beneficiaries. In addition, CMS has spent approximately $27 million in operational costs. In other words, the MHS program is costing much more than would have been spent on services for the participating beneficiaries had the program not been implemented; thus budget neutrality is not being met.

You noted concerns about the design of the Phase I pilot program. The care management design of each MHS program was proposed by the MHS organizations themselves. The MHS organizations also have flexibility to make changes in the design of their interventions to best serve their target population. CMS worked very closely with each organization during their implementation periods to meet their needs as fully as possible, within the constraints of the Medicare program and population.

You also noted that the impact of care management has been demonstrated in commercial health plans and self insured businesses, in both published and unpublished studies. However, prior studies did not consider whether those benefits could be replicated in the fee-for-service Medicare population. Medicare Health Support was designed to help answer that question. The challenges facing this program include Medicare claim costs that are not directly related to the patient's chronic condition; longstanding behaviors and significant social needs of the population; high mortality rates; multiple providers; and limited contact with treating physicians. Moreover, the MHS organizations have been inconsistent in replicating results between their initial intervention group and a second "refresh" intervention group (adding new beneficiaries to replace those who died or became ineligible)

CMS remains committed to exploring strategies to improve the health and wellbeing of beneficiaries with chronic conditions. A great deal has been learned from MHS Phase I, which will be applied to future efforts to improve the quality of care for beneficiaries with chronic conditions and to save resources for the Medicare Trust Funds.

3. *Massachusetts Health Reform: Medicaid Waiver Renewal*
Question
As you know, the financing of Massachusetts' health reform initiative is based in large part on the state's Medicaid waiver. It is absolutely critical to my state – and to the future of that important, landmark effort – that the waiver is renewed and strengthened before it expires in less than a year.

We know the first year has been a huge success – hundreds of thousands of previously uninsured citizens now have health coverage and the cost of a quality health insurance plan in the Connector has been reduced significantly. You have called health reform in Massachusetts an "important national model." I hope you continue to believe in this sentiment and will uphold the Administration's commitment to working with the state to ensure its success.

Governor Patrick's administration has recently submitted its extension application. Can you please discuss your views on the Massachusetts reform initiative and on the waiver renewal? In particular, will you commit to ensuring that the amount of Medicaid funding we receive under the new Waiver recognizes a reasonable increase

in Medicaid expenditures for the newly insured individuals who are covered through this successful partnership over the length of the next Waiver period?

Response: I recognize that while Massachusetts's Section 1115 demonstration is only one part of the Commonwealth's larger health reform efforts, it is an instrumental component in that it provides the Federal expenditure authority for eligibility expansions and support to the health care safety net. Having said that, we need to establish that the demonstration is, and will remain, budget neutral to the Federal government and that it is achieving its intended goals.

This, in combination with the complexity of the Massachusetts demonstration, makes it imperative that the staff of the Centers for Medicare & Medicaid Services (CMS) and the Commonwealth of Massachusetts work closely and expediently to address the multiple components of this renewal, including eligibility, health care reform, supplemental payments to hospitals, demonstration costs and cost-containment alternatives. We recently addressed many of these issues in a letter to the Commonwealth on February 19, 2008. I understand that these discussions are already underway and CMS has requested additional information from the Commonwealth to move forward in the process. The Administration remains committed to working with Massachusetts to expedite the renewal process for this demonstration, within the confines of statutory and policy requirements.

Senator Lincoln:

1. **Question**
Mr. Secretary, the budget proposes to increase funding to states by nearly $19.7 billion through 2013. Can you shed some light on how you propose to increase the annual CHIP funding allotments? Furthermore, can you comment on whether the proposed funding level is sufficient to cover all children currently enrolled in the CHIP program (let alone provide coverage to children who are currently eligible but not enrolled in the program)?

Response: As part of a larger SCHIP reauthorization proposal, the President's FY 2009 Budget provides $19.7 billion in SCHIP allotment increases through FY 2013 to meet anticipated States needs in covering uninsured, targeted low-income children. I look forward to working with Congress to more efficiently target funds to States in order to avoid large allotment surpluses in some states and shortfalls in other states.

As a result of these proposed additional resources, the Administration estimates that in 2013, 5.6 million children on average will be enrolled in SCHIP, or nearly nine million children enrolled at some time during the year. In FY 2006, approximately 4.0 million children on average were enrolled in SCHIP, or 6.6 million children enrolled at some time during the year.

2. **Question**
The Center on Budget and Policy Priorities indicates that at least 24 states are facing budget shortfalls in fiscal year 2009 totaling more than $34 billion. With few options for fiscal relief, states are often forced to make cuts in their health and welfare programs just when their citizens most need this assistance. During the last recession, 34 states cut eligibility for their public health programs, leaving more than a million people without health coverage. With many Americans already at risk of losing their public coverage, why does the president's budget recommend cutting more than $18 billion in federal Medicaid funding and shifting these costs to states that will have no option but to cut their Medicaid programs?

Response: The FY 2009 President's Budget works to enhance access and continuity of coverage by improving program integrity, increasing State flexibility, and promoting cost-effective management of Medicaid dollars. Many reforms build on past efforts by Congress and the Administration to restrain grow rates and promote long-term viability of the Medicaid entitlement program, which together, will save $17.4 billion over five years in Medicaid legislative changes and $800 million in administrative changes over five years. Through these efforts, we can restrain the five-year annual average growth rate of Medicaid from 7.4 percent to 7.1 percent.

3. **Question**
Mr. Secretary, your FY 2009 budget calls for a $1.1 billion reduction in reimbursement to community pharmacies in Medicaid. This would come on top of an $8 billion reduction in payments that would result from the so-call AMP pharmacy payment changes made in the Deficit Reduction Act of 2005. As you know, CMS issued regulations last year to implement the DRA that would pay pharmacies less than their costs for many generic drugs, according to both GAO and your own Inspector General's office. Given the severity of the cuts pharmacies already are facing, I am deeply troubled by you budget's proposal to cut another $1.1 billion from our Nation's pharmacy providers. How does your department justify additional cuts of this magnitude?

Response: The President's FY 2009 Budget seeks to rationalize pharmacy reimbursement by building on changes to pharmacy reimbursement in the Deficit Reduction Act of 2005 (DRA), Public Law 109-171, which set the Federal Upper Limit (FUL) for all multiple-source drugs at 250 percent of the average manufacturer price (AMP). The FUL encourages states to pay pharmacies more appropriately for the estimated acquisition costs of generic drugs.

By lowering the FUL reimbursement for multiple source drugs to 150 percent of AMP, this proposal would result in significant savings for both state and federal governments. The FUL would be set at one and one-half times the average manufacturer price. We believe that the mark up will be sufficient to cover the wholesaler's fees and retail pharmacy costs. While states must not exceed the FUL for drugs in the aggregate, they retain the authority to set their own

reimbursement levels and dispensing fees paid to pharmacists. CMS encourages states to set fees they pay pharmacies that are adequate and reasonable to compensate them for their costs in dispensing these prescriptions.

In addition, we disagree with the GAO and OIG reports, both of which were issued prior to our final AMP regulations, and we do not believe that the AMP-based FULs would result in pharmacies being paid less than their acquisition costs.

4. **Question**
As you know, a federal district court has issued a preliminary injunction blocking your department from implementing the AMP pharmacy payment regulations. In that lawsuit the judge found that your department's rule would cause the pharmacies "to suffer irreparable harm." And, more important, the judge also found that if your Department's rule were to be implemented, "thousands" of pharmacies would "be forced to reduce hours and services, forced out of the Medicaid program, or forced to close." In your opinion, if the court should overturn the rule and the plaintiffs prevail, will CMS be able to revise the rule under the existing federal statute, or will the court decision require Congressional action to revise the federal law?

Response: Our Department's rule was published to implement, and is consistent with, the statutory provisions of the Deficit Reduction Act of 2005 (DRA). These DRA provisions were enacted, in part, due to a report of the Office of Inspector General that found the amount States and the Federal government had been paying pharmacies for Medicaid-covered drugs exceeded pharmacies' actual acquisition costs. We cannot specifically comment on pending litigation, however, we agree with the policy of the DRA, that drug pricing transparency will lead to more equitable and appropriate reimbursement for prescription drugs. Unfortunately, the United States District Court for the District of Columbia has temporarily enjoined CMS from taking any action to implement some portions of our congressionally-mandated rule, specifically those which allow for the use of average manufacturer prices (AMPs) to set Federal Upper Limit (FUL) reimbursement for multiple source drugs and make these AMPs available to the public, thereby making drug pricing transparent. We believe that our rule is authorized by the Social Security Act and the DRA, but the outcome of any lawsuit is never certain. There is a possibility that the district court will permanently enjoin the implementation of the rule, and Congress will not realize the cost savings it intended when it decided to base the FULs on AMP in the DRA. Legislation supporting CMS's interpretation would avoid that result.

5. **Question:**
Mr. Secretary, I am concerned that the budget fails to provide any account-level detail on discretionary spending after the first year. It claims savings from reduced spending on domestic programs – in healthcare specifically, $8.7 billion or 14.4% – but doesn't say where those cuts will come from. Can you tell us where to expect to see these cuts?

Response:
The outyear spending totals in the FY 2009 Budget reflect the President's recommendations for aggregate discretionary spending. However, there is no policy attached to the funding levels beyond 2009. Decisions about specific outyear funding levels for all HHS discretionary programs have not been made. Those specific policy decisions will be made in the development of subsequent annual budget submissions.

6. **Question**
Mr. Secretary, I'm concerned about the Medicare skilled nursing cuts proposed in the President's budget because, as I'm sure you agree, patients in nursing home are among the sickest of all Medicare beneficiaries. Underlying my concern is the fact that Medicaid and Medicare together pay for the care of 3 out of every 4 nursing home patients. Historically, Medicaid has under-funded nursing home care by billions of dollars a year. I'm concerned that any cuts to Medicare funding for skilled nursing care will create an unstable care environment and ultimately undercut the steady progress nursing homes are making in improving quality. What will the Administration do to ensure that Medicare and Medicaid funding together are adequate to protect quality of patient care?

Response: Spending on SNF services continues to increase, with a corresponding increase in the volume of services provided by SNFs. To control this spending growth and encourage efficiency in Medicare, the President's budget proposes to adjust the Medicare payment update for skilled nursing facilities (SNF) in 2009 and thereafter. This proposal is consistent with recommendations made by the Medicare Payment Advisory Commission (MedPAC) for 2009 and builds upon those recommendations for future years. MedPAC estimates that SNF Medicare margins will average 11.4 percent in FY 2008. Further, MedPAC analysis shows that beneficiaries experience few problems accessing SNF care. The proposed Medicare payment adjustment would encourage program efficiency without affecting the ability of SNFs to furnish high quality care to Medicare beneficiaries. The proposal would also strengthen the long-term financial security of Medicare, which is critical to stability in access as well as quality.

7. **Question**
I am dismayed that more than two-thirds of the Medicare cuts are targeted at hospitals. The budget would cut $89.8 billion over five years at the national level, and the impact of these cuts would be approximately $867 million over five years for Arkansas. Hospitals face a number of challenges today – the need to keep pace with current technologies and facility improvements, growing numbers of uninsured Americans, preparing for pandemics, and caring for an aging population often with more complex care needs than ever before. Do you really think that eliminating funding, and especially disproportionate share ("DSH") payments for hospitals that treat a large share of low-income patients will truly result in savings to the

government? I can assure you that a sicker population – one that does not seek or gain access to necessary treatments – will only add to this nation's healthcare crisis...whether it's the economic toll of employees not able to go to work or the pressure of more and more uninsured Americans. I would urge you to reconsider the role these hospitals play in our communities and how their funding should be consistent with other funding priorities, like health IT or pandemic and bioterrorism preparedness.

Response: Despite average negative profit margins, hospitals continue to have significant access to capital to expand their services. Hospital construction spending has grown 191 percent between 1999 and 2007, with $32.6 billion spent on construction in 2007 alone. In addition, the Medicare Payment Advisory Commission (MedPAC) has noted that all indicators of payment adequacy were positive for hospitals. MedPAC has also noted that the rate of cost growth has been high for the hospital industry when there has been low financial pressure. Hospitals historically have demonstrated that they can reduce costs without hindering access.

The Administration has been working on improving the accuracy of payments to hospitals and improving the quality of care provided. Medicare Severity-Diagnosis Related Groups (MS-DRGs), value-based purchasing, elimination of payments for never events, and the efforts of Medicare Quality Improvement Organizations all encourage hospitals to improve the quality and efficiency of the services they provide. It is only appropriate that some of the benefits from these efforts result in savings for the Medicare program.

Disproportionate Share Hospital (DSH) payments help compensate hospitals for the care they provide to uninsured individuals. The President's budget includes a comprehensive tax proposal to provide credits for the cost of health care. These tax credits will help reduce uncompensated care, and thus, make it possible for us to reduce the size of Medicare DSH subsidies.

Senator Bunning:

1. **Question**
   In 2007, the Administration published a rule to phase out Medicaid reimbursement for certain school-based transportation and administrative expenses. Congress has put a moratorium on implementing this regulation until June 2008. What would be the affect of this rule on states, like Kentucky, that have Medicaid waivers? Is this rule part of the Administration's efforts to restrain growth in the Medicaid program?

   Response: The Administration's rule on school-based administration and transportation services addresses long-standing concerns about improper billing under the Medicaid program by school districts for administrative costs and transportation services, which has been a longstanding concern of the Department of Health and Human Services (HHS). Both HHS' Office of the Inspector

General (OIG) and the Government Accountability Office (GAO) have identified these categories of expenses as being susceptible to fraud, waste, and abuse. Congress has also expressed concern over the dramatic increase in Medicaid claims for school-based administrative costs and transportation services. This regulation is an important step in protecting the fiscal integrity of the Medicaid program.

Under the Medicaid program, Federal payment is available for the costs of administrative activities "as found necessary by the Secretary for the proper and efficient administration of the State plan." The final rule would eliminate reimbursement under the Medicaid program for the costs of certain activities based on a Secretarial finding that these activities are not necessary for the proper and efficient administration of the State plan, nor do they meet the definition of an optional transportation benefit. Based on these determinations, under the final rule, Federal Medicaid payments would no longer be available for administrative activities performed by school employees or contractors, or anyone under the control of a public or private educational institution, and transportation from home to school and back for school-aged children.

The final rule would not affect the treatment of expenditures for direct medical services that are included in the approved State Medicaid plan and provided in schools, nor does it affect transportation of school-aged children from school or home to a non-school-based direct medical service provider that bills under the Medicaid program, or from the non-school-based provider to school or home. As a result, we do not believe these changes will impact children eligible for Medicaid.

An impact analysis was included in the final rule, which was published in the Federal Register on December 28, 2007. We do not have state-specific estimates, but the final rule argues that the impact on local school districts will not exceed the threshold of "significant" economic impact. States have the option under the final rule to continue funding school-based administrative activities using State-only funds. We do not anticipate this rule having a differential impact on States with waivers as opposed to those without.

The rule is not part of any effort on the part of the Administration to "restrain growth in the Medicaid program." Rather, it clarifies that Medicaid is not the appropriate funding source for school-based administrative activities or for transportation from home to school and back. These activities or services are fundamentally undertaken for the educational mission of the school, rather than for administration of the Medicaid State plan and do not directly benefit the Medicaid program.

2. **Question**
In the HHS budget documents, the Administration recommends that inpatient rehabilitation facilities receive a freeze in their payment update for 2010 and 2011,

along with reductions in later years. The Administration also proposed in a footnote to repeal certain provisions of Sections 114 and 115 of the Extension Act of 2007 which deal with inpatient rehab facilities and long-term care facilities. You've calculated these changes to save $510 million in the FY09 and $4.8 billion over five years.

a) Exactly which provisions in Sections 114 and 115 do you want to repeal? Why do you want to repeal this legislation, which Congress passed and the President signed into law less than two months ago?

Response: The President's budget proposes to repeal Section 114(c) of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA), which required the suspension of certain payment policies for long-term care hospitals (LTCHs) that the Secretary had already implemented, or was considering implementing. We believe that these payment policies would protect the Medicare program from patient shifting between acute care hospitals and LTCHs, resulting in two Medicare payments for what is essentially one episode of patient care. Such practices undermine the basic premise of cost control with adequate payment that is the key feature of Medicare's prospective payment systems. In addition, these payment policies would have the effect of encouraging program efficiency within the LTCH industry.

The President's budget also proposes to repeal Section 115(b) of MMSEA. This provision involves inpatient rehabilitation facilities (IRFs) and permanently lowers the IRF compliance percentage to 60 percent. The compliance percentage, which is sometimes also referred to as the IRF classification criteria or the "75 percent rule", is the percentage of patients admitted to the IRF that must require intensive rehabilitation treatment for one or more of 13 specified conditions. In addition, this provision permanently included patient comorbidities in the calculations used to determine whether an IRF meets the IRF compliance percentage.

The "75 percent rule" has been a long-standing Medicare requirement that was designed to guarantee access to IRFs for the atypical subset of patients who require IRF care following a major illness or injury. Ultimately returning to 75 percent as the compliance percentage will encourage program efficiency and ensure that patients requiring a high level of intensive rehabilitation services are appropriately treated in an IRF. In addition, MedPAC has noted that IRFs have successfully reduced costs in response to the tighter fiscal pressures imposed by the 75 percent rule.

With respect to comorbidities, it is not unusual for patients admitted to IRFs to have more than one ailment for which the patient exhibited a need for medical treatment. However, the patient's principal diagnosis (not the comorbidities) most accurately denotes whether a patient has one or more of the 13 conditions

identified in the "75 percent rule" since it is based on clinical evidence presented in the patient's medical record.

Question

b) The 2007 Extension Act already froze the rehab facility payment rates through FY09. Please explain how the $510 million in savings for FY09 is calculated in your budget?

Response: The $510 million in savings in the President's FY2009 budget is the estimate of the savings associated with the repeal of Section 115(b) of MMSEA. Repealing this provision would bring the compliance percentage, i.e., the percentage of an IRF's patients that must require intensive rehabilitation treatment for one or more of 13 specified conditions, back to the original transition to 75 percent instead of permanently setting it at no greater than 60 percent, and would remove the requirement to include comorbidities in the calculation of the compliance percentage.

Question

c) Please provide a breakdown as to how much of the 5-year savings ($4.8 billion) is attributable to the proposed changes to the payment rate for rehabilitation facilities as opposed to repealing portions of Section 114 and 115?

Response: The $4.8 billion in savings over the five years reflects the savings associated with the repeal of the inpatient rehabilitation facility (IRF) provisions of Section 115(b) of MMSEA, as well as the reductions in the IRF update factor proposed in the President's FY2009 budget. The table below illustrates the specific breakdown.

Inpatient Rehabilitation Facility (in millions)

FY	Update	75% Compliance, Comorbidity exclusion	Total*
2009	0	(510)	(510)
2010	(170)	(590)	(760)
2011	(450)	(630)	(1,080)
2012	(540)	(630)	(1,170)
2013	(640)	(660)	(1,300)
Totals	(1,800)	(3,020)	**(4,820)**

3. **Question**

Your budget also proposes to set a base payment rate for 5 post-acute conditions that are treated in skilled nursing facilities or inpatient rehabilitation facilities. You calculate this will save $250 million in FY09 and $1.6 billion over 5 years.

a) Please tell me exactly what the 5 conditions are?

Response: The Administration's proposal to establish site neutral payments in post-acute care settings establishes a new post-hospital payment rate for five conditions that are commonly treated in both skilled nursing facilities (SNFs) and

inpatient rehabilitation facilities (IRFs). These five conditions are unilateral knee replacement, unilateral hip replacement, unilateral hip fracture, chronic obstructive pulmonary disease, and other pulmonary diseases.

Question

b) How have you ensured that patients with one of these 5 conditions are receiving care in the most appropriate setting, and not just in the cheapest?

Response: Leading experts in rehabilitation medicine, as well as a 2005 Government Accountability Office study, have questioned the use of IRFs to treat a growing number of relatively non-complex joint replacement cases. They reason that IRFs are organized to provide intensive inpatient rehabilitation care and such facilities should not be treating these non-complex cases. Accordingly, it is difficult to justify the dramatic payment differentials between the two settings for these cases. The average payment to an IRF for a total knee replacement is more than 80 percent greater than the average payment made to a SNF. For a total hip replacement, the average IRF payment is close to 40 percent greater than the average SNF payment.

4. **Question**

I have been a supporter of the Medicare prescription drug benefit from day one and believe the benefit is working well for most beneficiaries. However, one area that I think needs more focus is how the benefit is working for residents in long-term care facilities. Often times, these residents are the most vulnerable served by Medicare. Since most of these individuals are dual eligibles, they are auto-enrolled in a Part D plan if they do not choose a plan by themselves. I've heard that many times they are enrolled in a plan that may not be the best for them. For example, the plan may not adequately cover their medications or require prior authorizations for many of the medications they are on. Finally, I've heard from several of the long-term pharmacies in my state that many times they don't receive their full payment because the Part D plan doesn't recognize the pharmacy cannot collect a copay from the beneficiary.

What steps is your department taking to strengthen Part D for residents in long-term care facilities?

Response: CMS is committed to ensuring that Medicare beneficiaries in long-term care (LTC) facilities continue to receive the medications and pharmacy services they need without interruption. CMS continues to work with pharmacists and other healthcare providers, advocacy groups, and agencies to provide all beneficiaries residing in LTC facilities with access to affordable prescription drug coverage, enhanced compliance with treatment regimens, and improved health and reduction of adverse health effects.

CMS has taken several steps to strengthen Part D for residents in long-term care facilities, in particular to protect dual-eligible beneficiaries.

On March 17, 2008, in the 2008 CMS Call Letter, CMS reinforced our policy that Prescription Drug Plan sponsors accept Best Available Evidence (BAE) at point-of-sale. This policy requires sponsors to establish the appropriate cost-sharing for low-income beneficiaries when presented with evidence that the beneficiary's information is not accurate. Under existing BAE policy, sponsors are required accept specified forms of documentation of a beneficiary's corrected LIS status, to change the beneficiary's cost-sharing levels in the sponsor's system based on that documentation, and to submit to CMS requests for correction of these data in our system if the changes do not occur as a result of the routine State reporting. In 2009, we will be directing sponsors to accept BAE at point-of-sale and update their systems within 48-72 hours of their receipt of the documentation. Further, in cases involving immediate need (i.e., when the beneficiary has less than 3 days of medication available), sponsors must have a process in place to permit the beneficiary to receive an emergency supply of medication. Sponsors must then update their systems within 48-72 hours to allow the pharmacy to re-submit claims at the corrected cost-sharing level.

Senator Roberts

1. *Hospital Payments*

Question

The budget proposes drastic reductions to Medicare reimbursement to hospitals—more than $135 billion over 5 years. The President recommends freezing hospital updates for 3 years followed by reductions of Market Basket minus 0.65% into perpetuity. At their recent meeting, MedPAC recommended a full update for hospitals for FY 2009. One of the reasons they are recommending a full inflation update is that overall Medicare data reflect "falling, negative margins" in each year from 2003-2008. How can the administration rationalize reducing payments for hospitals given the MedPAC recommendation? Please explain the Administration's justification for this.

Please explain why the administration proposes to eliminate bad debt reimbursement for unpaid beneficiary cost-sharing, cutting $8.4 billion from hospitals. Many beneficiaries are simply unable to pay their co-pays. Why should hospitals be held liable for this?

What would be the specific impact on hospitals in rural areas and particularly critical access hospitals? Describe to me how this policy is consistent with paying critical access hospitals on a cost basis when these facilities have so few dollars over which to spread these losses.

Response: Despite average negative profit margins, hospitals continue to have significant access to capital to expand their services. Hospital construction spending has grown 191 percent between 1999 and 2007, with $32.6 billion spent on construction in 2007 alone. MedPAC also noted that all indicators of payment

adequacy were positive for hospitals. For example, there has been a net increase in the number of hospitals, and an increase in the volume of services provided.

The Administration has been working on improving the accuracy of payments to hospitals and improving the quality of care provided. Medicare Severity-Diagnosis Related Groups (MS-DRGs), value-based purchasing, elimination of payments for never events, and the efforts of Medicare Quality Improvement Organizations all encourage hospitals to improve the quality and efficiency of the services hospitals provide. It is only appropriate that some of the benefits from these efforts result in savings for Medicare.

With respect to your concern with the policy to phase-out provider reimbursement for bad debt, we believe these are obligations between providers and beneficiaries. It is not Medicare's responsibility to cover out-of-pocket costs that beneficiaries do not pay, particularly since providers are now reimbursed through prospective payment systems or fee schedules rather than on a cost basis. Further, Medicare is currently the only payer that reimburses bad debt.

As the stewards of the Medicare Trust Funds, it is important that we encourage providers to be proactive in pursuing the bad debts owed to them. This proposal will create greater incentives for providers to recoup their debts, leading to greater program efficiency and strengthening the long-term financial security of the Medicare program. We do not believe that this provision will cause providers to suffer financially because bad debt is only a small fraction of Medicare revenues for providers. For example, the reduction in Medicare bad debt payments accounts for less than 1.0 percent of revenues for hospitals, only 0.5 percent of Medicare revenues for skilled nursing facilities, and 0.1 percent for dialysis facilities. Please note the budget does not include a specific impact projection for critical access hospitals (CAHs), as you requested.

2. *Skilled Nursing Facilities*

Question

Over the past five years, Medicare funding for skilled nursing facilities has been relatively stable and, during this period, we've seen noteworthy improvements in quality of care. I am very concerned that the FY 2009 budget proposal concerning SNFs will undermine quality. I'd appreciate your comments on this concern, particularly given that the SNF's and the frail elderly they care for will essentially experience a "triple whammy" due to: (1) worsening economic conditions and state budget shortfalls with concomitant Medicaid cuts; (2) President's proposal to further squeeze Medicaid; and (3) Medicare market basket freeze in the face of the likely growth in already significant Medicaid losses for SNFs. Consistent Medicare funding is especially important at a time when states are struggling to balance their budgets, and many states are taking steps to cut Medicaid, a trend likely to accelerate if the President's proposed cutbacks in Medicaid funding also are adopted.

How can you make certain these cuts will not adversely impact SNF beneficiaries, particularly in rural states?

Response: Spending on SNF services continues to increase, with a corresponding increase in the volume of services provided by SNFs. To control this spending growth and encourage efficiency in Medicare, the President's budget proposes to adjust the Medicare payment update for skilled nursing facilities (SNF) in 2009 and thereafter. This proposal is consistent with recommendations made by the Medicare Payment Advisory Commission (MedPAC) for 2009 and builds upon those recommendations for future years. MedPAC estimates that SNF Medicare margins will average 11.4 percent in FY 2008. Further, MedPAC analysis shows that beneficiaries experience few problems accessing SNF care. The proposed Medicare payment adjustment would encourage program efficiency without affecting the ability of SNFs to furnish high quality care to Medicare beneficiaries. The proposal would also strengthen the long-term financial security of Medicare, which is critical to stability in access as well as quality.

3. *Pandemic Flu*

Question

I have been following the avian influenza outbreak in India very closely and I am aware that the country has been in somewhat of a panic over the last month over what may be the single largest avian flu outbreak to date. Of particular concern is that India is one of the countries that have not taken steps to prepare for a pandemic including stockpiling antivirals and other medical supplies. I know that you have taken great steps to prepare the United States by implementing the National Strategy for Pandemic Influenza (NSPI) over the last two years that includes the development and stockpile of pre-pandemic vaccines and antivirals.

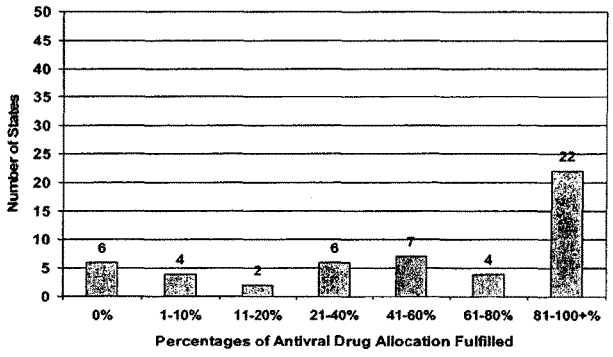
My concern is several states have not and probably will not take steps to stockpile antiviral medications that will be our first line of medicinal defense in a pandemic. The NSPI calls for states to be a partner in pandemic planning and the federal government offers states a 25 percent subsidy to purchase their allotment of antivirals. To date, states have stockpiled approximately 19 million of the 31 million courses of antivirals as outlined in the NSPI. Some states have stockpiled their full allotment of antivirals, some have stockpiled a portion of their allotment, and some have stockpiled none of their allotment and probably never will.

a) If these states refuse to stockpile antivirals in advance of a pandemic, the U.S. will never reach its goal of stockpiling enough antivirals for 25 percent of the population. Will HHS be content with the U.S. not hitting the goal of stockpiling enough antivirals for 25 percent of the population as recommended by the World Health Organization? How do you plan to address the shortfall? With regard to funding already appropriated to subsidize state antiviral purchases, how do you plan to use the unexpended funds allocated to states that decide not to stockpile antivirals?

Response:
The national pandemic influenza antiviral drug stockpiling goal is 81 M treatment courses with 6 M designated for early containment usage at pandemic onset and 75 M treatment courses for treatment of infected persons.

As of Feb. 22, 2008, forty five (45) States and Other Entities have procured 21.7 M treatment courses of influenza antiviral drugs (Fig. 1). Only six (6) States do not intend to use their federal subsidy allocation. The present deadline for States to utilize their federal subsidies to purchase antivirals for pandemic stockpiles is July 31, 2008. By the end of March 2008, HHS will complete communications with those States that have not fully utilized their federal subsidy allocations to ascertain the status of their commitments to complete this pandemic preparedness measure. Subsequently HHS will appraise the State antiviral drug stockpile program and determine the next steps including reapportionment of federal subsidies to States towards completion of the national pandemic antiviral stockpiling goal.

Figure 1. Summary of State Pandemic Influenza Antiviral Drug Stockpile Purchases



Information current as of **February 22, 2008** 5

Major issues preventing some States from purchasing influenza antivirals were the expiration dating and shelf life extension of these products. Recently FDA approved a supplemental application from Roche for Tamiflu® to increase expiration dating from five (5) to seven (7) years; the new expiration dating would apply to both federal and Sate pandemic stockpiles of this product. Coordination between the manufacturer, FDA, States, and third party companies is underway for the relabeling of the product already in State stockpiles.

Currently HHS has obligated $118 M of the $170 M appropriated for federal subsidies to State antiviral drug stockpiling. HHS will obligate these funds over the next six months as orders by States using the federal antiviral drug contracts emerge.

Decisions on remaining funds, if any, will be part of the next steps process described above.

b) **Question:**
Should the pandemic's gateway into the U.S. be Florida, for example, that has not taken steps to stockpile antivirals, what will be the consequences for the citizens of Florida? Will they be in a worse position than citizens of states like California who have taken steps to prepare?

Response:
The State of Florida like other States will receive at the onset of an influenza pandemic its *pro rata* allotment (e.g., 5.76% =2.5 M treatment courses) of influenza antiviral drugs from the Strategic National Stockpile. The federal stockpiled antiviral drugs will comprise 59% of the total number of antiviral drug treatment courses recommended for each State; stockpiling the remaining 41% is the responsibility of each State, which 23 States have completed to date. Florida and other States, which have not completed their State stockpiling of antiviral drugs, have until July 2008 to utilize their full allotment of federal subsidies and federal contracts with antiviral drug manufacturers to procure these drugs at significant savings. Afterwards States may continue to purchase these antiviral drugs for their pandemic antiviral drug stockpiles using their own contracts with the manufacturers.

I have stated on numerous occasions with the States that pandemic preparedness is a shared responsibility, that the federal government cannot shoulder the entire burden, and that States, local government, businesses and families must rely on themselves to become fully prepared.

4. Medicaid Pharmacy Payments

Question

a) Mr. Secretary, your FY 2009 budget calls for a $1.1 billion reduction in reimbursement to community pharmacies in Medicaid. This would come on top of an $8 billion reduction in payments that would result from the AMP pharmacy payment changes made in the Deficit Reduction Act of 2005. As you know, CMS issued regulations last year to implement the DRA that would pay pharmacies less than their costs for many generic drugs, according to both GAO and your own Inspector General's office. Given the severity of the cuts pharmacies already are facing, I am deeply troubled by you budget's proposal to cut another $1.1 billion from our nation's pharmacy providers. How does your department justify additional cuts of this magnitude?

Response: The President's FY 2009 Budget seeks to rationalize pharmacy reimbursement by building on changes to pharmacy reimbursement in the Deficit

Reduction Act of 2005 (DRA), Public Law 109-171, which set the Federal Upper Limit (FUL) for all multiple-source drugs at 250 percent of the average manufacturer price (AMP). The FUL encourages states to pay pharmacies more appropriately for the estimated acquisition costs of generic drugs.

By lowering the FUL reimbursement for multiple source drugs to 150 percent of AMP, this proposal would result in significant savings for both state and federal governments. The FUL would be set at one and one-half times the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. We believe that the mark up will be sufficient to cover the wholesaler's fees and retail pharmacy costs. While states must not exceed the FUL for drugs in the aggregate, they retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists. CMS encourages states to set fees they pay pharmacies that are adequate and reasonable to compensate them for their costs in dispensing these prescriptions.

In addition, we disagree with the GAO and OIG reports, both of which were issued prior to our final AMP regulations, and we do not believe that the AMP-based FULs would result in pharmacies being paid less than their acquisition costs.

Question

b) As you know, a federal district court has issued a preliminary injunction blocking your department from implementing the AMP pharmacy payment regulations. In that lawsuit the judge found that your department's rule would cause the pharmacies "to suffer irreparable harm." And, more importantly, the judge also found that if your department's rule were to be implemented, "thousands" of pharmacies would "be forced to reduce hours and services, forced out of the Medicaid program, or forced to close." In your opinion, if the court should overturn the rule and the plaintiffs prevail, will CMS be able to revise the rule under the existing federal statute, or will the court decision require Congressional action to revise the federal law?

Response: Our Department's rule was published to implement, and is consistent with, the statutory provisions of the Deficit Reduction Act of 2005 (DRA). These DRA provisions were enacted, in part, due to a report of the Office of Inspector General that found the amount States and the Federal government had been paying pharmacies for Medicaid-covered drugs exceeded pharmacies' actual acquisition costs. We cannot specifically comment on pending litigation, however, we agree with the policy of the DRA, that drug pricing transparency will lead to more equitable and appropriate reimbursement for prescription drugs. Unfortunately, the United States District Court for the District of Columbia has temporarily enjoined CMS from taking any action to implement some portions of our congressionally-mandated rule, specifically those which allow for the use of average manufacturer prices (AMPs) to set Federal Upper Limit (FUL) reimbursement for multiple source drugs and make these AMPs available to the

public, thereby making drug pricing transparent. We believe that our rule is authorized by the Social Security Act and the DRA, but the outcome of any lawsuit is never certain. There is a possibility that the district court will permanently enjoin the implementation of the rule, and Congress will not realize the cost savings it intended when it decided to base the FULs on AMP in the DRA. Legislation supporting CMS's interpretation would avoid that result.

Senator Stabenow:

1. **Question**
   Recently the Kaiser Family Foundation issued a report noting that the states have made aggressive efforts in the past year and a half to expand coverage to low-income children and working families, but the actions may be curtailed as a deteriorating economic climate and new limits on federal assistance take effect.

   But these efforts are in jeopardy. When state economies are struggling, they may lack the resources to expand or even maintain their existing Medicaid coverage. And that is a double whammy because if a state must cut into its share of Medicaid, the state also loses what the federal government will match, too.

   How does the administration justify continuing to push for draconian cuts to Medicaid that will ultimately lead to a rise in the uninsured? Shouldn't we be working with states to help working families and their businesses find insurance?

   Response: The FY 2009 President's Budget works to enhance access and continuity of coverage by improving program integrity, increasing State flexibility, and promoting cost-effective management of Medicaid dollars. Many reforms build on past efforts by Congress and the Administration to restrain grow rates and promote long-term viability of the Medicaid entitlement program, which together, will save $17.4 billion in Medicaid legislative changes over five years and $800 million in administrative changes over five years. Through these efforts, we can restrain the five-year annual average growth rate of Medicaid from 7.4 percent to 7.1 percent.

   Additionally, a transformed health care system is one that avoids costly and unnecessary medical visits, and emphasizes upfront, affordable private health insurance options. 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.

2. **Question**

Health care as both an economic and a moral issue. When companies in my states are competing against foreign companies that don't bear the cost of health care, they are a huge competitive disadvantage. For example, the Big Three, the backbone of my state's economy, pay on average about $1,500 per employee for health care yet their competitors pay less than $100 per employee. This disparity is costing us jobs as well as hurting our role as a global powerhouse.

Yet in the proposed HHS budget, there is a provision doubling the employer's responsibility for Medicare's end-stage renal disease program from 30 to 60 months. When employers are struggling to maintain current health benefits and employees must decide between their benefits and a pay raise, does it make sense for the federal government to saddle our businesses with a new health care cost?

Response: Medicare is usually secondary coverage for those beneficiaries who are working and disabled. Under current law, certain beneficiaries who are under 65 and still working may be eligible for Medicare because they have been diagnosed with end stage renal disease (ESRD). For those beneficiaries, group health plan coverage they have as a result of their or their spouse's employment is the primary payer for the first 30 months of Medicare eligibility and Medicare is secondary. The budget proposal recognizes this coverage that is already available, and extends the time period that these health plans remain primary, consistent with the current threshold for disabled beneficiaries. As always, Medicare will remain secondary during this time and assist with costs that are not covered by the employer group health plan.

3. **Question**

You and I have talked about the need to create incentives for hospitals, doctors, and other health professionals to adopt information technology. CMS even projected that if 1 in 5 doctors adopted e-prescribing, we could save Medicare nearly $350 million in FY09. But how can we move toward e-prescribing if we are cutting provider payments? For my hospitals alone, your cuts would cut over $4 billion out from under them over the next five years. A number of us on this committee support Senator Kerry's E-MEDS proposal, and I hope you will work with us and the provider community to on legislation like that bill that move us forward, not backward, in adopting health IT.

Response: The Administration strongly supports the broad adoption of interoperable health information technology, including e-prescribing, and we have been working toward that end for several years. The President's Executive Order on value-driven health care is intended to ensure that health care programs administered or sponsored by the federal government build on collaborative efforts to promote the following four cornerstones for health care improvement: (1) interoperable health information technology; (2) the measurement and publication of quality information; (3) the measurement and publication of price information; (4) and the promotion of quality and efficiency of care.

Within the Medicare program specifically, CMS has taken a leadership role in the ongoing development of uniform standards for electronic-prescribing for the Medicare Part D program. Beyond Part D, facilitating the widespread adoption of e-prescribing is one of the key action items in the Administration's effort to build a nationwide, interoperable electronic health information infrastructure. CMS is currently implementing a 5-year demonstration project that will encourage small to medium-sized primary care physician practices to use electronic health records to improve the quality of patient care. Over a 5-year period, the project will provide financial incentives to as many as 1,200 physician practices that use certified electronic health records to improve quality as measured by their performance on specific clinical quality measures. Please be assured that you have my commitment to continue to work to promote widespread adoption of health IT.

4.
Question:
As you know, the FDA reauthorization bill signed into law last September included a provision designed to curb abuses of the citizen petition process. We understood there was an issue about authority and action with respect to citizen petitions, so last year we passed a law to enhance FDA's ability to address this long standing issue. Four months later, we haven't been briefed on FDA's implementation of the citizen petition reform, nor have we yet to witness any change in FDA's actions with respect to Citizen Petitions.

Given the impact skyrocketing health care costs are having on federal health programs, as well as on the pocketbooks of American consumers, it is imperative that this provision be implemented.

Will you please tell us what steps the FDA has taken to this point to ensure compliance with the law?

Response:
Please be assured that FDA is making every effort to comply with Section 914 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which added section 505(q) to the FDCA. This provision of FDAAA took effect upon enactment. Therefore, FDA has had to interpret the new provision and develop implementing procedures while simultaneously addressing citizen petitions and petitions for stay that are subject to the new requirements. FDA has received at least 11 petitions subject to section 505(q). FDA has taken a number of steps to implement this new statutory mandate. The Agency has established a working group that includes members of several offices within FDA to address questions about interpretation of the statute, as well as new implementation procedures. FDA has had to make determinations relating to the certification requirements, scope, and, after reviewing submitted petitions, whether delay in approval of pending applications is necessary to protect the public health. The first petitions subject to section 505(q) were submitted on October 15, 2007. Thus, none of

these petitions has been pending for over 180 days. We are working on responses to all the petitions that are subject to section 505(q).

We note that although this provision may have been designed to limit the delay of drug approvals because of petitions submitted on behalf of innovator drug companies, over half of the current pending 505(q) petitions were filed by or on behalf of generic drug manufacturers seeking to block or delay approval of other generic drugs.

We would be happy to brief your staff on our implementation efforts, but believe that it is too soon to evaluate the effects of the new provisions on the citizen petition process. We note that section 914 requires us to submit a report to Congress annually on the numbers of covered petitions and applications affected by those petitions, and we will submit that report after our first year's experience with implementing the law.

5.
Question:
There is going to be a huge debate over whether the Food and Drug Administration is appropriately funded to protect the health and safety of our nation. One issue of importance to me is funding at the Office of Generic Drugs, or OGD. For Fiscal Year 2009, the Administration's budget flat funds OGD at the 2008 level of $41.9 million.

Do you believe that number is sufficient to make substantial progress toward, if not meet, the statutory requirement that generic drug applications be completely reviewed within 180 days?

Why didn't the Administration request additional funds for OGD to hire more reviewers, which would allow OGD to improve its performance in processing generic applications in a timely manner?

Response:
FDA has increased the number of approvals and tentative approvals (a tentative approval indicates that all scientific and regulatory requirements have been met, but the applications cannot be fully approved because of patent or exclusivity still in force) from 310 in 2001 to 682 in 2007 (a 33% increase over approvals in FY 2006). However, the receipts of applications have outpaced those approval actions.

FDA has been in negotiations with the generic industry on potential user fees for the generic drug review program.

Pending the outcome of user fee negotiations, the Agency will continue to increase the capacity to deal with generic drug applications to the extent possible. In addition, OGD is working with an outside contractor to determine additional measures that may be taken to further streamline the review process. Interim

feedback from the contractor suggests that there is small additional actions that may be done.

6. **Question**

Currently, family-planning clinics are having to pay as much as ten times more for birth control pills – prices have escalated from four or five dollars per month to forty or fifty dollars per month. This is because university-based and family planning clinics that do not receive federal Title X funds can no longer have access to deeply discounted birth control pills. Private drug companies are prevented from offering the discount prices for birth control pills they have long provided to private safety net clinics.

Mr. Secretary, there is a crisis in affordable contraceptives on our campuses and across the country. Some universities are only dispensing the morning after pill, no birth control pills because students cannot afford to buy them at the new prices.

Has your Department been monitoring this crisis? Can you give me a report on the scope of the problem and how you plan to deal with it?

Response: The Deficit Reduction Act (DRA) of 2005 included significant changes regarding how manufacturers calculate "best price" under the Medicaid Drug Rebate program. Under the Medicaid Drug Rebate program, "nominal sales"– deep discounted pricing that is offered by pharmaceutical manufacturers – are excluded from manufacturer "best price" determinations. Under Section 6001(d) of the DRA, effective January 1, 2007, only nominal sales to the following entities will be exempt from manufacturers' "best price"determinations:

- 340B entities;
- Intermediate care facilities for the mentally retarded;
- State-owned or operated nursing facilities; or
- Other facilities that the Secretary of HHS determines are safety net providers to which sales of such drugs at a nominal price would be appropriate, based on factors such as the type of facility or entity, services provided, and patient populations.

The statute allowed the Secretary to determine other entities to which sales of drugs at a nominal price would be excluded from best price. However, the statute did not mandate that the Secretary do so. On July 17, 2007, CMS issued a final rule which continued the policy set forth in the proposed rule. The final rule exercises the Secretary's authority to choose not to expand that list of entities because we believe the entities listed in the statute capture the appropriate safety net providers and are sufficiently inclusive (entities as described in section 340B(a)(4) of the Public Health Service Act (PHSA), ICFs/MR, and State-owned or operated nursing facilities). Additionally, we believe that adding other entities or facilities would have an undesirable effect on the best price by expanding the entities for which manufacturers could receive the best price exclusion beyond

those specifically mandated by the DRA and lowering manufacturer rebates to the Medicaid Program.

There are numerous entities that fall under the 340B umbrella that are able to serve many low-income populations. For instance, if a college student is considered low-income, that person may be able to receive contraception from a Title X clinic. The President's FY09 Budget includes a $17 million increase in Title X funding.

7. **Question**

Last year, I was an original co-sponsor of two pieces of legislation to overturn the so-called "75 percent" and "25 percent" rules which I saw as a barrier to care for many individuals requiring intensive rehabilitation care.

I was not alone in my concern. For example, sixty of my Senate colleagues signed on to the bill overturning the 75 percent rule. Last December, this Committee put together the Medicare, Medicaid, and SCHIP Extension Act. Much to the Chairman's credit, that bill included a provision to permanently hold the 75 percent rule at the 60 percent level. I and many others on the Committee believe that this was a huge win for patients across the country.

That is why I noted with interest something that appeared on pages 59 and 60 of the President's Budget in Brief booklet. On page 59, the document proposes a payment update freeze for inpatient rehabilitation facilities. There is a footnote attached to that proposal. On page 60, footnote 1 says that the savings estimate "Includes the impact of repealing certain provisions of Section 114 and 115 of the Extension Act of 2007." I am very interested in this language, because Section 115 is where this Committee included the 75 percent rule fix that we worked so hard to get passed into law. Additionally, Section 114 contains language overturning another regulation on long-term acute care hospitals that I worked with Senator Conrad to include.

My question is: what "certain provisions" of Sections 114 and 115 does CMS propose to repeal?

Response: The President's budget proposes to repeal Section 114(c) of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA), which required the suspension of certain payment policies for long-term care hospitals (LTCHs) that the Secretary had already implemented, or was considering implementing. We believe that these payment policies would protect the Medicare program from patient shifting between acute care hospitals and LTCHs, resulting in two Medicare payments for what is essentially one episode of patient care. Such practices undermine the basic premise of cost control with adequate payment that is the key feature of Medicare's prospective payment systems. In addition, these payment policies would have the effect of encouraging program efficiency within the LTCH industry.

The President's budget also proposes to repeal Section 115(b) of MMSEA. This provision involves inpatient rehabilitation facilities (IRFs) and permanently lowers the IRF compliance percentage to 60 percent. The compliance percentage, which is sometimes also referred to as the IRF classification criteria or the "75 percent rule", is the percentage of patients admitted to the IRF that must require intensive rehabilitation treatment for one or more of 13 specified conditions. In addition, this provision permanently included patient comorbidities in the calculations used to determine whether an IRF meets the IRF compliance percentage.

The "75 percent rule" has been a long-standing Medicare requirement that was designed to guarantee access to IRFs for the atypical subset of patients who require IRF care following a major illness or injury. Ultimately returning to 75 percent as the compliance percentage will encourage program efficiency and ensure that patients requiring a high level of intensive rehabilitation services are appropriately treated in an IRF. In addition, MedPAC has noted that IRFs have successfully reduced costs in response to the tighter fiscal pressures imposed by the 75 percent rule.

With respect to comorbidities, it is not unusual for patients admitted to IRFs to have more than one ailment for which the patient exhibited a need for medical treatment. However, the patient's principal diagnosis (not the comorbidities) most accurately denotes whether a patient has one or more of the 13 conditions identified in the "75 percent rule" since it is based on clinical evidence presented in the patient's medical record.

8. **Question**
Last November, CMS published a final rule on non-Hodgkins lymphoma treatments known as radioimmunotherapy that would reimburse 50% less for these treatments than the year before and this rule would breakdown these treatments into diagnostic and therapeutic treatments. However, the FDA has recognized treatments such as Bexxar and Zevalin only as a single therapeutic treatment.

In Section 106 of the Medicare, Medicaid and SCHIP Extension Act, the members of this committee came to a bipartisan solution to this problem and instructed CMS to make a fair payment for therapeutic treatments for radioimmunotherapy drugs. However, it is my understanding that CMS is restricting these fair payments to only a part of these treatments and only to what *they* define as therapeutic, even when that completely goes against how the FDA approves these treatments in defining the *entire* treatment as therapeutic.

For these patients with lymphoma, many times these treatments are a last resort to extend their life and as one of my Michigan constituents told the NY Times in December, "I am feeling a bit resentful about having this taken away — if I can't have access to a drug that would extend my life." When we are talking about life and

death here, can you explain to me how an FDA interpretation of an approved drug treatment does not stand with your interpretation of these drug treatments?

Response: Radioimmunotherapy (RIT) treatment for cancer involves a number of different types of medical services in the planning and delivery of treatment, including administration of radiopharmaceuticals, radiation dose calculations, physics consultations, and imaging studies. RIT resembles other types of cancer care that also require certain preparatory steps to safely and effectively provide the treatments.

- RIT typically requires a small diagnostic dose of a radiopharmaceutical to be initially provided, in order to image the distribution and residence time of the radiopharmaceutical in the body in order to plan for the therapeutic dose for an individual patient. The administration of the diagnostic radiopharmaceutical and the associated imaging studies do not treat a patient's cancer but are steps in preparing for the treatment.

- Once the dose planning step has been completed and it has been determined that the therapeutic RIT step is appropriate to treat a patient, specific dosing is calculated, and a much larger therapeutic dose of the same radiopharmaceutical is administered to the patient. This therapeutic radiopharmaceutical administration provides the patient-specific dose that treats the patient's cancer.

The distinction between diagnostic and therapeutic radiopharmaceuticals was clearly established in rulemaking under Medicare's hospital outpatient prospective payment system (OPPS) prior to the passage of the Medicare, Medicaid and SCHIP Extension Act of 2007. This legislation specifically authorized payment at hospital charges adjusted to cost for therapeutic radiopharmaceuticals for the first six months.

There is no concept of "therapeutic regimen" that has been adopted for OPPS payment purposes because, as in the case of RIT treatment, the OPPS most commonly pays separately for the steps involved with the planning and delivery of cancer treatment. In the case of RIT, the OPPS has adopted different payment methodologies as required by legislation and as established through rulemaking to pay for the various necessary planning and treatment services.

9. **Question**

I am concerned about the lack of progress at CMS in approving new compendia in Medicare Part B, especially for cancer patients that are being denied access to desperately needed therapies. The committee has been working on this issue for a while now and almost acted legislatively last December, before many provisions were stripped out at the very end. Is the agency committed to reestablishing the broken compendia system by approving new compendia as soon as possible?

Mr. Secretary, I'm concerned about the Medicare skilled nursing cuts proposed in the President's budget because, as I'm sure you agree, patients in nursing home are among the sickest of all Medicare beneficiaries. Underlying my concern is the fact that Medicaid and Medicare together pay for the care of 3 out of every 4 nursing home patients. Historically, Medicaid has under funded nursing home care by billions of dollars a year. I'm concerned that any cuts to Medicare funding for skilled nursing care will create an unstable care environment and ultimately undercut the steady progress nursing homes are making in improving quality. Can you tell me what the Administration is doing to ensure that Medicare and Medicaid funding together are adequate to protect quality of patient care?

Response: We understand the importance of recognizing additional Part B drug compendia along with the need to establish a regular, timely, and transparent process for consideration of additional compendia. Therefore, in the November 2007 physician fee schedule final rule, CMS established a sub-regulatory annual process for making changes to the list of compendia for Part B drugs. That process involves:

- Annually accepting requests to revise the list of compendia. This period would begin on January 15 of a year. Requests would be submitted within 30 days (i.e., by February 15).

- CMS publishing a listing of the timely, complete requests received (by March 15) and allowing the public 30 days to submit comments on the requests (by April 15).

- A complete request would have to contain specific information identified in the final rule.

- CMS will evaluate how well a compendium achieves desirable characteristics of compendia that were recommended by a special advisory panel.

- CMS will publish a decision within 90 days after the close of the public comment period (i.e., by July 15).

The process for 2008 is occurring ahead of schedule because of: (1) proactive CMS interactions with the stakeholder community during the period leading up to January 15; (2) timely submission of requests; (3) CMS' prompt initial review of requests for completeness; and (4) CMS' posting the requests for the 30-day public comment period as soon as our initial review was complete. CMS has posted four requests for public comments on February 6, 9, 13, and 20. The comment periods for these requests close on March 7, 9, 13, and 20, respectively. The requests can be found on the CMS website at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcd_6. CMS also received a fifth request after the 30-day period, but has decided to review it in

light of the public interest on this topic. The fifth request was posted on March 4 and the comment period closes on April 3.

After the comment periods end, CMS will publish decisions as soon as the evaluation process has been completed but no later than 90 days after the close of the comment periods (which occur in June 2008 for four requests and July 2008 for the fifth). CMS could announce decisions earlier if the evaluation is completed earlier than the end of the 90-day period.

Once CMS publishes the decisions, we expect that contractors who pay Medicare claims would immediately utilize the newly approved compendia. The use of newly-approved compendia will not be delayed until 2009.

10. **Question**

I am concerned about the Medicare skilled nursing cuts proposed in the President's budget because, as I am sure you agree, patients in nursing home are among the sickest of all Medicare beneficiaries. Underlying my concern is the fact that Medicaid and Medicare together pay for the care of 3 out of every 4 nursing home patients. I'm concerned that any cuts to Medicare funding for skilled nursing care will create an unstable care environment and ultimately undercut the steady progress nursing homes are making in improving quality. Additionally, I am concerned that state fiscal crises and your regulations will curtail Medicaid payments. Can you tell me what the Administration is doing to ensure that Medicare and Medicaid funding together are adequate to protect quality of patient care?

Response: Spending on SNF services continues to increase, with a corresponding increase in the volume of services provided by SNFs. To control this spending growth and encourage efficiency in Medicare, the President's budget proposes to adjust the Medicare payment update for skilled nursing facilities (SNF) in 2009 and thereafter. This proposal is consistent with recommendations made by the Medicare Payment Advisory Commission (MedPAC) for 2009 and builds upon those recommendations for future years. MedPAC estimates that SNF Medicare margins will average 11.4 percent in FY 2008. Further, MedPAC analysis shows that beneficiaries experience few problems accessing SNF care. The proposed Medicare payment adjustment would encourage program efficiency without affecting the ability of SNFs to furnish high quality care to Medicare beneficiaries. The proposal would also strengthen the long-term financial security of Medicare, which is critical to stability in access as well as quality.

11. **Question**

I'd like for you to comment on some inconsistencies in Administration policy as it relating to the health and welfare of our nation's oldest and most vulnerable citizens. Just a few months ago, the Centers for Medicare and Medicaid Services said a market basket update is necessary to promote "program efficiency, quality and sustainability" for skilled nursing facilities. Now, the Presidents budget for FY 2009 was released and it does not include a market basket for the care of our oldest and sickest nursing

home residents. Can you explain this inconsistency and elaborate on why a market basket update was not included?

Response: The FY 2009 Budget proposals addressing Medicare consistently focus on encouraging efficient payments, enhancing program integrity, and promoting greater beneficiary involvement in health care decisions. All of these efforts are building blocks to strengthen Medicare's financial security and to improve the quality of health care services available to people with Medicare both now and in the future.

The FY 2009 Budget proposal addressing the Medicare SNF payment update is consistent with recommendations made by the Medicare Payment Advisory Commission (MedPAC) for 2009 and builds upon these recommendations for future years. MedPAC estimates SNF Medicare margins averaging 11.4 percent in FY 2008. This year's Budget proposal is informed by these healthy, real-time margins, not prior-year proposals or statements.

We continue to see Medicare spending on SNFs increase, with a corresponding increase in the volume of services provided by SNFs. Further, MedPAC analysis shows that beneficiaries experience few problems accessing SNF care. The proposed adjustment would encourage program efficiency without affecting the ability of SNFs to furnish high quality care to Medicare beneficiaries. The proposal also would strengthen the long-term financial security of Medicare.

12. **Question**

I saw where HHS recently released estimated savings from e-prescribing (as part of its proposed standards for e-prescribing in Medicare). The estimated savings, according to your proposed rule, are based upon very conservative adoption rates so they could go much higher.

Findings include:

- Savings from generic substitution.
- Administrative savings for physician offices.
- Administrative savings for pharmacists.
- Savings as a result of avoiding adverse drug events.

In fact, in my home state of Michigan, the Southeast Michigan e-Prescribing Initiative, or SEMI, which is a collaboration between the Henry Ford Health System, GM, Chrysler, and Ford, and Medco Health Solutions, has filled more than 6 million prescriptions to date, resulting in more than 423,000 prescriptions being changed as a result of e-prescribing safety alerts.

Interestingly, your proposed e-prescribing rule included estimated savings to the physicians' offices through administrative efficiencies such as fewer calls to the pharmacy. No other study that I have seen had calculated administrative savings to

the physician office. Can you talk a little more about CMS's e-prescribing estimates?

Response: In addition to testing the standards' functionality and interoperability with the foundation standards, the CMS FY 2006 e-prescribing pilot test was one of the first studies undertaken to demonstrate the potential impact of e-prescribing on these provider and pharmacy workflows in long-term care settings, pharmacies, large provider communities, and small (2-3 physician) practices. Pilot site experience showed that, among prescribers or their agents who adopted e-prescribing, obtaining prior approvals, responding to refill requests, and resolving pharmacy callbacks were all done more efficiently with e-prescribing than before. Both providers and pharmacies perceived a greater than 50 percent reduction in time to manage refill requests and significant time savings in managing pharmacy call backs. The results
requests and significant time savings in managing pharmacy call backs. The results of the pilot test are described in the Findings from the Evaluation of E-Prescribing Pilot Sites, http://www.healthit.ahrq.gov. The administrative savings described in the proposed rule are based on these pilot findings. The proposed rule provides details on how these findings were incorporated into the analysis (http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-5681.pdf)

In our analysis, we conservatively estimated the administrative benefit at 25%, or one-half of the pilot test result that showed, in one instance, a greater than 50 percent reduction in time savings for participating providers. In response to the NPRM, we have received industry comments that we greatly underestimated the benefits of e-prescribing to providers, but maintain that we would prefer to underestimate rather than overstate benefits. We expect that once the standards are in place, appropriate e-prescribing products and technology are available, and e-prescribing gains acceptance among providers, through experience, and by word of mouth and industry education, we will adjust our projections based on better and more complete data from the industry.

Senator Cantwell:

1. **Question**
   The President's Medicare budget states the need to encourage efficient, high-quality care. However, there is little being advanced to achieve this goal when further examining the proposal itself. Although there is potential in expanding programs such as value-based purchasing and fraud investigation, the budget focuses primarily on blunt, across-the-board rate freezes to providers such as hospitals and home health agencies. These measures are disastrous for seniors in my state, where efficient care is the norm rather than the exception. As you may know, Medicare costs in our state are far below the average—Washington state ranks 35th in the nation when comparing federal spending per beneficiary.

Mr. Secretary, in developing this budget, did the Administration consider how it would impact regions already making strides in delivering efficient care?

How does penalizing an efficient provider with long-term rate freezes encourage the "efficient, high quality care" touted in the President's budget?

Response: Slowing the growth of entitlement spending is an essential factor in meeting the President's goal of eliminating the overall Federal deficit in five years and is also a critical component of ensuring the long-term viability of the Medicare program for future generations. Medicare providers should be able to absorb these payment freezes through increased program efficiencies. Private markets adapt to produce efficiencies and improve productivity. Moreover, under our hospital value-based purchasing proposal, with incentives for both improvements in care as well as meeting specific quality of care measures, it would be possible for efficient, high-quality hospitals to actually increase their payments in comparison to other hospitals.

2. **Question**

Proposals to reform Medicare Advantage Private Fee-for-Service plans are absent in this budget. As this Committee has heard from patient advocates and medical practices, including the Everett Clinic of Washington state, Private Fee-for-Service plans just aren't living up to the hype. They aren't give providers the resources they need to cover costs that go with care coordination—the extra attention and follow-up needed to ensure the best patient outcomes. They don't communicate with providers to get them patient histories and information that could be crucial in creating the best care plan for enrollees. They are also an administrative nightmare—doctors in Washington state tell me that these plans often deny legitimate claims. The resulting fight to get reimbursement means that some providers actually lose money trying to haggle with Private Fee-for-Service companies.

I fail to see how continued support for these plans under current policy leads to a more efficient, quality Medicare program. Why do these Private Fee-for-Service Medicare plans get a free-pass in this budget?

Response: The savings as proposed in the President's FY 2009 budget do not come solely from Medicare Parts A & B, but the President's budget proposals will also result in significant cuts to Medicare Advantage (MA) plans. These cuts will also apply to Private Fee-for-Service (PFFS) plans. The reductions in payments to Original Medicare would result in $44 billion in payment cuts to MA plans, an amount that is roughly one quarter of the total provider outlay savings over five years.

It is important to note that PFFS plans were designed as another plan type for beneficiaries to choose as an alternative to Original Medicare. PFFS plans are

similar to Original Medicare in structure in that they both pay on a fee-for-service basis, but PFFS plans also provide extra benefits and other cost-sharing options different from Original Medicare. The Administration continues to believe that beneficiaries across the country should have access to MA plans, and PFFS plans have played an important role in providing this access, particularly in rural areas.

3. **Question**
There is significant potential for value-based purchasing, if implemented responsibly, to change the way we pay for services under Medicare. It's exciting to consider a program that, for example, encourages hospitals to make sure that a patient takes the right medication, follows a proper nutrition plan, and takes other steps necessary to avoid costlier services down the line. Right now, providers aren't getting rewarded for this kind of care. In fact, it is inefficiency that is rewarded when patients with poor outcomes require additional hospital visits, surgeries and other avoidable treatment.

Can you elaborate on the timeline this Administration envisions for implementation of value-based purchasing? Will you work with this committee to ensure that such a program accurately measures quality and provides suitable reward for efficient providers?

Response: Value-Based Purchasing (VBP) is the next step forward in increasing the value of Medicare spending, and we are ready to move forward. In November 2007, CMS issued a Report to Congress that detailed a plan for hospital VBP, which included a performance scoring methodology and incentive structure. In developing this report, CMS solicited extensive industry and researcher expertise.

Since fiscal year 2005, CMS has been providing differential payments to hospitals that publicly report a defined set of inpatient care quality measures. The hospital VBP proposal would build on what CMS is currently doing by linking payment to performance on those measures—rather than just linking payment to reporting the measures. We would be happy to work with this committee to ensure that a meaningful hospital VBP program is implemented.

Senator Ensign:

1. **Question**
I noticed that the President's Budget estimates that 22.3 percent of Medicare beneficiaries will be enrolled in the Medicare Advantage program in 2008. At what point will enrollment in Medicare Advantage be sufficient to allow us to move to a system in which plan competition will reduce mandatory spending? Is there a certain enrollment percentage (e.g., 25%, 30%, 35%) that will need to be met? What do you expect plan competition to look like when this threshold is met? And, how much savings do you expect?

Response: The Administration continues to support policies that will ensure all beneficiaries across the country have access to these plans. MA plans provide an

important choice for beneficiaries, and most offer additional benefits beyond what traditional Medicare would cover. Enrollment is obviously one factor to consider in discussing potential reforms to the MA program, but we believe that preservation of beneficiary choice and access to plans throughout the country is critical.

2. **Question**
The President's Budget mentions that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provided for a more comprehensive review of the Medicare program's finances and required the Medicare trustees to issue a warning when general revenue Medicare funding is projected to exceed 45 percent of Medicare's total expenditures. Although the President's Budget characterizes his budget proposals as addressing the trigger, does the President intend to submit legislation to Congress pursuant to the cost-containment provisions in the MMA? If so, what types of reform proposals do you expect will be included in the legislation?

Response: The President's "Medicare funding warning" legislative budget proposal would apply a -0.4% sequester to the Medicare payment for all providers when general revenue exceeds 45 percent of spending. While not addressing the underlying funding challenges, this stop-gap proposal is designed to improve the fiscal sustainability of the Medicare program in case Congress fails to control excess general revenue spending.

If all of the President's CMS FY 2009 budget proposals were enacted, Medicare spending would fall below the trigger level in the short term. In addition, the insolvency date of the Part A trust fund (currently at 2019) would be pushed back by ten years.

In addition to the FY 2009 Budget proposals that restrain the growth in Medicare spending, the Administration intends to respond to the Trigger warning within the 15 day statutory guideline outlined by the MMA. I expect that you will hear from us soon on this issue, but any further details are premature at this time.

3. **Question**
As you know, I am strong advocate for health information technology, which will improve lives and enhance quality of care. In fact, Senator Kerry and I have developed legislation to encourage the adoption of e-prescribing in Medicare. How much long-term savings do you think we could achieve through full adoption of e-prescribing in Medicare? What do you see as the primary drivers of long-term cost-savings as a result of e-prescribing implementation?

Response: We believe that e-prescribing can lead to long term Medicare savings in several ways.

Reduction of adverse drug events (ADEs) is one area in which the Medicare program can realize significant savings through e-prescribing. While there is

documented information on the reduction of ADEs in inpatient settings gathered from computerized physician order entry (CPOE systems), there is little information available for ADEs in ambulatory settings. However, an oft-cited Institute of Medicine report in 2005 estimated that approximately 530,000 preventable adverse ambulatory drug events among Medicare beneficiaries, at a cost of between $2,000 and $6,000 per event, take place annually. The data from the CMS 2006 e-prescribing pilot study indicated that e-prescribing may be able to reduce these adverse drug events by as much as 50 percent. The Medicare program will ultimately benefit from avoided hospitalizations, treatments and physician office visits that often result from adverse drug events. In the November 16, 2007 e-prescribing NPRM, we estimated that in a five year period alone, from 2009 to 2013, reduction of adverse drug events through e-prescribing, at a conservative 25 percent benefit, would yield over $156 million dollars in savings. A July 2007 study conducted by the Pharmaceutical Care Manufacturer's Association (PCMA) estimates that government options to increase e-prescribing could reduce federal health expenditures by up to $29 billion over the next decade and help physicians to prevent nearly 1.9 million adverse drug events over the same time period.

By providing physicians with relevant formulary and benefit information at the point of care, e-prescribing also leads to more efficient utilization of generic drugs. A recent Medco study of physicians using e-prescribing technology (http://medco.mediaroom.com/index.php?s=43&item=100) found that physicians increased their generic substitution rates by over 15 percent. When you consider that the average name brand prescription costs about $111, and the average generic prescription costs $32, any shift to generics in the more than one million Medicare Part D prescriptions dispensed each week, would lead to significant Medicare program savings.

E-prescribing will also lead to more efficient workflows and administrative cost savings for providers and dispensers. The impact analysis of our recently released proposed rule, Standards for E-Prescribing Under Medicare Part D describes these savings in further detail (http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-5681.pdf).

4. **Question**

Over the next year, what will you do to help achieve the President's goal of most Americans having access to electronic medical records by 2014? When do you expect issues related to standards and interoperability to be resolved? Is there a date certain? At what point can we encourage the use of interoperable electronic health records in Medicare? How should we do this and how much long-term savings do you think we could achieve through full adoption of electronic health records in Medicare?

Response: The Administration strongly supports broad adoption of interoperable health information technology, including electronic health records and e-prescribing. We have been working toward that end for several years now and will continue to do so. More specifically, the Centers for Medicare & Medicaid Services (CMS) is implementing a five-year demonstration project that will encourage small- to medium-sized primary care physician practices to use electronic health records (EHR) to improve the quality of patient care. This project is a major step toward the President's goal of most Americans having access to a secure, interoperable EHR by 2014.

Over a five-year period, the project will provide financial incentives to as many as 1,200 physician practices in up to 12 sites that use certified EHRs to improve quality as measured by their performance on specific clinical quality measures. More specifically, under the demonstration, practices will be eligible to earn incentive payments for the implementation and adoption of interoperable health information technology in their practice and achieving specified standards on clinical performance measures for diabetes, congestive heart failure, coronary artery disease and the provision of preventive health services. Additional bonus payments will be available, based on a standardized survey measuring the number of EHR functionalities a physician practice has incorporated.

5. **Question**

Medicare payments to physicians are scheduled to be cut by about 40 percent in the coming decade. Physicians have faced payment cuts for each of the last 7 years, beginning in 2002. Do you think, as a way to keep physicians in Medicare and preserve access to care, that physicians should be allowed to balance bill patients for the portion of their costs that Medicare does not cover?

Response: Creating some stability in Medicare physician payment levels is important in order to ensure beneficiary access to care. But at the same time, we need to ensure that we are getting the most appropriate value for our expenditures, that quality of care is of the highest levels, and that the fee-for-service payment system doesn't create incentives to generate excess volume and intensity of services.

We do not have a magic bullet to deal with the Medicare physician payment issue, but we look forward to working with Congress to address the issue. In addition, we are working on some important elements that could be building blocks that ultimately are part of a revised Medicare physician payment system. We have been implementing the Physician Quality Reporting Initiative (PQRI), which creates payment incentives for physicians who report quality measures. We are very interested in building on the success of our Physician Group Practice demonstration and incorporating a mechanism for physician group practices to

report and perform on quality measures. We are implementing the medical home demonstration project and are interested in the potential for the model to change how care is furnished to and coordinated for Medicare beneficiaries. We are very interested in creating financial incentives to encourage physicians to implement electronic health record systems. We have been working to develop meaningful, actionable, and fair measures of physician resource use to initially be used for confidential feedback reporting to physicians about the comparative costs of their care. As in other payment systems, value-based purchasing and transparency initiatives give consumers access to data that can improve their healthcare choices. We are evaluating the possibility of posting the names of physicians who successfully report PQRI measures on the CMS website.