

NOMINATION OF GOVERNOR KATHLEEN SEBELIUS

HEARING OF THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

ON

NOMINATION OF GOVERNOR KATHLEEN SEBELIUS, OF KANSAS, TO BE
SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

MARCH 31, 2009

Printed for the use of the Committee on Health, Education, Labor, and Pensions



Available via the World Wide Web: <http://www.gpo.gov/fdsys/>

U.S. GOVERNMENT PRINTING OFFICE

48-540 PDF

WASHINGTON : 2010

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NOMINATION OF GOVERNOR KATHLEEN SEBELIUS

TUESDAY, MARCH 31, 2009

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m. in Room SH-216, Hart Senate Office Building, Hon. Edward M. Kennedy, Chairman of the committee, presiding.

Present: Senators Kennedy, Dodd, Harkin, Mikulski, Murray, Reed, Sanders, Brown, Casey, Enzi, Burr, Isakson, McCain, Murkowski, Coburn, and Roberts.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. We will come to order. We are expecting Senator Enzi to be here in just a moment or two, but he has asked us to go ahead, and we shall.

Our hearing today is on the confirmation of Kathleen Sebelius to serve as the next Secretary of Health.

Few debates in Congress touch our lives as profoundly and personally as healthcare. Over the past 10 months, I have seen our healthcare system up close. I have benefited from the best of medicine.

But we have too many uninsured Americans. We have sickness care and not healthcare. We have too much bureaucracy—paperwork and bureaucracy. Costs are out of control.

Today, we have an opportunity like never before to reform our healthcare, and we need a Secretary of Health who has the vision, the skill, and the knowledge to help us get there. Governor Kathleen Sebelius has those traits and more. She was named one of the five top Governors by *Time* magazine. She earned that accolade by reaching across the aisle to find solutions that worked.

Her Healthy Kansas initiative put thousands of people on the road to better health. As insurance commissioner and as Governor, she has been a strong voice for the rights of patients and consumers.

When it comes to reforming our healthcare system, we know that challenges are great. I have the confidence that Governor Sebelius can lead the way with common sense solutions. Although her duties as Secretary may begin with healthcare reform, they do not end there. Food safety, drug safety, medical research, disease prevention—all of these and more have urgent need for attention. She

is the right person for the job, and I strongly support her nomination.

Governor, we welcome you today and thank you for your willingness to help serve in this important position.

I know Senator Enzi will be here in just a moment or two. I will ask that we move ahead then with—ah, there we are.

Senator ENZI. I went to the wrong room.

The CHAIRMAN. Good to see you. We have got two arrivals here, two arrivals. We are doubly blessed this morning.

So we will move ahead with our friend and colleague and leader, Senator Enzi. We thank you very much for being here.

STATEMENT OF SENATOR ENZI

Senator ENZI. Thank you, Mr. Chairman. It is always good to have you back, and it's a great day for a hearing.

I would like to begin by thanking you for holding this hearing today, and I have previously said confirming the President's nominees is one of the most important constitutional duties of the Senate. I know that the members of the committee take the "Advise and Consent" clause of the Constitution seriously.

What we are undertaking today is more of a review of the nominee's qualifications regarding the substantive issues, if she is confirmed as Secretary of the Department of Health and Human Services. It should not be overlooked that the Finance Committee has the primary jurisdiction over this nomination.

Because of the overlap in our work and the significant role the Secretary of Health and Human Services will have in the operations of the Food and Drug Administration, the Centers for Disease Control, and the National Institutes of Health, the HELP Committee has established a tradition of holding a hearing on this important Cabinet-level position.

I would also like to thank Governor Sebelius for joining us today and for the opportunity to meet with her earlier. I am hopeful that we will have a strong working relationship, as will our staff. If confirmed, there are going to be areas where we disagree, but my hope and expectation is that we will focus on solutions and, therefore, can produce meaningful results for the hard-working Americans that meet the test of the 80 percent rule.

People who have worked with me over time know the 80 percent rule is one of the main rules I always try to follow to get things done. In applying this rule, I try to focus on the 80 percent of the issues the Senate generally agrees, while not fixating on the remaining 20 percent, which are divisive and can sometimes overwhelm the majority of issues that we agree on.

One area where I hope we can agree on is healthcare reform. Ensuring access to affordable, quality, and portable healthcare for every American is not a Republican or a Democrat issue. It is an American issue. Our healthcare system is broken, and fixing it is one area where I hope the 80 percent rule comes into play so that common sense reforms can be made. The American people deserve solutions.

I also hope we can agree on the process used to advance the healthcare reform. An open, transparent process with a full debate is the best way to achieve a bipartisan product.

I was disappointed to see the recent comments of the Senate majority leader, who suggested that he wanted to use budget reconciliation to pass healthcare reform. Using budget shortcuts, known inside the beltway as reconciliation, shuts out members of the minority party. It will also shut out many centrist Democrats who want to see healthcare reform based on a competitive private market which is fully paid for. That is not a formula for bipartisan success.

At both the member and staff level, Senators on both sides of the aisle continue to meet regularly to discuss healthcare reform and, specifically, what shape it will take. I believe that if we continue to negotiate in good faith, this process will lead to a bipartisan health reform bill that will enjoy broad bipartisan support both now and in the future.

I hope that Governor Sebelius will join Senator Baucus, Senator Conrad, and Senator Byrd in their efforts to prevent the use of reconciliation from derailing this bipartisan process. The next Secretary of Health and Human Services will undoubtedly have a critical seat at the table during these discussions.

As the Governor of Kansas, the nominee before us has enormous responsibilities and has put forth her own healthcare reform proposals there. I know that we have a shared commitment to reducing the number of uninsured Americans, containing costs, improving quality, making healthcare more accessible to everyone, and increasing the access to health information technology.

During my initial meeting, we discussed the unique challenges that face rural and frontier States. People living in rural areas in Kansas, similar to Wyoming, face difficulties in access to primary care physicians and preventive services. Rural and frontier areas struggle to attract and retain doctors and other healthcare providers.

In the 10 steps healthcare reform bill I introduced last year, I emphasized the importance of access to affordable healthcare for people in rural and underserved areas. I know Governor Sebelius understands the challenges in this area, and I am looking forward to finding solutions for this common priority.

We may not always agree on every issue. I am and will remain staunchly pro-life and will continue to advocate for legislation to protect the rights of the unborn. My hope and expectation, though, is that we will focus on legislating solutions that will make a positive difference in people's lives.

I will have a series of questions for the Governor when we begin the question and answer portion of the hearing and will have follow-up questions for the record.

Again, I would like to express my appreciation that the Senator is back and for having this hearing today.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

Mr. Chairman, I would like to begin by thanking you for holding this hearing today, and welcoming you back to the Senate. As I have said previously, confirming the President's nominees is one of the most important Constitutional duties of the Senate. I know that the members of this Committee take the "Advise and Consent" clause of the Constitution seriously.

I would also like to thank Governor Sebelius for joining us today. I am hopeful that we will have a strong working relationship, as will our staff. If confirmed, there are going to be areas where we disagree, but my hope and expectation is that by focusing on solutions, we can produce meaningful results for hard working Americans that meet the test of the 80-20 rule.

People who have worked with me over time know that the 80-20 rule is one of the main rules I always try to follow to get things done. In applying this rule, I try to focus on the 80 percent of the issues the Senate generally agrees, while not fixating on the remaining 20 percent, which are divisive and the subject of amendments on the Senate floor. One area where I hope we can agree on is health care reform. Ensuring access to affordable, quality and portable health care for every American is not a Republican or a Democrat issue—it is an American issue. Our health care system is broken, and fixing it is one area where I hope the 80-20 rule comes into play so common sense reforms can be made. The American people deserve solutions.

I also hope we can agree on the process used to advance healthcare reform. An open, transparent process with a full debate is the best way to achieve a bipartisan product. I was disappointed to see the recent comments of the Senate majority leader, who suggested that he wanted to use budget reconciliation to pass health care reform.

Using budget shortcuts—known inside the beltway as reconciliation—shuts out members of the minority party. It will also shut out many centrist Democrats, who want to see health care reform based on a competitive private market, which is fully paid for. That is a formula for bipartisan success.

At both the member and staff level, Senators on both sides of the aisle continue to meet regularly to discuss health care reform, and specifically what shape it will take. I believe that if we continue to negotiate in good faith, this process can lead to a bipartisan health reform bill that will enjoy broad bipartisan support now and in the future. I hope that Governor Sebelius will join Senators Baucus, Conrad and Byrd in their efforts to prevent the use of reconciliation from derailing this bipartisan process.

The next Secretary of HHS will undoubtedly have a critical seat at the table during these discussions. As the Governor of Kansas, the nominee before us had enormous responsibilities and has put forth her own health care reform proposals there. I know that we have a shared commitment to reducing the number of uninsured Americans, containing costs, improving quality, making health care more accessible to everyone and increasing access to health information technology.

During my initial meeting with Governor Sebelius we discussed the unique challenges that face rural and frontier States. People living in rural areas in Kansas, similar to Wyoming, face difficulties in access to primary care physicians and preventive services. Rural and frontier areas struggle to attract and retain doctors and other healthcare providers. In the 10-steps health care reform bill I introduced last year, I emphasized the importance of access to affordable health care for people in rural and underserved areas.

Governor Sebelius understands the challenges in this area—and I am looking forward to finding solutions for this common priority.

We may not always agree on every issue. I am and will remain staunchly pro-life, and will continue to advocate for legislation to protect the rights of the unborn. My hope and expectation, though, is that we will focus on legislating solutions that will make a positive difference in people's lives. The first and foremost priority of our Government should be, "do no harm."

I understand that the Senate Finance Committee, of which I am a member, has primary jurisdiction over her nomination to head the Department of Health and Human Services (HHS). But because of the overlap in our work, the HELP Committee has established a tradition of holding a hearing on this cabinet level position.

I will have a series of questions for the Governor when we begin the Q and A portion of the hearing, and will have follow-up questions for the record.

In closing, I would like to again thank Chairman Kennedy for calling this hearing today.

The CHAIRMAN. Thank you. Thank you very much.

I want to welcome an old friend, Senator Dole. All of us are very familiar with his service to the Senate over a long period of time as our majority leader. I thank him very much.

It is always a welcome opportunity to be with Senator Roberts. We have worked together on many different issues, and I have valued the opportunity to see him and welcome him back now.

We will start off with those two leaders, and then we will proceed with the remaining members. And after that we will introduce our nominee.

Senator ROBERTS. Mr. Chairman, I might inquire if that means that I am to go first? And as opposed to Senator Dole, I always live in mortal fear of when I go first, and then Senator Dole follows me. Is it your preference that I speak now, or would you prefer to have our colleague go first?

The CHAIRMAN. Well, that sounds—I don't see Senator Dole shaking his head in disapproval. So we will go ahead.

Senator ROBERTS. Well, I have a lot of nice things to say about you, Bob. So I thought I would go first, if that is all right with you?

Senator DOLE. I get paid by the hour, so I will just—

[Laughter.]

The CHAIRMAN. OK.

STATEMENT OF SENATOR ROBERTS

Senator ROBERTS. All right. I will be happy to start off.

Thank you, Mr. Chairman. It is good to have you back.

The CHAIRMAN. Thank you.

Senator ROBERTS. It is good to see you as chairman, sir.

It is a special day and, indeed, for the State of Kansas because we have with us today the man who is, without question, the favorite of Kansans and probably the most beloved public servant in support of our Governor, Kathleen Sebelius.

Senator Bob Dole, honored to have you here. We Kansans are always mindful of the great legacy that you forged for us in the Senate. I continually strive to live up to your years of service to our State.

I would remind everybody that while it is not a topic of conversation for this hearing, that every time you pass the World War II memorial or you talk to a World War II veteran who has experienced a great moving experience in visiting that memorial, you can thank Bob Dole. That is the kind of man he is.

And thank you, Bob, for being such a friend of our family down through the years.

Mr. Chairman, I would like to ask unanimous consent that the statement by Senator Nancy Kassebaum Baker be included.

Senator Baker said, as a former chairman of this committee, "It is with the highest regard that I endorse the nomination of Governor Kathleen Sebelius as Secretary for the Department of Health and Human Services."

So I would ask that her statement be included.

The CHAIRMAN. It will be included.

Senator ROBERTS. Well, Governor Sebelius, welcome.

It is a special and great opportunity for a Kansan to be represented as a member of the President's Cabinet, and I want to thank President Obama for nominating our Governor for this very important position.

The Governor and I have had a special relationship. Her father-in-law, former congressman Keith Sebelius, was my godfather in this business. I had the privilege of serving as his administrative assistant during his entire congressional career. He was a great congressman and mentor and friend.

And I have known Kathleen and her husband, Gary, throughout the years. Gary is now a judge. We have enjoyed a very special relationship. I remember well when Gary was a student at Kansas State University, and I was the administrative assistant to his father.

And so, we had a quite unique relationship in that respect, and I would only say that I am sorry that his good friend Rudy Verdesco could not be here with us today to share during this time. Obviously, we are not going to get into telling stories.

Governor Sebelius, I look forward to building on that relationship as we work toward improving our Nation's healthcare system. I think Senator Enzi pretty well summed it up in regards to the challenge, as did our chairman, Senator Kennedy. So I look forward to working with you.

We will have another experience. As a member of the Finance Committee, I will have another privilege to introduce you at that particular time.

So thank you very much, Mr. Chairman.

[The prepared statement of Senator Roberts follows:]

PREPARED STATEMENT OF SENATOR ROBERTS

Today is a special day indeed for the State of Kansas. We have with us today one of Kansas' favorite and most beloved public servants in support of our Governor, Kathleen Sebelius.

Senator Bob Dole, it is an honor to have you here. Kansans are always mindful of the great legacy that you forged for us in the Senate, and I continually strive to live up to your years of service to our State.

Governor Sebelius, welcome. It is a special and great opportunity for Kansas to be represented as a member of a President's cabinet.

Governor Sebelius and I have a special relationship. Her father-in-law, former Congressman Keith Sebelius, was my godfather in this business.

I had the privilege of serving as his AA during his congressional career, and he was a great Congressman and mentor.

I have known Kathleen and her husband Gary throughout the years and we have enjoyed a good relationship.

Governor, I look forward to building on that relationship as we work towards improving our Nation's health care system.

[The prepared statement of Senator Kassebaum Baker follows:]

PREPARED STATEMENT OF NANCY KASSEBAUM BAKER

Mr. Chairman and members of the HELP Committee, it is my honor and pleasure to address this committee on behalf of my Governor, Kathleen Sebelius. She has represented Kansas with distinction for 7 years. Prior to that she served as the Insurance Commissioner of Kansas where she gained national respect for her knowledge and leadership in the area of health insurance.

Governor Sebelius grew up in a family prominent in Democrat politics in Ohio. She married into a family prominent in Republican politics in Kansas. After converting her husband, Judge Gary Sebelius, she managed to continue to work across party lines in the most constructive and substantive ways. This has not been easy in an independent-minded but strongly Republican State.

I have worked with Governor Sebelius on several projects that we both believed important to our State. Her leadership in bringing to successful fulfillment the Tallgrass Prairie National Preserve is one example.

Kathleen Sebelius brings to the Department of Health and Human Services the type of leadership needed at this time. The important and challenging issues that will be before this committee and the Department will demand the thoughtful consideration, good humor and resolve that Governor Sebelius has always shown in public service.

As a former chairman of this committee, it is with the highest regard that I endorse the nomination of Governor Kathleen Sebelius as Secretary for the Department of Health and Human Services.

The CHAIRMAN. Thank you very much.

Now, Senator Dole.

STATEMENT OF ROBERT J. DOLE, FORMER U.S. SENATOR
FROM KANSAS

Senator DOLE. It is an honor to be back in the Senate, and I am accompanied today by a good friend and a fellow Kansan. I served with her father, I served with her father-in-law in Congress, so there has been a long relationship. We call it bipartisanship in Kansas, and maybe the fact that we start off by a Republican introducing a Democrat will be a good omen for what we hope will be a very productive year in healthcare reform.

My view is that it is time to bite the bullet, and I want to commend both the chairman and Senator Enzi, but primarily the chairman. We have been here a long time together. And it has been high on your priority list for as long as I can remember, and you got here before I did. I think Strom was here, too, but not many others.

I went back and checked, and I introduced a bill, along with Senator Domenici and Senator Danforth, in 1977 that pretty much picks up a lot of the pieces we are finding in different bills now. It wasn't all my idea. We had a lot of help from Democrats and Republicans. In those days, bipartisanship was pretty well accepted, and normally, we could work out our differences.

I can't think of a tougher job to step into now than the Secretary of HHS. I mean, we have a little group of us four former leaders—Senator Mitchell, Senator Daschle, Senator Baker, and myself—called the bipartisan panel, and we have been doing different things in energy. But now we are working on healthcare, and we hope to unveil our product sometime in the next couple of months.

We have been working on it over a year, and we understand just some of the difficulties that Governor Sebelius is going to have to face up to in the next several months. And Kansas has tended to be a Republican State for the past 300 or 400 years, and one thing about Kathleen is that she is willing and able to work with the Republicans and Democrats to try to get something done. And as I said, I can't think of any more difficult challenge. It is a critical time.

As Senator Kennedy alluded to, where you are able to have the best care, you get the best care in America. I have been blessed with the same opportunities when it comes to good healthcare over the past 30, 40 years. There are many of us who understand from personal difficulties, illnesses or whatever, how important affordable and accessible healthcare is. This committee is going to be very, very important, along with the Finance Committee, in making certain that we get something done.

Now I know the numbers, just look at the numbers. There is really no need to talk about bipartisanship because the Democrats have the numbers. I think that misses the point.

This should be bipartisan, nonpartisan, as Senator Mikulski knows, and we have worked on a lot of issues together, because the American people understand that when the Ds and Rs are together—it doesn't have to be some gigantic legislation, but something that is really important to a segment of the American people—that it is going to be successful. It is going to be accepted, and it is going to do a lot of good things for a lot of good people who now can't afford good quality healthcare. In many cases, it is not accessible.

I may be wrong, but I think the time has come that we need to do it and to do it this year. The President has made it a priority. I know this committee has made it a priority. I know Senator Baucus and Senator Grassley on the Finance Committee have made it a priority. And if we will all just give and take a little, we could end up with some pretty good legislation.

Governor Sebelius's strength is the fact that she understands healthcare. As the Kansas insurance commissioner, she has had a lot of experience, and she knows the critical issues. So she doesn't

walk in as somebody who agreed to take the job. She walks in as someone who is willing and able and would make the commitment and try to make it work, try to bring parties together in very critical areas.

We spend a lot of money on healthcare, \$2.2 trillion per year and an estimated 46 million uninsured. I am not certain who counts 46 million, but that is a lot of people to be without insurance.

Now some of those could buy insurance. They have the means, but they don't. Some are younger. A lot of younger people I see up beyond the dais who think, "Nothing is ever going to happen to me. I will buy a new car." And so, there are some people who just don't think they need to buy insurance.

There are millions, millions of people who just can't afford it, and they have children, and they have grandchildren. Half of all personal bankruptcies are due to healthcare costs. People just can't afford to take care of their healthcare bills and avoid bankruptcy.

So, I would say to this committee and particularly Governor Sebelius, I think you have the challenge of the year when it comes to legislative achievement. I am not in Congress anymore, but I know a few people who are. I know the four of us—Senator Mitchell, Senator Daschle, Senator Baker and myself—want to be helpful in any way that we can. If it means disappearing for several months or whatever you think that will be the most helpful because we think it is important to pass good, sound legislation.

I think not acting is not an option anymore. We have been patching up healthcare, all of us. We have all been a part of it, and some of it has been very good and very timely, but it is not a solution. There are always some people left on the sidelines. There is always somebody rushed to the emergency room because they didn't have the resources to go anywhere else.

And so, where do you find this person that is going to be able to come in and sit down with members and staff and agencies and work out what I said is the No. 1 topic of the year? We can't accept the status quo, and it is going to take members of both parties, not just one or two, but a pretty good chunk of both parties, even though, as I indicated, Democrats have plenty of—well, they have got a big bench. They have got a lot of reserve strength.

It is one of these times, as was the Americans with Disabilities Act, as the Senator from Massachusetts recalls, where you just have to say, OK, let us just put partisanship aside, and we don't care who gets the credit. Let us get it done. And obviously, the Senator from Massachusetts was a key player in that debate.

We had people you wouldn't expect from both sides of the aisle cooperate. In the final analysis, I think we had about 90-some votes. I don't recall. But it shows that things that people say can't be done can be done.

We have before us a nominee who has the skills, who has the experience. You know, the family has sort of grown up in politics. And as I said, I had the honor of serving with your father, and I think we even voted together on one occasion. But he was a very fine guy and a man of integrity, as was Senator Roberts' boss, Congressman Sebelius, who was a great friend, and that is just the way it works sometimes.

I would just conclude Pat has put in the record the letter from Senator Kassebaum, and so I don't need to put it in the record again. But I will just quote just one sentence so she will know that I did it.

Kathleen and Nancy have been friends for a long time. They have worked together on healthcare. And they worked together on the Kennedy-Kassebaum healthcare bill, which is one of the most recent bills, and what Nancy understands and always understood is that bipartisanship is a good word and that we shouldn't hide from it. We ought to develop it and nurture it and let it grow.

In my time in the Senate, it always occurred to me that if I could go to Kansas and people knew that not only X number of Republicans were for it, but also X number, a good number of Democrats supported the legislation, the constituents would find it much more acceptable because they knew it was broad based, and you had to bring different people with different philosophies and different ideas together.

You never get all you want. I mean, they always talk about Ronald Reagan as the ideal conservative. But I remember him telling me when I was the Republican leader, "If you can get me 70 percent, take it. I will get the rest next year or maybe later." He never said "maybe never." So Senator Kassebaum, as the chairman knows, understands the need for working together.

And finally, as I have said, I have known the family for a long time, and I know they are, well, men and women of honesty and integrity and willing to accept this challenge, and I look forward to working with her. And hopefully, our little committee with Mitchell and Daschle primarily—and me and Howard Baker as sort of accomplices, or whatever—we want to work together.

I know there must be 25 or 30 plans floating around out there, and so we want to make a pledge to the chairman now. We have got a lot of resources. We have been working on this for more than 2 years. It is funded by foundations without an agenda, without any partisan agenda. And we have a staff that I think has done a wonderful job, and we will be working with Governor Sebelius.

So, I guess the question is can we forge a bipartisan proposal that is accessible, available, and affordable? And I think we can with steady and strong leadership, and Governor Sebelius is ready to lead us in that direction.

Thank you.

I would ask that my entire statement be made a part of the record.

The CHAIRMAN. It will be made a part of the record.

[The prepared statement of Former Senator Dole follows:]

PREPARED STATEMENT OF SENATOR BOB DOLE

Mr. Chairman, Senator Enzi, thank you for that introduction. Today, it is my honor to accompany to the Senate a friend and fellow Kansan, Governor Kathleen Sebelius. They call it bipartisanship.

I'm here at a critical time in the Senate as you take on the task of reforming a health care system which is on life supports. Though our country spends \$2.2 trillion per year on health care, an estimated 46 million Americans are uninsured and millions of these

cannot afford adequate coverage. Statistics show that half of all personal bankruptcies are caused by health care costs that families cannot anticipate or afford. Most Americans who have insurance receive the best medical care available, but the quality of care, for others, causes the deaths of an estimated 98,000 Americans a year.

The status quo is clearly unacceptable, so not acting is not an option, and I believe nearly every Member of Congress agrees. Fixing our health care system will require members of both parties and the Obama administration to put partisanship aside. Success will require leadership that ends this crisis and provides accessible, reasonable and affordable care to all Americans.

Most importantly at this point in time, we need a Secretary of HHS who has the skills, experience and courage to shape and guide legislation through Congress. It will not be easy.

For more than 20 years, Kathleen Sebelius has served the State of Kansas as a legislator, insurance commissioner and Governor. All of her accomplishments required bipartisan approaches.

As insurance commissioner, she rooted out fraud and abuse and saved Kansas millions of dollars. She fought the sale of Blue Cross and Blue Shield of Kansas when she believed the sale would benefit insurance companies and leave patients with higher bills. As Governor, she protected prescriptions for seniors in jeopardy of losing their medication. More children in Kansas have health insurance because of her work to implement the Children's Health Insurance Program and her work with Kansas's Health Wave Initiative.

Her work has earned her the respect of Democrats and Republicans, including our former colleague, Nancy Kassebaum Baker, who could not be here today but has asked me to have her letter included in the hearing record at this point. **"Is There Any Objection?"**

I was asked if I could speak in support of Governor Sebelius' nomination after my friend and colleague, Senator Tom Daschle, withdrew his name from consideration. President Obama lost a highly qualified nominee but had another first rate nominee on hand in Governor Sebelius if she would accept it. She did, and I'm honored to introduce and endorse her nomination today. We are from different parties. We have different views on different issues. Abortion is one of the most controversial. I'm pro-life. The Governor is pro-choice. However, President Obama won and now gets to make cabinet selections. He has determined that Governor Sebelius is well-qualified, that she understands the importance of the enormous task she will have when confirmed by the entire Senate. The key words are that the Governor is "well-qualified."

The bottom line is that the position of Secretary of Health and Human Services has never been more important as it appears Congress will "bite the bullet" and attempt to find a bipartisan solution to a real problem that affects real people who cannot afford adequate, accessible and affordable health care. I've been working with a group called the Bipartisan Policy Center, along with former leaders Howard Baker, Tom Daschle, and George Mitchell, to come up with what we hope are meaningful, bipartisan suggestions. We've been working for more than a year, and I know firsthand how hard it is to get agreements.

I know the Sebelius family very well—Keith and Betty (both deceased), their son Gary, and grandsons Ned and John. I served in Congress with both Keith and Kathleen's father, John Gilligan. Both were highly regarded men of integrity.

Governor Sebelius will work with members on both sides as the country struggles to find an answer to the most important domestic issue of our day: Can we forge a bipartisan proposal that is accessible, available, and affordable? We can with steady and strong leadership and Governor Sebelius is ready to lead us in the right direction. Thank you.

The CHAIRMAN. Thank you, Senator Dole.

You brought back a lot of memories in the legislation, the ADA program, and our other legislation that was so important in the past. You ran us through the history of healthcare. It is good to listen to your comments and hear again the history of so much of healthcare that you were a part of and that continues to be a part of our whole legacy here on healthcare.

We always value it and we are always impressed by your knowledge about this legislation. Your strong commitment on healthcare will be enormously valuable to all of us as we are working on this issue on our committee, other committees, and the Finance Committee. We are working closely with them.

We value your knowledge and understanding and participation. It is an enormously valuable and useful effort for all of us, and we are very, very glad to have your presence here and to listen to your comments.

I will excuse Senator Dole, if he feels that he has to leave.

Senator DOLE. Is it OK if I stay a while?

The CHAIRMAN. Stay a while. We are more than delighted to have him here.

Senator BROWN. Mr. Chairman.

The CHAIRMAN. Yes.

STATEMENT OF SENATOR BROWN

Senator BROWN. Mr. Chairman, I apologize for arriving late. I was at a banking markup, and I just wanted to take just 30 seconds to welcome Governor Sebelius. Senator Dole, it is good to see you. Thank you for your comments.

Governor Sebelius comes from a long line of public servants in my home State. Her father, as we know, was Governor some 30 years ago, and she was so active always in Ohio in so many good, public-spirited ways, as her family continues to be.

Her dad, after leaving the Governor's office and going to Notre Dame, came back and, at the age of about 80, was elected to the school board, served two terms in Cincinnati dealing with so many of those problems that big city public school systems have.

She has been a terrific Governor, and I look forward to working with her as Secretary of Health and Human Services.

Thank you, Mr. Chairman, for that.

The CHAIRMAN. Thank you very much.

Governor, we are delighted to have you here. You have had a long career, a distinguished career in a number of different areas of public policy and have been especially focused on the issues of

healthcare. And obviously, it is an area where all of us on this committee are deeply interested.

So it is a very distinguished background and experience, and it really is a special honor to have a chance to introduce you here at this time before our committee. And I would ask you to proceed, if you would?

**STATEMENT OF KATHLEEN SEBELIUS, GOVERNOR,
STATE OF KANSAS, TOPEKA, KS**

Governor SEBELIUS. Well, thank you very much.

Chairman Kennedy, Senator Enzi, members of the committee, I want to thank you for inviting me here today to discuss my nomination as Secretary of Health and Human Services.

I want to start by recognizing two people who are not with me today. As has already been mentioned, Senator Kassebaum, the former chair of this committee, was hoping to come. She wanted to say hello to old colleagues and be here today.

She was one of the 20,000 Kansans who lost power over the weekend with our ice storm. So that kind of rearranged her plans. I am hopeful that she is able to participate in this hearing at least by television, which will mean her power is back on at home.

The other person I want to particularly mention is my husband, Gary Sebelius, who, 34 years ago, brought me from Washington to Kansas. He was the Kansan. He is a Federal magistrate judge, and his overly packed criminal docket on Tuesdays prevented him from rearranging that schedule. But they are here in spirit.

I am honored to have the two Kansans who have already spoken here with me because not only have they been colleagues in the workplace, but they are good friends of the family. And as Senator Sherrod Brown has already said, he has been a longtime friend of the Gilligan family. So I feel well represented by family friends here today.

I am so honored that President Obama has asked me to fill this critical role at such an important time. The Department of Health and Human Services strives for a simple goal—protecting our Nation's health and providing essential human services.

Among its many initiatives, the department supports genomics research to find cures for debilitating diseases that afflict millions of Americans and challenge their families; provides children the healthcare, early education, and childcare they need to enter school ready to learn; and protects the health and well-being of seniors through Medicare. The department is also charged with sustaining our public health system and promoting safe food, clean water and sanitation, and healthy lifestyles.

Working in concert with scientific advances and medical breakthroughs and an ever-evolving understanding of the human condition, the department's efforts have made a difference over time. Yet at the beginning of the 21st century, we find new and daunting challenges. Perhaps most importantly, as members have already reflected, we face a healthcare system that burdens families, businesses, and government budgets with skyrocketing costs. Action is not a choice. It is a necessity.

I am excited to join the President in taking on these challenges, should I be confirmed. Many are the same challenges I have ad-

dressed as Governor, as insurance commissioner, and as a State legislator.

I am proud to have worked for more than 20 years to improve Kansas's access to affordable quality healthcare, to expand access to high-quality childcare and early childhood education, to assist our seniors with Medicaid challenges and Medicare billings, to work to expand the pipeline of healthcare providers, and to ensure access to vital health services in our most rural areas.

I have also been a healthcare purchaser, directing the State employee healthcare benefits program, as well as overseeing operation of health services in our correctional institutions, Medicaid and CHIP programs, and coordinating with local and community partners on health agencies across Kansas.

As insurance commissioner, I took the then unprecedented step of blocking the sale of Blue Cross Blue Shield of Kansas to a healthcare holding company, Anthem of Indiana, because all the evidence before me suggested that premiums for Kansans insured by Blue Cross would have increased too much.

These efforts have yielded results. Our uninsured rate in Kansas is lower than the national average. Our health statistics are improved, and Kansas has been ranked first for healthcare affordability for employers and received a five-star rating for holding down health costs.

I hope you give me the opportunity to apply my experience as Governor and insurance commissioner to the challenges of advancing the health of the Nation. These challenges are significant. Healthcare costs are crushing families, businesses, and government budgets. Since 2000, health insurance premiums have almost doubled, and an additional 9 million Americans have become uninsured.

We have, by far, the most expensive health system in the world. We spend 50 percent more per person than the next most costly Nation. Americans spend more on healthcare than on housing or food. General Motors spends more on healthcare than they do on steel.

High and rising health costs have certainly contributed to the current economic crisis and represent the greatest threat to our long-term economic stability. Rapid projected growth in Medicare and Medicaid accounts for most of the long-term Federal fiscal deficit. And at the State and local levels, policymakers are forced to choose between healthcare and other priorities like public education and public safety.

American jobs are also at stake. Businesses are striving to maintain both coverage and competitiveness, and currently there is no relief in sight. That is why I share the President's conviction that, as he says, healthcare reform cannot wait. It must not wait. It will not wait another year. Inaction is not an option. The status quo is unacceptable and unsustainable.

Within days of taking office, the President signed into law the reauthorization of the Children's Health Insurance Program, a hallmark of the bipartisanship and public-private partnerships we envision for health reform. Implementing this program in partnership with the States will be one of my highest priorities.

President Obama has also worked to enact and implement the American Recovery and Reinvestment Act. This legislation includes essential policies to prevent a surge in the number of uninsured Americans and makes positive investments now that will yield health and economic dividends later.

Through health information technology, the Recovery Act lays the foundation for a 21st century system to reduce medical errors, lower healthcare costs, and empower health consumers. It supports vital information gathering by investing over a billion dollars in comparative effectiveness research, to provide information on the relative strengths and weaknesses of alternative medical interventions to health providers and consumers. The Recovery Act also makes an historic investment in prevention.

The President's budget, submitted in February, continues the work begun in the Recovery Act. It dedicates \$634 billion over the next decade to reforming the healthcare system. Its proposals would align payment incentives with quality, promote accountability and efficiency, and encourage shared responsibility. Still, the President recognizes that the reserve fund is not sufficient to fully fund comprehensive reform and is committed to working with Congress to find additional resources to devote to healthcare reform.

We appreciate the tremendous leadership of this committee to work to solve the great challenge for our Nation and hope to see action in the coming months. Should I be confirmed, health reform will be my mission, as it is the President's, along with the tremendous responsibility of running this critical department. So I would like to highlight a few opportunities and challenges facing the department.

The Centers for Disease Control and Prevention, CDC, is critical to forging a 21st century health system that prioritizes prevention. Its mission is to create the expertise, information, and tools that people and communities need to protect their health. If confirmed, I will continue the proven strategies for success, as well as revitalize the CDC for its heightened role in a reformed health system.

As Americans focus more on prevention and leading healthier lifestyles, HHS must live up to its responsibility to protect the public from health risks. It is a core responsibility of the agency, through the FDA, to ensure that the food we eat and the medications we take are safe.

Unfortunately, there is a growing concern that the FDA may no longer have the confidence of the public and of Congress. If confirmed as Secretary, I will work to restore in the FDA the trust of the American people and restore the agency as the leading science-based regulatory agency in the world.

As important as it is to protect people by regulating drugs, it is equally important that we discover new drugs and treatments that can prevent, treat, and cure disease. The National Institutes of Health provide that critical support. The mission of NIH is science in pursuit of knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life, combat illness, and ease the burden of disability.

If confirmed, I will work to strengthen NIH with leadership that focuses on the dual objectives of addressing the healthcare chal-

lenges of our people and maintaining America's economic edge through innovation.

Leading the Department of Health and Human Services and working with the President to reform the health system won't be easy. If it were, as the President has noted, our problems would have been solved a century ago.

The status quo cannot be sustained and is unacceptable for our economic prosperity and for the health and wellness of the American people. Previous opponents of health reform are now demanding it, putting the common interests in an affordable quality system of care for all, ahead of special interests, and policymakers, like those of you in this room and men and women who serve in Congress are reaching across party and ideological lines to accomplish this urgent task.

I hope I have the opportunity to join you, and I look forward to your questions.

[The prepared statement of Governor Sebelius follows:]

PREPARED STATEMENT OF KATHLEEN SEBELIUS

Chairman Kennedy, Senator Enzi, members of the committee, thank you for inviting me here today to discuss my nomination to be the Secretary of Health and Human Services.

I am honored that President Obama has asked me to fill this critical role at such an important time.

The Department of Health and Human Services strives for a simple goal: protecting our Nation's health and providing essential human services. Among its many initiatives, the Department supports genomics research to find cures for debilitating diseases that afflict millions of Americans and challenge their families; provides children the health care, early education, and child care they need to enter school ready to learn; and protects the health and well-being of seniors through Medicare. The Department is also charged with sustaining our public health system and promoting safe food, clean water and sanitation, and healthy lifestyles.

Working in concert with scientific advances, medical breakthroughs, and an ever-evolving understanding of the human condition, the Department's efforts have made a difference. People born in 2000 can expect to live nearly three decades longer than those born in 1900. Since 1900, infant mortality has dropped by 95 percent and maternal mortality by 99 percent. Diseases like polio have been eradicated.

Yet, at the beginning of the 21st century, we face new and equally daunting challenges. We face an obesity epidemic that threatens to make our children the first generation of American children to face life expectancies shorter than our own. Globalization has made a flu strain in a remote country a potential threat to America's largest cities. We now must guard against manmade as well as natural disasters, as disease has become a weapon. Perhaps most importantly, we face a health system that burdens families, businesses, and government budgets with sky-rocketing costs. Action is not a choice. It is a necessity.

WORK ON IMPROVING THE HEALTH OF KANSANS

I'm excited to join the President in taking on these challenges. Many are the same challenges I've addressed as Governor, as Insurance Commissioner, and as a State Legislator. I'm proud to have worked for more than 20 years to improve Kansans' access to affordable, quality health care; to expand access to high-quality child care and early childhood education; to assist seniors with Medicare challenges; to work to expand the pipeline of health care providers; and to ensure access to vital health services in our most rural areas. In Kansas, affordable health care for children, seniors, and small businesses has been a special priority for me.

I was asked by my predecessor, Republican Governor Bill Graves, to lead the team to design and implement the Children's Health Insurance Program. Our separate insurance initiative called Health Wave is modeled on the State employee program. Its enrollment started at 15,000 in the first year; today, it covers over 51,000 children. And the Legislature just voted to support my recommendation that our CHIP program be expanded.

I have also worked to make life-saving medications affordable. I established counseling programs to help seniors navigate the complicated Medicare prescription drug

benefit plan. When seniors started falling through the cracks of the new drug program, I directed the State to pay their prescription costs to Kansas pharmacies to prevent the loss of coverage. During this period, we filled 45,000 prescriptions for Medicare-eligible seniors.

These efforts have yielded results. The uninsured rate in Kansas is lower than the national average. Our health statistics are improved. And Kansas has been ranked first for health care affordability for employers and received a five-star rating for holding down health care costs.

I have also been a health care purchaser, directing the State employee health benefits program as well as overseeing the operation of health services in our correctional institutions and Medicaid and CHIP programs, and coordinating with local partners on health agencies across Kansas. I took these jobs seriously. In November 2005, we successfully negotiated a new health insurance contract to reduce premium costs with no loss of benefits for thousands of State employees. At a time when health costs were skyrocketing, I worked with the Legislature to streamline the health care bureaucracy, and leverage our purchasing power within State government. I signed legislation to create a new independent State agency, the Kansas Health Policy Authority, to manage nearly all of the State's spending on health care, simplify the process of obtaining health care, and use the State's buying power to reduce costs. We have launched focused prevention and wellness efforts, in collaboration with schools, communities, employers, and senior centers. Our health IT work has been nationally recognized, and we are the first State in the country to use a "smart card" for our Medicaid population. As Insurance Commissioner, I created a Fraud Squad that worked with the Attorney General's Office to aggressively pursue fraud and abuse, and recovered millions of dollars during my tenure.

In these roles, I know first-hand the challenge of standing up to the special interests to protect consumer interests. As Insurance Commissioner, I made a patient-protection bill the centerpiece of a 2000 legislative proposal. In 2002, I took the then-unprecedented step of blocking the sale of Blue Cross and Blue Shield of Kansas to the health care holding company of Anthem of Indiana. I did so because all evidence suggested that premiums for Kansans insured by Blue Cross would have increased too much, and providers would have been adversely impacted. I was the first State Insurance Commissioner to block such a deal, although others have followed.

HEALTH REFORM

I hope you give me the opportunity to apply my experience as a Governor and Insurance Commissioner to the challenges of advancing the health of the Nation. These challenges are significant.

Health care costs are crushing families, businesses, and government budgets. Since 2000, health insurance premiums have almost doubled and an additional 9 million Americans have become uninsured. Since 2004, the number of "under-insured" families—those who pay for coverage but are unprotected against high costs—rose by 60 percent. Just last month, a survey found over half of all Americans (53 percent), insured and uninsured, cut back on health care in the last year due to cost.

The statistics are compelling, as are the stories. During the transition, the President encouraged Americans to share their personal experiences and stories through Health Care Community Discussions. Over 30,000 people engaged in these discussions. In Manhattan, KS, a parent told the story of a 27-year-old son who was working at a convenience store. Although he was offered insurance, he thought it was too expensive. A bicycle accident sent him to the emergency room and generated a hospital bill of more than \$10,000, which he and his parents are struggling to pay off.

In Pittsburg, KS, a health care provider shared that during the last 3 years, three women in similar situations had been identified with breast cancer. One woman received care, as she had insurance, and had a good health outcome. Two women had to wait for a pre-existing condition time delay on their health insurance to lapse; both ended up with their cancers advancing, and neither received care. Heartbreakingly, both women died within the year.

And, in Houston, TX, the challenges health costs pose to businesses were discussed. One participant asked, "How can you go out on a limb and start a new business when health care is a noose around your neck?"

We have by far the most expensive health system in the world. We spend 50 percent more per person than the next most costly nation. Americans spend more on health care than housing or food. General Motors spends more on health care than steel.

This cost crisis in health care is worsening. The United States spent about \$2.2 trillion on health care in 2007; \$1 trillion more than what was spent in 1997, and half as much as is projected for 2018.

High and rising health costs have certainly contributed to the current economic crisis. A recent study found nearly half of Americans with homes in foreclosure named medical problems as a cause. Rising health costs also represent the greatest threat to our long-term economic stability. If rapid health cost growth persists, the Congressional Budget Office estimates that by 2025, 25 percent of our economic output will be tied up in the health system, limiting other investments and priorities.

This is paralleled in Federal and State budgets. Rapid projected growth in Medicare and Medicaid accounts for most of the long-term Federal fiscal deficit. And, at the State and local levels, policymakers are increasingly put between the “rock” of health care costs and the “hard place” of other priorities, like public education and public safety.

American jobs are also at stake. “Old-line” industries are striving to maintain both coverage and competitiveness—locally and globally. New industries and businesses are struggling to offer coverage in the first place. Both workers and their employers are concerned about the future of employer-sponsored health insurance. Currently, there’s no relief in sight.

This is why I share the President’s conviction that “health care reform cannot wait, it must not wait, and it will not wait another year.” Inaction is not an option. The status quo is unacceptable, and unsustainable.

Within days of taking office, the President signed into law the reauthorization of the Children’s Health Insurance Program. This program’s success in covering millions of uninsured children is a hallmark of the bipartisanship and public-private partnerships we envision for health reform. Implementing this program in partnership with the States will be one of my highest priorities.

President Obama has also worked to enact and implement the American Recovery and Reinvestment Act in partnership with governors, mayors, Congress, and private partners. This legislation includes essential policies to prevent a surge in the number of uninsured Americans. It also will help an estimated 7 million people affected by unemployment keep their health insurance through COBRA (i.e., continuation coverage for certain workers leaving their jobs). There is essential additional aid to States providing health benefits, making sure that people with disabilities and low-income Americans who rely on Medicaid benefits don’t lose coverage as States try to balance their budgets. The Recovery Act prevents an already-bleak health-coverage situation from getting worse.

The Recovery Act also makes positive investments now that will yield health and economic dividends later. Through health information technology, it lays the foundation for a 21st-century system to reduce medical errors, lower health care costs, and empower health consumers. In the next 5 years, HHS will set the standards for privacy and interoperability, test models and certify the technology, and offer incentives for hospitals and doctors to adopt it. The goal is to provide every American with a safe, secure electronic health record by 2014.

The Recovery Act supports vital information gathering as well as information technology. It invests \$1.1 billion in comparative effectiveness research to provide information on the relative strengths and weaknesses of alternative medical interventions to health providers and consumers.

The Recovery Act also makes an historic investment in prevention. We cannot achieve our ultimate goal—a healthier nation—unless we shift away from a sick-care system. We pay for emergencies, not the care that prevents them, with little emphasis on the responsibility each of us has in keeping ourselves and our families well. The \$1 billion for prevention in the Recovery Act will empower every American through immunizations, chronic disease prevention, and education.

The President’s budget submitted in February continues the work begun in the Recovery Act. It dedicates \$634 billion over 10 years to reforming the health care system. Its specific proposals would align payment incentives with quality, promote accountability and efficiency, and encourage shared responsibility. The President recognizes that while a major commitment, the reserve fund is not sufficient to fully fund comprehensive reform. He is committed to working with Congress to find additional resources to devote to health care reform.

The President is also committed to hearing from Americans across the Nation. In March, he held a White House health care forum and several regional forums in places like Iowa, Vermont, and North Carolina. There, bipartisan forums brought together people from all perspectives—across the political spectrum and representing all people with a stake in the system—to focus on solutions.

We appreciate the tremendous leadership of this committee to address this urgent challenge. The leadership in Congress is getting to work to solve this great challenge for our Nation, and we hope to see action in the coming months.

Should I be confirmed, health reform would be my mission—as it is the President's—along with the tremendous responsibility of running this critical Department. And so, I would like to highlight a few of the opportunities and challenges currently facing the Department.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The Centers for Disease Control and Prevention (CDC) is critical to forging a 21st-century health system that prioritizes prevention. Its mission is to create the expertise, information, and tools that people and communities need to protect their health. For example, thanks in part to CDC immunization programs, most childhood vaccine-preventable diseases have been reduced by 95 percent from pre-vaccine levels. For each birth cohort vaccinated, society saves \$33.4 billion in indirect costs; direct health care costs are reduced by \$9.9 billion; approximately 33,000 lives are saved; and 14 million cases of disease are prevented. In addition, today, heart disease rates have declined by half, in no small measure because of the role of community-based prevention.

If confirmed, I will continue proven strategies for success as well as revitalize CDC for its heightened role in a reformed health system. I will work to strengthen its ability to detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote health behaviors, and foster safe and healthful environments. CDC could also focus on ensuring effective coordination between public and private resources at the national, State, and community levels to promote wellness throughout the lifespan, and ensure healthy communities. Through executive actions, partnership, and health reform, CDC can play a vital role in reducing the impact of childhood diseases, chronic diseases, and diseases that target the aging population. Moreover, CDC will play a crucial role in health reform since strong and effective disease prevention and health promotion go hand in hand with the President's goal of providing affordable, quality health coverage to all Americans.

FOOD AND DRUG ADMINISTRATION

As Americans focus more on prevention and leading healthier lifestyles, HHS must live up to its responsibility to protect the public from health risks. It is a core responsibility of HHS, through the FDA, to ensure the food we eat and the medications we take are safe. The FDA is responsible for the safety of thousands of items Americans depend upon every day, from toothpaste to fruits and vegetables to the extraordinary drugs, vaccines, and medical devices that save our lives. The agency regulates goods that account for 25 percent of all consumer spending—more than \$1 trillion. Unfortunately, there is growing concern that the FDA may no longer have the confidence of the public and Congress. Nearly two-thirds of Americans do not trust the FDA's ability to ensure the safety and effectiveness of pharmaceuticals.

If confirmed as Secretary, I will work to restore trust in the FDA as the leading science-based regulatory agency in the world. I will do so by working to strengthen the FDA's ability to meet the pressing scientific and global challenges of the 21st century, and by sending a clear message from the top that the President and I expect key decisions at the FDA to be made on the basis of science—period.

NATIONAL INSTITUTES OF HEALTH

As important as it is to protect people by regulating drugs, it is equally important that we support efforts to discover new drugs and treatments that can prevent, treat, and cure disease. The National Institutes of Health (NIH) provides that critical support, and has funded a range of discoveries that have enabled us to live longer and more healthful lives. In many areas—for example, what we are learning from the human genome project—we are on the verge of even more exciting and promising scientific discoveries.

The mission of NIH is science in pursuit of knowledge about the nature and behavior of living systems, and the application of that knowledge to extend healthy life, combat illness, and ease the burden of disability. It is well documented that investment at NIH reaps significant rewards, not only for the health of our citizens, but for the strength of our economy. Yet funding in the previous administration slowed considerably. We have seen a sharp fall in the success rates for grant applicants, now as low as 10 percent for many NIH Institutes. This has come at a time when the economic downturn has hurt the ability of businesses, universities, and

charities to serve as alternative sources of research support. NIH has also suffered from some instances of people putting politics before science.

If confirmed, I will work to strengthen NIH, with leadership that focuses on the dual objectives of addressing the health care challenges of our people and maintaining America's economic edge through innovation. We will ensure that the agency has the support to capture the opportunities of biomedical research that are core Department's mission of improving the quality and length of our lives.

CONCLUSION

Leading the Department of Health and Human Services and working with the President to reform the health system won't be easy. If it were, as the President has noted, our problems would have been solved a century ago. But the status quo cannot be sustained, and is unacceptable both for our economic prosperity and the health and wellness of the American people. Previous opponents of health care reform are now demanding it, putting the common interest in an affordable, quality system of care for all ahead of special interests. And policymakers like you are reaching across party and ideological lines to accomplish this urgent task. I hope I have the opportunity to join you, and I look forward to your questions.

The CHAIRMAN. Thank you very much, Governor.

Here is the million-dollar question on the minds of all Americans. It is a simple one. How in the world are you going to get healthcare reform? We will just move on from there.

[Laughter.]

Give you another opportunity later on in the—

Governor SEBELIUS. My answers are limited to an hour and a half.

The CHAIRMAN. OK. There we go. Just seriously, you have been on the front lines of healthcare. What have you learned from those experiences that will help us enact healthcare reform?

Governor SEBELIUS. Well, Mr. Chairman, in my service as Governor and as insurance commissioner, I have learned some valuable lessons. I would say the first of which States can't do it alone. A lot of States have been struggling over the last decade or more to expand health coverage to our citizens, but it is a daunting task without a Federal policy in place and a Federal partner.

I am very pleased that we have an administration committed to tackling this key problem and a lot of enthusiasm, both among Republicans and Democrats, that we need to reform the healthcare system. No question that costs are crushing, and addressing the cost system means overhauling the way we focus our healthcare system.

Certainly the efforts that this Congress has already made in investing in prevention is a huge step forward. I am a believer, along with a lot of the members of this body, that prevention services, intervention at an earlier stage in illness is one of the ways to reduce costs.

Insuring every American helps us recapture the overpayment of Americans who are now accessing the health system through the doors of an emergency room, where they get the most expensive, least effective kind of care. We see it over and over again in Kansas. We see it in every town in America, and that is primarily caused by a failure to have a health home and a primary provider.

Certainly reorganizing the incentives for primary care and earlier intervention and tackling the problems of chronic disease.

The assets of the agency, which I have been asked to lead and which I hope I have an opportunity to do, if confirmed, can be enormously powerful in building the blocks of the health reform puzzle.

zle—making sure that the Medicaid and Medicare program work efficiently and effectively; making sure that we adequately roll out the expanded application of CHIP, the program for children's health insurance, which has been probably one of the most significant enhancements to health insurance in the last several decades; and making sure that our research and scientific capabilities are directed to the best possible care at the best possible price.

I am enthusiastic that the lessons learned as Governor and insurance commissioner can now be taken to the national level.

The CHAIRMAN. Let me ask you, should we wait? There are many who think that we should wait on healthcare and healthcare reform, try and get the costs down at different parts, perhaps have a gradual movement toward healthcare reform. But what is your sense about whether we should or shouldn't wait to see this reform taking place, given our current economic crisis?

Governor SEBELIUS. Well, Senator, I think our current economic crisis presents the inevitability that we cannot wait. I believe, as the President has articulated over and over again, that we can't fix the economy of America without fixing the healthcare system. It is so intricately tied to the costs that employers are now spending and finding themselves less competitive with global partners. It is incredibly tied to the burden that American families face with bankruptcy and health costs.

So, I think the urgency is upon us, and I think the lessons from Massachusetts, your home State, a State which has an impressive attempt to expand coverage to all in Massachusetts, gives us some important rules to keep in mind. The folks in Massachusetts would tell you that they decided to work in incremental steps, to first tackle the opportunity to expand healthcare to all citizens and second to tackle the cost situation.

Unfortunately, they are in a situation right now where coverage has been expanded, and that is very good news. But costs continue to rise. So I think the lesson learned is that not only must we approach health reform, but it needs to be a comprehensive effort. That unless we face the costs at the same time we are expanding coverage, we really haven't made as much progress as we can, and we won't have provided the pathway to prosperity for American workers, for American businesses, and American families.

The CHAIRMAN. All right.

We are going to try to get a 5-minute rule on this. But to do that, we are going to have to ask all of our colleagues to be as brief as they possibly can in order to try and get through as many questions as we can. We thank all of our colleagues for respecting that.

Senator ENZI.

Senator ENZI. Thank you, Mr. Chairman.

As I mentioned when we met, this committee does pass a lot of legislation, and one of the reasons it does that is because we work together. One example of that is the National Service Act that was just passed last week.

Senator Mikulski did a marvelous job of pulling everybody together, holding the hearings in Senator Kennedy's absence. Senator Hatch did a great job of working from the other side. And Senator Coburn did a marvelous job of introducing matrices, and Senator

Mikulski listened to that. So there was an improvement in the bill through that part of the process.

But a good working relationship requires both the majority and the minority to listen and work with each other. And in light of that, the first question I always ask is, if confirmed, will you pledge to cooperate in this type of a working relationship with the Senators of the committee, both Democrats and Republicans, by promptly responding to any written or phone inquiries, sharing information as soon as it becomes available, and directing your staff to do the same?

Governor SEBELIUS. Senator, you have my commitment, if confirmed, that I will be not only an eager partner to work with Congress, but that I understand bipartisanship, as Senators Dole and Roberts have already indicated. I am a Democrat in a State where the majority of voters are Republicans. The vast majority of our legislature are Republicans. And yet, time and time again, I have found ways to work across party lines and get things done.

I think that is what the American people expect of me as Secretary. If I am confirmed, I pledge to work in that same fashion that I bring out of Kansas.

Senator ENZI. Thank you.

I know that you are a former legislator. So I know that you have a full appreciation for how debate and respect for the process does lead to bipartisan legislation.

In the interest of the bipartisan support for health reform, I hope that you will join Senator Baucus and Senator Conrad, the chairman of the Budget Committee, to discourage members from using the budget reconciliation process to pass healthcare reform so that there is the appearance and the reality of an open process. Would you do that?

Governor SEBELIUS. Well, Senator, I know that the President is very dedicated to having a bipartisan process for health reform. He talked extensively during the course of the campaign about the need to reform the health system but chose a different pathway than the previous experience, which was really to lay out some principles but make it very clear that he believes strongly that this cannot be a success unless Congress is engaged and involved in the process.

I think you saw his efforts shortly after the campaign to reach out to Americans in community conversations across the country. The recent health summit, where members of the House and Senate, Republicans and Democrats, as well as stakeholders from across the spectrum were invited to the White House, those summits have been continued in regional meetings chaired by Governors across the country. One, in fact, is taking place today in North Carolina, Senator Burr's home State.

I think there is an absolute dedication to engaging Republicans and Democrats in this effort. I would say I think there is also an urgency about this effort this year to get something passed, and at least in the preliminary discussions that I have had with members of Congress, there is an interest in not taking any tools off the table prematurely, but being very dedicated to a bipartisan process and a bipartisan bill.

Senator ENZI. I am afraid that if that reconciliation winds up in the budget bill, it will be like a declaration of war or, hopefully, not quite that drastic. But even you mentioned West Virginia, Senator Byrd has even done an example of why that should not be the process. I think we have set up a schedule as this board of directors to meeting a tight timetable for getting something done.

And this time with having Congress involved in the process, I am confident that something will happen with it and in a relatively short period of time. But I hope that that wedge doesn't get thrown in there because it is a major concern on one side of the aisle.

I will move quickly to health IT. I had discussions with the Mayo Clinic and with some other clinics and then the CEO of Safeway, who has talked about the need to be able to aggregate information in health IT. And I think that some of the legislation that we have done already the privacy is so strong that I am not sure the individual can look at the record, let alone the doctor look at the record. And it definitely cannot aggregate so that you can figure out problems to solve in a major way.

Since my time has expired, I will submit that to you in writing, along with a number of other questions that I have here. So I reserve the time.

The CHAIRMAN. Thank you very much.

Senator Mikulski, very delighted to have you.

STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Thank you, Senator Kennedy. It is so great to see you back in the chair. I mean, we are really genuinely and enthusiastically happy to see you.

Governor Sebelius, we are happy to welcome you and see Senator Dole.

Just very quickly, the women of Kansas have a terrific reputation. When I first came to the Senate, there were only two women. Now there are 17. But the other woman was my very good friend, Senator Nancy Kassebaum Baker.

It is a treasured relationship, and I see common characteristics in you both. No. 1, a style of civility, which I think will go a long way; No. 2, competent and yet unfailing common sense, finding that sensible center; and then also compassion, but a desire to find, again, those pragmatic solutions. So we are happy to see another woman from Kansas.

Governor SEBELIUS. I thought you were going to start with my gray hair and Nancy's gray hair.

Senator MIKULSKI. No, no, no. No other woman would ever go in that direction.

[Laughter.]

We both value the miracles of modern chemistry.

[Laughter.]

But let me go on, though, to how I see you. I see you as the CEO of HHS, bringing your very extensive executive experience and executive ability to the job of managing 67,000 employees.

Let me go right to health reform and something that is the baseline in it, which is health IT. Whatever we want to do in health reform, health IT will help with both case management, reducing medical errors, all these good things. However, there is a great fear

over interoperability. It is one I share. It is one providers, hospitals, and all share.

How will you stand sentry over this process to avoid what we fear is a “techno Katrina?” We are all saying that—even the President said this is low-hanging fruit. Oh, we can do it. But what we are concerned about is the failure of interoperability, the failure of compatibility. The failure to have clear national standards quickly could result in a fiscal and case management boondoggle.

So we want a boon and not a doggle. Tell me how you are going to do it.

Governor SEBELIUS. Well, Senator, I think you have identified one of the linchpins of the health reform effort that has to be underway, and I am so appreciative that Congress, in the passing of the Recovery Act, identified that expenditures for health IT was a fundamental building block for a new system of healthcare.

As you have just said, it doesn’t matter if we just take all the paper and translate it to computers and have systems that still don’t speak to one another, providers who have to replicate their forms and billing opportunities 10 and 15 and 20 times, hospitals that can’t track a patient—

Senator MIKULSKI. Governor, you are identifying the problem. But how are you going to make sure we get to the solution?

Governor SEBELIUS. Well, the department has just identified a new leader for the health IT system in David Blumenthal, who is nationally renowned and has the expertise, I think, to be the point person for this very important effort. And the challenge is, as you said, to have standards that work.

There is a broad-based stakeholder group at the table. They have a very aggressive timetable to develop interoperable standards and address the initiative to begin then to have investments available for clinics and doctors and hospitals to put the system in place. But step one is to get a platform where people talk to each other.

As Governor of Kansas, we have worked on a health IT system for the last 3 years. I think we actually are ahead of a lot of the country, where we put insurers, providers, the major hospital groups, and others at the table because we knew that investments were not worthwhile unless there was a common platform.

We are going to be the first State in the country that has implemented a smartcard for Medicaid patients, where they will be able to swipe a card in services and benefits. We have a single billing system that will be in place by the end of this year. So providers will fill out one form, and any insurance company who wants to do business in our public system in Kansas will have to abide by that one billing form.

I have some experience as insurance commissioner and as Governor in working on this platform, and I think we have the right leader in place to move this initiative forward.

Senator MIKULSKI. Well, here is where I am. First of all, I am an enthusiastic supporter of your nomination. I think you do bring the right stuff to the job, and I think that right stuff is exactly your personality characteristics, your know-how, and your executive ability.

On this health IT, whether it is prevention, controlling costs, etc, I am sure Dr. Blumenthal will do a good job. I am going to ask you,

as someone who I think will be Secretary, to have someone who really follows this on a day-to-day basis so we don't get lost in wonkishness and so on. We really do have to have national standards, lessons learned from the VA.

You know how to set up the process. Blumenthal knows how to do it. There is a great sense of urgency for the private sector to develop the products we might use. But without national standards, we could head for a techno Katrina. I do not want to do that, where we do a dollar dump and at the end of the day, and we have a lot of microchips floating around but not really the kinds of outcomes the President wants, you want, and I believe the bipartisan effort wants.

I am going to ask you to real aggressively stand sentry on this because the development of national health IT standards will be the linchpin of the technology we need to get to the policy reforms.

Governor SEBELIUS. Well, Senator, you have my commitment, if confirmed, that I will do just as you asked and also look forward to working with you and others in Congress who have worked on this critical issue for years, who have the expertise, who have thought about it for a good deal of time.

You are absolutely right. This has to be done right. It has to be done well. It has to be a system that works not only for urban communities but, as Senator Enzi has already pointed out, our most rural areas. We can't have a system where the systems can't talk to one another.

If it is done right, I am a believer that not only will it lower medical errors and lower costs, but empower consumers and providers in a way that we have not seen and unlock the innovation for health reform in America.

Senator MIKULSKI. Thank you.

Mr. Chairman.

The CHAIRMAN. Senator Isakson.

STATEMENT OF SENATOR ISAKSON

Senator ISAKSON. Thank you, Senator Kennedy. Glad to have you back in the chair.

Governor Sebelius, great to see you.

Senator Dole, it is a pleasure to see you again. We are longtime friends, and I still enjoy your wit to this day.

The first question I have, being from Georgia, we recently had the salmonella outbreak, which started in the plant in Camilla but then spread to closings of plants in Texas and Virginia. Because of the pervasive nature of that recall and the number of people that passed away and were infected with salmonella, there have been some people calling for a separation of FDA into two different functions, from food on one side, drugs on the other.

Do you have a position on that proposal?

Governor SEBELIUS. Well, Senator, I watched with interest some of that preliminary discussion. And again, if confirmed, I intend to be very actively involved in the debate about—I think step one is restoring FDA as a world-class regulatory agency. It was at one point the gold standard for regulatory agencies not only in this country, but in the world.

I think there are serious issues that need to be addressed within the organization to make sure our food supply, which, as Senator Roberts and Senator Dole can tell you, we take very seriously in Kansas food safety and safe and secure food supply. And our drug supply is safe and secure.

So there is, again, new leadership who has been identified for the Food and Drug Administration. I am hopeful that if the Senate approves their nominations rapidly, we can have that kind of enhanced leadership in place. The President has proposed in the budget an almost 30 percent increase in resources.

But I think that part of the challenge at this point is that however well the Food and Drug Administration operates, we have to have a new platform for safety and security of food and drugs in this country. And it has to be a much more collaborative approach with industry. It can't just be the responsibility of Government. It has to be up and down the food chain.

Too often we are reacting to situations. As you say, the salmonella outbreak, today I learned that pistachios have also been recalled. And the reaction time needs to be faster, but also we need to involve industry in making sure that we look at products as they move through the food chain and that there is some collaborative operation to make sure that those supply chains are also very involved in keeping our people safe.

So I think it is premature to discuss whether or not we divide or keep together an agency. I think step one is restoring the agency that has this responsibility to its rightful purpose, which is a safe and secure food supply.

Senator ISAKSON. On the same subject matter, but about the stress on FDA right now in terms of workload and some of the problems that have existed. There is legislation that was pending last year in the Senate and is pending again now to put regulation of tobacco in the FDA. Would you support that? And if so, would that regulatory authority add too much stress on an already overly stressed department?

Governor SEBELIUS. Senator, I support the idea that the FDA will regulate tobacco. The President has supported tobacco regulation within the FDA, and I think that there is no question, as we talk in this room about health reform, what we know is smoking is the No. 1 cause of health-related diseases. It is probably the most expensive cause of illnesses that land people in the hospital.

And for the Food and Drug Administration to actually have the authority to exercise its regulatory power and not only have enhanced and more significant warning labels, more information available to consumers, help to regulate the products that are often enticing the youngest Americans to start smoking with whether it is flavored cigarettes or a variety of things can only in the long-term benefit our overall health and our economy.

Senator ISAKSON. Well, thank you very much, and I will just make a comment at the end because I know my time is up.

One other pending issue that will come under your jurisdiction if you are confirmed is the whole issue of biological pharmaceuticals and follow-on biologics, and we are the best inventor and discoverer of pharmaceuticals that have helped save thousands and

thousands of lives. And now biologically based pharmaceuticals are growing exponentially.

So as we deal with that whole area of oversight and approval of those biologics, let us not forget the process that we have for chemical compounds that has led us to be a country that can really invent a lot of pharmaceuticals and a lot of breakthroughs and have the incentives to recover the R&D money. Let us make sure we do the same thing with regard to biologics.

Again, congratulations on your nomination.

The CHAIRMAN. Senator Harkin.

STATEMENT OF SENATOR HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman. Let me join with others in welcoming you back to take charge of our committee and health reform this year.

Welcome to Governor Sebelius, and congratulations on your nomination for this very important position.

I apologize for being here late and having to leave early, but right now I am chairing another hearing on agriculture on the reauthorization of the child nutrition bill this year. That has to do with our school lunches and school breakfasts, which Senator Dole has been such a great leader on all his lifetime, and trying to get junk food out of our schools and get more healthy and nutritious food for our kids in schools.

Now, while that may not be directly in your jurisdiction, I certainly hope that you will work closely with Secretary Vilsack and Secretary Duncan in helping us get this bill through that will get the junk food and sugary sodas out of schools and get healthier foods in our schools for our kids.

I hope you will be involved in that, even though it may not be directly under your jurisdiction. That is my way of saying that is why I have to leave a little early.

But I am really delighted to see you here with Senator Dole because my first question has to do with an issue that both of us have worked on for a long time, him a lot longer than me. Senator Kennedy has also been a great champion of disability issues.

As you know, we passed the Americans with Disabilities Act in 1990. Shortly after that, we started a process to try to address the issue of people with severe disabilities and the fact that they are shunted into nursing homes.

When I tell people this today, they say I must be mistaken when I tell them that right now if you are a person with a severe disability and you are eligible for Title XIX under Medicaid, Medicaid must, must pay for your institutional setting in a nursing home. If you want to live in your own home or in a community setting, they don't have to pay for it. And so, Medicaid forces people with disabilities into nursing homes where they may not want to be.

So, we started shortly after that, Senator Dole and I and others, in the early 1990s pushing a bill, which we called the Medicaid Community Tenant Services and Supports Act. The people in the community knew it as MiCASSA. But we could never get it through because they said it was going to cost gazillions of dollars.

Well, since that time, we have had further studies done, and we know now that it doesn't cost that much. And so, we now have a

new bill. We call it the Community Choice Act, to give people with disabilities the choice. Do they want to live in a nursing home, or do they want to get their services and supports in their own home or in their community, near their families, near their friends?

Then 10 years ago, 10 years ago this year, we had the U.S. Supreme Court decision in *Olmstead*, the *Olmstead* case, in which the U.S. Supreme Court said that people with disabilities have a constitutional right to live in the least restrictive environment. That was 10 years ago, and we still haven't taken care of it. It is just hanging on us.

I would just like to ask if you would support the Community Choice Act as well as the U.S. Supreme Court decision in *Olmstead* as we do healthcare reform? To make sure that in healthcare reform that people with significant disabilities have the choice and opportunity to receive their supports and services within their own homes and communities rather than just in institutional settings.

Governor SEBELIUS. Well, Senator, I am not familiar with all of the provisions in the act, the Community Choice Act. What I can tell you, though, is that Kansas has been fairly aggressive as a State in pursuing Medicaid waivers to ensure that money does follow those of our disabled citizens who want to live in a less restrictive setting.

We have addressed the challenges—some would say not enough, there is more work to be done—but the challenges of building a workforce, a competent workforce who is available to take care of citizens in a less restrictive setting, particularly those with severe disabilities. We have enacted legislation that has actually closed two of the hospital settings and moved those resources into communities.

So I am very much committed to actually following the dictates of the *Olmstead* Act. And as we address health reform, I think it is critical to look at citizens at all ends of the spectrum, those who are very healthy and those who are very disabled, and find the best possible avenue for support and health outcomes.

I don't think there is any question that people prefer to live in less restrictive settings. And so, we have workforce challenges. We have financial challenges. But it is one that I am very familiar with and believe in very strongly.

Senator HARKIN. I appreciate that, but the ultimate decision ought to be with the person.

Governor SEBELIUS. That is right.

Senator HARKIN. The person ought to decide, not Medicaid or CMS or anybody else. If that money can flow to a person to go to an institution, it ought to flow to that person regardless of where that person wants to live. And that is really the essence of the Community Choice Act.

Governor SEBELIUS. Well, I promise, if I am confirmed, I will definitely take a look at it and work with you to see what we can do with the Medicaid system to make that happen.

Senator HARKIN. I appreciate that. I would be remiss if I—no, I don't have any time left. OK. I will submit my other questions in writing.

Governor SEBELIUS. I do want to, though, also—if I can, Mr. Chairman? The Senator began his comments with a very critical

issue, and I think it is one that is so tied to the topic, that sort of the umbrella topic of today's hearing, which is health reform. Certainly addressing childhood obesity, addressing the health of our children is a critical component of this.

We have the first generation of children in America, if the statistics continue, who will have shorter expected lifespans than their parents, first time ever in the country. It is a rampant crisis that we need to address.

I, again, congratulate you for your work on school nutrition, for wellness and prevention work. But addressing the responsibility that we have to take some action outside of ensuring that Americans have access to healthcare, I think we need to have some personal responsibility re-instilled. Individuals have a responsibility about what they eat, how they exercise, and what kinds of choices they make with particularly tobacco.

The more we can drive that through the auspices of the agency through prevention efforts, I think the better off we are going to be in the long run.

The CHAIRMAN. Thank you very much.
Senator McCain.

STATEMENT OF SENATOR MCCAIN

Senator MCCAIN. Congratulations on your nomination, Governor, and we look forward to speedy confirmation.

And Senator Dole, it is wonderful to see you back again as always. We miss you every day.

Governor, I would like to discuss with you for a moment the issue of employer-provided health insurance. As you know, the employer-provided health insurance is a result of World War II, when price and wage controls were imposed. So employers provided additional healthcare benefits, and those are tax free.

First of all, would you agree with me that there is a certain unfairness associated with this in two ways? One is that traditionally, the higher up in the food chain the individual is, the more benefits and the more likely gold-plated insurance is provided. Also, small business people are generally unable or certainly large numbers of them are unable, because they are small business people, to provide health insurance policies to their employees.

Would you agree with that premise?

Governor SEBELIUS. Well, Senator, I certainly agree that in the marketplace, those who are self-employed and those who are small employers are often priced out of the market. Yes, sir.

Senator MCCAIN. Well, do you agree with my first point or disagree?

Governor SEBELIUS. Well, I think there is no question that employer-based health insurance is the backbone of the health insurance system we have right now.

Senator MCCAIN. My question was whether you agree or disagree that employer-based health insurance generally is much more generous to the upper-level management in American corporations and businesses?

Governor SEBELIUS. Well, I am not familiar with differentials in the health system. I know in a State employee system and a manufacturing operation that the workers have good benefits, and I

think they don't differ from the benefits of the executives in those systems.

Senator MCCAIN. Would you support removing the tax exclusion and substitute a refundable tax credit of, say, \$5,000 per family so that they can go out and purchase their own health insurance policy of their choice?

Governor SEBELIUS. Well, Senator, I support what the President has articulated, which is that——

Senator MCCAIN. You know we are asking for your views before this committee, Governor.

Governor SEBELIUS. I support what the President has articulated, which is that if Americans have health insurance that they like, they should be able to keep it. Dismantling the current system of employer-base coverage, to me, is not the most effective strategy to reach full coverage for every American since so many of our Americans currently rely on employer-based coverage.

Senator MCCAIN. A lot of people view some of the proposals by the Administration as a Government-run health plan that would be made available to all Americans. Do you support the creation of a Government-run health insurance plan?

Governor SEBELIUS. I don't support the notion that the Government would run the health insurance plan, and I think, again, back to your earlier question, starting with the platform that we have, where the vast majority of Americans with insurance have employer-based insurance, a number of people are involved in public insurance. And then the question becomes how to close that gap? How to deal with the 15 percent of Americans who don't have coverage?

And I see that as a public-private——

Senator MCCAIN. So you do not support a creation of a Government-run health insurance plan?

Governor SEBELIUS. Senator, I——

Senator MCCAIN. These are pretty straightforward questions, Governor, I would think.

Governor SEBELIUS. Well, if you are talking about insuring all 15 million Americans in some Government-run plan, no. I am talk——

Senator MCCAIN. No, I am not asking that. I am not asking that. I am asking you——

Governor SEBELIUS. Maybe I don't understand you.

Senator MCCAIN [continuing]. If you would support the creation of a Government-run health insurance plan?

Governor SEBELIUS. If the question is do I support a public option side by side with private insurers in a health insurance exchange, yes, I do.

Senator MCCAIN. Thank you.

I thank you very much, Mr. Chairman.

The CHAIRMAN. Senator Murray.

STATEMENT OF SENATOR MURRAY

Senator MURRAY. Mr. Chairman, let me say it is great to have you back and in charge of us. Enjoy seeing you here today. Thank you.

Governor, it is wonderful to see you here today. Thank you so much for being willing to take on this tremendously important job

at this time in our Nation's history when we are facing a terrific economic crisis. And the issues that fall under your jurisdiction, should you be confirmed, are essential to our economic recovery and very complex. So thank you very much for your willingness to do this.

Healthcare obviously is the issue that everyone knows needs to be addressed. And one of the parts of healthcare reform that I am sincerely worried about is the shortage of healthcare providers we have today. As our baby boomers are retiring—many of them in the health professions, leaving it—and then becoming part of the generation that requires the most healthcare workers, we have a real lack of healthcare workers today.

I have held a number of roundtables around my State on healthcare, and every single one of them talk about the fact that we don't have enough doctors, nurses, and healthcare providers. So I wanted to ask you today about how we can find and train and recruit workers into the healthcare field, even beginning back in middle school and high school years?

Governor SEBELIUS. Well, I appreciate that question, Senator Murray, and I appreciate your leadership in this area because it is absolutely critical. I think that the Congress made a major step forward with the Recovery Act, providing additional resources for the pipeline of health workers, expanding the HealthCorps, looking at ways we can make sure that there are more providers, particularly in our most underserved areas.

But the challenge of getting more of our young people involved in math and science at an earlier age and making sure that medical professions and other scientifically based professions are attractive to our youngest students is, I think, an additional challenge we have across America that we haven't—we have sort of lost that focus in our earliest learning and in our schools.

I can tell you, as a Governor, it is a challenge that my colleagues and I took on as an initiative a couple of years ago, working with not only school systems, but providers across the country to reinvigorate science and math curriculum to make sure that those pathways were open. Because you are absolutely right—if you don't decide until you are in high school or sometimes in college, you then have a lot of makeup work to do. We need that pathway to be built.

Senator MURRAY. I think it is a part of healthcare reform that we can't—as we do healthcare reform—we can't lose sight of. If there aren't enough doctors or nurses, the cost of healthcare goes up, particularly in our more rural communities. So I believe it has to be part of healthcare reform.

Governor SEBELIUS. Well, I also think part of the challenge and part of the solution may be to change the payment incentives. I mean, right now, it is not only how many health providers we have, but how few providers there are in family practice and in family medicine and in preventive medicine, as opposed to specialty areas.

I think it is both the numbers overall, but it is also refocusing, hopefully, the payment incentive so that primary care becomes a much more lucrative profession. It is rewarded as the front end of the system. It strikes me as that is where we need a lot of the focus. If we intervene earlier, if people have a health home, if we

focus on prevention and wellness, we won't need as many specialists at the end of the day.

Senator MURRAY. I hear about primary care, a lack of primary care physicians everywhere I go. So I appreciate that.

Let me ask you about, speaking of payments, Medicare payments to physicians. That is modified annually using a formula known as the sustainable growth rate, SGR. That is the system of reimbursement that is based on a very outdated scale that came about from looking at cost-of-living and healthcare costs and patient utilization.

That formula is a real detriment in many of our States, including mine, because over time we are being reimbursed because we have less utilization. We focus on healthy outcomes rather than how many times you go to the doctor. And over time, our State reimbursement for Medicare is much lower than some other States that focus on higher utilization.

We have doctors now who are not seeing Medicare patients all across our State. I know other States are seeing that as well. And I would like to find out from you how you think we ought to address the current SGR formula so that it can more actively reflect better healthcare outcomes?

Governor SEBELIUS. Well, Senator, I appreciate that question. It won't come as a big surprise to you that I have heard about this issue every place I have gone. And certainly in conversations with providers, it is a huge looming cliff.

The SGR cut that is proposed to be enacted next year would reduce provider rates by over 20 percent, clearly unacceptable. Let me just say if I am confirmed as Secretary, that will be a top priority to work with those of you in Congress to address a long-term solution.

I do believe as part of health reform, Medicare can lead as by example. And part of the leadership will require a reconfiguration of the overall payment system. SGR is part of it, but only a piece of it, as how we redirect those payments to reward appropriate care, great outcomes, preventive care, as opposed to what we are doing now, which, as you suggest, is more about patient contact than patient outcome.

I think we have a huge opportunity with the Medicare system to not only redesign and address the SGR itself, but to also redesign a whole payment system that redirects care to our senior population and the disabled population relying on Medicare services in a much more cost-effective and patient-effective manner. Better health outcomes and lower costs.

Senator MURRAY. OK. Thank you very much. My time is up.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Coburn.

STATEMENT OF SENATOR COBURN

Senator COBURN. Mr. Chairman, welcome back. It is good to see you.

Governor, thank you for being here. Congratulations on your nomination.

I want to clarify something you said earlier, and this is your quote. "We cannot fix this economy without fixing the healthcare

system.” Are you implying that we can’t recover from this recession unless we do major reform to the healthcare system?

Governor SEBELIUS. Senator, I think it is so intimately tied to a lot of our economic challenges that I think reforming the healthcare system puts us on a pathway to a sustainable long-term, prosperous economy.

Senator COBURN. But you are not saying that if we didn’t do it, we wouldn’t recover from this recession?

Governor SEBELIUS. I am very hopeful that we are on a recovery mode from this recession. But as I listen to business executives, as I listen to health providers, as I listen to the families across Kansas and across America, the current rate of growth of healthcare costs is unsustainable. And I do think it is a component of fixing the overall economic future for this country.

Senator COBURN. First of all, let me clarify, Senator McCain was not proposing eliminating employer-based health insurance. I hope you understood that. That was not the intent of his question.

The second point, I want to identify with Senator Mikulski. Health IT is important, but it is only important if we have interoperability. Do you have plans to disband the 501(c)(3) that is set up to do the certification now that Secretary Leavitt set up, the private board that is doing that certification and moving us toward interoperability?

Governor SEBELIUS. Senator, I have to confess I am not familiar with the 501(c)(3). I know there is a——

Senator COBURN. Well, it is set up now as a public-private corporation that is actually making the decisions about interoperable standards, and they have moved this from the 20 percent we had to about 60 percent, and a goal that in 2012 we will have 100 percent interoperable standards.

Is it your intention to let that continue to run, or are you going to interrupt that and do something different?

Governor SEBELIUS. Senator, as you know, I am not confirmed as Secretary yet. I plan to take health IT as an important challenge and a preliminary challenge. Dr. David Blumenthal has just been named——

Senator COBURN. Well, let me ask you, just to answer that, if you will go back and look at that?

Governor SEBELIUS. I would be very happy to do that.

Senator COBURN. And I plan on submitting several questions for the record. I would like to come back for a second round. I have a meeting here in just a minute.

Would you agree that our biggest problem for access is cost?

Governor SEBELIUS. Yes.

Senator COBURN. All right. So if cost is the biggest problem to access, why are we wanting to raise \$1.3 trillion or another \$130 billion a year for Government funding for increased access when we really should be working on decreasing the cost rather than increasing the expenditures? The Obama plan takes us from 17 percent of our GDP to 19 percent based on the money that they are “reserving” in the Obama budget for that.

If the biggest problem is cost, why aren’t we working on cost rather than increasing the amount of expenditures?

Governor SEBELIUS. Well, Senator, first of all, I am not sure of the figure. I know that President Obama's budget lays out a \$634 billion reserve fund that is entirely paid for, and he has suggested that that is not sufficient. So that is the number I am more familiar with.

I do think that, like a lot of the experts feel, that we may have a short-term bell curve in spending increase before we can incur the long-term savings, cost savings that will come with a total shift in our healthcare system. I am one who believes that there is enormous cost benefit in fully enacted health IT. But we won't see that before we have that in place.

Senator COBURN. We won't see that until 2015 at the earliest.

Governor SEBELIUS. Well, you may—

Senator COBURN. Let me move on to another question. Comparative effectiveness was in the stimulus package. We spent \$780 million last year through NIH and AHRQ for vigorous comparative effectiveness research—long-term, controlled, double-blinded perspective studies. And they have had a marginal impact on practice.

Not because doctors aren't willing to follow it, it is because there wasn't a clear decision made out of those long-term studies. What makes you think that on very short-term studies that we can come and have answers that are going to be better than the long-term studies that we are funding now that we can all of a sudden decide which way to go?

Governor SEBELIUS. Well, Doctor, you are a healthcare provider. So you are familiar with best practices and keeping up to date on what the strategies are that are the most effective and also, as we talked about, knowing about the training and individualized oversight that providers have with their patients.

I think having the best possible research, comparative research on alternative interventions to inform not only healthcare providers across the country about what works and what is the most effective strategy, but health consumers. We are talking about informing consumers and having individuals learn more about their health outcomes and take more responsibility.

And it seems to me that having the research available, having the research in a transparent fashion, and having the research developed across the country is a very important piece of making sure we are getting the best possible outcomes for the people of America.

Senator COBURN. Thank you, Mr. Chairman.

I would like to follow up in the second round, if I may?

The CHAIRMAN. Senator Dodd.

STATEMENT OF SENATOR DODD

Senator DODD. Well, thank you, Mr. Chairman. Let me join my colleagues and welcome you to the committee once again. We missed you terribly and it is great to have you back here with us, leading us again.

And congratulations, Governor. We have had a chance to talk, and you are in the best possible company with Bob Dole.

So, Bob, welcome back to the committee once again and for your leadership and your service here.

I would like to raise, if I can—first of all, I think we are very fortunate, indeed, that you are willing to do this, Governor. And

your experience as insurance commissioner, Governor, State representative brings a wealth of experience to this job, and obviously, your knowledge of the issues is tremendously important. So we look forward to working with you.

And Mr. Chairman, I would ask consent to have a full statement of mine included in the record, if I could, regarding the nominee?

The CHAIRMAN. It will be included.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

Thank you Chairman Kennedy. I want to welcome and congratulate Governor Sebelius on her nomination to be Secretary of the Department of Health and Human Services (HHS).

Having served on this committee for 26 years, I can't recall another time when the challenges facing the Secretary of HHS were so complex. Our economy is in the worst shape it has been for decades and we have a health care system that is broken—impacting our families, our businesses and our competitiveness as a nation. The Department of HHS and health agencies are in desperate need of attention and leadership. It is critical to restore the Department to one whose decisions are based on the best available science, not the political ideology of the moment.

President Obama has already made tremendous progress here with the signing of an Executive order overturning President Bush's harmful restrictions on embryonic stem cell research and the signing of a Presidential Memorandum on scientific integrity. And, he has moved quickly to appoint highly qualified candidates such as you to key positions within the Department such as FDA Commissioner and HRSA Administrator.

Governor Sebelius, you bring a wealth of experience working in a bipartisan fashion to improve the lives of families. The knowledge and expertise you gained as Governor, Insurance Commissioner, and State Representative will be instrumental in achieving comprehensive health care reform—reform that at long last makes health care accessible and affordable for all Americans.

The case for reform of our health care system has never been stronger. Over the last few months I've been holding a listening tour on health care around Connecticut. More than 1,500 people from all walks of life across the State have shown up at these events and have told me about the challenges they face to accessing necessary, quality, affordable healthcare. And although there are some disagreements about solutions, they have all told me we must reform the health care system. It is my hope that you will join me for one of these events in Connecticut.

It is often said that Americans have the best health care in the world and for many Americans that may be true. But how effective can that system be if rising costs to families make it unaffordable and inaccessible to millions of Americans? In my State, health care premiums have shot up 42 percent in the last 8 years—in the last 2 years, nearly 1 in 10 of our people have had no health insurance at all.

And how can we have a world-class health care system if high-quality care and value are inadequate in many parts of the country despite \$2 trillion in annual health care spending?

At the same time, our health care system is failing millions of our Nation's children and adolescents. The United States is a leader among industrialized nations in infant mortality, affecting African-American babies at more than two times the rate as non-Hispanic white babies. That is unacceptable.

Our system is creating a generation of children who may well be the first generation of American children who will live shorter, less healthy lives than their parents. That, too, is unacceptable.

This is happening, in part, because our system is driven not by the prevention of illness and disability but the treatment of illness and disability. It's completely backwards—and it has to change. And with your leadership and the work of this committee, I believe it can and will change.

Since the beginning of this Congress, and even before, the members of this committee have been preparing to work with our colleagues and the President to reform our health care system. The President made clear in his address to Congress and in his budget that reform must happen this year. Chairman Kennedy and Finance Committee Chairman Baucus are working to get this done this summer—and I am proud to support them in that endeavor. Bipartisan discussions, though at an early stage, are underway. This week the Senate will debate a budget resolution that allows for this committee and the Finance Committee to report out health reform legislation. And I know that you, Governor Sebelius, will be a tremendous partner for us in this effort.

While health care reform is a top priority for me and for this entire committee, I also want to address another vitally important issue and a responsibility of the Department—early childhood education and development. This is an issue that has long been near and dear to my heart. I am encouraged by the commitment President Obama has made to early childhood education, and I look forward to working on new proposals as well as strengthening current programs like Head Start and CCDBG to benefit our children and their families. An investment in our youngest Americans pays off in their readiness for school, their health, job creation now and in the future, and the need for fewer social services later in a child's life.

Governor, given the challenges facing this huge—oftentimes disparate—Department, it is my hope that your team will be in place as quickly as possible. As I mentioned, I am pleased that the President has nominated a Commissioner and Deputy Commissioner for the Food and Drug Administration, as well as a new administrator for the Health Resources and Services Administration. I also want to encourage the swift selection of leaders at the National Institutes of Health and Centers for Disease Control and Prevention. And I look forward to working with Chairman Kennedy to help move these nominations as expeditiously as we can.

I believe you will make an outstanding HHS Secretary, Governor Sebelius, and have no doubt that you will serve our country and President Obama well in this role as you have in every other position you have held. And I look forward to working with you, Chairman Kennedy, and my colleagues on the committee to bring meaningful, lasting change to our Nation's health care system in the months and years to come.

Senator DODD. Let me just focus, if I can, on children. Obviously, the matters that we have dealt with here recently, with the CHIP reauthorization, have been tremendously helpful. Although even with that, there will be a number, a significant number of children who are still left out of the healthcare system.

I am looking at a report this morning that you may have seen, may not have seen. This is a study on late pre-term births, a cause for concern. Senator Lamar Alexander and I wrote premature birth legislation in the previous Congress to try and put some resources into this general area. And obviously, these studies here, average expenditures for premature low-birth weight infants were more than 10 times higher than uncomplicated newborns.

This study talks about babies born just a few weeks prematurely are more likely to have developmental and behavioral problems later on as well as health issues than those who arrive closer to full term. The study was released on Monday from very respected sources on this subject matter.

There has been this notion for years, of course, that children are just small versions of adults, and therefore, what most of us grew up with at a time when there were limited pharmaceutical products and so forth, for children, it was just dividing aspirins in half and quarters and so forth. And we have learned over the years, as a result of legislation here under the leadership of Senator Kennedy and others, that we need to deal—the physiology of children is very different than adults, and we need to deal with them accordingly.

I just wonder if you might take some time and talk a little bit about this. I think it is a tremendously important area. I note that I think the deputy now of FDA is going to be a person with a strong background in pediatrics. And, in particular, he understands the needs of children and including providing benefits for maternal care.

In light of these studies with premature births, it seems it ought to be an important part of healthcare formulation, and I wonder if you might address that issue.

Governor SEBELIUS. Certainly, Senator. First of all, I think there is no question you have been one of the Nation's leaders on children's issues, on family issues, on making sure that whether it is childcare or the Family Medical Leave Act or a whole variety of areas, we keep children as the No. 1 focus. And once again, you have identified a critical cost-effectiveness strategy.

If we provide and if we identify women early on in their pregnancies and they have adequate and routine prenatal care, the likelihood of delivering a full-term baby at adequate birth weight is significantly different than if a woman has no prenatal care and shows up in the delivery room for a first or second visit. That not only is a huge cost issue but, as you have identified, is a huge quality of life issue.

Children born prematurely have all kinds of struggles, health struggles, mental health struggles, long-term health issues, not to mention just the cost of ICU care, which often is borne by Medicaid budget. So I think that the President understands this challenge very well. Not only, as you suggest, has he nominated a deputy at FDA who is a pediatrician and comes from that background and

those sensitivities, but also in his 2010 budget outline, blueprint, there is a proposal for a nurse visiting program.

A visit early on in a pregnant mother's care, identifying at-risk moms, trying to follow up on them on a regular basis, getting the kind of care and assistance needed along the way. There is study after study which indicates those are very successful programs. Successful in terms of health outcomes and very successful in terms of cost reduction. So I think the President has identified one pathway.

We in Kansas have had a Healthy Start-Healthy Kansas strategy that not only helps to follow moms but has the visitation at the stage when the mother leaves the hospital. First-time at-risk mothers, again, we know have challenges and issues that need to be dealt with. So having healthcare wrapped around that very important time I think is very effective for the children, very effective for the mothers.

Senator DODD. Well, I thank you for that.

This study pointed out there is a 40 percent cost savings for every week that a delivery is delayed in getting close to the due date, 40 percent per week, which is a remarkable savings. Senator Coburn talked about cost savings. That if you can really deal with a premature birth issue in an effective way, it is not only obviously in terms of developmental issues for that child and the pressures on that family, but for those who are only impressed about the cost issues, this is certainly a way to make a difference.

I would be remiss—

Governor SEBELIUS. And as you know, Senator, overall health reform helps that because if we have access early on, if Americans have health homes, have a doctor who they are seeing on a regular basis, the likelihood of having good prenatal care throughout a pregnancy is significantly higher than the situation we have right now.

So health reform really goes to the heart of that issue to make sure that all pregnant mothers would have access to high-quality care.

Senator DODD. And the obesity issues, cessation of smoking issues, all of these other matters that do contribute to premature birth and low-birth weight babies obviously have a huge impact as well in all of that.

One statistic that always just bothers me more than almost any other one we talk about when we are talking about healthcare, and that is that the United States has the highest infant mortality rate of any industrialized country in the world. That ought to be just a source of collective shame.

I mean, the fact that this country with all of its assets has that statistical record is something we have got to come to terms with, and with all—well, anyway, the statistic speaks for itself.

I just wanted to mention as well, you mentioned childcare and the Childcare Development Block Grant. That only happened about 20-some odd years ago because the fellow sitting next to me and the fellow sitting next to you in the majority leader's office that day decided to work it out so we could start the Childcare Development Block Grant.

And Senator Ted Kennedy and Senator Bob Dole made all the difference in the world 25 years ago on that issue. So since you brought it up, and I was the author of the bill, but it never would have happened had it not been for these two gentlemen. So thanks.

The CHAIRMAN. Well, I think all of us know that Senator Dodd was the leader on that issue, and we all are grateful to him as well for the other many healthcare issues. So we thank you. Thanks very much.

Senator DODD. Thank you, Senator.

The CHAIRMAN. Senator Murkowski.

STATEMENT OF SENATOR MURKOWSKI

Senator MURKOWSKI. Thank you, Mr. Chairman. It is nice to see you up on the dais here this morning.

And welcome, Governor. I appreciate your willingness to step into this position. It is incredibly important, as we all have mentioned.

I want to talk a little bit about access this morning. You and I had an opportunity to chat about this when you visited with me. I had a conference call last week and brought in about a dozen primary care doctors, some mid-level providers, and was asking them about the issue of access for Medicare beneficiaries. I asked them to give me a couple of legislative fixes that they would suggest.

Almost unanimously what these providers said that they had been hearing from their Medicare patients is that they simply wish that they could opt-out of Medicare and into private insurance. After that conference call, I had a tele-town hall meeting, with about 4,000 Alaskans that were speaking on the issue of access to Medicare and I heard the same refrain, which I find absolutely stunning.

You pay into the system your whole working life, and they are now at the point, as retirees, where they are saying I am prepared to reject a program, forgo the benefits, just so that I can have access to a medical care provider.

In Anchorage, our largest city, we have a situation where we have providers that are no longer accepting Medicare-eligible individuals. One in ten is not taking any new Medicare-eligible patients. So we have a situation where we are talking about all the great things that we are going to be doing here in Congress on healthcare reform, but I don't have providers that are willing to take any new or existing Medicare-eligible individuals.

This is a huge issue for us, and it is not just in Alaska. It is not just in rural America. When Senator Daschle was doing his healthcare tour, he heard the same things when he was in Dublin, IN, last December. The MedPAC, the Medicare Payment Advisory Committee, estimates that 17 percent of all seniors nationwide had significant problems accessing primary care healthcare services.

So I guess my question to you this morning is this: We clearly have very serious problems when it comes to the reimbursement issues that we have discussed, access, making sure that you have providers that will accept those that are Medicare eligible. How do we strengthen this Medicare program so that when you have that Medicare card it also means that you have access to care?

Because right now, in the largest city in my State, having that Medicare card means nothing because patients can't get into a primary care provider. And right now, they can't. So what do we do?

Governor SEBELIUS. Well, Senator, I appreciate your concern, and it is a huge concern and one that I share. Clearly, having a card does you little good if you can't see a doctor and can't get the care that has been promised to you by that card. So the issues of access in your State, in parts of rural America, in areas of the country where access is a problem need to be addressed, and I can assure you, if confirmed, I would love to work with you on that.

It is my understanding that in Alaska there has been a fairly recent payment adjustment, and I am hopeful that you may see some relief in the access issue based on that. But I think addressing, as we move forward, what are the various reasons that providers are not opting to take Medicare patients—if it isn't a payment situation, what are the other additional factors—is something that I just can commit that I would be eager to work with you to try and resolve.

Senator MURKOWSKI. So much of it is the payment side. It is the reimbursement side, and we hear that time and time again.

And yes, you are correct. We were able to get an increase in reimbursement effective the first of the year. What we are seeing, interestingly enough, is physicians are not taking on new Medicare-eligible individuals. What they are doing is as their existing patients are aging into Medicare, they are keeping them on.

What we were seeing last year was folks who had gone to the same provider for 10 or 15 years, are fine so long as they don't hit that magic age of 65. But when that birthday rolls around, their doctor tells them, "I am sorry. I am not able to see you." We think that we may have stemmed that. That, in fact, they are willing to keep their existing patients on.

But we are not able to add anyone new, which is a very, very serious problem. And unfortunately, we are not seeing it really get better. So we need to be working with you on this. We need to be addressing the increased healthcare cost that we face in a rural State like Alaska and addressing reimbursement that is a reasonable reimbursement rate.

I would extend the offer to you to come up and see some of the challenges that we face, as well as some of the remarkable achievements that we have made in delivering healthcare through telemedicine and just being smart with what we do with limited healthcare dollars. But we do need some help, and we will look forward to the opportunity to be working with you.

Thank you.

The CHAIRMAN. Just a point. I want to say about Senator Murkowski, it isn't just the States like Alaska. This is a problem that is all over the country. And we have about 8 to 10 individual openings for qualified people for nursing and for other professionals in this area, and there is a critical national need, and I am glad you mentioned this. It is incredibly important to Alaska and to other States. Thank you for bringing this up.

Senator Reed.

STATEMENT OF SENATOR REED

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

Welcome, Governor, and I look forward to you assuming these responsibilities. Your judgment, your experience, both as an insurance commissioner and a Governor, really puts you extraordinarily prepared to lead on the most important issue we face within the country, which is healthcare reform and other issues you will address.

The cost of not reforming our healthcare system is demonstrated in many ways. One way is the increasing burden that hospitals are bearing because of uncompensated care. In my State, it is estimated a 40 percent increase since 2005 in just uncompensated care—free care, essentially—by hospitals. They can't sustain this.

If we don't respond, we are going to have a situation where our hospital community begins to implode. So I wonder if you have any ideas along the lines specifically with respect to hospitals in terms of healthcare reform?

Governor SEBELIUS. Well, Senator, I think you are absolutely right that the hospital system is being crunched. Not only the people who are coming through the doors of emergency rooms accessing care that often is uncompensated, we have people in trauma centers who end up for lengthy and very extensive periods of time that are uncompensated.

We have, as Senator Dodd just talked about a little bit, in I would say ICUs across this country, babies who are born at precariously low-birth weights who now, through the miracles of modern medicine, are able to live. But often the cost of those lengthy stays in the hospital is, if not uncompensated, undercompensated.

The hospital is often in a situation where they are really struggling to survive. And what I know in a State like Kansas, and I am sure it is true in every State in the country, if you close the hospital, you close the town. People will not choose to live in an area where they can't have access to healthcare.

So, clearly, providing a payment system, a reasonable payment system for everybody who accesses hospital care will greatly reduce not only the burdens that currently are on those who have private insurance. It is estimated about 16 cents of every dollar of private insurance coverage pays for uncompensated coverage. So those with insurance are currently bearing an additional cost.

But also reduce dramatically that strain on hospitals who deliver critical care to the insured and the uninsured. I mean, the notion that a hospital would close because of uninsured care, therefore jeopardizing long-term coverage for those who are insured is the worst of all worlds. And I think that is the situation we find ourselves in.

Senator REED. Let me ask you a related question. As we expand healthcare, as we reform healthcare, we need the healthcare professionals to do that. This raises two issues, Title VII, which is the Health Professions Act, which we have worked under the leadership of Chairman Kennedy to strengthen and to expand.

Also just generally graduate medical education, a new model so that we have practitioners who are generalists rather than, in

some cases, the overabundance of specialists. Your thoughts on those two topics?

Governor SEBELIUS. Well, Senator, you have pretty well articulated the situation—not only the need for the pipeline of health professionals to deliver care, but a shift in the training and the expertise of those professionals so that we essentially grow the market of primary care, of family docs, of folks who are going to be on the front end of prevention and wellness and early intervention.

That is in part a payment system. It is in part addressing some of the situation that is in the current Medicaid proposals that are pending dealing with a change in the payment for graduate medical education. There is a step in the recovery bill addressing the workforce issues. One of the things that we found in our State, and I am sure is true across the country, is that we are not only talking about doctors, but in many cases, talking about nurses.

The nurse profession is often delivering primary care and is on the front lines. We can't train more nurses unless we have more nurse faculty. So it really is a multi-pronged approach, a comprehensive approach, but one that, if confirmed, I can assure you is one that I have worked on as Governor and one that I would certainly continue to work on as Secretary.

Senator REED. Thank you very much, Governor. Thank you.

The CHAIRMAN. Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Mr. Chairman.

Governor, welcome.

And Senator Dole, before he leaves, Senator, good to have you here as always, and we are delighted you would come and spend your time to introduce the Governor.

Senator DOLE. I want to congratulate you on your being man of the year—

Senator BURR. Thank you.

Governor, I think I heard in your answer to Senator Reed, and I just wanted to re-cover it, that the disparity in reimbursements causes the low number of primary care docs and people to choose other specialties. I think until we are willing to address reimbursements and actually reimburse primary care in a sufficient way, you will continue to have med students that when they get through with their visit to the bank, as they begin to borrow money for medical school, decide that a specialty gets that student loan paid off faster.

And for a primary care physician, it looks more like an amortization for a home mortgage, and I hope we can work on that.

I have two very specific questions. The national average monthly premium for basic 2009 Medicare drug benefit is targeted to be \$28. That is 40 percent below what we projected for Part D in 2003, when we created it. Given that the program has held down cost to beneficiaries, do you think that this competitive model should be considered in the context of the overall healthcare reform that we are going through?

Governor SEBELIUS. The way that Part D is constructed, Senator?

Senator BURR. Correct.

Governor SEBELIUS. First of all, I don't think there is any question that having a prescription benefit for seniors was long overdue and hugely important to the medical care of seniors across this country as we have shifted in the health system from longer hospital stays, which used to be the norm 10 years ago, to often preventive drug applications. Not having that health benefit was extraordinarily difficult for many seniors in this country.

I think there are some issues about Part D, which, if confirmed, I would look forward to working to help resolve. Not the least of which is the design construct of the program, the so-called donut hole, which often is very difficult for seniors who have budgeted certain amounts and, as you say, have now relatively low premiums at the front end only to hit a situation where they have no coverage for a period of time in a drug use.

Senator BURR. Under our own design, we knew there were flaws—

Governor SEBELIUS. Yes.

Senator BURR [continuing]. To the overall product. What we didn't anticipate was that the level of competition you put in Part D by design would drive down the premium of the basic Part D. And I would just encourage you that I think on both sides of the aisle we were shocked at this. We continue to be shocked at it, and the element of competition has to be an important driver in the context of overall healthcare reform.

Last question. Ryan White Care Act is up for reauthorization this year. Do you believe that it is important that Ryan White money follow HIV-infected individuals?

Governor SEBELIUS. Well, Senator, I don't think there is any question that that money is essential, and it is important as the reauthorization discussion goes on. And again, if confirmed, I look forward to having an opportunity to look at the comprehensive strategy that we address to patients in various parts of the country and make sure that they have access to assistance.

I think there are some alarming data. I saw recently that in Washington, DC, they are now projecting that the HIV rate is over 3 percent, which is regarded as an epidemic level. So I think we have some real challenges, whether it is parts of the country that have a smaller number of patients that don't have as much access to help and support or areas where we have a huge epidemic.

The reauthorization, Senator, I think gives us an opportunity to look comprehensively at the best strategy moving forward.

Senator BURR. I hope you will do that with us because there are areas of the country that Ryan White Care Act funding does not find HIV patients, and I think that was really the nucleus of why we created this, which was to make sure that the funding was there to provide the services.

I certainly look forward to your time as Secretary and urge the chair to move it as quickly as we can.

Thank the chair.

Governor SEBELIUS. Thank you.

The CHAIRMAN. Thank you very much.

Senator Sanders, we want to thank you. You have been here the whole hearing this morning. It doesn't surprise any of us that know

of your dedication and commitment to this committee. But in any event, thank you very, very much for your presence.

STATEMENT OF SENATOR SANDERS

Senator SANDERS. Thank you, Senator. And welcome back.

And Governor, we look forward to your speedy confirmation.

Let me make a brief statement and then ask you a few questions because I think it is important to raise the issue of the role of private insurance companies in our healthcare system. I, just last week, introduced a single-payer national healthcare program to be administered at the State level because I happen to believe that the function of private health insurance is not to provide quality, cost-effective healthcare to individuals, but to make as much money as they possibly can in a number of very questionable ways.

I think that at a time when approximately 30 percent of every healthcare dollar spent through a private insurance company ends up in administration, profiteering, advertising, or whatever, that so long as we remain dependent on private insurance companies, we are never going to have quality, cost-effective healthcare for all Americans.

I suspect that position is a minority position here. But let me ask you a question about an issue that a number of people on both sides of the aisle have raised, and that is the issue of primary healthcare. I know you wrote in your statement of your concern about the lack of physicians, the lack of nurses, the fact that it is true some 16 million Americans today do not have a doctor of their own. They end up in the emergency room. They end up in hospitals at a far greater cost.

When Barack Obama was a Senator, he supported a very substantial increase in the number of community health centers in America so that, in fact, we would have a community health center in every underserved area in this country, supported a very significant increase in the National Health Service Corps. In fact, in the stimulus package, we doubled funding for community health centers, tripled funding for the National Health Service Corps.

Will you work with me and many members of this committee so that we continue the effort to expand the National Health Service Corps, help pay doctors' debts so we can get them out into primary care, and move forward on community health centers?

Governor SEBELIUS. Senator, absolutely, you have my commitment that, if confirmed, I would love to work with you on that initiative. First of all, I want to just thank you for your leadership. Community health centers have been a passion of yours and a mission of yours, and I think it is probably largely due to your tenacious efforts that that is included as a significant investment in the American Recovery Act.

Having said that, I see community health centers and the National Health Service Corps as a key building block in health reform. I think one of the challenges that we have is to make sure that the essential components of what is in place right now, whether it be the community health center program and the service corps, who provides essential primary care, or the expanded CHIP program or the services of Medicare and Medicaid, that they are operating as effectively and efficiently as possible for taxpayer dol-

lars, but also getting the best health outcomes possible as we look at the challenge of sort of closing the gap.

So, as Secretary, I would absolutely love to work with you on making sure that these are effective, efficient, and expanded.

Senator SANDERS. Thank you. As I am sure you are aware, our chairman was the founder of that very extraordinary program.

One of the problems we are having, as we expand community health centers, is this whole issue of how you designate an underserved area. And it is not the best—we need some work on that, and I would look forward to working with you to clarify what constitutes an undesignated area because sometimes you have real desperate need, but for bureaucratic reasons, they are not designated. So there is work to be done there.

Let me ask you a question about prescription drugs. As you may know, we pay the highest prices in the world for prescription drugs. Many of our people simply can't afford them. Canada, Europe charges substantially less for the same drugs that we purchase here.

Are you supportive, will you work with us on the concept of reimportation of prescription drugs?

Governor SEBELIUS. Senator, I am aware that Congress has designated that the Secretary can, if the system is found to be safe and secure, designate that reimportation from Canada is acceptable.

I would suggest, at least at this point, that restoring the FDA's competence and capabilities to its previously held gold standard is really step one, that having—we have recently had a situation with Heparin coming out of China. We have had melamine, which, again, showed up in pet and animal food, not in prescriptions. But there is some evidence that the current challenges are not being well met.

But I certainly am one who thinks that we need to take a look at the reimportation, make sure that there are avenues, lots of avenues for Americans to access high-quality, lower cost prescription drugs, and I look forward to having that dialogue, if confirmed as Secretary.

Senator SANDERS. Mr. Chairman, thank you very much.

The CHAIRMAN. Thank you very much.

Senator Roberts, thank you.

Senator ROBERTS. Mr. Chairman, thank you. And thank you for your patience.

And Governor, thank you for your stamina. As Henry VIII said to one of his wives, I won't keep you long.

[Laughter.]

We have had a good conversation, I would say to my chairman and members of the committee who are still here and anyone in the audience still here interested in healthcare. And the Governor and I talked about something called comparative effectiveness research. I think Dr. Coburn has already asked you a question about that.

And your response was that CER, or comparative effectiveness research—everything has to be an acronym here—on best practices should produce the best possible research. But I think the whole point is that I do not believe it will be the best possible research.

That is done at FDA over years of time. Sometimes FDA comes under a lot of criticism because of that.

The possibility could very well be in the push to control cost and cost containment that has already been mentioned by Senators Murkowski, Coburn, Burr, and others and members on the other side of the aisle, it will be used to justify what I call rationing healthcare, i.e., cost containment.

You and I both know the situation in Kansas very well with 83 critical access hospitals, very similar to the testimony given or the great argument or rationale being expressed by Senator Murkowski and the problem in Alaska.

Senator Burr mentioned the donut hole in regards to Medicare Part D, and this is reflective of the problem because I can remember talking to the president of the Kansas Pharmacist Association in a very small town in Kansas, and the provider of Medicare Part D in many of our small communities, it isn't Medicare. You don't dial 1-800-MEDICARE. I mean, that is sort of useless, to tell you the truth.

Then you have the Centers for Medicare and Medicaid Services, or the renowned CMS—used to be HCFA—and I won't tell you what our providers call CMS. It wouldn't be appropriate. But all they are—they just sort of view them as the Lizzie Borden of HHS.

This pharmacist was the provider and about the only provider of Medicare Part D, and that is replicated in many small communities. In that donut hole, we have 20 insurance companies that will provide healthcare during the donut hole period. But it is a different kind of a thing, and it is expensive.

But in trying to address this to a patient who said, "I fell into the donut hole. What am I going to do?" And he said, "Well, for you, it should be this plan, and I could provide you that plan. But I can't because I am not being reimbursed at the cost. I only get 70 percent of the cost."

That is why I say that maybe I am a contrarian here a little bit. I am for healthcare reform. I don't know anybody that is not for healthcare reform. But I worry about what lurks under the banner of reform, and I want to see our current healthcare delivery system at least stabilized to the degree that we can at least continue what we have. And I don't see that with doctors, hospitals, pharmacists, home healthcare people, clinical labs, ambulance drivers. Over and over and over again, the cost containment factor comes into play.

And I understand that we have to control Medicare spending, but this is not the way to do it. And the thing that really worries me about the comparative effectiveness research, we just had in a hearing last week in the House where Director Raynard S. Kington of the National Institutes for Health testified his agency may use the money from the economic stimulus law to fund grants for comparative effectiveness research that includes comparison of the cost of the treatments involved. Not care, but costs.

If we give that golden ring to CMS, Governor, I will tell you that they will run with it, and we will continue to have problems in rationing healthcare all throughout our healthcare delivery system. Now I got on my CMS rant, and I told you that when we had our talk, I wouldn't do that. I have. But could you just give a couple

words of assurance to us—I know Senator Murkowski has really said this more effectively than I have.

I will repeat it again when we meet Thursday on the Finance Committee. But could you just give me some assurance that you know what the problem is at least currently with CMS and we can at least take steps to prevent that and not make comparative effectiveness research conclusionary research, and it has to include clinical research as well as cost?

Governor SEBELIUS. Well, Senator, first of all, let me tell you that I hope I don't have the same fate as one of Henry VIII's former wives.

[Laughter.]

I appreciate you asking that question, and we did have this discussion earlier. I think the fundamental difference is that the current statutory authorization prevents CMS, prevents Medicare from using comparative effectiveness research as a cost decision-maker. It is prohibited by law. The Congress made that a part of the statutory authorization.

So unless that law is changed——

Senator ROBERTS. Right.

Governor SEBELIUS [continuing]. And I can commit to you, if I am confirmed as Secretary, I will make sure that the CMS follows the law.

Senator ROBERTS. We have—pardon the interruption. But there are several words in the budget that actually says that CMS will have that authority.

Senator Baucus, others of us want to make sure that we put language in there, and there is language that is proposed that care will be considered just as much as cost containment. So I think it is coming.

Governor SEBELIUS. Well——

Senator ROBERTS. It is just how it comes.

Governor SEBELIUS. I can't tell you that I am not concerned about ultimately—not with comparative effectiveness research, but ultimately reaching a point where in order to control costs, there is some effort to ration healthcare.

I, frankly, as insurance commissioner where I served for 8 years, saw it on a regular basis by private insurers who often made decisions overruling suggestions that doctors would make for their patients that they weren't going to be covered. And a lot of what we did in the Office of the Kansas Insurance Department was go to bat on behalf of those patients to make sure that the benefits that they had actually paid for were, in fact, ones that were delivered.

I have some experience in fighting for the fact that providers should make medical decisions. That is one of the reasons that we have people who go to medical school and not come up through an administrative agency in the Government or through an insurance company or any other number of ways that healthcare can get rationed.

I have worked in that system. I believe in that system. I do, though, support the notion that we would do comprehensive research on what are effective strategies to get the best health outcomes for American people?

We know that protocol varies dramatically. Sometimes in one area of the country, certainly across the country, that very different protocols are used with very different results. And I think the more providers can have access to that information and certainly that consumers can have access to that information, the more likely we are to have the best possible health outcomes.

Senator ROBERTS. I am already over time, Mr. Chairman. Thank you.

I will ask my least costly alternative question in reference to this when we see each other at the Finance Committee. Thank you so much, Governor.

The CHAIRMAN. Senator Casey.

STATEMENT OF SENATOR CASEY

Senator CASEY. Mr. Chairman, thank you very much. It is great to see you here, and I want the chairman to know and I want the Governor to know that when I left earlier, I was juggling with Senator Harkin in the Agriculture Committee. And he allowed me to be the chairman of the hearing for about 32 minutes.

[Laughter.]

I couldn't pass up that opportunity. My wife will never believe it. So I want you to know that is why I was not here.

Governor, thank you very much, and I know the hour is late. I want to try to get into two areas, if possible. One is on early education and development, a topic and an area of public policy that you not only know a lot about, but you have been one of the leaders in the country on. You have brought a great deal of achievement to your work as Governor in Kansas on both of these, or I should say, the whole range of issues.

In terms of what we are going to do in the Federal budget, in terms of Federal policy, I wanted to ask you about maybe three examples of this. One would be childcare and the funding levels. Two would be Head Start, and the third one would be Early Head Start. You and I spoke of this when you were kind enough to come by our office to talk about your confirmation.

One of the problems here is obviously not just a funding challenge, but also the ability or the limitations we have in enrolling people that are eligible. Childcare, a huge number—as you know, a huge number of families are eligible but not enrolled. In Early Head Start, I think the number is something like 3 percent of those eligible in that important program are, in fact, enrolled.

Can you just talk to us about the priority of those kinds of programs and what we can do about funding levels in the near term especially?

Governor SEBELIUS. Well, Senator, it has been a passion of mine that we focus as many resources as possible at the earliest possible age of children because we know that the results pay off in terms of incredibly improved outcomes. I was a working mother and knew personally with our two boys that having high-quality childcare and then early education was a critical component of my being able to go to work, of my husband's being able to go work.

So I dealt with the situation as a parent. As 20-some years ago when I was elected to the legislature, it became one of the first focus areas because we had a pipeline of childcare providers, which,

frankly, were underpaid and undertrained. I looked at ways to expand that. Put together a children and families committee and put together a children's budget in Kansas. And have continued those efforts.

One of the challenges which you have just addressed, which I am very excited to have the opportunity to work on, is a coordinated strategy with the childcare providers at the table, with the leaders of Head Start and Early Head Start at the table, along with those early educators who are often under the umbrella of the Department of Education.

We did a similar strategy in Kansas. I think having a collaborative and coordinated strategy, recognizing that parents are going to make a lot of different choices for their children. But about 85 percent of the mothers with children under 5 are in the workforce. So most American children are in a care situation outside of their homes, and having programs particularly for the highest risk children, for the most at-need children, which are not only safe and secure but introduce early learning skills.

We know that brain development is most robust in the first 3 years. If we miss those 3 years, there will be some children who will never catch up. So the more focus and attention—I was very heartened to see that in the Recovery Act, there was a significant expenditure for Early Head Start, for Head Start, and for the childcare block grant, which is so critical to provide those services.

I think the next challenge is to make sure that we are using those strategies to rise to a level of quality, that we have some quality standards introduced, that we have more parent involvement. One of the, I think, best features of the Head Start program from the outset was the involvement of parents engaged in their own children's well being and their own children's education. That has been a real hallmark of the program.

But I think that an investment has been made, but we, as you wisely say, need to continue that because we know that by the time many children reach kindergarten, they are already so far behind that they will never catch up with their peers. That is not a good strategy for that individual child, but it is really not a good strategy for this country.

Senator CASEY. I know I am almost out of time. I will submit another question for the record. I have an early education bill that we spoke of and will look forward to working with you on that.

I will submit a question for the record—we are at the 30-second mark—on nurse home visitation. You and I spoke about that. You are well aware of that program. In Pennsylvania, we have about 40 counties that have that kind of a program where a nurse is able to work with—more than work with—is able to counsel and help a new mother so that that new mother can have all the benefits of that kind of expertise.

It is a great, great pathway to making sure that a young mother has a shot at having the kind of help that she needs in addition to help from her own family, and I look forward to talking to you more about that. But I will, in the interest of time, submit it for the record.

Governor, thank you very much.

Governor SEBELIUS. Look forward to it. Thank you.

The CHAIRMAN. Senator, I'll be glad to recognize you and thank you.

Senator COBURN. I thank you for the opportunity for a second round of questions.

Governor, there is a Medicaid directive that states RU-486 is subject to the Hyde Amendment restrictions. Is there any plans or can you give us assurance that that policy will be unchanged?

Governor SEBELIUS. I am sorry, Senator. I didn't hear the first part of your question.

Senator COBURN. There is a Medicaid directive on the books by the previous administrative as to regards with RU-486 coming under the Hyde Amendment. Can you give us an assurance that that won't be changed, or are there plans to change that?

Governor SEBELIUS. Senator, as far as I know, there are no plans. I certainly have had no discussions with anyone about changing that policy. But again, I am not confirmed as Secretary. I haven't had those discussions, and I promise to continue to keep you informed.

Senator COBURN. All right. Thank you.

One of the other concerns you and I talked about was the conscience protections, and the Administration has announced plans to revise those and change those. I guess the question that I would have is can you give us—and you may not be able to do that at this time—but will you give us forewarning on what those changes are going to be?

As a pro-life obstetrician, I feel I have a constitutional right to have those protections as I practice medicine, and the idea that the Administration may try or attempt to take away a constitutional right that I have by saying what I must and must not do as a practicing physician is rather offensive to me.

What I would like is the assurance that we will at least get a heads-up on what that is going to be prior to a unilateral announcement of that. Can you give us that assurance?

Governor SEBELIUS. Senator, if confirmed, I would be glad to not only give you that early warning of what the plans are, but I can tell you right now that the President supports and I support a clearly defined conscience clause for providers and institutions. He always has. I always have. It has been in place in Kansas the entire time I have been in elective office.

I know there was some concern about the regulation that was proposed or implemented at the very end of the previous Administration that it was overly broad and, frankly, overly vague. So I don't think, from the discussions that I have had, there is any intention of interfering with the underlying legal basis that you have just suggested. And I will certainly be glad to keep you informed.

Senator COBURN. Thank you.

I want to go back to cost for a minute. You oversee about \$800 billion worth of spending through Medicare and Medicaid and SCHIP. A conservative estimate right now is that we have upwards of \$80 billion a year in both fraudulent payments and improper payments in Medicare alone and \$40 billion worth of fraudulent payments and improper payments in Medicaid. That comes to 20 percent of the program.

I am amazed, and I think most Americans should be amazed, that we are not tackling this problem where there is \$60 billion to \$120 billion worth of waste and fraud, and instead we are figuring on a tax system to allocate for 5 years \$650 billion, \$1.3 trillion is what if you extrapolate it out in terms of end cost.

What do you plan to do to get at least the improper payment rate down to what the average of the rest of the Federal Government is, which is under about 3.4 percent? What are the plans? Because that is where the gold is. That is where the gold is, getting rid of the fraud and waste and improper payments in Medicare and Medicaid.

Governor SEBELIUS. Well, Senator, as we discussed in your office, I certainly think that significantly more aggressive effort to go after fraud and abuse is well deserved.

I shared with you in my experience as insurance commissioner, one of the things we did was put together a very aggressive fraud unit in collaboration with the attorney general's office. You have suggested a similar opportunity may exist with the Federal Government in conjunction with the attorney general's office.

But it is something I certainly take very seriously and think you are absolutely right. First of all, the providers and companies and patients who are fraudulently billing the taxpayers not only need to be found and penalized, but those dollars need to be shifted to provide health services to all Americans.

So you absolutely have my commitment. I look forward to getting some of your best ideas and seeing how fast we could put them in place. You talked a lot about having preemptive policies instead of what we are doing right now, which is after the fact audits, of 10 years down the road. And I could not agree more that having a few strike operations may be the most effective way to send a signal that there is a new sheriff in town, and I intend to take this very, very seriously.

Senator COBURN. If, in fact, we could recapture that money, you wouldn't need the reserve fund in the budget. You would have enough money for anything the President wants to do.

Governor SEBELIUS. Well, I think there is no question that I would be enthusiastic about that, and I can guarantee you the President would, too.

Senator COBURN. Of course, that is the problem the American people have with us. We don't fix the problems we have. We just create new programs that ignore those, and one of the things we have to do on healthcare is that.

Mr. Chairman, I thank you for your indulgence. I am sorry to drag on. I will have several questions for the record.

Governor, thank you for being here and being so attentive to my questions.

Governor SEBELIUS. Thank you.

The CHAIRMAN. I would just say I think Senator Coburn emphasized a very important point, and I would welcome the opportunity to work with him, and we could share that with our colleagues and try and see what we could work out on our committee and on our sister committee, on the Finance Committee. But we will focus on our committee on that.

I think this is extraordinarily important, and I think we have come in touch with this issue time and time again and have done far too little. And we welcome the opportunity to work with him.

Let me just thank all of those who are here, still have remained with us. I was especially interested in the work on the cancer efforts. We have three major efforts on the cancer prevention and research and treatment, and these are really the heart of the whole effort on this.

I don't know whether you have any kind of comments you would like to make about each of those areas. You could go on for a long period of time on each of those. But is there any one of these that you think that we ought to be giving any special attention to now?

As I said, I certainly could, on any one of these, go on for some period of time. And I don't know whether it is fair to say one aspect of it is more worthy than others, but maybe you could just comment about that concept and what, if anything, you think that we ought to be moving ahead with?

Governor SEBELIUS. Well, Senator, I don't think there is, Mr. Chairman, any question that cancer is an illness that has touched every American. You are currently experiencing a battle with the disease. But I don't think there is anybody who probably is in this room who doesn't have a loved one or someone close by who hasn't been involved in a similar situation.

I am not as familiar as I probably should be with the individual legislative initiatives. I do know that the President has a commitment to dramatically increase cancer research. He believes, as I do, that curing cancer in our lifetime is a reality that we could achieve with the proper focus as we look.

I have had some preliminary discussions with individuals within the department as they look for new heads of both the National Institutes of Health and the National Cancer Institute, certainly leadership on the research and technology end, but also on the service end.

I know, as Governor, we in Kansas have identified that having a National Cancer Institute designation in conjunction with the university, given the fact that there are not centers in proximate areas, so our citizens can have access to cutting-edge treatments is a priority I think not only in Kansas, but across the country.

So I look forward, if confirmed, to working with you on this critical issue.

The CHAIRMAN. Well, thank you very much.

You obviously have thought about this and are ready to act on it, and we certainly welcome that.

At today's hearing, we have had the opportunity to examine the challenges that our new Secretary will face, and they are certainly large challenges. But we also have seen that our nominee has the abilities, I believe, to be able to handle all these challenges.

So I strongly support Governor Sebelius as the Secretary, and I look forward to working with her very closely in the months and years ahead to make a difference on the health for all of the citizens of our country.

Thank you very much.

Governor SEBELIUS. Thank you, Senator. Thank you, Chairman. [Additional material follows.]

ADDITIONAL MATERIAL

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, HARKIN, MIKULSKI, MURRAY,
 REED, BROWN, CASEY, AND HAGAN BY KATHLEEN SEBELIUS

QUESTIONS OF SENATOR KENNEDY

Early Childhood Education

Question 1. Historically early learning at the Federal level has been exclusively under the jurisdiction of HHS. But at the State level, early learning is often focused on State preschool, which is frequently run by State education agencies. As Governor of Kansas you invested significantly to ensure that children have access to high quality early learning opportunities. As Secretary, how will HHS work with the Department of Education in developing and implementing the Administration's early childhood policies?

Answer 1. If confirmed as Secretary of HHS, I plan to work very closely with Secretary Duncan to strengthen early learning programs at HHS and Education. Secretary Duncan and I will also work closely to support and implement the President's Early Learning Challenge Grants proposal, to encourage States to raise the quality of their early learning programs, ensure a seamless delivery of services, and ensure that children are prepared for success when they reach kindergarten.

As a Governor, I learned that collaboration between child care, Head Start, preschool, and other early childhood programs at education agencies is essential to achieving the objectives we are seeking for young children and their families. With that in mind, I intend to do everything I can to improve collaboration at the Federal level on early childhood education programs.

Question 2. What role do you see Head Start and Early Head Start programs playing in President Obama's Early Learning Challenge Grants proposal and comprehensive Zero-to-Five plan?

Answer 2. I believe that Head Start and Early Head Start are critical elements of our Nation's early childhood education system. The American Recovery and Reinvestment Act provided a needed expansion of these essential programs, including an additional \$1 billion for Head Start and \$1.1 billion for Early Head Start. These investments will support, reinforce, and extend the impact of the Administration's exciting new Early Learning Challenge grants and the President's early education agenda. If confirmed as Secretary of HHS, I intend to work closely with Secretary Duncan to ensure effective coordination of early learning programs within both departments.

Head Start & Early Head Start

Question 3. What steps will you take to encourage States to fully leverage and promote the contribution that Head Start programs and services make to children's school readiness and family engagement in order to promote early childhood system building at a State level?

Answer 3. I believe it is critical to promote and continue collaborations between State governments and the Head Start programs, and, if confirmed, I look forward to working with our State partners and members of the Head Start community to build upon the successes that have already been achieved in many States. Among the critical areas on which collaboration should focus are school readiness and family and parent engagement.

Question 4. What are your plans to ensure that Head Start programs can accomplish the goals and the mandates included in the last Head Start reauthorization.

Answer 4. I applaud Congress for enacting a landmark reauthorization of the Head Start Act, and I am very excited about the prospect of working to implement key elements of this vital legislation. In particular, I am interested in leveraging all the assets and tools of HHS to find ways to improve results for children and families served by Head Start. If confirmed, I will carefully review the status of needed regulations and work to promulgate them as expeditiously as possible. Moreover, I intend to work with Head Start programs to meet the requirements and accountability measures set forth in the Improving Head Start for School Readiness Act.

Question 5. The Head Start Act requires States to create advisory councils to better plan and coordinate the delivery of education and health services to young children, including better connecting Head Start, child care, pre-k, and the K-12 systems. As Governor of Kansas, you signed legislation creating the Kansas Early Learning Coordinating Council to help achieve those goals. Greater Federal resources and leadership are needed to support this vital State work. What role do

you see the State Advisory Councils playing to improve the delivery of early childhood services, and how would your Department support and expand their work?

Answer 5. As you indicate, as Governor of Kansas, I established an Early Learning Council to coordinate funding streams and link programs serving young children and their families. I found this to be a very effective strategy, and I believe the State Advisory Councils established in the Head Start Act, and similar structures, are valuable tools that can help States find creative and effective mechanisms to coordinate and improve early childhood programs funded by multiple sources. If confirmed as Secretary of HHS, I would commit to supporting these State Councils in their planning, coordination, and implementation activities.

Child Care

Question 6. What are your plans to improve the quality and availability of child care?

Answer 6. As a working mother of two sons, I remember the challenge of balancing work and child care. Research and common sense tell us that high-quality early childhood education programs make a greater impact on children, get young children ready to learn and thrive in school, and provide powerful returns for our economy and our ability to compete in the 21st century.

As Governor of Kansas, I worked to create a statewide early-learning council to help coordinate and improve early childhood programs across our State. I am proud of what we did to make child care available to more working parents, but I take even greater pride in our comprehensive strategies to improve quality through investments in capable staff, challenging curricula, and effective programming.

If confirmed as Secretary, I look forward to building upon the tremendous investments already made, through the Recovery Act, in the Child Care and Development Block Grant (\$2 billion), Early Head Start (\$1.1 billion), and Head Start (\$1 billion).

Question 7. While early care and education must be a priority within the Administration on Children and Families (ACF), recent structural changes seem to have lowered the visibility and priority of child care within ACF. As Secretary, would you re-establish the Child Care Bureau as a separate entity and align it in stature with the Office of Head Start in ACF?

Answer 7. Promoting high-quality child care, and ensuring its availability to more children, is a top priority of this Administration. If confirmed as Secretary of HHS, I will carefully review HHS's organizational structure to ensure that it is designed to meet these goals and deliver results that support priorities of our children and families. Child care and early childhood programs are crucial priorities within HHS.

QUESTIONS OF SENATOR HARKIN

Question 1. Gov. Sebelius, as you will recall, the Dietary Supplement Health & Education Act of 1994 provides the FDA with the authority to oversee and regulate the supplement industry. In December 2006, Congress passed the "Dietary Supplement and Nonprescription Drug Consumer Protection Act" which the President signed into law and which required for the mandatory reporting of serious adverse event reporting for supplements.

Do you agree with me, and with past Secretaries of HHS and FDA Commissioners, that those laws are still adequate, not in need of amending, and give the FDA sufficient authority to regulate the industry and protect the public/consumers?

Answer 1. Millions of Americans rely upon dietary supplements to supplement their nutritional intake, believing such products can help bolster their immune systems, protect them from diseases, and slow down the aging process. I know that clinicians and advocates believe that these products should be studied to ensure they are effective and safe. When it comes to these products, the FDA has a responsibility—just as it does with food, drugs, and devices—to ensure that the marketing claims are truthful, and, more importantly, that Americans cannot be harmed. Yet, the FDA must strike an appropriate balance between regulating these products and maintaining access for consumers. If I am confirmed as Secretary and determine that additional authorities are needed, I will work with you to ensure that consumer access is not compromised.

Question 2. How will you revitalize the Office of Civil Rights at HHS? In particular, how will you ensure that the Office provides sufficient oversight over the HIPAA Privacy Rule, both in terms of enforcement of current rules (which was lax under the Bush administration) as well as ensuring that the regulations keep up with developments in health IT?

Answer 2. Ensuring the privacy and security of patients' personal health information is of paramount concern. Existing policy (the Health Insurance Portability and

Accountability Act, or HIPAA) provides a basic level of protection, but we need to do more. The privacy and security rules must be revised to keep up with ongoing developments in health information technology (HIT), and must take into account the constantly-evolving nature of HIT.

Besides being reviewed and updated, the privacy rules must be enforced. As you know, a recent HHS Office of the Inspector General report found that the Department has done little to ensure that entities covered by HIPAA use sufficient measures to stop privacy breaches before they occur. As Secretary, I will work to ensure that the Office of Civil Rights has the necessary leadership and resources to protect effectively the rights of individuals to preserve the confidentiality of their medical information.

Question 3. Much concern from consumers has been articulated about food safety and how the new Administration is going to improve the food safety system. Recent outbreaks of food-borne illness have had a negative impact on consumer confidence in our food supply. Several contamination events have harmed numerous people and animals and have led to a dangerous mistrust of FDA's ability to keep our food supply safe.

What lessons do you think HHS has learned from these incidents and what actions could be taken in the future to ensure a safer food supply?

Answer 3. Like all Americans, I have been shocked by the recent outbreaks caused by contaminated food—including spinach, tomatoes, and now peanut butter. It is staggering that problems at just one facility can contaminate hundreds of products, sicken thousands of consumers across the country, and even take the lives of our friends and neighbors. We must do better.

Among other things, we must shift our focus away from simply working to catch contamination of the food supply after it has already happened and towards preventing contamination from occurring in the first place. Doing so may require a new regulatory approach and new authorities, and it will certainly require a new shared responsibility with industry and State and local officials. If confirmed, I look forward to restoring trust in FDA as a world-class public health agency, and to working with Congress to ensure that the food we eat and the medicines we take are safe.

Question 4. President Obama has called for a Food Safety Working Group to coordinate food safety activities across the agencies. How will you, in your capacity as Secretary of Health and Human Services, coordinate between FDA, USDA's Food Safety and Inspection Service, and the Centers for Disease Control and Prevention to mitigate the growing number of food-borne illness outbreaks in the United States?

Answer 4. As Secretary, I will ensure that all parts of the Department, from the FDA to CDC to NIH, are working together to safeguard our food supply. I will also work to ensure effective inter-departmental coordination between HHS, USDA, and other key agencies. The President has acted to strengthen this coordination through his White House initiative that established the Food Safety Working Group. Moreover, the President's 2010 budget includes new funding for the food safety center at FDA. This investment will help the agency work with farmers, the food industry, consumer organizations, and the public to develop a strong public health approach to food safety.

Question 5. Various groups have put forth ideas on how to change the government's food safety systems. Currently these systems are fractured across many agencies and have differing levels of effectiveness and authorities. Food safety must become a high priority within your Department, the Department of Agriculture, and within the Administration to ensure the safety of food consumed by the public.

How would you improve the structure of FDA's leadership to place a greater emphasis on food safety? Would it be effective to establish a new high-level position that would focus solely on improving and advocating for food safety programs at FDA?

Answer 5. As I stated in a previous answer, I believe our immediate goals must be to ensure that we have a modern regulatory system in place, to increase our focus on prevention, and to reassess and improve our existing legal authorities. I also believe we must ensure effective coordination between all our food safety agencies, both within HHS and across other Federal departments. With the right leadership and the right priorities, I believe we can accomplish these goals.

Question 6. What are your thoughts on how a greater emphasis on preventive services can be incorporated into health reform? Do you believe that a reformed

health system should require coverage for preventive services recommended by the U.S. Preventive Services Task Force in public and private plans?

Answer 6. Wellness and prevention are urgent priorities. This century's epidemic is chronic disease: over 70 percent of costs and deaths result from it. Yet, we spend only 1 to 3 percent of our \$2.6 trillion health system on prevention.

President Obama has committed to expanding clinical and community-based prevention to shift our health care system from an "acute care" system to one that prioritizes health promotion and disease prevention activities. As part of his health reform agenda, the President established the coverage of evidence-based prevention services as an objective of a reformed health system. If confirmed, I will work with the President and Congress to make a greater focus on prevention a key cornerstone of health reform.

Question 7. Mental health and substance abuse are key as we are discussing reducing the costs of health care and addressing prevention and public health. It is integral that there is coordination amongst SAMHSA, CDCP and NIH amongst the other agencies. As you know, mental health and substance abuse is interconnected with physical health. For example, it has long been recognized that patients who suffer from depression are more likely to have heart attacks or other cardiac events.

How would you work with other agencies to develop and implement a strategic approach to the promotion of mental, emotional, and behavioral health and the prevention of MEB disorders and related problem behaviors in young people and to ensure alignment of resources, programs, and initiatives with this strategic approach and for encouraging their State and local counterparts to do the same?

Answer 7. I commend the Congress for passing mental health parity legislation last year. I believe that private and public insurance plans should include coverage of all essential medical services, including mental health care, and that serious mental illnesses must be covered on the same terms and conditions as are applicable to physical illnesses and diseases.

QUESTIONS OF SENATOR MIKULSKI

Question 1. Governor Sebelius, in your role as Secretary of Health and Human Services, you also will have responsibility in combating the threat of bioterrorism. Recently, former Senators Bob Graham and Jim Talent released their World at Risk Report.

Do you agree that a bioterrorist event from a weapon such as anthrax remains at or near the top of our Nation's most serious threats?

Answer 1. Yes.

Question 2. Assuming you do agree, what efforts does HHS plan to pursue to help DHS and the Administration address and communicate that threat to Congress and State and local governmental authorities?

Answer 2. HHS has supported DHS's risk and net-assessment efforts and will assist in whatever ways are necessary to communicate with the Congress, State, and local authorities regarding those efforts and other appropriate medical and public health solutions that are needed to counter the threat. Additionally, the Office of the Assistant Secretary for Preparedness and Response (ASPR) at HHS has sponsored stakeholder workshops and invited presentations at emergency preparedness and other scientific meetings to discuss the anthrax threat and countermeasure activities.

Question 3. Specifically with regard to the World at Risk Report, did HHS collaborate with the Commission on the document?

Answer 3. Yes, the Principal Deputy Assistant Secretary for ASPR, Dr. Gerald Parker, briefed the Commission on HHS programs and views. Jonathan Tucker, a Commission representative, conducted interviews within the Department.

Question 4. Alternatively, are there any points, conclusions, warnings, etc. contained in the Report that HHS disagrees with or takes issue?

Answer 4. In general, HHS agreed with the strategic conclusions of the report.

Question 5. Does HHS plan to pursue any new or heightened initiatives based on the Commission's findings?

Answer 5. In August 2008, President Bush submitted a supplemental budget request totaling \$905 million to initiate efforts for medical countermeasure advanced development and dispensing in the United States, focused primarily on anthrax. To date, no appropriation has been provided based upon this request.

Within the existing budget, HHS will continue its efforts to develop, stockpile, and build manufacturing infrastructure for new anthrax vaccines, antitoxins, and anti-

biotics, including antibiotic MedKits for responder populations. These efforts will focus on the development of next generation broad-spectrum antibiotics to treat illness against enhanced anthrax agents that are antibiotic-drug resistant, and on working with the Department of Defense to establish new public-private centers of excellence for countermeasure development/manufacturing in the U.S. against biological threats, including anthrax.

Question 6. In that HHS is responsible for the development, acquisition, and delivery of appropriate countermeasures, how closely has HHS been involved in the Federal Government's overall threat assessment dialogue?

Answer 6. HHS has provided scientific input to both the DHS risk and net-assessment processes. Threat and risk information then informs the Department's research, development, and acquisition priorities.

Question 7. Specifically, is there a coordinated interagency process to prioritize HHS's development and acquisition efforts based on current USG threat information?

Answer 7. The Public Health Emergency Medical Countermeasure Enterprise, established under Pandemic and All-Hazards Preparedness Act in December 2006, provides the framework across the U.S. Government to coordinate research, development, stockpiling, and utilization of medical countermeasures for chemical, biological, radiological, and nuclear threats. The Enterprise Governance Board, comprised of agency heads primarily from Departments of Health and Human Services, Defense, Homeland Security and Veterans Affairs, provides strategic guidance and policy setting for these activities. Senior advisors in these agencies constitute the Enterprise Executive Committee, which provides tactical implementation of these policies and interacts with and directs interagency project teams that deliberate and study different aspects of these countermeasure activities.

In addition to these questions, I also have some regarding the funding of bio-defense medical countermeasures, the development and acquisition of new medical countermeasures, and the coordination between HHS and the Department of Defense around the Strategic National Stockpile. I look forward to your responses and working with you on these very important issues surrounding the Nation's preparedness against the threat of bioterrorism.

QUESTIONS OF SENATOR MURRAY

Trauma Care

Question 1. Our Nation's trauma centers rely upon up to 16 highly trained subspecialties to be available 24/7 to literally put people back together again.

For example, Harborview in Seattle is the only Level 1 trauma center in Washington State, and is responsible for serving a four-State region (Washington, Alaska, Montana and Idaho).

It is absolutely essential that critically injured patients have access to life-saving trauma care services where and when they need them.

As we are looking at reforming the health care delivery system to re-align incentives such that reimbursement better flows with appropriate patient care—such as through medical homes, better preventive care and disease management—how do we also ensure that the changes in reimbursement do not inadvertently and negatively impact trauma care services?

Answer 1. Trauma centers are a critical part of our health care infrastructure, and serve all Americans, regardless of ability to pay. One of the main reasons that emergency departments and trauma centers are struggling has to do with uninsurance and uncompensated care. As we move toward a system in which more Americans are covered, much of the financial pressure on emergency departments and trauma services will be relieved. That said, it will be critical to ensure that the financial incentives are aligned appropriately to assure that trauma care remains available, without creating incentives to use emergency services in non-emergencies. This will create a win-win both for primary care and for trauma care.

Prevention and Outreach

Question 2. There is no doubt that reform is needed to ensure affordable access to quality health care for all Americans, but we must also derive more value from our health care dollars. We need to not just help people when they are sick, but actively focus on keeping people healthy.

Senator Harkin has been a leader on prevention, and I agree with him—we need to get health care costs under control and that's not going to happen unless we place a major new emphasis on disease prevention and wellness.

One of my concerns regarding prevention and wellness programs is accessibility. There's not much use having prevention or wellness services if no one knows about them or how to access them.

There are some issues now with certain preventive services that are available to the uninsured or underinsured but DOCS don't even know about them, so they don't know to offer them to their patients.

Further, while we have worked to expand prevention services under Medicare, the use of these services are vastly under-utilized. For example, a 2006 study found that only 36 percent of women covered by Medicare were getting a yearly pap-smear.

These services will only net gain in cost savings and better health outcomes if they are utilized—what will you do as Secretary to increase promoting prevention and wellness services?

Answer 2. The Department of Health and Human Services (HHS) has a critically important role in promoting prevention and wellness services to the American people. Specifically, HHS supports research, education, and awareness, as well as direct services related to prevention across the various agencies and offices.

If confirmed as Secretary, I will take a number of steps to better promote prevention. Such steps include, but are not limited to, bringing in new leadership with expertise and experience in prevention, integrating and coordinating prevention efforts both within the department but also governmentwide, working to expand access to preventive services through existing public programs as well as within a health reform initiative, and focusing on strengthening the public health workforce to assist States and localities implement prevention programs.

Emergency Preparedness Act

Question 3a. As you may know, the Fred Hutchinson Cancer Research Center is a non-profit research institution based in Seattle, WA and is currently taking a leading role in an NIH-funded and directed global HIV/AIDS vaccine clinical trial. The program, entitled the HIV Vaccine Trials Network, is an international collaboration of scientists and institutions working to accelerate the search for an HIV vaccine. The Hutch is coordinating the trial and research activities of more than two dozen research institutions, at the direction of NIAID. This effort is one of the few bright spots in our efforts to fight AIDS globally, and is even more necessary, given the recent report indicating that HIV/AIDS has reached "severe epidemic" levels right here in our Nation's capital. However, these trials—and the entire work of the Network—may be jeopardized due to concerns about risks and liability exposure associated with potential litigation about the conduct of clinical trials necessary to advance the research effort.

As Secretary, would you consider using existing statutory authority, specifically, the Public Readiness and Emergency Preparedness Act, to provide the Hutch liability protections to ensure that these trials continue and an effective vaccine is ultimately discovered and administered to those in need?

Answer 3a. This question raises a number of important issues and illustrates the complexity inherent in new vaccine discovery.

Question 3b. Another potential solution would be to make these institutions employees of the Federal Government for purposes of liability protection under the Federal Tort Claims Act. Would you support legislation that would extend the protections of the FTCA to the Hutch, since it is carrying out its coordinating function on behalf of HHS?

Answer 3b. The issue of further extending government liability protections to a private entity such as a Federal grantee during the clinical trial phase of vaccine development deserves careful consideration. The critically important activities undertaken by Federal grantees are not currently considered direct action by the Federal Government, and we must take care to ensure an appropriate balance of Government responsibility and control in supporting their work. A number of options have been proposed and discussed in detail at the National Institutes of Health, including NIH assistance in the purchase of liability insurance. If the concerns of NIH grantees about potential liability exposure are a threat to the important work of vaccine discovery and development, I will closely examine all options available to me to ensure that these trials move forward.

HIV Travel Ban

Question 4. Last summer, as part of a law reauthorizing the PEPFAR program, the Congress removed HIV infection as a statutory grounds for ineligibility for a visa or for admission to the United States.

Is HIV still on the HHS list of "communicable diseases of public health significance" which prevents entry into the United States?

If confirmed as Secretary of HHS, what steps would you take to implement the changes to the HIV travel ban included in the PEPFAR reauthorization?

Answer 4. HIV is still on the list of “communicable diseases of public health significance,” which prevents entry of HIV-infected individuals into the United States. However, HHS has already begun work to implement this change and, as Secretary, I would do whatever necessary to expedite this process.

Medicare Advantage

Question 5. The Washington State health care system has long been known for its culture of wellness, prevention, and collaboration to effectively coordinate health care for patients. The Dartmouth Atlas project researchers have shown that this way of providing health care keeps costs low, while the quality of our health care is high. What is happening in Washington is what we are trying to make happen for the rest of the country.

But decisions we make this year could jeopardize the positive parts of health care in our State, and exacerbate the problems we do have, such as severe primary care shortages in Medicare. For example, proposals to bring Medicare Advantage rates—already the lowest in the country—down to the unsustainably low FFS rates in Washington, would mean taking over \$300 million in Federal funding out of a health care system that is already paid some of the lowest rates in the country. That change would underscore the existing system that rewards volume, not value, where there is great disparity across the country, and that has led to my State’s primary care shortage.

How can we work together to protect the valuable Medicare coverage—through both coordinated care Medicare Advantage plans and independent community docs, that seniors in my State receive?

Answer 5. I agree that Washington State’s health care system is a leading model for how we should transform the entire health care system. It consistently produces high-quality outcomes while managing costs. The entire U.S. health care system should follow the State’s lead to reward prevention, primary care, and care coordination. The Medicare Advantage program can play a large role in promoting these goals. I share your deep concern regarding the growing shortage of primary care physicians and other health professionals, and I believe we should examine Medicare’s payment system in its entirety to ensure that our Nation promotes and rewards primary care.

I also share the President’s view that we must reform the way Medicare pays Medicare Advantage plans, and I am concerned about the high incidence of overpayment to these plans. But we must also carefully consider any changes to the program to ensure that our reforms reflect local health care dynamics and practices of care. Toward that end, the President’s budget includes a proposal to promote greater competitive bidding for Medicare Advantage. I look forward to working with you and the entire Congress to reform payments to Medicare Advantage plans while also promoting broader health reform goals.

Washington State as an Example

Question 6. Just yesterday I had the opportunity to talk with Washington’s Governor about the success we have seen in our State’s health care system, as well as about the economic and budget hurdles that have led the State to significantly cut our State-funded Basic Health Plan that provides coverage to many low-income citizens, in order to help fill the deficit. We believe we can help the country solve some of the national health care problems by providing a model for how care can be delivered in a low-cost, high-quality way, and I would like to invite you to come visit Washington and see in-person the kind of innovations and organizations that make our system work. But we also need Federal assistance to ensure that the people currently covered by the Basic Health Plan will have someplace to go for their health care as the State is forced to cut back.

How can Washington State serve as a model, how can we help you as you work toward developing new payment systems that reward value, not volume, and new coverage models that do not depend as heavily on the State budget process?

Answer 6. As a Governor, I consistently learned from other States’ examples, and I will continue to look to the States if I am confirmed as Secretary. Washington State’s Health Care Authority has been a model for improving affordability, quality, and access through programs such as Washington Wellness, Health Technology Assessment, and Community Health Services. I will work with States to build on and support their success. Moreover, the Administration is committed to tackling the system-wide cost drivers that are crushing our families, businesses, and State governments. As the President has said, health reform cannot wait, and I fully agree.

Coordination of Early-Childhood Learning Programs

Question 7. Historically, early learning at the Federal level has been exclusively under the jurisdiction of HHS. At the State level, early learning is often focused on State preschool, which is frequently run by State education agencies, such as Washington State's Department of Early Learning. States like Washington are working hard to connect Head Start, child care, pre-kindergarten, and K-12 systems to create collaboration among education agencies and human services agencies to improve services to families.

Right now many States are struggling to make these important connections. President Obama has identified these collaborations as a priority at the Federal level and has proposed creating early-learning challenge grants to States through the Department of Education, which could help encourage States to develop plans for the delivery of coordinated early learning services.

How can the Department of Health and Human Services work with other agencies, particularly the Department of Education, to improve the coordination and delivery of services in a way that best serves young children in my State and across the Nation?

Answer 7. As a Governor, one of my highest priorities was children, and there is no better public investment than providing support for early childhood education and development. President Obama has demonstrated his support through provisions in the Recovery Act that increase funding for Early Head Start by \$1.1 billion, Head Start by \$1 billion, and Child Care Development Block Grant by \$2 billion, as well as his unprecedented commitment to key early learning programs at the Department of Education. The President's budget calls upon States to raise the bar in their early childhood programs, and work to ensure that children are supported in their learning through a seamless system of early care and education.

As I approach early childhood issues, I am anxious to leverage all resources within the Department of Health and Human Services and better coordinate and promote the education and development of young children, while supporting their families. I will work to ensure coordination between all the appropriate departments, including the Department of Education, and our State partners to make sure we are providing the best possible start for our Nation's children.

Home Visiting Programs

Question 8. Research tells us that the first months and years of a child's life are critical in laying the foundation for later success in school and beyond. Early childhood home visitation programs have been shown to decrease child abuse and neglect, while increasing school readiness and early identification of developmental and health delays, including potential mental health concerns. Several effective home visiting programs have been identified, including those providing services delivered by nurses, social workers, child development specialists, or other well-trained and experienced staff.

If confirmed as Secretary of HHS, how would you further a seamless home visiting program that includes health, well-being, and school-readiness components for children from birth through kindergarten?

Answer 8. I share your belief in the critical importance of the first years of life, and we must do more to give our children the best start possible. As Governor of Kansas, I also helped design and implement an effective home visitation program. As you know, the President's FY 2010 budget blueprint calls for creating a visitation program that makes funds available to States to provide home visits by trained nurses to first-time low-income mothers and mothers-to-be. If confirmed as HHS Secretary, I look forward to working with you and other Members of Congress to design, enact, and implement an effective home visitation that will make a measurable difference in the lives of children.

QUESTIONS OF SENATOR REED

Question 1. The President's budget makes a strong commitment to funding the Low-Income Home Energy Assistance Program (LIHEAP), requesting \$3.2 billion, but as we know, the economic downturn is increasing the importance of LIHEAP in the lives of low-income families. Indeed, this was in part why Congress provided a total of \$5.1 billion in regular and emergency funding for the program in fiscal year 2009. Recognizing the need, will you work with the Congress to support greater resources for this program in the fiscal year 2010 budget process?

Answer 1. I share the President's strong commitment to LIHEAP, and we both believe this program has been effective in helping low-income families meet their home heating and cooling expenses. The need for LIHEAP is never greater than when unexpected energy price increases put already vulnerable low-income families

at even greater risk—a situation that occurred last year when the price of oil skyrocketed. To meet this very real problem, the President's FY 2010 budget calls for creating a new trigger mechanism to provide automatic increases in energy assistance whenever there is a spike in energy costs. If confirmed as Secretary, I look forward to working with you and other Members of Congress to craft a reliable, efficient trigger to meet the heating and cooling needs of low-income families.

QUESTIONS OF SENATOR BROWN

NIH

Question 1. Important medical research being conducted at the NIH represents our greatest promise at curing disease, improving health, and saving lives. However, NIH currently dedicates only about 5 percent of its annual extramural research budget to pediatric research.

If our investment in pediatric research is not increased, discoveries of new treatments and therapies for some of the most devastating childhood diseases and conditions will be hindered, and the next generation of pediatric researchers will be discouraged from entering the field.

As HHS Secretary, how will you alter NIH's research priorities to give pediatric studies the prominence they deserve?

Answer 1. The NIH considers pediatric research a major commitment. Twenty-two of the twenty-seven Institutes and Centers fund pediatric research. For fiscal year 2008, the NIH created the Research, Condition, and Disease Categorization Process (RCDC), a computerized process the NIH uses at the end of each fiscal year to sort and report the amount it funded in each of 215 historically reported categories of diseases, conditions, or research areas. Using the RCDC method, pediatric research constituted 9 percent of the total NIH budget in fiscal year 2007, and 9.4 percent in fiscal year 2008.

NIH will use economic stimulus funds to expand extramural pediatric research opportunities. The new Clinical and Translational Science Awards (CTSAs) specifically encourage pediatric research, and the pediatric community has responded vigorously with proposed activities under this program. These activities are additionally augmented by funds from the Best Pharmaceuticals for Children program. The CTSA program will continue to grow and encourage pediatric research, including the development of pediatric drugs and devices. Additionally, NIH is increasing its efforts to train a new generation of pediatric scientists. If confirmed as Secretary, I look forward to meeting with leaders in pediatric research at the NIH to further address these issues.

Drug Discount Program

Question 2. I would like to bring to your attention a non-controversial final notice that got stalled in OMB in the last months of the Bush administration. It would implement children's hospitals eligibility for the 340B drug discount program. Congress enacted a provision providing for this eligibility in the DRA.

It has been more than 3 years since the statutory effective date and 1½ years since the proposed notice was published. Does the Administration have plans to publish this notice in order to allow children's hospitals the opportunity to apply and participate in 340B by the next quarter of this year?

Answer 2. Expanding access to affordable drugs is a top priority for the Administration. If I am confirmed as Secretary, I will examine every option to increase drug affordability. Certainly, the 340B drug discount program, which has been proposed by many providers and advocates, is one such option. Given the program's effectiveness, expanding eligibility merits close scrutiny for short-term action.

Antibiotic Resistance

Question 3. Antibiotic resistance is quickly turning previously treatable conditions into deadly ones. Staph infections, for one, are becoming more prevalent and more life-threatening. According to a recent study, more than 94,000 invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) infections occurred in the United States in 2005 and more than 18,500 of these infections resulted in death. Worldwide, tuberculosis is facing the same challenge.

Senator Hatch and I have called for a new Office of Antimicrobial Resistance in the Department of Health and Human Services. What are your thoughts on creating a new office, within HHS, to deal with antimicrobial resistance issues?

Answer 3. Antimicrobial resistance remains a major public health challenge and must receive priority focus in this Administration. HHS has taken steps to address this challenge, although it is clear that more work remains to be done. If confirmed as Secretary, I will look at every option to better coordinate and integrate activities across the Department, and a new Office would certainly merit such consideration.

Dental Care

Question 4. Though often overlooked in health policy discussions, access to dental care is of the utmost importance. Dental problems inhibit an individual's ability to work and a child's ability to excel in school.

Last Congress, I introduced the Deamonte Driver Dental Care Access Improvement Act, named after the Maryland boy who died as a result of an untreated tooth abscess. The bill would expand the dental care that community health centers provide for low-income Americans, establish a pilot program for new allied dental health professionals, and invest in preventative oral health.

As HHS Secretary, how will you focus the Department's attention on dental care problems?

Answer 4. Dental care is an important part of prevention and wellness. Prevention has been a focus of the Administration—the Recovery Act included a historic investment in proven interventions, which will be a cornerstone of comprehensive health reform. A focus on dental care and other key components of prevention will lead to a healthier, more productive population, and save health care costs in the long run.

Food Safety

Question 5. Late last year, the CDC identified another outbreak of salmonella infections across the country. The CDC has reported that 550 people in 43 States and Canada have been infected by this outbreak. The Ohio Department of Health has reported that 100 people in my State have been affected by this outbreak.

Ohio—and the country as a whole—has been overwhelmed in recent years by recall after recall. Last spring, a dozen Ohioans—and 1,400 Americans—were made ill by contaminated peppers. It took the CDC and the FDA 3 months—and one false accusation of the domestic tomato industry—to determine that these peppers originated in Mexico.

How do you envision reforming FDA so that it can once again fulfill its mission to keep Americans safe? Do you believe that the United States should have a better traceability system so that we can better track food outbreaks? Do you believe that FDA should have the ability to recall foods that the Agency believes are harmful to our citizens?

Answer 5. There is a need within FDA and our other food safety agencies for increased integration and coordination to ensure an effective, modernized approach to food safety. If confirmed as Secretary, I will work with FDA, Congress, and my counterparts in the Administration to determine the most appropriate organizational structure to achieve this goal. Effective product tracing should be a part of a modernized approach. It would allow FDA to more quickly identify the source of a contaminated food and where it has been shipped. In addition, providing FDA with mandatory recall authority would give the agency an important tool to remove unsafe foods from warehouses and store shelves before they get to consumers.

Other

Question 6. As has been widely reported, Dr. Peter Pronovost from Johns Hopkins University has devised a 5-point checklist to prevent catheter line infections in hospitals. This simple tool saved 1,500 lives and \$100 million over an 18-month period in Michigan.

I have been working with the Ohio Hospital Association to bring this life-saving mechanism to my State and am pleased to report that the Agency for Healthcare Research and Quality (AHRQ) recently announced that 10 States, including Ohio, have been selected to participate in a program to test methods of reducing central-line associated blood stream infections in hospitals.

How do we ensure that common-sense quality improvements—like Dr. Pronovost's checklist—are quickly adopted nationwide? Is this a job for a Federal Health Board, for AHRQ, or for HHS more broadly?

Answer 6. Empowering providers and patients with the information to make informed health care decisions is a key tenet of a high-quality health care system. Agencies such as AHRQ must work hand-in-hand with provider and patient organizations to disseminate useful research and innovations to inform practice. A collaborative approach can ensure that Americans receive up-to-date, high-quality care.

QUESTIONS OF SENATOR CASEY

Question 1. Governor Sebelius, I was very pleased to see that the President included a new budget line for nurse home visitation in his budget outline. The Nurse-Family Partnership is one nurse visitation model that operates in 40 counties across PA and is noted for its strong evidence-based results and ability to break the cycle of poverty for young women and their children. I understand the program saves be-

tween \$3 and \$6 for every dollar invested. This is another example of an excellent evidence-based program that can literally change the trajectory of the lives of mothers and children. I know I am one of many champions here in the Congress for this program.

As we create this funding stream which is money well spent on the future of our country, can you tell us a bit about how you envision this playing out.

Will the program be funded through Medicaid or some other funding stream?

Do you see a role for this kind of program in overall health care reform and if so, what role?

Also, how do you envision ensuring that programs across the country are able to maintain the high standards that have given us such positive outcomes from programs such as the Nurse Family Partnership?

Answer 1. Thank you so much for your support and deep commitment to home visitation programs and for your commitment to evidence-based interventions that improve the life trajectories of low-income and disadvantaged children.

As you know, President Obama is committed to a comprehensive "Zero-to-Five" agenda, and the Recovery Act has made an important down-payment on expanding access to essential programs by increasing funding for Head Start by \$1.0 billion, Early Head Start by \$1.1 billion, and the Child Care Development Block Grant by \$2.0 billion.

The President's budget blueprint calls for creation of a Nurse Home Visitation Program, which will provide funds to States to offer home visits by trained nurses to first-time low-income mothers and mothers-to-be. As you note, the program has been rigorously evaluated over time and has been proven to have many long-term positive effects. With respect to financing, the President's budget blueprint creates a separate mandatory funding program for the Nurse Home Visitation.

If confirmed as Secretary of HHS, I would look forward to working with you and other Members of Congress to design, enact, finance, and implement the most effective home visitation program possible for at-risk children and families.

With respect to any new national program, including the Nurse Home Visitation program, it will be critical that key program requirements, funding mechanisms, measurement tools, and technical assistance are in place to ensure that program elements that proved essential to the success of early models are replicated in new sites.

QUESTIONS OF SENATOR HAGAN

Question 1. The threat of a flu pandemic is one of the most important public health issues our Nation faces. The 2005 HHS pandemic plan estimates that a severe pandemic could sicken 90 million Americans. The plan estimates the direct and indirect costs for medical care could reach \$181 billion for a moderate pandemic. The previous Administration made it a top priority by providing a detailed preparedness plan and by requesting that Congress appropriate the necessary funding for vaccine development, antiviral drug and vaccine stockpiling, disease surveillance, and to promote preparedness at the local, State, and Federal levels. Do you expect the Obama administration to continue to emphasize the importance of a robust public-private partnership to ensure that our Nation is fully prepared for a flu pandemic?

Answer 1. Pandemic influenza remains a concern internationally and domestically, and the Administration will continue to support HHS efforts to ensure that the Nation is fully prepared. Our preparedness efforts will continue to focus on expanding public-private partnerships to help address the threat.

Question 2. *USA Today* recently reported a troubling increase in resistance to the antiviral drug Tamiflu by H1N1 flu strains that are circulating this season, and a new CDC report also raises concern about the growing resistance of the H1N1 flu strain to the drug. What steps do you expect HHS to take with regard to the growing resistance? And what steps do you think are necessary to ensure that the pandemic flu antiviral stockpile is not adversely impacted by this resistance issue?

Answer 2. HHS continues to conduct advanced research and development of new antiviral countermeasures to combat these threats. Although the current resistance relates to seasonal flu, we recognize the potential implications to a novel influenza virus. If confirmed, I will closely review the status of the Department's efforts in this area and work with Members of Congress to ensure that appropriate steps are being taken.

RESPONSE TO QUESTIONS OF SENATORS ENZI, HATCH, MCCAIN, MURKOWSKI,
COBURN, BURR, AND ALEXANDER BY KATHLEEN SEBELIUS

QUESTIONS OF SENATOR ENZI

Health Care Reform

Question 1. When talking about his health care plan on the campaign trail, President Obama stated several times that “if you like what you have, you can keep it.” Expanding public programs like Medicaid will create strong incentives for employers to no longer offer health insurance. This means that potentially millions of workers with private coverage could lose their existing coverage and be forced into a government program which will not allow them to see the doctor of their choice. Should public programs like Medicaid be expanded if it means that millions of Americans would lose the health insurance that they currently have?

Answer 1. We believe in the principle of choice. The President’s plan to assure affordable health insurance is built on strengthening and expanding our existing health care system. Medicaid as a cost-effective and appropriate strategy for expanding coverage to the lowest income Americans. While the President’s campaign plan did include such an expansion, most Americans would be able to keep the coverage they have today or choose from a set of private plans along with a public plan option. We expect that the number of privately insured people will rise, not fall, under health reform.

Question 2. Are you willing to explore new approaches to medical liability reform, like the bill Senator Baucus and I have introduced, which gives grants to States that develop new methods for resolving medical malpractice claims and reducing medical errors, in order to bring down health care costs?

Answer 2. Independent and objective studies have consistently found that malpractice costs explain only a small part of medical costs. However, clearly some doctors are facing exorbitant premiums and I believe we all need to work together to look for creative solutions. The most important goal is to improve health care quality for patients to prevent medical mistakes from happening in the first place. This can be done in a number of ways. One such way requires investing in health information technology that can alert doctors when patients have allergies or drug contra-indications to requiring transparency about health care quality through reporting requirements.

I believe we should work to improve outcomes for patients without being doctrinaire about solutions to this problem. If confirmed, I look forward to working with Congress on this issue.

Question 3. I like to get things done. To get things done, I live by what I call the 80 percent rule. We can agree on 80 percent of the issues and about 80 percent of each issue, and we can get things done. I think the 80/20 rule also holds true when it comes to health care costs. About 20 percent of the population in the U.S. account for about 80 percent of the health care costs. I want all people to be able to afford health care, but given the current fiscal environment, I think it would make a lot of sense to target Federal funds to those really sick people out there that don’t have health insurance. Do you agree we should target Federal funds to the sickest, costliest Americans?

Answer 3. You raise two important points. First, I do agree that our cost containment efforts must prioritize the 20 percent of patients that account for 80 percent of health care costs. As such, my top priority as Secretary would be to increase quality and reduce costs for patients with chronic diseases such as obesity, cardiovascular disease, and diabetes, as well as those facing end-of-life issues. Second, I do agree that all our health initiatives, including health reform, should reflect careful consideration of the needs of the most vulnerable among us.

Question 4. Governor Sebelius, as you know, pharmacists play a vital role in helping patients take their medications as prescribed. When patients adhere to their medication therapy, it is possible to reduce higher-cost medical services, such as emergency department visits and catastrophic care. What policies can we put in place as part of health care reform to encourage greater utilization of pharmacist-provided services as a means to improve health care outcomes and reduce costs?

Answer 4. Pharmacists play a critical role with respect to improving health care quality and containing costs through patient education, care coordination, and medical management. Health reform will likely include expanded implementation of these services, and we will rely on pharmacists to help inform our efforts. Further, if we expand coverage and reimbursement for such services, pharmacists would directly benefit.

Question 5. All health care reform proposals indicate an increased need for primary care physicians to manage chronic illnesses, serve as medical homes and perform preventative care. What steps would you consider to incentivize more medical students to choose careers in primary care?

Answer 5. I believe that we must address the primary care workforce shortage on a number of fronts. First, we need to expand support for workforce training programs, including title VII, title VIII, and National Health Service Corps programs, which incentivize students to pursue careers in the primary care health professions. Second, we must tackle payment reform in the Medicare program to ensure that primary care providers are paid fairly. Finally, we should take steps to support the actual practice of primary care, which could include assistance with adopting health IT or implementing disease management and care coordination programs.

Health IT

Question 6. Secretary Leavitt and I both shared a passion for technology. We worked together very closely on increasing adoption of health information technology. I'm curious what type of a role you envision for yourself in relation to health information technology? What do you see as the Federal Government's role in encouraging adoption of health IT?

Answer 6. We currently have a 21st-century operating room but a 19th-century administrative system for health care. One out of every four health care dollars goes to administration. Only 17 percent of U.S. physicians and 8–10 percent of U.S. hospitals have meaningful electronic health records. In order to move our health care system forward into the 21st century, we need to establish standards for interoperability and privacy protections as soon as possible. We have been talking about health IT for many years, and haven't gotten very far. That's why the Government needs to make an up-front investment that will be spent in a targeted, effective manner—to provide every American with an electronic medical record, reduce medical errors, and improve the quality of care for patients. The ultimate goal of this effort is consumer empowerment; it will save not only money, but also lives.

Question 7. What ideas do you have to assure rules and laws designed to prevent profit from referrals to personally owned facilities don't interfere with the flow of patient information?

Answer 7. It is fundamentally important that our health IT infrastructure is fully interoperable to ensure the exchange of critical health information among patients and their healthcare providers. In addition, we must reduce unnecessary barriers to the flow of information among providers, while ensuring that we protect patients by minimizing improper referrals for care. If confirmed, I commit to working to ensure an appropriate balance of those efforts.

Medicare

Question 8. The Medicare Trust Fund will be insolvent by 2019, and States are reporting that they can no longer afford the rapidly escalating costs of the Medicaid program. Given this impending fiscal crisis, how can proposed expansions of these programs be sustainable? How can we pay for the existing programs, as well as the proposed expansions, in a way that will not do irreparable long-term damage to our economy?

Answer 8. The cost pressure on Medicare and Medicaid is the result of high health care costs in general. That is why reforming our health care system to lower costs and expand coverage will help address the long-term budgetary challenges facing these programs. Medicare and Medicaid have performed as well as, if not better than, private insurers on cost. Their growth rates are comparable to, and their payment rates are lower than, those of the private sector. That said, a top priority is to modernize these programs to make them leaders in value-based purchasing and quality.

Question 9. In 2006, I traveled around Wyoming talking to seniors and encouraging them to sign up for Medicare Part D. I held over a half dozen town halls and got the same question at each town hall, "my plan doesn't cover the drugs I need." Each time this question was asked, it was a Veteran doing the asking. This was because the Veterans Health Administration uses price controls and inflexible formularies, which often results in Veterans not being able to get the drugs they needed. Will you support or oppose proposals that attempt to make the Medicare Part D drug benefit more like the VHA, especially by imposing price controls and rigid formularies that will restrict Medicare beneficiaries' access to prescription drugs?

Answer 9. Repealing the non-interference clause is intended to grant the HHS Secretary greater flexibility in ensuring affordable drug prices. It does not mean cre-

ating a one-size-fits-all Medicare drug plan for all Medicare beneficiaries. Yet, there may be some lessons the Medicare program can learn from the VA, such as ways to promote lower-cost generics when medically appropriate. Working together, I believe we can improve Medicare Part D to adopt best practices by the VA and also private purchasers, without creating a one-size-fits-all drug benefit.

Question 10. The Government Accountability Office, the Congressional Budget Office and several healthcare researchers have previously documented how government price controls, like the ones found in the Medicaid drug benefit, increase costs to other consumers. Would you expand such government price controls over prescription drugs, if it means increasing the costs for Americans with private health insurance?

Answer 10. We need to develop careful policies to ensure that the Federal Government does not overpay for any medical service, including prescription drugs. At the same time, we need to make sure that changes to Federal programs minimize any market distortions or cost-shifting. But the goal should be to lower costs for all consumers. For example, we can do more to promote more lower-cost generics.

Question 11. Being from Wyoming, which is more than just a rural area, it is a frontier area, I too wanted to ensure seniors in rural and frontier areas were able to get prescription drug coverage as good as the rest of the country. To address these fears, Congress decided to include a fallback plan for areas without sufficient plan choice. To my surprise, this was an issue folks worried about for absolutely no reason. For 2009, seniors in Wyoming have 48 different Medicare prescription drug plans offering coverage. Do you know how many Medicare prescription drug plans are offered in Kansas? Do you agree this “private health insurance model” used for Medicare Part D is working in rural areas and could serve as a valuable model for health care reform?

Answer 11. We believe in building on the current system, preserving the private health care system, and ensuring that all Americans can choose their doctors. Americans should have the choice about where to get insurance and what type of insurance they want. Under the plan the President proposed on the campaign trail, the American people could keep their current, *private* insurance. They can choose from an array of other, *private* insurance options. They can choose their own doctors. They can choose their own hospitals. They also can join a public plan if they choose to do so. The Government is simply making it easier and cheaper for them to make these choices, and making sure that insurance companies aren’t unfairly denying coverage to people who need it. It’s time to bring businesses, the medical community, and members of both parties together to solve this problem for once and for all and I look forward to working with you to achieve this goal.

In Kansas, there are 48 free-standing prescription drug plans, and approximately 58 plans that are offered through Medicare Advantage companies. In total, there are approximately 106 Medicare prescription drug plans currently providing coverage in Kansas.

Question 12. Your testimony mentions “CMS should ensure that all those eligible for Medicare, Medicaid, and SCHIP are enrolled.” How do you propose we do this? Half of the kids eligible for SCHIP in Wyoming aren’t enrolled, despite an ambitious campaign by the State to enroll more kids.

Answer 12. In our great Nation, 45 million Americans do not have health insurance. This is a tragedy. Our public programs—Medicare, Medicaid and SCHIP—are the bulwark against the lack of insurance in our country. In fact, last year, the number of uninsured in our country dipped only because of these public programs; the number of people in private health insurance dropped. That’s why it’s critical that CMS specifically, and HHS in general, work to expand coverage to those eligible, especially in these difficult economic times.

Question 13. How much of every Medicare dollar spent is diverted from patients because of waste, fraud, and abuse? How does that compare with private health insurance plans?

Answer 13. We should have zero tolerance for fraud in the Medicare and Medicaid programs, and, if I am confirmed as Secretary, I will make it a top priority to manage these programs well. The extent to which Medicare overpays relative to private sector is not precisely known, but independent assessments have found that Medicare gets at least \$6 for each \$1 in investments to reduce fraud. Congress has given CMS and HHS new authorities to reduce fraud, and we should make sure that all of these new tools are employed to the fullest degree.

Question 14. Given that Medicare can arbitrarily impose price controls and thereby shift its costs onto private insurance plans, is it not true that any comparison of costs will be inherently and unfairly biased in favor of Medicare?

Answer 14. Our goal is to end cost-shifting and to ensure lower costs for all consumers.

NIH

Question 15. There are already centers across the country dedicated to embryonic stem cell research. If Congress or the Administration were to provide funding opportunities for embryonic stem cell research, would you agree that the agency should support existing entities rather than create duplicative efforts, such as a federally funded center that will cost more to create and take funds away from grantees in other research areas?

Answer 15. I support Federal funding for embryonic stem cell research, and want to ensure that all research on stem cells is conducted ethically and with rigorous oversight. NIH not only utilizes researchers working at the agency, but provides grants to support the work of scientists at universities and health care institutions across our country. I look forward to working with the experts at the agency to determine the best ways to finance the most promising stem cell research, including supporting researchers who are already engaged in cutting-edge stem cell research.

Question 16. As a part of the NIH reforms enacted in 2006, Congress provided authority to the Director of NIH to make decisions based on science rather than politics. What will you do to ensure that decisions to fund research are made by the scientists and not the politicians?

Answer 16. The NIH grant process relies on the input of experts who provide high-level analysis of the merits and value of grant applications, and I believe it is important to ensure that the wisdom of scientists continues to be the major force guiding grant making decisions at the NIH. If confirmed, I look forward to working with Congress to ensure that the NIH remains a science-driven institution, funding the basic research necessary to help create breakthroughs in medicine.

Question 17. Governor Sebelius, what is the role of HHS in seeing that all Americans are able to access health care that reflects cutting-edge research? How can we best be sure that the latest in medical knowledge is not only being translated to the bedside, but is also being implemented in communities?

Answer 17. President Obama supports increasing funding for the National Institutes of Health (NIH). If confirmed, I want to not only ensure that the agency has the resources needed to engage in cutting-edge research, but to help more Americans access the innovations that result from NIH research. If confirmed, I look forward to working with members to determine ways to ensure that science-based programs and effective treatments are available and accessible across the United States.

Question 18. The safety and effectiveness of novel therapies is best determined by clinical and translational research. How will you increase the speed of this research while maintaining patient protection during the conduct of clinical trials? Specifically will you address the relative slowness of the IRB system?

Answer 18. Both President Obama and I support increasing funding for the NIH, and I hope to work with the scientists at the agency to determine how increased resources might be used to improve the clinical trial process and maintain safety for patients who enroll in these important research efforts.

Question 19. How will you use NIH resources to fund important clinical research, which may have a high potential benefit, but uncertain commercial value?

Answer 19. Much of the NIH's work involves supporting investigator-initiated research, and helping to fund the scientists in labs across the United States who are engaging in important research that leads to medical breakthroughs. If confirmed, I look forward to working with the experts at the agency to ensure that the most promising research is funded, and that science guides the research supported and carried out by this agency.

Question 20. The integrity and validity of some scientific research has been questioned due to potential conflicts of interest among academic scientists with relationships with industry sponsors of their work. This reaches into issues of continuing medical education, ghost-writing of putatively scholarly articles, and food and drug samples for doctors' offices. What specific steps will you take to minimize conflicts of interest in the performance of federally funded research—especially clinical and translational research?

Answer 20. Many universities have been developing or refining their own conflict-of-interest guidelines, setting out disclosure requirements and systems for adjudicating conflicts on a case-by-case basis. The NIH can assist universities with advice and principles that govern conflicts in the new system developed for the intramural program. However, it is important to distinguish between “interests” and “conflicts.” We want our scientists to have interests. We want them to share information and collaborate, including with the private sector, to challenge each other’s ideas and advocate for their own ideas. We do not want, nor is it in the Nation’s interest, to create a world where university and government scientists are completely isolated from industry scientists. That is not how science works.

A major component of avoiding significant conflicts—academic ties, financial ties, institutional biases—is to insist on full public disclosure of all such relationships. Case-by-case review of any situation that is not completely straightforward would ensure that we manage those conflicts that arise from legitimate interests, and we prohibit interests that do not further the scientific mission of NIH and its grantee institutions.

CDC

Question 21. Do you agree that the Director of the CDC needs more flexibility to be able to more effectively allocate funds to public health initiatives, programs and projects?

Answer 21. Yes. Currently, much of CDC’s prevention funding is disease-specific. Yet, we know that many chronic diseases, such as heart disease or diabetes, share common risk factors including smoking and obesity. Community prevention programs that increase physical activity, improve diets, and reduce smoking will convey benefits across a number of disease States. Flexibility in allocating funds would help our efforts in this regard.

Question 22. We hear a lot about the need for prevention and how to incorporate primary and secondary prevention into the daily lives of all Americans. As the national leader on all issues related to health, how will you establish a healthy environment at the Department that provides a model for other companies and public agencies to follow?

Answer 22. The Department could take a number of steps to improve the health of its employees. Such steps might include providing healthier food options in cafeterias and vending machines, expanding opportunities for physical activity, and ensuring all Federal campuses institute smoke-free policies.

Question 23. As the leader of the Department of Health and Human Services what will you do to ensure public health funding is used efficiently and effectively? What will you do to help increase accountability for public health programs?

Answer 23. In this environment of scarce Federal resources, we must make doubly certain that we are spending tax dollars wisely and efficiently. As such, I believe that HHS can play a critical role by expanding quality measurement and reporting initiatives to better integrate metrics specific to public health and prevention. Although prevention awards made by HHS should allow flexibility to meet State and local needs and health concerns, there should be a common evaluation and analysis of effectiveness and efficiency, as feasible. Programs that fail to meet established goals and objectives should be eliminated.

Ryan White

Question 24. Do you believe that funding allocations for the Ryan White HIV/AIDS treatment program should be based on the principle that the “money should follow the patient?”

Answer 24. HIV is a problem across all parts of the United States, and I believe that we need a national response to the epidemic. We should be working to prevent regional disparities, and to ensure that any American with HIV can get the necessary treatment and support services. That’s why the President and others have called for the development of a National AIDS Strategy, to help us provide adequate care and treatment to all Americans living with HIV, and prevent new cases from occurring, particularly among high-risk populations. I also believe that, as part of the overall health reform effort, we can work to ensure that Americans with HIV, like Americans with other chronic diseases, receive access to quality, affordable, and accessible health care. Also, as you know, the last reauthorization of the Ryan White CARE Act in 2006 includes policy changes that will improve our ability to better track HIV cases and target the funding.

Question 25. The Ryan White program is the safety net for States that need additional resources to provide medical care to individuals with HIV/AIDS. Yet, funds

have been used for services that are not directly related to the health of the patient and not necessary to receive care. What will you do to ensure that the Ryan White program is truly the payer of last resort?

Answer 25. The Ryan White programs provide critical services and supports to individuals living with HIV and AIDS. These programs fill gaps left by public and private insurance programs. In the last reauthorization of the Ryan White CARE Act, Congress established a requirement that 75 percent of funds under Parts A, B, and C must be for core medical services. These parts comprise, by far, the majority of the funding for the Ryan White programs. The gaps in health and related service needs that the Ryan White program must fill vary dramatically from State to State and jurisdiction to jurisdiction. While States can apply a higher portion of their funding for core medical services, the flexibility to allocate up to 25 percent of funds for other services enables funding to support essential services to help to bring people into care and help individuals adhere to their treatment regimens. If confirmed as Secretary, I will work to improve chronic disease care and management, including administration of the Ryan White programs, as part of our health reform process.

Question 26. This year the CDC reported that 56,300 new HIV infections occurred—a number that is substantially higher than the previous estimate of 40,000 annual new infections. Many are concerned that not only is the epidemic larger than we previously thought, but that testing initiatives are failing because of a lack in funding and coordination. What will you do as Secretary of Health and Human Services to coordinate CDC funding for HIV/AIDS prevention programs (including testing initiatives) and HRSA funding for the Ryan White treatment program?

Answer 26. The comprehensive national strategy for HIV/AIDS will include a plan for coordinating efforts across departments such as HHS, HUD, and VA. Within the department, we will work with CDC and NIH to ensure that the strategy is based on sound science about what works and that resources are allocated to implement the strategy. The strategy will promote linking prevention with other services such as testing for other sexually transmitted diseases and improving access to primary care services. The strategy will also explore new incentives to achieve recommendations for universal testing, broader uptake of HIV treatment guidelines, and greater CMS involvement in efforts to assure testing and quality improvement efforts by HIV providers receiving reimbursement through Medicaid or Medicare.

Question 27. A recent study published in the Lancet showed that a combination of universal voluntary HIV testing and immediate antiretroviral treatment following diagnosis of HIV infection could reduce HIV cases in a severe generalized epidemic by 95 percent within 10 years. As Secretary of Health and Human Services, how will you increase awareness about the need for universal testing both at home and abroad?

Answer 27. I support the development of a National AIDS Strategy, which will allow us to coordinate our prevention and treatment efforts in the battle against AIDS in the United States. The CDC estimates that approximately one-quarter of people living with HIV are unaware of their status, and I believe that a National AIDS Strategy will allow us to develop better mechanisms for promoting and expanding the availability of testing in the United States.

If confirmed, I also look forward to working with the Office of the Global AIDS Coordinator in the State Department to help with implementation of the President's Emergency Plan for AIDS Relief, and to work with organizations and individuals around the world to help people learn about their status.

Finally, we must work both at home and internationally to remove the stigma associated with HIV and HIV testing, and help ensure that testing is linked to care, treatment, and prevention programs.

FDA

Question 28. I am concerned about the FDA, its management, and its ability to do its job with the resources it has. It is important to have a strong FDA and maintain public confidence in the actions of that agency. What steps will you take as Secretary of HHS to work with the FDA Commissioner to insure that FDA is well-managed, well-funded, and its inspection and surveillance capabilities are improved?

Answer 28. I believe it is essential to restore the leadership, credibility, and authority of the Food and Drug Administration (FDA) to protect America's food supply, assure the safety of our medicines, and accelerate new cures and treatments for diseases like cancer, AIDS, and Alzheimer's. If confirmed, I commit that the FDA will be free from political interference, and I will work with the Commissioner to ensure that the FDA is strongly committed to science and focused on its core mission.

In addition, we should examine our process for certification of food, as well as our process for assuring the safety of imported food. We also need to make sure we're doing enough inspections and using all available tools to protect our food supply.

Question 29. The drug industry user fees pay for more than half of the FDA drug review program. This has caused a lot of consternation among some patient and consumer groups concerned about potential industry influence on the agency. Proposed legislation that would give FDA regulatory authority over tobacco would rely on user fees to support the new programs. Do you have concerns about the tobacco industry paying for 100 percent of the proposed tobacco review program?

Answer 29. My understanding is that the proposed legislation is written in such a manner to ensure that the user fee-collection system will not give the tobacco industry influence with the FDA, nor will it make the FDA dependent on continued tobacco sales.

Neither the legislation nor the user-fee structure in the legislation gives the tobacco industry any influence over how the FDA would implement this legislation. Under this legislation, the tobacco industry does not have any authority over how the money is spent, how FDA sets its priorities, or how much FDA receives, nor does the amount of the user fees collected depend on any of these decisions.

The legislation further insulates the FDA from industry influence or undue reliance on the manufacturers by ensuring that the amount of user fees to be collected does not depend upon the amount of tobacco used, but rather on manufacturers' share of the entire U.S. market.

Question 30. As the committee of jurisdiction over FDA, we must consider the FDA regulation of tobacco in the context of its other responsibilities. In recent years, Congress has tasked FDA with new duties related to bioterrorism, pandemic flu, and mad cow disease. FDA is asked to protect the public from potentially dangerous and counterfeit drugs from abroad. Well-documented recent incidents involving the safety of fresh produce and medical products prove the point that FDA already struggles with the challenges of regulating an expanding universe of products and threats. Shouldn't we focus on better enforcing the dozens of tobacco regulations already on the books instead of burdening an overworked and underfunded FDA?

Answer 30. I support giving the FDA the authority to regulate tobacco, but recognize that the agency is strained in fulfilling regular responsibilities. That is why we believe it needs additional support. Despite significant progress in reducing rates of smoking, tobacco use remains the No. 1 cause of preventable deaths in this country. Smoking contributes to the development of heart disease, strokes, emphysema, and cancers. Pregnant women who smoke are significantly more likely to have low-birth-weight babies.

The President believes that the FDA could play a major role in reducing tobacco use, by increasing oversight of marketing of tobacco products; strengthening warning labels such as those implying healthier products with words like "lite" tobacco; and banning additives, like strawberry flavoring, that make smoking more attractive to children. Reducing tobacco use and the prevalence of the diseases it causes will significantly reduce health care costs and improve the quality and longevity of life for countless Americans.

Question 31. Last year, the HELP Committee unanimously reported a bill Chairman Kennedy and I developed with Senators Hatch and Clinton to encourage cheaper versions of biologic drugs. We worked hard to balance incentives, so biotech companies keep creating new life-saving products, with a streamlined process, so the FDA can speed review of biosimilars and consumers can realize cost savings. As we continue to push for enactment of this legislation, I ask that you support our efforts to maintain that balance between cost savings and preserving innovation. Can you give us that commitment?

Answer 31. Patient care and treatment for conditions such as multiple sclerosis and rheumatoid arthritis have been revolutionized with the advent of biologic drugs. The President supports passage of legislation that would create an expedited approval pathway for follow-on biologics at the Food and Drug Administration, which would help expand access to these safe and effective life-saving drugs. He understands that such legislation must include an appropriate incentive for continued innovation in this market.

Question 32. The current system of passive adverse event reporting is underpowered to detect drug side effects that are not detected during clinical trials, and cannot find evidence of an increase in the incidence rate of common adverse events, such as cardiovascular problems, that have a very high background in the general population. Section 905 of the Food and Drug Administration Amendments Act of

2007 (P.L. 110-85) established a system of routine active surveillance for post-market drug safety through a public-private partnership. This has become known as the Sentinel Initiative. How will you ensure that this important initiative continues and expands?

Answer 32. Both President Obama and I support efforts to revitalize the FDA and improve the agency's ability to ensure the safety of food and drug products used by American consumers. Active surveillance will help us to detect possible issues with treatments as early as possible and to alert health professionals about the potential dangerous side-effects of drugs already on the market. I look forward to working with the agency to ensure that HHS is using all available tools to prevent exposure to unsafe products and minimize adverse events.

Question 33. What improvements should FDA make administratively to better protect the safety of food and drugs imported into the United States? In your view, can the safety, quality and authenticity of imported products be assured by inspection or testing programs alone? What additional resources would FDA need to monitor the safety of medical products that are, either totally or partially, made overseas?

Answer 33. This is an important issue that, if confirmed, I look forward to working with Congress to address. Concern has been raised that our current system is inadequate. Many have offered ideas related to certification processes, which I believe should be thoughtfully considered.

Question 34. In light of recent safety issues with imported products, and data suggesting that drug importation would not save a significant amount of money, would you as HHS Secretary lift the prohibition on importation? If so, what amount of resources would the FDA need to insure the safe commercial importation of drugs, and would personal importation require more or fewer resources?

Answer 34. There are a number of options to lower the cost of drugs. We need to examine all of these options, from expanding the use of generic drugs, to providing greater flexibility to negotiate lower priced drugs when appropriate, to allowing reimportation of drugs from developed nations that, like the United States, have strict safety measures. That said, the recent incidents involving heparin and other consumer products has highlighted the potential challenges that must be addressed before we import drugs that we can be sure are safe and effective.

Question 35. The FDA is the gold standard among public health regulators the world over. The label is the most important communication mechanism for patients and providers about the benefits and risks of a drug or device. Patients and doctors need to know that they can rely on the label for accurate information. To ensure that science is the guiding principle for all information with the label, I believe the FDA must be the sole arbiter of what is and is not in the label. Do you agree that we should rely on the agency to provide accurate information in the label regarding the benefits and risks of a medical product?

Answer 35. I am concerned about recent instances in which the FDA took months to negotiate and approve safety-related changes to product labeling. I know that Congress worked to address some of these concerns in its recent FDA reauthorization by requiring companies to develop a Risk Evaluation and Mitigation Strategy (REMS). The REMS process will provide more tools to the FDA Commissioner in the agency's efforts to improve patient safety and expedite labeling changes to protect patients, and I look forward to working with the agency to uphold the protections enacted by Congress if I am confirmed as Secretary. I also look forward to working with Members of Congress to ensure the FDA maintains its reputation as the gold standard of consumer protection, and can continue to be relied upon by both patients and providers as a source of unbiased information regarding the benefits and risks associated with approved medical treatments.

Preparedness

Question 36. How can the Federal Government work most effectively with the States to make sure our country is adequately prepared to respond to the threats of terrorism and natural disasters?

Answer 36. Considerable progress has been made in recent years toward better protecting the country from all manner of disasters, including both natural events and the threat of terrorism. Working with other partners in Government, including the Department of Homeland Security, HHS has developed a series of plans and policies for response. Through grants to States and localities, HHS has built infrastructure for preparedness and response, trained and equipped front-line responders, and developed better systems for communication before and during a crisis. However, we are far from the level of preparedness that we seek. Major gaps remain

in many critical areas, including surge capacity for mass medical/casualty care, rapid disease detection, and food safety. The current Federal structure for public health emergency preparedness has several specific problems. Major limitations include: lack of strong leadership; understaffing; and inadequate coordination within and across Federal agencies. This can and must be improved.

Moreover, preparedness is a dynamic process that requires constant attention and sustained investment. Sadly, much of what has been accomplished in terms of building preparedness and response capacity is now at risk due to budget cuts and the economic crisis. Successful preparedness depends on vigilance, planning, and practice. If confirmed as Secretary of HHS, I intend to focus early and consistently on these issues. I will swiftly put in place an expert, experienced team to lead HHS disaster preparedness and response efforts. We will work closely with our partners at all levels of government, and with the private and not-for-profit sectors to ensure we have robust, clear, and well-established preparedness plans. This will include direct participation in drills and exercises to ensure full understanding of the complexities of the various potential scenarios, the level of preparedness for differing contingencies, and the critical areas for further work and development.

Comparative Effectiveness

Question 37. Recently, money for comparative effectiveness was included in the stimulus package. Many policy experts are also calling for more studies to compare the effectiveness of different treatments. While I agree that it is important that we pay for proven interventions, I am concerned that a drawback of such an approach can be that such studies tend to be “one-size-fits-all,” with the winning treatment recommended for everybody. At the same time, “personalized medicine,” in which genetic screening and other tests give doctors evidence for tailoring treatments to patients, is being touted as a way to improve care, but can result in the recommendation of a more expensive, but effective, treatment. How do you reconcile these two approaches so that we pay only for what works, but still give people the most appropriate care for them as an individual patient?

Answer 37. Comparative effectiveness researchers must acknowledge and examine differences among patients that may affect risk for disease, clinical presentation and diagnoses, and response to treatment strategies, which includes personalized medicine. Both doctors and patients must be active participants in comparative effectiveness research initiatives as we move forward. The goal of this effort is to improve care for patients, not hinder it through ineffective “one-size-fits-all” approaches.

Question 38. Comparative effectiveness research has great potential, but can be very difficult to conduct well. Do you have any recommendation as to what sort of entities should conduct this research?

Answer 38. Many of our agencies—NIH, AHRQ, and CMS—have begun to fund comparative effectiveness-related research, and to take the critical step of developing appropriate methodologies for such research. That said, we must be careful that political interests do not influence either the objectives of the conduct of comparative effectiveness research, and it may be appropriate to consider a new entity to lead such research. If confirmed, I look forward to working with the Congress as we move forward in this area.

Question 39. Comparative effectiveness has been touted as a critical component to addressing the quality issues surrounding health care reform. First, will this form of “research” be subjected to the same patient protection rules (IRB, HIPAA) as standard clinical research? Second, how will you increase the performance of necessary comparative effectiveness investigations involving comparing the value of two different drugs for the same medical purpose made by two different drug companies—research that is rarely undertaken now?

Answer 39. I am committed to patient protection rules in research and would expect them to apply to comparative effectiveness research. Comparative effectiveness research can take the form of clinical research, but it often takes the form of health services research. Every project should be assessed prospectively to determine the risk to patients and level of scrutiny required. In addition, the American Recovery and Reinvestment Act supports improving the methodologies for this type of research, improving its relevance and reliability.

Question 40. Comparative effectiveness, about which we have heard so much, is really a form of clinical research. Will this form of research come under the same rules as conventional clinical research, including IRB and HIPAA privacy rules?

Answer 40. As I stated in my answer to the previous question, comparative effectiveness research can take the form of clinical research, but it often takes the form

of health services research. Every project should be assessed prospectively to determine the risk to patients and level of scrutiny required.

Mental Health Parity

Question 41. Governor Sebelius, last year we passed landmark legislation to guarantee parity in health insurance for mental illnesses. How involved will you be in developing the regulations to implement that landmark legislation? What is the current status of the regulations?

Answer 41. I applaud Congress for taking action and passing mental health parity legislation last year. I believe both private and public insurance should include coverage of all essential medical services, including mental health care; and that serious mental illnesses must be covered on the same terms and conditions as are applicable to physical illnesses and diseases. Although a firm time line has not been established, I will work aggressively at HHS to implement the law swiftly and fairly.

Management and Coordination

Question 42. Prevention research is both basic and clinical. It is also supported by both the CDC and NIH. How are the efforts of these two agencies coordinated to prevent duplication?

Answer 42. President Obama has committed to expanding clinical and community-based prevention to shift our health care system from an "acute care" system to one that prioritizes health promotion and disease prevention activities. To be successful, prevention efforts must be coordinated and integrated across all of the Federal agencies, including CDC and NIH, but also AHRQ, which can help develop evaluation metrics; HRSA, which supports education and training of primary care providers; CMS, which can increase coverage for preventive services; and each of the other Federal health agencies. If I am confirmed as Secretary, I will develop an agency-wide strategy on prevention to leverage resources, reduce duplication, and develop measurable objectives to assess effectiveness.

Question 43. Many communities in the United States have many layers of health care services including city, county and State. These various agencies do not always work in a coordinated fashion with each other and with the Federal Government to bring the best services to needy people in these communities. How will you ensure that these agencies work more constructively with each other and with your agency?

Answer 43. The increasing fragmentation of our Nation's health system, which is reflected by the actual delivery of care as well as the financing mechanisms, has resulted in serious problems with respect to health care quality and efficiency. As you note, this challenge exists at the State and local as well as the Federal level, and is particularly problematic with respect to integration of health care, public health, and social services. This issue is a top priority for me and I believe the first step must be to focus on the programs, policies, and operations of HHS. Specifically, as we look at individual issue areas like public health or health care quality, we must examine the activities and resources of each department to assess for redundancy or duplication of effort, and we must integrate and coordinate activities as appropriate. If confirmed, I would like to hear your ideas and work with you to accomplish a high-functioning and highly efficient department.

SCHIP

Question 44. What are your views on how the SCHIP program should be reauthorized and what role will you play in enacting such a reauthorization? What steps will you take as Secretary to ensure that SCHIP dollars are used to provide health care coverage for lower income children before expanding the program to cover children from families with higher incomes?

Answer 44. I commend Congress for acting quickly to reauthorize CHIP earlier this year. Covering all children is central to our health reform agenda. To accomplish that goal, we need new initiatives to cover uninsured children who are eligible but not enrolled in CHIP and Medicaid, and most significantly, broader health reform. Like you, we believe in the importance of working to enroll lower income children, who are most in need of CHIP's assistance. We support provisions, such as those in the recently enacted CHIP reauthorization legislation, that provide States with incentives to enroll the lowest income children. If confirmed, implementing the reauthorized CHIP program will be a top priority.

Early Childhood Education

Collaboration

Question 45. Historically early learning at the Federal level has been exclusively under the jurisdiction of HHS. But at the State level, early learning is often focused on State preschool, which is frequently run by State education agencies—as it is in Kansas. States are working hard to create collaboration among education agencies and human services agencies to improve services to families. As Secretary, how would you work with other agencies, particularly the Department of Education, to improve the coordination and delivery of services to children under the age of 5?

Answer 45. As a Governor, I learned that collaboration between child care, Head Start, preschool, and other early childhood programs at education agencies is essential to achieving the objectives we are seeking for young children and their families. If confirmed as Secretary of HHS, I plan to work very closely with Secretary Duncan to coordinate our Federal early learning programs.

State Advisory Councils

Question 46. The Head Start Act requires States to create advisory councils to better plan and coordinate the delivery of education and health services to young children, including better connecting Head Start, child care, pre-k, and the K–12 systems. As Governor of Kansas, you signed legislation creating the Kansas Early Learning Coordinating Council to help achieve those goals. What role do you see the State Advisory Councils playing to improve the delivery of early childhood services?

Answer 46. As you indicate, as Governor of Kansas, I established an Early Learning Council to coordinate funding streams and link programs serving young children and their families. I found this to be a very effective strategy, and I believe State Advisory Councils and similar coordinating structures are valuable tools that can help States find creative and effective solutions to better serving children.

State Challenge Grants

Question 47. Right now many States struggle to connect Head Start, child care, pre-k, and their K–12 systems. President Obama has proposed creating early learning challenge grants to States through the Department of Education, which would help States coordinate early learning services. Little has been said by the Administration as to how these new challenge grants would be coordinated with other Federal resources and programs. Even less has been said about how these new grants would be funded while also sustaining increases to the Head Start and CCDBG programs contained in the ARRA. As Secretary, how will you work with Secretary Duncan to ensure that these grants are not duplicative of the purposes of the Head Start program? To what extent should Federal support be extended to programs that serve more than economically or otherwise disadvantaged children?

Answer 47. The President's proposed Early Learning Challenge grants provides an exciting opportunity to encourage States to raise the quality of their early learning programs, work to ensure a seamless delivery of services, and ensure that children are prepared for success when they reach kindergarten. If confirmed as Secretary of HHS, I intend to work closely with Secretary Duncan on this initiative, and work to coordinate early learning programs in both departments. I strongly support finding effective and efficient ways for Federal programs to meet the needs of socially and economically disadvantaged children and their families.

Abstinence Education

Question 48. Do you think it is important to provide a clear, undiluted message to our Nation's youth about avoiding behavior that puts their health at risk?

Answer 48. I believe it is important to be honest with young people about risky behaviors. In the context of abstinence education, I share the Administration's support for programs that stress the importance of abstinence while providing medically accurate and age-appropriate information to youth who have already become sexually active.

Question 49. As the Secretary, would you support a dedicated funding stream for Abstinence Education, separate from Comprehensive Sex Education, to assure that the message about abstinence and primary prevention is clear to our young people?

Answer 49. I support a wide range of public and private initiatives to reduce teen pregnancy using evidence-based models. Specifically, I share the Administration's support for programs that stress the importance of abstinence while providing medi-

cally accurate and age-appropriate information to youth who have already become sexually active.

Question 50. If evidence exists demonstrating that abstinence education is effective, would you support continued separate funding for this approach?

Answer 50. I would welcome the opportunity to review evidence regarding the effectiveness of abstinence-based education. As you may know, a recent HHS-funded, experimental study of abstinence-only programs found no behavioral effects relating to sexual abstinence or condom use.

QUESTIONS OF SENATOR HATCH

Employer Mandate

Question 1. According to a study published in 2007 by the *National Bureau of Economic Research*, an employer mandate of \$9,000 for family coverage would reduce wages by \$3 per hour and cause 224,000 workers to lose their jobs.

Harvard economist Amitabh Chandra stated that, “the populist view is this will only come out of profits. But, ultimately, the money will come out of wages. And, worse, for some people, it can’t come out of wages.”

What are your thoughts on imposing an employer mandate during the current troubling economic conditions on our labor sector and economy in general?

Answer 1. Business leaders in America are at the top of the list of those demanding health reform. They know that the real job killer is the status quo, not policies that improve the efficiency and accountability of the health system. They, along with workers and families, will benefit from policies like improved prevention, better chronic disease management, and health information technology that give us more value for the health care dollar. Yet, the solution cannot just come from Government. The President’s campaign plan emphasized shared responsibility. We believe that health reform can best be achieved with everyone participating and contributing to Health reform.

- Individuals have a responsibility to focus on health and prevention.
- Government has a responsibility to increase access and improve affordability.
- Insurance companies have a responsibility to ensure no discrimination; and
- Businesses have a responsibility to provide coverage or pay for it if they don’t.

This approach strengthens the employer-based system, ensuring it is an option for those that want to keep it. Most large businesses are currently offering coverage, and nothing would have to change for most of them under health reform—except that health costs may come down as system improvements kick in. The President also proposed on the campaign trail to offer small businesses a targeted tax credit, since these firms are the engine of job growth, particularly in our current economic crisis, and yet are crippled by high premiums and need the most help.

We are also committed to working with the American public and with Congress on this and other issues related to health reform. The President wants an open discussion about health reform and is open to all serious options.

STAAR/Antimicrobial Resistance

Question 2. Members of this committee have become increasingly more concerned about the issue of antimicrobial resistance and a number of bills were introduced during the 110th Congress, including the Strategies to Address Antimicrobial Resistance Act—or STAAR Act—which I introduced with Senator Brown. With regard to your comments about the role of the CDC, I am interested to hear your thoughts about this topic.

In the STAAR Act, Senator Brown and I have suggested a holistic approach to the problem of antibiotic resistance and establish a network of experts across the country to conduct regional monitoring of resistant organisms as they occur—which would be like a snapshot to pick up on problems early. Would you agree that there is importance in augmenting CDC’s current surveillance system with some sort of expert system?

Answer 2. Surveillance, including local and regional monitoring and reporting of antimicrobial resistance, is critically important in picking up on problems early. This kind of surveillance has to be part of a comprehensive strategy to prevent antimicrobial resistance and its spread.

Question 3. States have begun to require hospitals to implement testing programs as a method to identify, and appropriately care for patients with resistant infections. Do you see a role for the Federal Government to promote testing to provide consistency and a higher quality of care? If so, what do you envision its role to be?

Answer 3. The Federal Government can play an important role in promoting high-quality care, particularly for those with resistant infections. Strengthening surveillance, including promotion of patient testing for resistant infections at the local and State level, will be an important component of our Federal strategy. Disseminating evidence-based guidelines for care of patients with resistant infections (or those suspected to be resistant) and aligning financial incentives to support the provision of high-quality care are two ways to promote testing by providers.

Food Safety

Question 4. Over the years, there seems to be an increasing number of food safety recalls, more recently with peanut butter and now pistachios.

Do you believe this is a result of more adulterated food entering commerce or has the Government's method of finding those adulterated foods improved?

The method and process the CDC uses to identify the potential food hazard is often criticized as being tedious and slow. Do you have any ideas on how this process should be improved?

Answer 4. I agree that we must work to restore public confidence in our food safety agencies. One of our most significant challenges lies in the public's perception that we're not up to the job, which is the result of several factors. For example, the Government's ability to detect outbreaks and identify problems has remained problematic over recent years. In addition, the globalization of the food supply and the increasing complexity of distribution systems have introduced new challenges resulting in high-profile national recalls. If I am confirmed as Secretary, enhancing the Nation's food safety systems will be one of my top priorities, and I would work with FDA, CDC, my counterparts in other Federal departments, and Congress to make needed changes.

Office of Generic Drugs

Question 5. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, creating the generic drug industry and saving consumers billions of dollars. Since two-thirds of today's prescriptions are generic, I feel that this law has provided tremendous benefits for consumers. The law guarantees patients that generic products are safe and effective. It guarantees generic manufacturers that their applications are reviewed within 180 days. And it guarantees innovators that scientific experts have determined generic products are bioequivalent. Unfortunately, questions have been raised on these matters.

The biggest issue to me is that the Office of Generic Drugs (OGD) has not received the same funding levels as the Office of New Drugs—this office, receives guaranteed funding through user fees and appropriations. Not only has the Office of Generic Drugs had inadequate funding, it also has seen an erosion of its scientific base, and declining morale due to funding constraints. In fact, the agency admitted last year that it is still difficult to keep pace both with incoming applications and with other matters requiring OGD resources such as Citizen Petitions, lawsuits challenging the approval of generic drugs, and providing guidance to industry.

I am concerned that we may have a system that is broken and would appreciate your willingness to work with Congress to take the steps necessary to improve this situation.

Governor Sebelius, I have a keen interest in the success of the Office of Generic Drugs at the Food and Drug Administration. I have a series of questions for which I would like your response. Let me add that I recognize the need to move your confirmation along quickly. So, while I would like to have your answers to these questions promptly—and this should be achievable because I submitted the questions for the HELP hearing for Senator Daschle and their answers should have been in progress at the Department—I am comfortable with your providing answers to the more detailed of these questions by July of this year.

Governor, there is a rising tide of concern about the quality of generic drugs, which has been acknowledged by FDA's Janet Woodcock and Gary Buehler, two very respected officials. Indeed, Congress has heard serious criticisms about the Office of Generic Drugs (OGD) on a number of fronts:

- First, it is clear to all that OGD is seriously understaffed. That leads to gaps in recruiting and training staff, and to increasing workloads.
- Second, as I will discuss further in subsequent questions, credible concerns have been raised about the adequacy of OGD's scientific infrastructure leading to questions about whether patients can be assured that generic products now on the market are truly the same as the innovator product.
- Third, there are incredible lag times in review for a disturbing number of products. In fact, last year, FDA told the Congress that there was one product for which the application had been pending almost 11 years. There were nine applications

pending over 9 years, and 100 pending over 4 years. That seems extremely inconsistent with the law's requirement for a 180-day clock.

- Fourth, there are issues of morale relating both to the other better-funded parts of the Agency and also to the delay in the move to White Oak. I was the chief architect of the FDA Revitalization Act which authorized the unified campus now at White Oak, which I intended to serve as a magnet for academic creativity similar to the National Institutes of Health Campus. Leaving OGD out seems to send a clear signal that it is not as important as the other components.

So my question to you is quite simple. What will you do to reverse these trends and to establish an adequate scientific base at the Office of Generic Drugs? Will this be a priority for you?

Answer 5. Generic drugs play a critical role in keeping medicines affordable. For these drugs to fulfill their role, Americans must have access to them as soon as the law permits, and they must be as safe and effective as the brand name drug. I will work hard to make sure that the Office of Generic Drugs has adequate resources to review applications in a timely manner and to carry out those reviews with the best available science.

Question 6. I am aware that in April of last year, the FDA advised Congress that from 10/01/07 until 4/15/08 the Agency had hired 31 new staff representing a variety of scientific and clinical expertise who were undergoing training and afterwards would be expected to make significant contributions to review performance. Could you provide us an update as to the total number of such new hires and their contributions to review performance?

Answer 6. It is important for agencies to share information on the impact of major personnel changes with Members of Congress and their constituents. If I am confirmed as Secretary of HHS, I will ask FDA to provide this information to you in a timely manner.

Question 7. Governor Sebelius, could you provide the committee with the following information: The number of scientists hired in the last year by FDA's Office of Generic Drugs? An estimate of how many new scientists may be hired and added to OGD this year? An estimate of the Agency's funding allocated to the Office of Generic Drugs last year?

Answer 7. I agree it is important for Congress and the public to understand basic facts about the Office of Generic Drugs. If I am confirmed as Secretary of HHS, I will ask FDA to provide this information to you in a timely manner.

Question 8. Let me turn now to some of my specific concerns about the possibility that generic products approved by FDA may not, in fact, be bioequivalent to the innovator product. A couple of years ago, FDA approved generic copies of Wellbutrin, a widely used antidepressant. Many patients complained the generics didn't work, leading to serious problems like recurrence of depression and suicidality. An independent study showed the generics dissolved much more quickly than the brand, and this might be why the drug didn't work for some patients. In September 2008, FDA announced it would conduct a human clinical trial to address whether generic versions are truly the same as Wellbutrin.

Governor Sebelius, could you please answer the obvious question as to why the FDA is spending taxpayer dollars to prove generic products are the same as Wellbutrin when the law requires generic drug companies to do that? Does this mean, in fact, that a generic product which is not the same as the innovator is now on the market? But beyond that, could you or your staff explain to the committee the fundamental problem or reason that this situation could occur?

Answer 8. I agree that generic drugs must be shown to have the same safety and effectiveness as the brand name product and that Americans must have confidence in generic drugs. FDA therefore has two important responsibilities. First, it must rigorously assure that the tests it requires of generic drugs are adequate to establish that a generic is as safe and effective as the brand name product. Second, it must communicate effectively to the medical community and to the public about the quality of generic drugs and the standards it uses to approve them. I will work to ensure that FDA meets both of those responsibilities.

Question 9. Here is another specific case study I would like to discuss with you. In fact, it was the subject of a colloquy among several of us back in 2007, and involves bioequivalence methods for locally acting drugs, which FDA's Office of Generic Drugs (OGD) has recognized as a scientifically challenging area. As with most locally acting drugs, OGD historically required human bioequivalence studies for generic Vancomycin capsules, a locally acting antibiotic for life-threatening infections. In 2006, OGD abandoned human studies and instead said generics could be

approved if they dissolve rapidly in laboratory flasks. After the new method was criticized as adopted without public process and apparently data-free, OGD evaluated the method. The resulting data indicated the method was flawed. So in 2008, OGD abandoned its 2006 method and reverted to human studies, unless generics contain the same inactive ingredients in the same quantities as the brand, in which case OGD now proposes a new dissolution test. OGD's unexplained adoption and subsequent abandonment of bioequivalence methods for this life-saving antibiotic seem to be based in an unclear policy, if there is any policy basis at all, and do not enhance public confidence in generic drugs. Thus: Would you please provide the committee the record of FDA's development of these bioequivalence methods, including the specific data sets and scientific evidence FDA reviewed to: (a) develop the 2006 method, (b) abandon the 2006 method, and (c) adopt the 2008 method, the individuals who participated in developing the methods, and any other records discussing the methods?

Governor Sebelius, will you require FDA to test its latest Vancomycin capsule dissolution bioequivalence method and fully discuss in public forums, including FDA Advisory Committees, the scientific uncertainties and any potential risk to patients associated with the new dissolution method *before* using it to review or approve generic drugs? If not, how can the public be assured that generic copies will work the same as the brand, given that FDA already got bioequivalence wrong once for this drug, when it adopted its now-abandoned 2006 method?

Answer 9. Your question reflects the importance of FDA communicating clearly and effectively about its policies and changes to its policies over time. If I am confirmed as Secretary of HHS, I will ask FDA to provide information to you about the development of the test methods used to evaluate the bioequivalence of Vancomycin, and I will work to ensure the agency communicates effectively about its policies.

Question 10. In another case, in 2003 FDA approved generic copies of EMLA, a topical anesthetic. The approvals of EMLA generics were based on a blood-level bioequivalence test method, but FDA's stated and long-standing policy is to require human bioequivalence studies for generic versions of topical drugs like EMLA.

Governor Sebelius, could you please explain how FDA could say publicly that the science does not exist to allow use of blood-level bioequivalence studies for drugs like EMLA, but nonetheless approve generic copies of EMLA based on this method, and then used the flawed EMLA precedent as a substitute for scientific evidence in proposing bioequivalence methods for more complex topical drugs?

Would you please provide the committee the record of FDA's development of the blood-level bioequivalence method for EMLA generics, including the specific data sets and scientific evidence FDA reviewed to develop the method, the individuals who participated in developing the method, and any other records discussing the method?

Answer 10. If I am confirmed as Secretary of HHS, I will ask FDA to provide information to you about the development of the test methods used to evaluate the bioequivalence of EMLA.

Question 11. As you know, bioequivalence is the key test for approval of generic drugs. That said, appropriate methods for establishing bioequivalence of drugs are important to assuring the safety and effectiveness of both brand and generic drug products. In this time of constrained resources and a drive for more science-based policy decisions at FDA, do you agree that bioequivalence science and method development should reside in a single place in the Agency and not as competing efforts within both the Office of New Drugs and the Office of Generic Drugs?

Answer 11. I agree that bioequivalence testing methods must be based on the best available science. If I am confirmed as Secretary of HHS, ensuring that FDA decisionmaking is science-driven and that FDA's resources are used efficiently and effectively will be among my highest priorities for the agency. Having said that, it is also important that we avoid doing something that would inadvertently and unnecessarily delay the approval of safe and effective generic drugs. If confirmed, I will ask a new FDA Commissioner to review the question of bioequivalence method development.

CDC/Prevention

Question 12. As a longtime proponent for preventive health measures, I agree that the CDC plays a vital part in promoting good health and preventing disease and I was interested to hear in your testimony the figures related to health care costs that could be avoided with sufficient investment in prevention. What are your preliminary ideas about strengthening the agency's role and are there other Federal agencies you see being involved with promoting the goal of prevention in our health care system?

Answer 12. Wellness and prevention are urgent priorities. This century's epidemic is chronic disease: over 70 percent of costs and deaths result from it. Yet, we spend only 1 to 3 percent of our \$2.6 trillion health system on prevention.

The Centers for Disease Control and Prevention plays a pivotal role in promoting health and preventing disease. It has a large, talented, and dedicated workforce with respected scientists working in multiple disciplines. I will reinvigorate this team to focus on expanding the knowledge base and actual implementation of prevention and public health measures, commit to using evidence and science for public policy decisionmaking, and recruit and retain the best public health scientists. CDC should be a key part of health reform that improves health care quality through a focus on prevention and wellness. Specific priority areas of focus include obesity, smoking, HIV prevention, and preparedness and response.

NIH

Question 13. With regard to funding for the National Institutes of Health (NIH), what level of support do you think is needed to sustain scientific progress and capitalize on the discoveries of the past decade?

Answer 13. NIH research is under severe stress: after seeing its funding doubled between 1998 and 2003, the agency has been essentially flat-funded for the past 5 years, with scant increases that are well below the Biomedical Research and Development Price Index. This has produced a 17 percent loss of "buying power" for the agency since 2003, and an acute drop in the success rates for grant applicants, now as low as 10 percent for many NIH Institutes. A plan to achieve sustained growth of the NIH budget is much needed. "Feast or famine" is to be avoided. President Obama's pledge to increase funding for basic science research will enable the United States to regain its leadership in the area of biomedical research, expand training opportunities for the next generation of scientists, and stimulate local economies to create jobs.

With regard to reauthorization, the NIH Reform Act of 2006 represented a major legislative effort, and at the present time there are no fundamental issues that require such a complex undertaking in the 111th Congress. However, NIH leadership believes that there are a series of technical fixes that could clarify the intent or strengthen the Reform Act, and, if confirmed, I hope to work with you to make these changes.

Privacy

Question 14. With health reform in mind, the President and CEO of the Mayo Clinic, Dr. Denis Cortese has said, "Perhaps it's time to stop talking about the French Model, or the Canadian Model, or the German Model and start talking about the Utah model." What Dr. Cortese is talking about is the care provided by Intermountain Healthcare in my home State of Utah.

A pioneer in the use of information technology, Intermountain has long used electronic medical records to implement best practices and clinical protocols, resulting in higher quality care that actually costs less. For example, Medicare spending on patients with severe chronic illness could be reduced by a third, with improved quality, if the Nation provided care the way it's provided by Intermountain Healthcare, according to research from Dartmouth Medical School.

Essential to providing this high level of care is the appropriate use of and sharing of patient identifiable health information. I am very concerned that some of the provisions in the HIT (health information technology) portion of the stimulus bill could actually impede Intermountain and other providers' ability to provide this high-quality low-cost care. It is incongruous that, on the one hand, we are seeking to reform health care to provide better care at lower cost while, on the other hand, the stimulus bill makes significant changes to the HIPAA Privacy Rule that could actually impede providers' ability to appropriately use health information to provide better care.

One provision of particular concern reflects an unrealistic sense of hospitals' ability to track and store patient health information held in multiple information systems. The so-called "accounting of disclosures" provision would, for example, require enormous expenditures for a sweeping expansion of HIPAA's current accounting of disclosures requirement to include all non-oral disclosures for treatment, payment and health care operations. Intermountain Healthcare tells me that it would cost approximately \$250 million over 3 years to develop the capacity to move toward compliance with the new requirements. (Programming and other set-up cost approach \$68 million; storage costs for maintaining a rolling period of 3 years of audit data would be approximately \$78 million; Infrastructure development and maintenance costs, including personnel for managing the audit data, would cost approximately \$106 million.) Importantly, the current HIPAA rule rejected this approach

because these disclosures are so routine, so fundamental to the delivery of health care, and so voluminous.

As you implement the privacy provisions in the stimulus law, I ask that you look carefully at the cost of compliance and the impact on both the delivery of cost-effective and high-quality patient care at an individual patient level and, perhaps even more importantly, the ability to use patient health information to deliver better care to patient populations. Indeed, while electronic medical records are vital to improving care for a specific patient, they are an irreplaceable tool for improving care provided to all patients.

With respect to the stimulus law's expansion of the current accounting for disclosures requirement, the statute specifically states that the regulations:

"shall only require such information to be collected through an electronic health record in a manner that takes into account the interests of the individuals in learning the circumstances under which their protected health information is being disclosed and takes into account the administrative burden of accounting for such disclosures."

Included in this review should be consideration of the number of patient requests to date received by health systems for an accounting of disclosures report compared to the number of patients for whom care is provided by health systems, and whether there are alternate ways for patients to learn about how their protected health information is being disclosed. Can you please let me know if these important issues will be part of the discussion as you begin to put forth regulations on this issue?

Answer 14. It is absolutely critical that we ensure the privacy and security of patients' medical information. Only if we gain the trust of consumers will we ensure an effective and successful system. At the same time, it is important that we are mindful of the very real complexities and challenges faced by the providers and others in the health care system who must implement the interoperability standards we set. The best way to prevent problems from occurring is to move forward with a transparent process—to maintain a dialogue with all affected stakeholders. That way we can better understand and work to minimize the potential burdens on providers while we ensure that patients' information is confidential, secure, and used only in appropriate ways.

Question 15. I am disappointed that the security breach notification requirements the stimulus bill did not incorporate a risk-based standard (such that affected individuals are notified only when there is a reasonable likelihood of harm that could occur as a result of a breach of personal health information). In putting forth regulations relating to breach notification, please bear in mind that patient notification when there is no discernable risk of harm could unduly alarm the patient and multiples of such notifications could result in a patient's failure to pay attention to a breach notice which did require mitigating action on the part of the patient. I would be interested in being kept informed with respect to the development of these regulations, and your view of whether it is possible to somehow minimize the likelihood of patient notifications of security breaches that have no potential for harm.

Answer 15. Patient trust and confidence in the privacy and security of their personal health information is critical to the success of an interoperable health IT infrastructure. The breach notification requirement established by the HITECH Act will improve transparency and accountability. The earlier patients learn of a breach, the more likely they will be able to take steps to protect themselves. However, we recognize your concern that patients not be burdened with or worried by an abundance of "false alarms." In developing the guidance regarding "unsecured protected health information" and the regulations on breach notification, we would welcome your thoughts and suggestions, and, if confirmed, I would be happy to keep you informed of our progress.

Question 16. Governor Sebelius, about 10 years ago, the Government funded entity that oversees organ donations and distributions, UNOS, proposed to move the allocation of donated livers from a State to a regional system. That proposal was dropped due to significant and substantive opposition from States like my own. Just a few days after the start of this new Administration, UNOS revived this proposal and could move as early as this June to give it final approval. I have serious reservations about the substance and the timing of this proposal and am very much opposed to it going into effect—is this something you would be willing to take a look at for me?

Answer 16. Organ donation is an essential, life-saving gift from one person to another, and it is essential to the public's trust in the program that distribution be handled judiciously. If I am confirmed, I will be glad to review this proposal.

Dietary Supplements

Question 17. Governor Sebelius, as you might know the Dietary Supplement Health and Education Act of 1994 provides the FDA with the authority to oversee and regulate the supplement industry. In December 2006, Congress passed the “Dietary Supplement and Nonprescription Drug Consumer Protection Act” which the President signed into law and which required for the mandatory reporting of serious adverse event reporting for supplements. Do you agree with me, and with past Secretary’s of HHS and FDA Commissioners, that those laws are still adequate, not in need of amending, and gives the FDA sufficient authority to regulate the industry and protect the public/consumers?

Answer 17. Millions of Americans rely upon supplements to supplement their dietary intake, believing such products can help bolster their immune systems, protect them from disease, and slow down the aging process. I know that many clinicians and advocates believe that these products should be studied to make sure that the products are safe and effective. The FDA has a responsibility—just as it does with food, drugs, and devices—to make sure that the marketing claims for supplements are truthful, and more importantly that Americans cannot be harmed. Yet, the FDA must strike an appropriate balance between regulating these products and maintaining access for consumers. If additional authorities are needed, I will work with you to ensure that consumer access is not compromised.

Question 18. Governor Sebelius, are you aware that in the last several years the Lewin Group (a nationally recognized health care consulting firm) has both published and testified before Congress that dietary supplements not only improve health and quality of life but reduce health care expenditures by billions of dollars over a 5-year period—more specifically: (1) that the daily intake of 1,800 milligrams of omega-3 fatty acids can reduce the occurrence of coronary heart disease (CHD) resulting in a cost savings of in excess of \$3.1 billion due to CHD being avoided; (2) that a daily intake of 1,200 milligrams of calcium with vitamin D can prevent nearly a million hip fractures from occurring resulting at a cost savings of \$13.9 billion, and, (3) that if 10.5 million additional women of child bearing age would take 400 micrograms of folic acid daily, that more than 600 babies would be born without neural tube defects and result in a cost savings of \$1.3 billion. Hearing those benefits and cost savings would you be so inclined to include those three FDA fully recognized health claims and supplements in your health care reform package?

Answer 18. As a part of his health reform agenda, the President committed to covering evidence-based prevention services in public plans as well as private plans offered through the Exchange.

QUESTIONS OF SENATOR MCCAIN

Health Reform

Question 1a. Employer-based health insurance is an important component of our Nation’s health care system. President Obama’s budget states that any health reform initiative must allow those with employer-sponsored coverage the option of keeping their coverage. At the same time, many have proposed that a Government-run health plan be made available to all Americans. I have many concerns about such a proposal and fear that millions of Americans who already have insurance could be forced into a Government-run plan (Lewin study estimates 120 million Americans could lose their employer-based coverage and be pushed into a Government-run plan).

Do you support the creation of a national or regional-based health insurance exchange?

Answer 1a. The President’s campaign plan proposed a health insurance exchange. It would provide consumers with easily accessible information on health plans and pool purchase power for more affordable, high-quality coverage. We look forward to working with Congress on these and other ideas.

Question 1b. Would you support the creation of a Government-run plan to function in a health insurance exchange? If so, how do you envision the Federal Government competing against private insurers?

Answer 1b. The President has outlined a series of principles that he would like reforms to encapsulate, including the principle of choice. The President’s campaign plan proposed a public option alongside private insurance options in a National Health Insurance Exchange, which would give Americans greater choice of plans. Such a proposal would also ensure greater competition, pushing private insurers to compete on cost and quality instead of gaming the system to avoid costlier patients. At the same time, he recognizes the importance of a level playing field between

plans and ensuring that private insurance plans are not disadvantaged. That said, the President is open to exploring all serious ideas that achieve these common goals. He will work with Congress on this and other elements of the plan.

Question 1c. Would there be a minimum benchmark for benefits? If so, how would this level be determined?

Answer 1c. The President's goal is to provide all Americans with affordable, accessible, high-quality health care. We look forward to working with Congress on this and other ideas.

Question 1d. Would you support a mandate requiring individuals to purchase health insurance coverage? If not, would you support a mandate requiring employers to provide coverage to their employees?

Answer 1d. The President believes that every American should have affordable, high-quality coverage. Making health insurance affordable is key to making it universal. Most people don't have coverage because health insurance is unaffordable. As premiums have doubled in the last 8 years, the problem has only gotten worse. As for specific proposals, there are many ideas in Congress and in the country on how to cover all Americans, and we look forward to working with leaders in the House and Senate to finally achieve this critical goal.

Question 1e. How much would running a Government-run plan cost and where would the money come from?

Answer 1e. To be clear, the President's campaign health care plan envisioned a public plan operating in a health exchange alongside private plans; private insurers would continue a role under his vision for health reform.

Ensuring affordable coverage will require an up-front Federal investment. This investment, along with the Recovery Act initiatives, will yield long-run cost savings for both taxpayers and the Federal Government. The President is committed to working with Congress to find responsible ways to pay for this investment. This includes policies to reduce health care costs and premiums for families through the following improvements aimed at increasing the efficiency of the health care system:

- Expansion of Health IT, which should reduce unnecessary spending in the system that results from preventable medical errors and duplicative tests and facilitate improvements in the quality of health care.
- Improving prevention of illness through wider use of vaccines, screening tests, and proven community-based programs.
- Expanding the use of case management for chronic conditions such as asthma, diabetes, and congestive heart failure. This should reduce hospitalization costs and save money.
- Ensuring that providers and patients have access to comparative effectiveness information on what interventions work best to help patients get the best value for their treatment dollar.

Our goal is to fix our broken system and cover all Americans in a fair and fiscally responsible manner that improves quality and lowers the long-run growth of health care.

Question 1f. How would you ensure that those who are happy with their employer-based coverage can keep that coverage and not see premium increases due to the new Government-run plan?

Answer 1f. We believe successfully reforming the health care system involves building on the current structure, preserving the private health care system, and ensuring that all Americans have choices. As the President has said, he wants to make sure that if you like your health care, nothing has to change. In fact, health coverage will be more affordable to employers and workers as the policies to drive efficiency and value in the system take effect. We look forward to working with Congress to develop a plan that builds on the system we have while reforming it to ensure health care is affordable and all Americans are covered.

Question 2a. Under current law, individuals who receive employer-based health insurance can exclude those benefits from taxation—in effect, a huge tax subsidy that the Congressional Budget Office (CBO) estimates is about \$260 billion per year. Unfortunately, this is also an unfair tax advantage that is not enjoyed by the millions of Americans who do not receive employer provided health benefits. In my view, we must reform our tax code to make it fairer for all Americans by replacing the existing tax exclusion with refundable tax credits for all Americans, regardless of income level.

Would you support changing the tax code to promote fairer treatment for those that do not receive tax benefits from their employers?

Answer 2a. The President believes health reform should build upon the existing employer-based health care system, through which the majority of Americans receive their health care. The tax exclusion contributes to sustaining this system. That said, he recognizes that many members of Congress have views on that subject, and he and I look forward to working with Congress to examine ways to ensure the strength of our existing employer-based health care system while improving affordability and accessibility for all Americans.

Question 2b. If you would support removing the tax exclusion, what would those funds be redirected to cover?

Answer 2b. The President has stated that he would consider addressing reforms of the tax exclusion among other sources of financing if that is what it takes to cover all Americans. However, he has not proposed removing the tax exclusion because this would result in a tax increase for millions of middle-income Americans at a time when they cannot afford it.

Question 2c. Would removing or capping the exclusion, cover the estimated cost of the Obama health plan?

Answer 2c. The President's budget includes proposals that would raise \$634 billion over 10 years for health reform. About half of this funding would come from ideas to improve efficiency and accountability and promote shared responsibility in the health system. The President is committed to reducing the cost of the system as well as finding ways to pay for it. His budget also included a proposal to return to the Reagan-level of tax deductions for high-income taxpayers. This reserve fund is significant but not enough to fund health reform. We look forward to working with Congress to examine ways to fund needed up-front investments in our broken health care system, with the knowledge that such up-front investments will be more than recovered through long-run savings.

Question 3a. Even though the Medicare program is outside the purview of the HELP Committee, no one can deny its influence on every aspect of our health care system that is under our jurisdiction.

How soon do you expect to have a CMS Administrator in place?

Answer 3a. If confirmed as Secretary, one of my highest priorities will be to ensure that we have the highest caliber individuals to administer all of HHS's agencies, including the Centers for Medicare and Medicaid Services (CMS). For CMS, I will ensure that the Administrator has the necessary experience and trust of Congress to successfully administer the Medicare, Medicaid, and CHIP programs. And that person should also have the necessary experience to lead the transformation of the U.S. health care system to produce greater health care outcomes and value for all consumers and businesses. It is my hope that we can have a CMS Administrator who meets these criteria in place as soon as possible.

Question 3b. How do you plan to reform the Medicare program and what steps will you take to reform its payment system?

Answer 3b. The Medicare program faces many challenges, including transforming its fee-for-service program to ensure that it better rewards quality outcomes, primary care, prevention, and care coordination. I also believe the program can create strong incentives for Medicare Advantage and prescription drug plans to create greater value for their Medicare enrollees. Finally, the Medicare program's resources are not sufficient for the long-run. If confirmed as HHS Secretary, I will work with the Congress to undertake a fundamental review of Medicare's payment systems to ensure that the program rewards overall value of care. The President's Budget proposes several steps to move in this regard, such as encouraging more integrated and coordinated physician care and increasing incentives for hospitals to reduce avoidable and costly re-admissions. I look forward to working with Congress to implement these and other payment reforms.

Question 3c. What is your view on reforming Medicare payments to encourage high-value care?

Answer 3c. Reforming Medicare's payments systems should be a priority element of any health reform effort. Such reforms should ensure that Medicare beneficiaries receive the highest quality care and that Medicare trust fund resources are used prudently. Moreover, private insurers generally follow Medicare's lead, and we should expect that enacted Medicare payment reforms will set the example for the entire health care system. I share the President's view that Medicare's payment system for physicians should promote greater primary care and preventive care to ensure that chronic conditions are prevented and better managed to reduce overall health care costs. In addition, the President's Budget proposes several very impor-

tant Medicare payment reforms, such as bundling of hospital and post-acute care services. These reforms will move Medicare away from paying for care in a silo-ed fashion, which currently rewards health care providers for the volume of the care they provide rather than the value of the care.

Comparative Effectiveness Research

Question 4. I believe that, if done correctly, comparative effectiveness research can help provide patients and their doctors with the vital information necessary to make the right decisions in an individual's medical case. However, I have also heard from many patient and provider groups who have expressed concerns about just how this research will be conducted and used. While there would be benefits, they are justly concerned that such research can be used to hamper or impede access to beneficial care. I worry that comparative effectiveness research could be used in a similar fashion to NICE in the U.K., where centralized authorities decide which cancer patients can receive life-saving care and which are denied access to beneficial treatment options.

Do you share these same concerns?

Answer 4. Comparative effectiveness will help consumers and providers make informed health care decisions based on effectiveness and appropriateness of treatments. Business groups, including the National Business Group on Health, support this effort because it will bring value to health care spending. Comparative effectiveness is about spreading information on what's most effective; it has nothing to do with Government dictating choices. In fact, it is prohibited by law for Medicare to use comparative effectiveness research for payment decisions.

Question 5. I think that any comparative effectiveness research financed or conducted by the Federal Government should not be paired with regulatory powers to dictate practice patterns. Acting National Institutes of Health Director Raynard S. Kington testified that his agency may use money from the stimulus bill to fund grants for comparative effectiveness research that includes comparisons of the costs of the treatments involved.

What assurances can you offer the American public that the funds provided in the stimulus bill for comparative effectiveness research will not be used to create restrictions to access to care?

Answer 5. I can assure you that the information gleaned from comparative effectiveness research will not be used for coverage decisions for Medicare, as dictated by a 2003 law.

Question 6. Medical research and technology is moving increasingly towards individualized medical treatments, that is, the future of medicine seems to be moving towards treatments that are tailored to individual patients and may not work for everyone. However, this approach could potentially conflict with efforts to compare the effectiveness of treatments based on an "average" patient. I'm concerned that individuals in vulnerable populations, such as minorities, women, or individuals with multiple conditions could be squeezed into a one-size-fits-all treatment model.

How will you ensure that comparative effectiveness research supports personalized medicine?

Answer 6. The goal of comparative effectiveness research is to inform physician and patient decisionmaking—to empower doctors and patients with more information on quality care. It is not to mandate specific care. We are mindful of the need for research to address the needs of each patient and that is our goal with this and other research.

Small Business Health Insurance Market Reforms

Question 7a. I am greatly concerned over the wide disparities in health insurance costs, quality, and coverage across the Nation, and especially between States in the small business health insurance market.

How would you propose to solve this important issue that is overburdening our Nation's small businesses?

Answer 7a. The President's campaign plan proposed a health insurance exchange to enable small businesses and individuals to pool together to obtain affordable health coverage. He also proposed a small business tax credit to help make health care affordable for small businesses to cover their employees. The Congress also has many ideas on this subject. We look forward to working with you on this and other ideas.

Question 7b. Would you object to a national health insurance market/exchange?

Answer 7b. No, I would not. It was part of the President's campaign health care plan.

Question 7c. Would you allow this exchange to facilitate having people buy insurance across State lines? Could people simply buy insurance in a national exchange or will there also be a minimum benefit design too?

Answer 7c. There are many possibilities for how an exchange could be run to promote competition, transparency, quality, and affordability. We look forward to working with Congress to further those goals through a reform such as a health insurance exchange.

Question 7d. Who would be responsible for a minimum benefit design and how would you guarantee that it could be adapted as medical care evolves through innovation and technological breakthroughs?

Answer 7d. Our Nation is a world leader in the development of new technologies and treatments for some of humanity's most devastating illnesses. Ensuring the accessibility of effective innovations is a hallmark of any comprehensive health reform. If confirmed, I look forward to working with Congress to address this and other issues related to ensuring affordable, high-quality health care for all Americans.

Health Information Technology

Question 8a. The recently enacted economic stimulus bill provided \$19 billion for health information technology adoption. Given the poor track record of the Federal Government's efforts in modernizing and updating our agency record systems in agencies such as the FBI and FAA, many are concerned that this will not be sufficient funding.

Given the poor track record of the Federal Government in its efforts to modernize agency record systems, do you believe additional money will be required for this conversion to electronic medical records? If yes, how much?

Answer 8a. The Obama administration is committed to meeting the Recovery Act goal of ensuring that every American has an electronic medical record. The Recovery Act's investment of nearly \$20 billion will allow HHS to make critical up front investments to facilitate the adoption and use of health IT, while the provision of financial incentives through Medicare and Medicaid beginning in 2011 for the meaningful use of health IT will further advance this goal.

Question 8b. What steps will you take as Secretary to ensure that this \$19 billion of taxpayer dollars will lead to interoperability among the different electronic records systems used by providers and hospitals?

Answer 8b. A nationwide interoperable health IT infrastructure is a fundamental building block for broader health reform. A key Federal role is ensuring that systems are interoperable and that patient privacy is assured, and the Recovery Act gives HHS the tools to fulfill that role. The standards and certification process established in the Recovery Act will assure providers that the electronic medical record systems they purchase are indeed interoperable, while spurring innovation and competition as vendors develop products that meet these standards and the needs of providers in the system.

We have been talking about health IT for many years. If confirmed, I look forward to making sure that the Recovery Act investment will be spent in a targeted, effective manner to:

- provide every American with an interoperable electronic medical record,
- reduce medical errors,
- protect patient privacy,
- improve the quality of care for patients, and
- reduce costs in the healthcare system.

Question 8c. Converting to electronic medical records will be an expensive process at every level but especially at the provider level. What steps will you take to ensure that providers, especially those in small practices, are not overburdened with Health IT costs?

Answer 8c. Many physicians want to adopt health IT, but do not have the ability to invest upwards of \$40,000 in the technology systems. By providing physicians and other providers with financial assistance for adoption and use of interoperable HIT, we will help reduce this burden on providers. The Recovery Act creates grant and loan programs as well as education and technical assistance opportunities to help providers, especially those in small practices, to overcome barriers to adoption and assist them in using these systems to reduce costs and improve quality for their patients.

Indian Health Services

Question 9. As you know, the Federal obligation for the provision of health care services to Indians arises out of the special trust relationship between the United

States and Indian tribes. I believe that much more needs to be done to address health care needs on Indian Reservations and in Alaskan Native Villages and that is why I have sponsored efforts to elevate the position of Indian Health Services Director to the status of an Assistant Secretary in the Department of Health and Human Services.

As the Secretary of Health and Human Services, would you support a similar provision that establishes the post of Assistant Secretary for Indian Health?

Answer 9. I understand that tribes have recommended this for many years because of the importance of the Government-to-Government relationship, the trust responsibility of all agencies in HHS to tribes and their members, and their desire to have increased access to the Secretary to make sure the needs of IHS are addressed. I plan to review this proposal and try to find the best solution to ensure that the health and human services needs of Native Americans are addressed at the highest levels throughout the Department. If confirmed, IHS will be a high priority for me, and that priority will be reflected throughout HHS and its activities.

Question 10. There's all too often a perceived disconnect between the IHS and the higher functions at DHHS. In particular, DHHS hasn't adequately incorporated tribal recommendations in its final budget requests, despite tribal participation throughout the budget process via the National Indian Health Board and others. This has resulted in the Administration budgeting for far less than what the tribes tell us they require.

Can you assure the committee that you will cultivate collaboration between the Assistant Secretary for Health, the IHS Director, tribes, and tribal organizations when developing a responsible IHS budget to raise the health status of American Indian and Alaska Natives?

Answer 10. Yes. If confirmed, I will work to improve collaboration between all parties involved to improve the health status of American Indians and Alaska Natives. As you know, the Department conducts ongoing consultation with tribal Governments and tribal leaders. I want to use that consultative process to identify ways we can improve IHS and other HHS services, coordinate efforts to ensure the budget supports those services, and make them reflect a true partnership between the Department and Native communities. I am confident that Dr. Yvette Roubideaux, the President's nominee for IHS Director, and Dr. Howard Koh, the President's nominee for Assistant Secretary for Health, are equally committed to those goals.

Question 11a. I believe we must do more to ensure the ability of the elderly and disabled American Indians and Alaska Natives to access Medicaid and Medicare, in particular, the prescription drug benefits available under Medicare Part D. Currently, the Indian Health Care Improvement Act authorizes the use of Indian Health Service funding to pay for Medicare Parts A and B premium payments for Indians, but not for Part D.

Would you support amending the Indian Health Care Improvement Act to allow the use of IHS funds to pay the monthly premium of an Indian who is a Medicare Part D eligible individual enrolled in a prescription drug plan or Medicare Advantage-Prescription Drug Plan (MA-PD)?

Answer 11a. I definitely agree we need to do more to ensure elderly American Indians and Alaska Natives and those with disabilities have access to the prescription drugs and other Medicare and Medicaid services they need. If confirmed, I will give serious consideration to any feasible proposals that may be advanced as amendments to the Indian Health Care Improvement Act. I hope to have the opportunity to work with you toward that end. Of course, as you have noted, an infusion of IHS funds will be necessary to accomplish the goals of any such proposal.

Question 11b. Second, will you continue the administrative policy to deem IHS and tribal health care "creditable coverage" or, if not, whether you would support a legislative fix?

Answer 11b. It is my understanding that any provider of prescription drug coverage can have its coverage deemed as "creditable coverage" provided that beneficiaries receive at least the same level of prescription drug coverage as provided in Part D. As required by CMS, the IHS has performed an analysis of its drug coverage and has certified with CMS that its drug coverage meets the requirements of the creditable coverage definition. While I do not anticipate amending this policy, if confirmed, I will examine this issue closely to determine whether a change—administrative or legislative—is necessary.

Health

Question 1. Alaska's youth suicide rates have spiked; we witnessed 146 deaths by suicide in 2007, almost a 15 percent increase over previous years. In December alone, we lost two young lives to suicide in a town with less than 900 people and as I'm sure you know, Native American/Alaskan Native and Hispanic youth having the highest rates of suicide-related fatalities. How would you reduce youth suicide rates? What more can we do to stem the tide in the rising number of youth suicides?

Answer 1. I am aware of the devastating problem of suicide, especially among American Indian and Alaska Native youth, and solutions to this problem require the participation of many partners throughout the Federal Government and in tribal communities. For example, we need teacher and other staff education in schools to make sure they are able to identify and help at-risk kids. We need creative solutions, such as telepsychiatry, to bring needed mental health services to rural communities that have shortages of local providers. We need to strengthen policies and regulations to ensure that youth who attend boarding schools or regional treatment centers are still covered for needed mental health services.

All interventions must be culturally competent, incorporate strengths and positive aspects of Native culture, and integrate with broader efforts to address the poor economic and social conditions in Indian communities. Finally, adequate funding is the linchpin to the success of any intervention—the significant underfunding of IHS has limited the ability to provide adequate mental health services and recruit and maintain an adequate number of providers in many communities. I look forward to working with Congress to find solutions and resources for this devastating problem.

Education

Question 2. In 2005 and in 2008 the Office of Head Start (OHS) told the Chugachmuit and Aleutian Pribilof Islands Association Head Start agencies (each serving a collection of very small communities) that they would not be able to operate a center-based program in communities with fewer than 12 children enrolled. The Office of Head Start has confirmed, after closing at least one Head Start center in Alaska for as much as a year, that there is no statutory or regulatory minimum class size for Head Start centers, just a regulatory "recommendation." Will you confirm that under your leadership, the Office of Head Start will never again threaten to close, or close a Head Start Center in Alaska's very small communities if the only reason is that there are fewer than 12 children enrolled, without the consent of the grantee?

Answer 2. Ensuring access to quality early childhood programs to as many eligible children as possible is an important priority for the Obama administration. I will look carefully at the Head Start performance standards and take into consideration the special needs of rural communities and Native Alaskans served in the Head Start program. We need to make decisions based on the dual goals of flexibility in serving rural areas and assurance of viable, high-quality programs. We need to think creatively to attain those goals, and I want to work with you and others in Congress toward that end.

Indian Health

Question 1a. In my judgment, one of the most important responsibilities of the Secretary of Health and Human Services is to provide leadership to the Indian Health Service. Would you agree with this characterization and what role do you see yourself playing in improving the healthcare provided to America's first peoples?

Answer 1a. I agree completely. If confirmed, I intend to work with the Director of the Indian Health Service, the Centers for Disease Control, the Administration for Native Americans, and all appropriate agencies within the Department and across the Government to advance the mission of raising the physical, mental, social, and spiritual health of American Indians and Alaska Natives. President Obama has nominated Dr. Yvette Roubideaux to lead IHS, and I am excited about the extraordinary talent, experience, wisdom, and energy she will bring to that job.

The task is both enormous and urgent. The IHS patient population is underserved. As you know all too well, that is due, in large part, to historically inadequate funding—for direct and contract health services, for facilities, and for personnel—and I am pleased that the American Recovery and Reinvestment Act (ARRA) and the President's budget are signaling an effort to begin to address that funding shortfall. Of course, many other factors contribute to the significant health disparities facing the Indian population in both rural and urban areas. In addition to more funding, we need strategies to address the diabetes that is epidemic among American Indians and Alaska Natives, the high youth suicide rate you raised ear-

lier, and the underlying causes of these and other threats to the IHS population's health. Just as we need to do across the country, we need to emphasize prevention, and that includes efforts like ensuring that those living in rural areas have greater access to affordable fruits and vegetables and other healthy foods. We need to look at the whole picture, and that's what Dr. Roubideaux and I hope to have the opportunity to do.

Question 1b. Do you bring to the position of Secretary any direct experience in the challenges facing the Indian health care delivery system?

Answer 1b. Yes. In the State of Kansas, we have the White Cloud Indian Health Station, the Horton Health Center, the Haskell Health Center and the Hunter Health Clinic. These facilities provide service to the Kickapoo and Potawatomi Tribes as well as other tribes receiving services, including those getting care from the Hunter Health Clinic, which serves an Urban Indian population.

Question 1c. How would you characterize your familiarity with the challenges facing the Indian health care delivery system?

Answer 1c. Tribes have identified the need for resources to address the challenge of a growing population both for those who are currently eligible to receive services through the Indian Health Service and for those currently seeking Federal recognition who might become eligible for services pending Federal review or congressional action. The American Recovery and Reinvestment Act also acknowledged that certain needs must be addressed by providing \$500 million to address Health Information Technology activities and for the completion of two facilities construction projects already underway, including the IHS facility in Nome, AK. HHS and IHS consult with tribes on an annual basis to hear from them directly about challenges they are facing. In addition, there are several provisions in ARRA that address Medicaid and CHIP issues to benefit those who receive services from IHS or from programs operated by tribes or tribal organizations through self-governance contracts and compacts.

Question 1d. How do you intend to improve your understanding of the Indian health system and its challenges?

Answer 1d. The Department conducts ongoing consultation with tribal governments and tribal leaders in an effort to stay abreast of the needs of the Indian population. I want to use that consultative process to identify ways we can improve IHS and other HHS services and make them reflect a true partnership between the Department and Native communities. Dr. Yvette Roubideaux, the President's nominee for IHS Director, will also help me understand new ways to serve the American Indian/Alaska Native population. My experience in Kansas will certainly help, and I hope to visit IHS facilities across the country to understand the unique challenges various communities—rural and urban—face. I also understand the Department maintains the Intradepartmental Council on Native American Affairs (ICNAA) as authorized by the Native American Programs Act. The Director of the Indian Health Service co-chairs this Council with the Commissioner of the Administration for Native Americans. This Council serves to keep the Secretary apprised of the implementation of current initiatives as well as those under development that are critical to the effective service the Department provides to both Native American individuals and those specifically eligible to receive services from IHS and its programs.

Question 1e. The National Indian Health Board has long been of the view that the Director of the Indian Health Service should be elevated to an Assistant Secretary level position. Do you agree that the position should be elevated?

Answer 1e. I understand that tribes have recommended this for many years because of the importance of the Government-to-Government relationship, the trust responsibility of all agencies in HHS to tribes and their members, and their desire to have increased access to the Secretary to make sure the needs of IHS are addressed. I plan to review this proposal and try to find the best solution to ensure that the health and human services needs of Native Americans are addressed at the highest levels throughout the Department. If confirmed, IHS will be a high priority for me, and that priority will be reflected throughout HHS and its activities.

Question 2a. Some tribes continue to rely upon the Indian Health Service to deliver health care to our Native people. However, many tribes have elected to deliver the healthcare themselves under Indian Self Determination Act compacts and contracts. This is how Indian health care is delivered in Alaska. Self determination and self governance tribes have long been concerned that the amount of money that the Indian Health Service budgets to pay Contract Support Costs is grossly inadequate to meet its obligations to the tribes.

In your judgment, is this concern justified?

Answer 2a. Contract Support Costs (CSC) are essential to a self-governance tribe's ability to effectively operate a program assumed under the ISDEAA. Pre-award costs, start-up costs, direct and indirect CSC all require a level of funding adequate to meet the needs of this program. If confirmed, I will work to ensure that adequate funding is available and that competing priorities within IHS and tribally operated programs are not compromised.

Question 2b. How does the deficiency in Contract Support Cost funds affect the access to and quality of health care delivered to our Native people by contractors and compactors?

Answer 2b. To the degree that there are deficiencies in the CSC funds, if confirmed, I will support the IHS's continued consultation and participation with tribes to identify the best means of administering and allocating CSC funds. Consideration of access and quality health care must be first and foremost in the determination of sound CSC allocation policies.

Question 2c. How would you suggest that the Federal Government as well as the compactors and contractors address the Contract Support Cost shortfall?

Answer 2c. Continued consultation with Tribes is essential to determining the level of need in this program area. Certainly, lines of communication must be open. In addition, IHS must review its allocation policies to ensure that funding for CSCs are reasonable and necessary. Finally, it is crucial for Congress to work with the President and the Secretary to support increased funding.

Question 3. The American Indian and Alaska Native community has long believed that funding for the Indian Health Service is grossly inadequate. Senator Daschle was fond of reminding the Senate that America spends substantially more for the care of each Federal prisoner than it does for the care of each Indian. My colleague, Senator Dorgan, and I frequently speak to this issue on the floor of the U.S. Senate. Do you share our concern that the Indian healthcare delivery system is grossly underfunded and how would you intend to address this issue if you are confirmed?

Answer 3. I share that concern and applaud you, Senator Dorgan and Senator Daschle, for bringing this serious issue to the attention of your colleagues and the American people. The Indian Health Service meets less than 60 percent of the healthcare needs of this population. The current funding levels have not kept up with inflation, population growth, and the rising cost of medical services. As a result, IHS must grapple with rationing of needed healthcare services, a lack of infrastructure for health IT expansion, and an inability to maintain healthcare facilities. Notably, the IHS Federal Health Disparity Index study estimates that to fully fund the clinical and wraparound service needs of the Indian health care system, the IHS budget would need an additional \$15 billion.

If confirmed, I plan to work closely with Congress to find ways to increase the IHS budget so we can meet the healthcare needs of our First Americans. I recognize the challenges of finding this funding while our Nation deals with the economy and other issues, but I would like to make improving the IHS a priority during my term should I be confirmed.

Question 4. A few of my colleagues have been working together to resolve issues regarding the Indian 477 Employment and Training program. Through the program, American Indian Tribes are able to integrate their employment and training programs that they receive from the Department of Interior, the Department of Health and Human Services, and the Department of Labor. The 477 program enables tribes to integrate their employment programs, and reduce burdensome and redundant regulatory requirements. The spirit of the 477 program enables tribes to submit a single plan, single report, and single audit to the Department of Interior. Interior administers the programs. I want to take this opportunity to make you aware that over the last few years, the HHS has been attempting to pull out of the program over concerns regarding the contract mechanism the Department of Interior uses to deliver the funding, the budget and audit procedures that Interior uses, and the sharing of information between agencies. The program in particular controversy has been the TANF program at HHS. In the last Congress, my colleagues (Baucus, Dorgan, Cantwell, and Murkowski), and I mediated between the agencies, and encouraged the two departments, to work with OMB in resolving the concerns, with the goal to keep the 477 program intact. I wanted to ensure that during the Senate confirmation process that you are aware of this issue. Will you be able to provide me with an update on the status of negotiations with OMB and be willing to work to the fullest extent possible that HHS remains a committed and viable partner in the 477 program?

Answer 4. Thank you for bringing this to my attention. I am committed to supporting tribal employment and training programs. My understanding is that progress has been made in the discussions with the Department of the Interior and HHS, with OMB's assistance and that the Tribal TANF program has continued the tribes' participation in the 477 program. If confirmed, I will explore this issue in more depth and work to the fullest extent possible with Interior and OMB to resolve any outstanding issues with the Tribal TANF and 477 program. Toward that end, I will appreciate your input.

QUESTIONS OF SENATOR COBURN

Question 1. Which programs within the Department, if any, do you think can be eliminated because they are ineffective, duplicative, unnecessary, or have outlived their purpose?

Answer 1. President Obama has announced his plan to conduct a comprehensive, in-depth review of the various programs and policies at the Federal agencies. While we believe it is premature to announce a series of programs that should be eliminated ahead of that process, there are already initiatives that the President has stated should be cut. For example, Medicare Advantage overpayments are an area where we can make cuts, given the current budget realities.

Question 2. President Obama promised to conduct "an immediate and periodic public inventory of administrative offices and functions and require agency leaders to work together to root out redundancy." When do you plan to start this and when can we expect you to complete it?

Answer 2. As Governor, I have made it a high priority to ensure that taxpayer dollars are used efficiently and effectively. I directed the consolidation of our health agencies in Kansas, reducing bureaucracy and improving performance. I created a Fraud Squad that recovered \$7.5 million during my term. If confirmed, I will bring this same energy to running the Department of Health and Human Services, and I fully intend to work on improving the Department's performance every day that I am Secretary.

Question 3. President Obama has often pledged to conduct Government affairs with an unprecedented level of transparency. Currently all recipients of Federal grants, contracts, and loans are required to be posted online for public review. Do you support making all Federal assistance including subcontracts and subgrants transparent in the same manner? Will you comply on a timely basis with the Transparency and Accountability Act?

Answer 3. I do support the President's commitment to maximizing transparency in the Federal grant, contract, and loan process. If confirmed, I will help implement nearly 20 percent of the American Recovery and Reinvestment Act. The President directed that this critical funding be implemented with unprecedented levels of accountability and transparency. I also believe that transparency will improve the performance of the U.S. health system as a whole, as well as the individual programs I will oversee if I am confirmed as Secretary of HHS. I will examine the current scope and mechanism for public posting of such information and work to address any gaps that exist.

Question 4. A Federal court recently unilaterally determined that girls under the age of 18 should have unrestricted, over-the-counter access to Plan B—also known as "the morning after pill"—overruling FDA's decision to require that minors first obtain a valid prescription for the potentially dangerous drug. In my practice, I need to obtain parental consent before prescribing medicine to a minor, and in many areas minors can't even buy cough medicine over the counter. Will you appeal this decision to prevent minors from having unfettered access to a potentially harmful drug without a prescription or parental consent?

Answer 4. I intend to look at the Court's decision closely and consult with experts at FDA and the Department before making any decision.

Question 5. Legislation in the last Congress—which would have authorized FDA approval follow-on versions of biologic therapies—contained a provision which should concern anyone interested in patient safety. The provision would allow the substitution of follow-on biological products for a prescribed innovator product at the point of dispensing, without a physician's knowledge. Can you tell me if you agree that a biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product? Do you believe that patients deserve the benefit of a physician's choice of treatment? Are you willing to state that a physician may elect to prescribe a specific biologic

(follow-on or innovator) based on their own review of the clinical data and their own clinical judgment on what is the best therapy for their patient?

Answer 5. The President strongly supports the creation of a pathway for the approval of follow-on biologics. Lowering costs in the healthcare system is a critical goal of his health reform efforts.

The current monopoly in the biologic drug market prevents safe, lower-cost alternatives from coming to market, and keeps many necessary drugs out of the reach of patients. The time has come for—and the science supports—FDA authority to approve safe and more affordable follow-on biologics.

I do believe that patients and providers should partner together to make informed health care decisions. Yet, many experts believe that the branded drug industry has inappropriately promoted the perception that generic drugs are inferior in order to protect their profits at the expense of access to affordable drugs. We must ensure that the best decisions can be made for patients based on sound science and without undue influence from the branded drug industry.

Question 6. CDC recommends universal HIV/AIDS testing of pregnant women. The Kansas House Committee on Health and Human Services recently reported out a measure to provide for universal testing for pregnant women. This legislation has already passed the Kansas Senate. Do you support this legislation, and will you sign it if it passes both chambers? Will you similarly promote universal testing for pregnant women under the Ryan White Care Act?

Answer 6. I do support this legislation and will sign it into law if it passes both chambers.

Currently, all Ryan White HIV/AIDS programs are required to follow the Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents, which outlines specific recommendations for pregnant women. Therefore, it is recommended that all pregnant women undergo routine HIV testing, and that those who test positive receive appropriate treatment.

I support universal testing for the following reasons: (1) it de-stigmatizes HIV/AIDS in the overall context of health care; (2) it ensures that HIV testing becomes a normal part of the health care continuum; and (3) it is preventive, by helping to reduce the rate of HIV transmission.

Question 7. In 2006, the Centers for Disease Control and Prevention (CDC) released recommendations for HIV/AIDS testing. They recommend, among other things, “routine voluntary HIV screening as a normal part of medical practice, similar to screening for other treatable conditions.” Given that hundreds of thousands of Americans with HIV remain untested, and that this group is responsible for the majority of new HIV infections, will you commit to promoting CDC’s recommendation to increase testing for undiagnosed HIV/AIDS patients?

Answer 7. I support the CDC’s recommendation to increase testing for all patients and, if confirmed, I will work to promote this practice.

Question 8. Medicare spending has surged by 59 percent over the past 5 years alone to more than \$432 billion a year. Over the next decade, the Congressional Budget Office projects that Medicaid will expand by 8 percent annually. The Medicare Trustees’ Annual Report released earlier this year projects Medicare’s excess costs to be \$85.6 trillion—six times the U.S. economy in 2007. The trustees also estimate that Medicare’s long-term unfunded obligation—the benefits promised but unpaid for—will amount to more than \$36 trillion—every American household’s share of Medicare’s unfunded obligation is like a \$320,000 IOU. What are your plans to address this threat to our economic security and our children’s heritage? Shouldn’t we address the current entitlement crisis before even talking about expanding our entitlement programs?

Answer 8. Everyone agrees that Medicare faces a serious long-term financing problem that must be addressed. But the most serious challenge facing Medicare is skyrocketing costs in the health care system as a whole. Addressing the causes of these system-wide costs is the key to addressing Medicare’s long-term financing. We must also address existing Medicare policies that exacerbate the problem, such as Medicare’s current practice of paying private insurance companies an average of 13 percent more than it costs to treat the same beneficiaries under traditional Medicare—overpayments that will cost taxpayers more than \$150 billion over 10 years according to the Congressional Budget Office (CBO).

The real driver of costs in our health care system—and in Medicare and Medicaid—is that we have an outdated system of health delivery, a population of 45 million uninsured individuals that results in cost shifting, and a lack of investment in prevention and chronic care management. Medicare and Medicaid have performed as well as, if not better than, private insurers on cost. Their growth rates are com-

parable and payment rates lower than those of the private sector. That said, it is a top priority to modernize these programs to make them leaders in quality and efficiency.

Question 9. Both the NIH and the CDC have broad general authorities to do research and public health work on virtually any disease, and to do so in a scientifically sound manner. I believe that disease-specific legislation that directs work at the NIH or the CDC puts politicians in the role of playing politics with patients' lives. As you take over the leadership of NIH and CDC, will you join me in opposing disease-specific legislation? Would you agree that rather than pursue a silo-ed approach of funding individual programs for the myriad of diseases and conditions, that we should instead provide CDC and NIH with the necessary flexibility and hold the agency accountable for results?

Answer 9. I believe that every bill should be evaluated on its own merits. Yet, biomedical research priorities should be established on the basis of public health need and scientific opportunity; the intrusion of politics into this mix can seriously disrupt the process. Decisionmakers at NIH already seek advice from many sources when setting research priorities, including: (1) the scientific community, including both individual researchers and professional societies; (2) patient organizations and voluntary health associations; (3) Institute and Center Advisory Councils; (4) Congress and the Administration; (5) the Advisory Committee to the NIH Director (ACD); (6) the NIH Director's Council of Public Representatives (COPR); and (7) NIH staff.

The NIH builds its budget by evaluating those current opportunities and public health needs while maintaining strong support for investigator-initiated research. The formulation of the NIH budget provides an established framework within which priorities are identified, reviewed, and justified.

To assist the scientific assessment of research priorities, The NIH Reform Act of 2006 established the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) at NIH. This office identifies important areas of emerging scientific opportunity or rising public health challenges to assist in the acceleration of research investments in these areas.

Question 10. Is there any constitutional authority for Congress to impose a mandate on any American citizen to purchase a private commodity such as health insurance? Please cite it, if so. Is there any precedent in public policy at the Federal level for the imposition of a mandate on American citizens to buy a private good or service? If you support an individual mandate, what enforcement mechanisms would you propose?

Answer 10. I share the President's belief that every American should have affordable, high-quality health care coverage. Making health insurance affordable is the key to covering everyone. We intend to do all we can, working with Congress and through executive action, to lower the cost of health care in America. There are many ideas in Congress and in the country on how to cover all Americans and, if confirmed, I look forward to working with you to finally achieve this critical goal.

QUESTIONS OF SENATOR BURR

FDA

Question 1. You noted in your testimony the importance of FDA and strengthening the agency. I understand that deadlines for new drug approvals at FDA have slipped dramatically in the past year. How will you ensure that FDA is meeting statutory requirements to keep the drug approval pipeline open in a manner that Congress has directed? Additionally, do you believe that the FDA needs new regulatory authority to monitor the safety of our food supply in a more robust manner? Senators Durbin, Gregg and I have introduced an important food safety bill. Is passage of effective and bipartisan food safety legislation a priority of yours?

Answer 1. The FDA is currently hiring additional drug reviewers with the new resources provided by the Food and Drug Administration Amendments Act. Once hired and trained, these new staff will help the agency meet its drug review commitments.

I do believe that the FDA needs new regulatory authorities to enhance our Nation's food safety systems and, if confirmed as Secretary, I look forward to working with FDA and Congress on food safety legislation. Food safety is a priority shared by both the Administration and Congress.

Question 2. Last, recent U.S. Supreme Court cases have highlighted the critical importance for FDA to effectively evaluate pharmaceuticals and medical devices, inform clinicians of their appropriate use, and provide adequate safety information to

patients to make an informed decision about their use in treatment. Do you believe FDA should take a more proactive approach with the industry to improve drug labeling and device safety information? Do you believe our legal system adequately and efficiently compensates patients for injuries resulting from a drug or medical device?

Answer 2. FDA should proactively engage with industry to ensure that health care practitioners and patients receive the information they need to make informed decisions about drugs and devices. In addition, other safeguards should be in place to reduce the likelihood of harm from drugs and medical devices. I am interested in hearing any thoughts and ideas you and others may have on how the legal system can be improved in this area.

CDC

Question 3. In your statement, you discussed the importance of ensuring CDC is focused on the prevention of disease. I couldn't agree with you more, and I look forward to working with you to revitalize and strengthen CDC to meet the important goals of health promotion and disease prevention in an open, transparent way. Along those lines, I welcome your thoughts on whether you believe CDC has a transparent priority-setting process that is accessible to the public? Are you satisfied with the scientific criteria used to allocate resources and set priorities at CDC, based on disease burden or some other criteria? If not, what would you do as Secretary to better align priorities and resources with science?

Answer 3. The initial allocation of CDC resources begins with the annual appropriations bills, which include a detailed assignment of resources within the agency. CDC is faithful to congressional intent with regard to allocation of resources. Within the individual funding allocations, CDC uses science as a basis to further allocate resources.

More can be done to add transparency to the way in which CDC allocates resources. CDC has developed a research agenda to drive its activities, and that agenda has been subject to broad public consideration and engagement. Additionally, each of CDC's primary program areas is advised publicly by Boards of Scientific Counselors.

Notably, CDC's National Institute for Occupational Safety and Health (NIOSH) has, since 1996, implemented a robust public and professional engagement strategy to inform and develop its National Occupational Research Agenda. Given the burden of chronic and environmental disease along with injury, both Congress and the Administration can do a better job of highlighting the economic and disease burdens that are posed in these areas. While CDC needs to deploy the best science possible, it also needs to continue to support emerging and less quantifiable threats, both natural and manmade.

Question 4. Last, CDC under-went a major reorganization in the last few years, called the Futures Initiative. The goals of this reorganization were to facilitate agency-wide coordination, achieve a measurable impact on the Nation's health, increase effectiveness and accountability for the services provided, expand partnership opportunities, and enhance the ability to respond to public health emergencies. From your perspective, what has been the impact—both positive and negative—of this reorganization?

Answer 4. The reorganization allowed the agency to focus on better integrating its diverse programs. The integration was focused both within and across program areas. There was also a renewed emphasis on developing measurement tools and focusing on achieving tangible health impact—in both the short and long terms. One particularly positive outcome of the reorganization was a renewed realization of the underlying strengths of the organization and a renewed resilience.

At the same time, reorganizations are difficult and place stress on institutions and individuals, and it is my understanding that this was the case here. The reorganization occurred during a period in which numerous external events (e.g., avian flu, SARS, and budgetary strains) were affecting the agency's ability to function normally.

I believe CDC must constantly evolve to deal with the challenges it will inevitably face. Ultimately, the agency must strive to keep its focus on positively impacting the health of Americans and people around the globe.

Question 5a. I am sure you are familiar with the conclusions of the World at Risk Report recently released by the bipartisan WMD Commission, including the finding that terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon and, therefore, the U.S. Government should make bioterrorism a higher priority.

Do you agree that a bioterrorist attack remains at or near the top of our Nation's most serious threats?

Answer 5a. Yes.

Question 5b. What efforts does HHS plan to pursue to address and communicate that threat to Congress and State and local officials?

Answer 5b. HHS has supported DHS's risk and net-assessment efforts and will assist in whatever ways are necessary to communicate with the Congress, State, and local authorities regarding those efforts and other appropriate medical and public health solutions that are needed to counter the threat. Additionally, the Office of the Assistant Secretary for Preparedness and Response (ASPR) at HHS has sponsored stakeholder workshops and invited presentations at emergency preparedness and other scientific meetings to discuss the anthrax threat and countermeasure activities.

Question 5c. Does HHS plan any new or enhanced initiatives based on the Commission's findings?

Answer 5c. In August 2008, President Bush submitted a supplemental budget request totaling \$905 million to initiate efforts for medical countermeasure advanced development and dispensing in the United States, focused primarily on anthrax. To date, no appropriation has been provided based upon this request.

Within the existing budget, HHS will continue its efforts to develop, stockpile, and build manufacturing infrastructure for new anthrax vaccines, antitoxins, and antibiotics, including antibiotic MedKits for responder populations. These efforts will focus on the development of next generation broad-spectrum antibiotics to treat illness against enhanced anthrax agents that are antibiotic-drug resistant, and on working with the Department of Defense to establish new public-private centers of excellence for countermeasure development/manufacturing in the United States against biological threats, including anthrax.

PH Preparedness

Question 6. As you know, HHS is tasked with preparing for and responding to public health emergencies. How well prepared do you think the Nation is for a public health emergency, such as a bioterrorist attack or pandemic flu outbreak? Have you been able to assess the department's internal capabilities to respond to such an attack? Does the Obama administration intend to continue the Federal commitment toward public health preparedness and biodefense?

Answer 6. Considerable progress has been made in recent years toward better protecting the country from all manner of disasters, including both natural events and the threat of terrorism. Working with other partners in Government, including the Department of Homeland Security, HHS has developed a series of plans and policies for response. Through grants to States and localities, HHS has built infrastructure for preparedness and response, trained and equipped front-line responders, and developed better systems for communication before and during a crisis. However, we are far from the level of preparedness that we seek. Major gaps remain in many critical areas, including surge capacity for mass medical/casualty care, rapid disease detection, and food safety. The current Federal structure for public health emergency preparedness has several specific problems. Major limitations include: lack of strong leadership; understaffing; and inadequate coordination within and across Federal agencies. This can and must be improved.

Moreover, preparedness is a dynamic process that requires constant attention and sustained investment. Sadly, much of what has been accomplished in terms of building preparedness and response capacity is now at risk due to budget cuts and the economic crisis. Successful preparedness depends on vigilance, planning, and practice. If confirmed as Secretary of HHS, I intend to focus early and consistently on these issues. I will swiftly put in place an expert, experienced team to lead HHS disaster preparedness and response efforts. We will work closely with our partners at all levels of government, and with the private and not-for-profit sectors to ensure we have robust, clear, and well-established preparedness plans. This will include direct participation in drills and exercises to ensure full understanding of the complexities of the various potential scenarios, the level of preparedness for differing contingencies, and the critical areas for further work and development.

BARDA

Question 7. Senator Kennedy and I advocated for the creation of the Biomedical Advanced Research and Development Authority—known as BARDA—at HHS to speed up the development of more and better medical countermeasures to protect the American people. However, BARDA can only be successful if it is adequately funded. We authorized \$1 billion for BARDA over 2 years, but much of that has not

been appropriated. I am worried that our window of opportunity for persuading the private sector to invest in these needed drugs and vaccines is quickly closing. Will you advocate for funding BARDA at the level necessary to prepare our country to respond to a bioterror attack or pandemic?

Answer 7. Adequate preparedness depends on having access to the necessary medical countermeasures to protect health and control disease. Our current supply of medical countermeasures to respond to the array of potential biological threats before us is limited, compromising both health and national security. We know that market forces alone are not sufficient to engage the pharmaceutical industry to address these needs. HHS must provide leadership and spearhead a robust effort to ensure development and availability of new, more effective and accessible drugs, vaccines, and diagnostics to enable rapid identification and response to biological threats, whether those threats are the result of natural causes or bioterrorism. The Biomedical Advanced Development Research and Development Authority (BARDA), working in partnership with the private sector and NIH, can serve as a critical bridge, helping to take the promising discoveries through all the stages of product development and manufacture. Investment in medical countermeasure development and procurement represents a national security priority, a major public good, and a potential economic driver—both through job creation and through the benefits of reduced disease burden.

To enable success in its advanced development mission, we must fund BARDA adequately. Importantly, if we do not commit to increased BARDA funding, there is a risk that biopharma firms will lose confidence in the U.S. Government's commitment to an inclusive approach to biodefense.

Funding at the originally intended levels would also empower BARDA to fulfill its statutory "innovation" mission, and enable BARDA to support development of new, lower-cost, and more accessible medicines and vaccines for biodefense needs, infectious diseases in the developing world, and emerging pathogens.

Medicare

Question 8. Since more than 70 percent of all new cancer diagnoses occur in the elderly population, CMS would have a strong desire to get more Medicare recipients in for regular screenings, particularly for the most curable cancers like colon cancer. Will you work with the President and Congress to ensure that CMS provides Medicare recipients with access to reliable screening tools, such as CT Colonography, so that we can improve patient outcomes?

Answer 8. I share the view that Medicare should promote greater preventive care to ensure that chronic and acute conditions can be effectively managed—or prevented altogether—to improve the quality of life for Medicare beneficiaries and to avoid or delay very expensive hospital stays. As we consider adding new preventive benefits to Medicare, we should ensure that these decisions are based on sound medical evidence. Such criteria will ensure that Medicare beneficiaries and their physicians can establish the best treatments of care and that Medicare's financial resources are most wisely spent.

Medical Home

Question 9. Senator Durbin and I plan on introducing legislation in April that would establish eight medical home demonstration projects across the United States under the Medicaid and SCHIP programs. If these projects achieve the level of success that has been achieved by NC's Medicaid medical home program, Community Care (approximately \$200 million/year savings), the benefit to Americans' health and to our fiscal bottom line would be significant. Would you be supportive of implementing some medical home demonstration programs around the United States?

Answer 9. The medical home model is an effective way to provide continuous, coordinated high-quality care to patients, and achieve better outcomes, reduced disparities, and lower costs. The Medicare program has initiated a medical home demonstration program that may well merit expansion to additional sites and beneficiaries. Similarly, we will explore expanded testing of this model in other public programs, including Medicaid and SCHIP. Medical homes are an important element of policies to improve quality of care for people as we reduce costs.

QUESTIONS OF SENATOR ALEXANDER

Head Start/Early Education

Question 1. I am author of the Centers of Excellence program in the Head Start Act and am pleased that the fiscal year 2009 omnibus secured funding for this program. The Centers would serve an important role in the incoming Administration's efforts on improving and expanding early childhood education. Not only do they highlight the best programs in each State, but they also highlight those that are

best coordinating with other similar programs—Federal, State and local. It is my hope that you will look to the Centers of Excellence when discussing priorities in early childhood education with President-elect Obama and the Secretary of Education, Arne Duncan. What strategies do you intend to pursue to improve the coordination of the dozens of existing Federal programs dealing with early childhood education?

Answer 1. Thank you for your leadership in the reauthorization of Head Start, and for your tireless efforts to assure high-quality early childhood education. President Obama has made it a priority in his budget to encourage States to raise the quality of their early learning programs, work to ensure a seamless delivery of services, and ensure that children are prepared for success when they reach kindergarten.

I am interested in your ideas about how we can better implement the Centers of Excellence provisions and address coordination in the Head Start Act. If confirmed, I look forward to working with you to explore this and other initiatives designed to improve the quality of our existing early childhood education programs.

Question 2. The Head Start Act requires States to create advisory councils to better plan and coordinate the delivery of education and health services to young children, including better connecting Head Start, child care, pre-k, and the K-12 systems. What role do you see the State Advisory Councils playing to improve the delivery of early childhood services?

Answer 2. I believe State Advisory Councils and similar coordinating structures are valuable tools that can help States find creative and effective mechanisms to coordinate early childhood programs funded by multiple sources. Indeed, as Governor of Kansas, I established an Early Learning Council to accomplish this goal, and I believe this kind of approach can be successful in other States.

Question 3. Historically early learning at the Federal level has been exclusively under the jurisdiction of HHS. But at the State level, early learning is often focused on State preschool, which is frequently run by State education agencies. As Secretary, how would you work with other agencies, particularly the U.S. Department of Education, to improve the coordination and delivery of services to children under the age of 5?

Answer 3. If confirmed as Secretary of HHS, I plan to work very closely with Secretary Duncan to coordinate early learning programs in HHS and Education more effectively. As a Governor, I learned that collaboration between child care, Head Start, and education agencies is essential to achieving the objectives we are seeking for young children and their families. With that in mind, I intend to do everything I can to improve collaboration at the Federal level on early childhood education programs.

Question 4. During the 110th Congress, the Head Start Act was reauthorized and the revised Act improves quality, including increased training and education for teachers; expands access; and strengthens accountability in the program. Do you anticipate promulgating regulations to implement these important revisions during the first 6 months of your tenure as Secretary of Health and Human Services?

Answer 4. I applaud Congress for enacting a very important reauthorization of the Head Start program, and I am very excited about the prospect of working to implement key elements of this legislation. In particular, I am interested in leveraging all the assets and tools available to HHS to find ways to improve results for Head Start children. If confirmed, I will carefully review the status of needed regulations and work to promulgate them as expeditiously as possible.

Question 5. The new Head Start law allows for Head Start grantees to convert preschool slots to Early Head Start slots based on community need. The law specified that the Secretary would promulgate procedures for slots conversion within 1 year of enactment, before December 12, 2008. Would you develop procedures for conversion immediately, so that grantees could begin to serve additional infants and toddlers in Early Head Start?

Answer 5. These provisions included in the Head Start Act were a significant and important improvement for communities served by the program. If confirmed, I will carefully review the status of all Head Start regulations, particularly in circumstances where HHS has failed to meet statutorily mandated deadlines. I will advance promulgation of needed regulations as expeditiously as possible.

[Whereupon, at 12:32 p.m., the hearing was adjourned.]

