S. HRG. 109–56

NOMINATION OF MICHAEL O. LEAVITT

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

ON

MICHAEL O. LEAVITT, OF UTAH, TO BE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

JANUARY 18, 2005

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C O N T E N T S

STATEMENTS

TUESDAY, JANUARY 18, 2005

ADDITIONAL MATERIAL

NOMINATION OF MICHAEL O. LEAVITT

TUESDAY, JANUARY 18, 2005

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

The committee met, pursuant to notice, at 10:03 a.m., in room SD-106, Dirksen Senate Office Building, Senator Enzi (chairman of the committee) presiding.

Present: Senators Enzi, Gregg, Frist, Alexander, Burr, Isakson, Hatch, Kennedy, and Dodd.

OPENING STATEMENT OF SENATOR ENZI

The CHAIRMAN. I will call the hearing to order. Good morning and welcome to today's hearing on the nomination of Michael Leavitt to serve as the Secretary of Health and Human Services. It is my pleasure to welcome the former Governor, now Secretary Leavitt, and all those in attendance. I want to thank Governor Leavitt—I have had more contact with him as Governor than I have as Administrator, and I really appreciated the effort that he did in our neighboring State of Utah. And I want to thank him for his willingness to serve in this capacity. I know that you have been through nomination hearings for your previous job, and now to go through a second one is very much appreciated. And this one there will actually be two hearings on because the committee of final jurisdiction on it is the Finance Committee. So we are glad to have you do this extra duty and be with us today. I have known you for a long time and appreciate all the effort you have done. Back in my legislative career, you were working on the Western Governors University and did an outstanding job of putting that high-tech bit together. And you have served as the Governor of Utah, and that has a very rural capacity, as well as Salt Lake City. So you come with some diverse experience that will do our Nation well.

During the President's first term, we had some important health care reforms. Medicare reform is now on the books, an option that will have a dramatic effect on the costs borne by our Nation's seniors for medical care. In addition, the option of health savings accounts has been expanded to provide seniors and the young with an incentive to invest in these tax-free health insurance alternatives. And, finally, more than 600 community health centers have been opened or expanded to serve low-income and uninsured people across this country.

There is still much left to do. Fortunately, you have the skills and the ability to help keep our health care system responsive and our safety net intact to protect the most vulnerable among us. It

is clear from your record that you have a great appreciation for the importance of the family unit, the most local level from which we can address problems in this Nation. Our families are the cornerstone of our society and the building blocks of our communities, and it is where all of health and human services starts.

As you work on the health care issues that affect our families so directly, I want to assure you that Congress will work with you. In fact, we must work together and focus on the results if we are to keep the promises we made for the work on health initiatives.

When you are sworn in, you will be overseeing a budget of several hundred billion dollars and administering the operation of more than 230 programs that affect all Americans of every age. You will also have more people looking over your shoulder as you work than anyone else. Since every American takes his or her health care personally, you will have more bosses than any other worker in the world. We need to ensure their continued access to their family doctor, keep the treatments their doctor prescribes available and affordable, and make sure that health insurance companies do not forget about care as they work to control costs.

Now, President Bush has set forth his vision for improving health care and patient safety through better and more widespread use of information technology. Senator Kennedy and I share the vision, and we have already begun our discussions on how we can help to make that a reality. I look forward to working with you, who also has a lot of information technology background, and Senator Kennedy and our colleagues on this committee to bring health care information into the 21st century. I intend to focus on bioterrorism and public health preparedness with the help of subcommittee Chairman Burr. This will build upon the great work this committee did last year to pass President Bush's Project Bioshield into law. President Bush has proposed placing a community health care center or rural health clinic in every poor county in the United States. Such an effort will be a key part of any effort to address the problem of expanding access to low-cost health care to those who lack health insurance.

I think you will find the members of this committee to be supportive of your efforts in that matter, too. In Wyoming we have one community health center right now. That means we have a lot of counties that need one, but we do not have the money to provide them because most of our counties are the size of Connecticut. Fortunately, the unique challenges of providing services to the areas that have great distances between them is something that is well known to you. I am looking forward to working with you on how we can best address that problem.

Most people are concerned about their health insurance coverage and the cost. They want policies that are more affordable and accessible with more options. I also believe we can come up with creative solutions to make our medical liability system work better for patients and providers.

And then there are the front-page issues. At the forefront is our system of approving drugs and ensuring their safety. We must be sure the Food and Drug Administration is able to completely review and monitor the use of medications they approve in a timely manner. We also need to review the flu vaccine shortage and find

out what happened and come up with a plan that will prevent it from happening again. We have to encourage more companies to come back to the vaccine business. Relying on a couple of companies to produce one of the most critical and popular vaccines is a recipe for disaster.

I do not want to get into a laundry list of all of the issues. That is just a touch on a few of them. But there is a lot on our mutual to-do list. I appreciate the committee's willingness to work with you and also your volunteering to later have some informal sessions with us. I think that will achieve a lot. We appreciate your being here today and look forward to working with you.

Senator Kennedy.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. Thank you very much, Mr. Chairman, and thank you for having these hearings this morning. I want to commend Mike Leavitt for his nomination. I look forward to working with him as Secretary.

No domestic agency of the Federal Government has a broader and deeper impact on the lives of the American people than the Department of Health and Human Services. Its programs reflect the ideals of our Nation and commitment to provide help to all those who need our help the most. HHS comforts and helps the elderly through Medicare and the Older Americans Act. It nurtures the young through Head Start, CHIP, and the maternal and child health programs. It sustains poor families through the Temporary Assistance to Needy Families Act. It brings health care to all in poverty through Medicaid. It offers help and hope to patients suffering from a host of diseases through the National Institutes of Health. And it guarantees every American that the medicines they take are safe and effective and the foods they eat are healthful through the Food and Drug Administration. It protects the health of every American against the epidemics of disease through the Centers for Disease Control.

Mr. Leavitt brings impressive skills to this critical post. As a former Governor, he knows how HHS works and does not work. At EPA, he confronted health issues similar to many of those dealt with by HHS. Everyone who knows him respects his intelligence, his high energy, and his experience as a manager and problem solver.

His new position will test all those skills, and he will face an especially heavy challenge this year. Many of the most important programs he oversees get lavish praise but little real support. Last year, the administration was able to push through the Congress a flawed Medicare drug bill that benefited drug companies and insurance companies at the expense of patients. Governor Leavitt will now have to implement that flawed bill. Press reports say the administration intends to block grant Medicaid and cut it deeply and to deeply cut Medicare as well. More than 50 million of the Nation's poor elderly, poor disabled, poor families and children depend upon Medicaid for health care. Forty-two million senior citizens and disabled Americans depend on Medicare. The administration's tax cuts for the wealthy and its misguided war in Iraq has created a catastrophic deficit, but it would be unconscionable to solve the

budget crisis by penalizing the poor and the elderly who did nothing to create it and to ask the wealthy and powerful to make no contribution at all.

We will continue our work this year on Head Start, the foundation of the Federal support for the Nation's most vulnerable children. Head Start has a 40-year track record of success, and reauthorization this year is an opportunity to build on that success, and to do more to open the American dream to many more children who deserve our help. A block grant for Head Start would be, I believe, a giant step backwards. We cannot turn Head Start into Slow Start or No Start.

The current extension of welfare reform expires at the end of March. Our ability to move the welfare debate forward will require more flexibility from an administration willing to work in good faith with Congress on this basic issue of what kind of country we are. We are impressed with what you Governor Leavitt, did in your State in terms of flexibility.

Other priorities facing the Department include the need to move the health care system into the modern age, using information technology, as the chairman has mentioned, and improve FDA's ability to detect and respond promptly to warning signals on the effects of new drugs. We must also continue the fine work of Secretary Thompson of putting disease prevention and health promotion higher on the national agenda.

So I welcome you. I was just looking over, Mr. Chairman, the public health legislation we have in this committee's jurisdiction the NIH, CDC, FDA, community health centers which you mentioned, bioterrorism, Head Start, LIHEAP, the Administration on Aging, Meals on Wheels, child care, child protection and many of those are in your Department. We work together with the Finance Committee, but we are very, very grateful to you for your willingness to come here and speak to us about not only these issues but also how you intend to lead the Department. You are very welcome to the committee, and we look forward to working with our Chair to make sure that we get you into your responsibilities as soon as we can.

The CHAIRMAN. Now it is my pleasure to recognize my friend and colleague from Utah, who has just returned to the committee, who used to chair this committee. We appreciate all of your efforts on all of the committees you have been on, and we look forward to your introduction of your fellow Utahan.

STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Senator HATCH. Thank you, Mr. Chairman, Senator Kennedy, other members of the committee. It seems rather odd to be at my first hearing back on the HELP Committee and to be on this side of the dais. But it is for the best of purposes.

It is both Senator Bennett's and my honor and privilege to introduce to you our good friend and fellow Utahan, Governor Mike Leavitt, and to urge that his nomination be approved on an expedited basis. Although his wife is not here today because of illness, I would like to recognize his beautiful wife, Jackie; and he has five wonderful children. And he is a wonderful family man, and Jackie

has herself assembled quite a record in working on issues that this committee is interested in such as, just to mention one, childhood vaccines.

I have also known Mike Leavitt for a long time and have worked closely with him on many key issues, not only Utah issues but national issues as well. In short, Governor Leavitt is bright, energetic, dedicated, and fair.

Now, I say with all respect to those who have gone before him, I can think of no better Secretary of Health and Human Services and no better candidate for it. Mike has devoted a considerable part of his life and time to public service, first in our home State of Utah and, of course, more recently here in Washington. He has proven himself to be an excellent manager, a smart decisionmaker, a tireless worker, and a successful executive. He has an established record of fiscal management, a demonstrated knowledge of health care, and a solid reputation as a decent, energetic, good family man.

His wife is a tremendous partner to him. I might mention that she comes from a little town in northern Utah named Newton. It used to be a town of about 300 people. That is where my wife comes from, too. It is a very well-represented city in Utah.

Now, an important hallmark of Mike Leavitt's service that I wish to commend to this committee is his fairness. You can count on him looking at all sides of an issue before making a policy decision, and I think you can count on him making the right decision. His record as EPA Administrator bears this out, but also his record as head of the Governors Association. This should also give great comfort not only to those of us in Government, but also to the hundreds of millions of people that HHS serves so well.

As our time is short, Mr. Chairman, I just want to leave you with one short story. After attending several briefings with this Secretary-designate, a senior official at the FDA told me the other day, "At our first briefing, Governor Leavitt was good. At the second meeting, he was excellent. And at the last briefing, he was teaching us." And that is typical of Mike Leavitt. This is the kind of man that Mike Leavitt is. He will be a great Secretary.

I take a great interest in this agency, always have, always will. I think both of you have outlined how important it is to the health and well-being of our country. And so with pride and admiration, along with Senator Bennett, I introduce to this committee Governor Mike Leavitt. So I would just ask of the committee let us get him confirmed and in the job as soon as possible because I think he will do a terrific job there.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

We have been joined by the Majority Leader, Senator Frist, so unless there is objection, we will allow him to give a statement at this time.

OPENING STATEMENT OF SENATOR FRIST

Senator FRIST. Mr. Chairman, thank you, and I will be brief.

Before we begin, let me take this opportunity to say how much I look forward to working with our new chairman as well as our

ranking member for what I know is going to be an exciting year and really entire Congress.

Just as an aside, it is interesting, as we went through all of our committee assignments, that this was probably the most popular committee for people to try to join from the Republican side this year. I think it reflects the confidence in the committee's leadership and our support for the issues that our nominee today will be leading on over the next Congress.

I also just very briefly want to recognize the tremendous leadership of Senator Gregg, who has done an outstanding job on this committee, and as we all reflected back over the last Congress, the tremendous strides we made on a number of issues. To be able to walk in the door a few moments ago and see our two members, Richard Burr of North Carolina and Johnny Isakson of Georgia, our new members, gives me a great deal of pride. I have had the opportunity to talk to both of them about issues that this committee will be addressing over the course of this Congress, and both are committed to and passionate about those issues.

Today's hearing is vital to ensuring our commitment to protecting the safety, health, and well-being of the American people. I am pleased that such a strong leader, Michael Leavitt, has been nominated by President Bush for this role. As members of this committee know better than anybody, the Department of Health and Human Services is the second largest Federal Department, overseeing more than 300 programs with a budget of $580 billion. The programs that you will oversee, Governor Leavitt, are critical, as you well know, to the everyday lives of every single American, and the impact will be tremendous on future generations.

You bring, as Senator Hatch just said, considerable experience to this post with your past positions of Governor of Utah, Chairman of the National Governors Association, and most recently Administrator of the EPA. Your leadership has been steady, demonstrated in Utah, as you addressed issues that we are so committed to on this particular committee, and that is access to health care for children and adults and keeping rising health care costs under control, which will be a huge topic and focus of this committee over the next Congress. The fact that Utah's uninsured rate remains below the Nation's average is a goal and a standard that we should use in this committee as we look at various policy proposals. Your experience as host of the 2002 Olympic Winter Games and co-chair of the National Governors Association Homeland Security Task Force makes you an ideal candidate.

We begin this 109th Congress with a real record of progress, having signed into law over a dozen pieces of critical health care initiatives which touch the lives of each American, the Medicare Modernization Act, which guarantees Medicare beneficiaries access to more affordable medicines, better health care choices, and higher-quality care. For the first time we really put a demonstrable emphasis on preventive care, and for the first time tied payments to quality of care, doors that had been opened, but doors that we need to explore much further in our policies in this Congress. The Project Bioshield Act of 2003, an issue that I have worked on and we have all worked on with the leadership of Senator Kennedy, has been an appropriate and timely investment that we are going to

have to build upon when we look to the future and recognize one of the greatest existential threats that the world will have to face, this country will have to face, is the challenge of bioterrorism. The Pediatric Research Equity Act of 2003, which we passed last year, addressed pharmaceuticals prescribed in children.

That is the past. We have more work to do. In addition, issues such as the Medicare prescription drug benefit which has been the single largest expansion of the Medicare program since its creation, will require a lot of work with implementation by the Centers for Medicare and Medicaid Services. We need to make health care more affordable. We need to eliminate the huge gaps in health care quality that we have today, and most of that work is done by this particular committee. We need to advance health care research, making sure that we get those discoveries from the laboratory bench all the way to the people where they will have their direct impact. And we must, as this committee does first and foremost, protect and improve the public health.

I mention all that, Governor, because as a physician and as an active member of this committee, in addition to being Majority Leader, I am excited and enthusiastic about your leadership. It will require bold leadership, courageous leadership, leadership with great definition, and you are absolutely in my mind the perfect person to provide that leadership.

At your first inauguration, you pledged to take the State of Utah to, and I quote, "a whole new level of performance." And you succeeded. I am confident that in this new capacity you will succeed once again. Congratulations.

The CHAIRMAN. I would like to recognize my other friend and colleague from Utah, Senator Bennett. You have had the opportunity to watch and work with Governor Leavitt, and I welcome your perspective for this committee.

STATEMENT OF HON. ROBERT F. BENNETT, A U.S. SENATOR FROM THE STATE OF UTAH

Senator BENNETT. Thank you very much, Mr. Chairman. I appreciate the opportunity.

I first met Mike Leavitt as we worked on school issues, which used to be part of the jurisdiction of the Department of Health, Education, and Welfare. And then we both entered the lists of electoral politics at the same time in 1992, he for Governor and I for Senator, and we both managed to finish second in the State convention in the State of Utah, which meant that we had to come from behind to win our respective primaries, and then ultimately our respective offices.

So we have seen an awful lot of Utah together and all the small towns and distant counties. We have heard a lot of terrible speeches given by our opponents, brilliant speeches given by each of us, as we have moved through this process together, and I consider him once of my best friends and one of the public servants I know the best.

I have a list before me prepared of all of his accomplishments. I think the committee has the same list, and so I will not bore you with reading them. But as I contemplated this, my mind went back to an exchange I had here on the floor of the U.S. Senate with Pat

Moynihan. There isn't anyone I admire more among the Senate than Pat Moynihan and his insight. But on this particular occasion, we were on opposite sides of the issue. The question was welfare reform. To listen to current commentators, welfare reform was one of the crown jewels of the Clinton administration, one of the crowning accomplishments that occurred under President Clinton's leadership. I remember that it took us a lot of time on the Republican side of the aisle to convince President Clinton that this was worthwhile, and he vetoed it twice before Dick Morris finally told him that if he did not pass it, he would not win the 1996 election, if he did not sign it, he would not win the 1996 election.

In that setting, we were on the floor debating welfare reform, and you will remember that Senator Moynihan was very, very adamantly against it. And he stood on the floor of the Senate, and he said, "If we pass welfare reform, we will have a race to the bottom. Everybody will compete to see how little they can do."

And I had watched Governor Leavitt deal with welfare reform in the State of Utah prior to that debate, and so I was bold enough to stand up in the Senate and disagree with Pat Moynihan and said, "I think quite the contrary. If we turn responsibility for welfare reform over to the States in the way this bill contemplates, we will see experimentation, innovation, and ultimately great improvement in the way welfare is handled. I don't think we will have a race to the bottom." Whereupon, Senator Moynihan said, "I agree with the Senator from Utah that you will not have a race to the bottom in Utah, but I guarantee we will have it in New York."

I cite that because it demonstrates that even outside the boundaries of the State of Utah, while Governor Leavitt was Governor, is efforts to bring innovative and creative and forward-looking reform to a very difficult problem were recognized—recognized by people from different States, from the different party, from different structure, because New York is quite different from Utah. This is a man who has proven that he knows how to get things done. He knows how to move in directions that are different when it is necessary to do that, and he knows how to reinforce established principles that need to be reinforced when it is necessary to do that.

I commend him to the committee with full and complete confidence that he will make an outstanding Secretary of Health and Human Services.

The CHAIRMAN. Thank you.

Governor Leavitt, we welcome you to this meeting of the Health, Education, Labor, and Pensions Committee. To date, the committee has received more than 35 letters of support for your nomination from a wide cross-section of business and advocacy groups as well as from individuals, and I anticipate we will be receiving more letters of support in the coming days.

I do ask unanimous consent to have the letters entered in the record. Without objection.

[The letters follow:]

THE 60 PLUS ASSOCIATION,
ARLINGTON, VA 22209,
January 14, 2005.

Hon. MICHAEL B. ENZI (R-WY),
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. EDWARD M. KENNEDY (D-MA),
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR ENZI AND SENATOR KENNEDY: The 60 Plus Association is pleased to announce its strongest support possible for the President's nomination of former Utah Governor, Michael O. Leavitt, to be Secretary of the Department of Health and Human Services (HHS).

60 Plus counts just over 5 million seniors as its base of support, with more than 5,000 in Wyoming and some 7,500 in Massachusetts, as well as 7,500 in Utah. 60 Plus has closely followed the compassionate career of this dedicated public servant. President Bush could not have chosen a more able leader than Governor Leavitt. The Governor has an intimate working knowledge of challenges that face him at HHS from shoring up Medicare-Medicaid and making sure the Nation's health care delivery system continues to function as smoothly as possible.

60 Plus had hoped that Secretary Thompson would remain at the helm of HHS but after nearly 4 decades of service to his Nation, he and Mrs. Thompson deserve a chance to "rest on their laurels" if you will. 60 Plus could not have recommended a better choice to be Secretary Thompson's successor than his fellow former Governor, Mike Leavitt.

Sincerely,

JAMES L. MARTIN,
President.

AMERICAN ASSOCIATION OF NURSE ANESTHETISTS,
WASHINGTON, DC 20003,
January 12, 2005.

Hon. Mike Enzi,
Chairman,
Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

Hon. Edward M. Kennedy,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

DEAR MR. CHAIRMAN AND RANKING MEMBER: On behalf of the more than 33,000 Certified Registered Nurse Anesthetists (CRNAs), who administer more than two-thirds of the Nation's anesthetics, I encourage Members of the Senate to confirm the President's nominee for Secretary of Health and Human Services (HHS), Michael Leavitt.

As a three-term Governor of the State of Utah, Mr. Leavitt was responsible for several important healthcare programs including his State's Medicaid program, for making government services more accessible via the internet, and for signing a proclamation proclaiming a National Nurse Anesthetists Week. We look forward to working with Mr. Leavitt to promote anesthesia patient safety, keep Medicare strong for seniors, support educational funding for nurses, advance access to quality healthcare that is affordable, and enact meaningful medical liability reform. The Administration has been more than gracious in extending us the open door to address issues of concern to our profession and our patients, so that we might together improve healthcare for Americans. I am sure that Mr. Leavitt will continue such a relationship.

If we can ever be of service during this process, please feel to contact Frank Purcell, Senior Director of Federal Government Affairs in our Washington, D.C. office at (202) 484–8400.

Sincerely,

FRANK T. MAZIARSKI, CRNA, MS, CLNC,
President.

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS,
ROLLING MEADOWS, IL 60008.
CONGRESS OF NEUROLOGICAL SURGEONS,
SCHAUMBURG, IL 60173,
January 17, 2005.

Hon. MICHAEL B. ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN ENZI AND RANKING MEMBER KENNEDY: On behalf of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons, we are pleased to endorse the nomination of Governor Mike Leavitt for Secretary of the Department of Health and Human Services (HHS) and we urge the Senate to approve his appointment as soon as possible.

Throughout his years in government service, Governor Leavitt has demonstrated his ability to be a leader and innovator on many healthcare issues. A results oriented leader, he has a proven track record of tackling and solving difficult healthcare problems, including expanding healthcare coverage for the uninsured and changing the welfare system. These initiatives have had a particularly positive impact on some of our Nation's most vulnerable citizens, our children. Governor Leavitt has also demonstrated his ability to work in a collegial and bipartisan fashion, which will clearly be vital to advancing some very challenging healthcare policy issues such as medical liability reform and the implementation of the Medicare Modernization Act.

America's neurosurgeons are confident that Governor Leavitt will be an outstanding Secretary of HHS.

Respectfully,

ROBERT A. RATCHESON, M.D.,
President, American Association of Neurological Surgeons.

NELSON M. OYESIKU, M.D., PH.D.,
President, Congress of Neuorlogical Surgeons.

AMERICAN HEALTH INFORMATION MANAGEMENT ASSOCIATION (AHIMA),
WASHINGTON, DC 20036,
January 21, 2005.

Hon. Mike Enzi,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, D.C. 20510.

DEAR SENATOR ENZI: I am writing to express our strong support for the confirmation of Governor Michael O. Leavitt as the Secretary of Health and Human Services. Governor Leavitt's roles as the Administrator of the Environmental Protection Agency and as Utah's Governor has provided him with a critical understanding of our government's executive operations at the national and State level, including first-hand involvement with Utah's healthcare program.

Governor Leavitt's unique experience makes him an ideal choice to lead the Department of Health and Human Services (DHHS). As you know, DHHS is moving forward with a range of critical initiatives that include the implementation of the

Medicare prescription drug program, Medicare reform, increased medical research and enhanced bioterrorism and public health efforts. In addition, DHHS is addressing many issues critical to AHIMA and its more than 50,000 members, including the development and adoption of health information technology, migrating from our outdated and broken 30-year-old ICD-9-CM coding system to ICD-I0-CM and ICD-10-PCS, protecting the privacy and security of health information, and expanding the health information management and allied health workforce. AHIMA believes that Governor Leavitt is the right choice to lead these efforts, at the right time.

AHIMA remains committed to its goal of "quality healthcare through quality information" and is dedicated to enhancing and improving healthcare. Founded in 1928 to improve the quality of medical records, AHIMA works diligently to advance the health information management profession in an increasingly electronic and global environment. AHIMA has a reputation for working on a bipartisan basis with elected officials and health policymakers and we look forward to working with you to confirm Governor Leavitt and to advance health information management and technology issues.

If I can provide you with any further information, please do not hesitate to call me in the AHIMA Washington, D.C. Office at 202–659–9440 or at Dan.Rode@ahima.org.

Sincerely,

DANIEL F. RODE,
Vice President,
Policy and Government Relations.

AMERICAN OSTEOPATHIC ASSOCIATION (AOA),
WASHINGTON, DC 20005–4949,
January 12, 2005.

Hon. MICHAEL B. ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN ENZI AND RANKING MEMBER KENNEDY: As President of the American Osteopathic Association (AOA), I write to express our strong support for the nomination of Governor Michael O. Leavitt to be Secretary of the Department of Health and Human Services (HHS).

The AOA represents the Nation's 54,000 osteopathic physicians practicing in 23 specialties and subspecialties. We applaud his nomination and encourage the Senate to approve his appointment at its earliest opportunity.

Throughout his career, Secretary-Designate Leavitt has demonstrated sound and disciplined leadership. These traits will benefit HHS as the agency addresses the numerous health care challenges facing our Nation. Additionally, he has a strong health care background and understands the access, workforce and financial challenges facing Medicare and Medicaid. We are especially appreciative of his efforts as Governor of Utah to improve the physician workforce in rural and underserved communities.

The AOA applauds his nomination and stands ready to work with Secretary Leavitt on improving the Nation's health care delivery system. Please contact the AOA's Department of Government Relations at (202) 414–0140 for additional information.

Sincerely,

GEORGE THOMAS, D.O.,
President.

ALLIANCE OF SPECIALTY MEDICINE,
January 17, 2005.

Hon. MICHAEL B. ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN ENZI AND RANKING MEMBER KENNEDY: The undersigned members of the Alliance of Specialty Medicine wholeheartedly support the nomination of Governor Mike Leavitt for Secretary of the Department of Health and Human Services (HHS). We urge the Senate to approve his appointment as soon as possible.

The Alliance is a coalition of 12 national medical specialty societies representing more than 220,000 physicians. Our non-partisan group is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care.

Governor Leavitt has the experience and leadership skills needed to take the helm of HHS at a crucial time. He will be tasked with the implementation of the Medicare prescription drug plan and solving physician reimbursement and medical liability challenges. Governor Leavitt knows the value of building a consensus to solve tough challenges together. He is a common-sense leader who knows how to deliver results.

The Alliance is ready to work with Secretary Leavitt on improving the health care and well-being for America's citizens. Please contact the Alliance at (202) 728–0610 for additional information.

Sincerely,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION,
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/CONGRESS OF NEUROLOGICAL SURGEONS,
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS,
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS,
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS,
AMERICAN GASTROENTEROLOGICAL ASSOCIATION,
AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY,
AMERICAN SOCIETY OF CATARACT & REFRACTIVE SURGERY,
AMERICAN UROLOGICAL ASSOCIATION,
NATIONAL ASSOCIATION OF SPINE SPECIALISTS,
SOCIETY OF THORACIC SURGEONS.

THE COUNCIL FOR AFFORDABLE HEALTH INSURANCE (CAHI),
ALEXANDRIA, VA 22314,
January 17, 2005.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR KENNEDY: I wanted to take this opportunity to express the Council for Affordable Health Insurance's (CAHI) strong support for Governor Leavitt's nomination as secretary of the Department of Health and Human Services.

CAHI is a research and advocacy association of insurance carriers active in the individual, small group, HSA and senior markets. CAHI's membership includes health insurance companies, small businesses, physicians, actuaries, and insurance brokers. Since 1992, CAHI has been an advocate for market-oriented solutions such as HSAs to the problems in America's health care system.

As a three-term governor, Mike Leavitt is a proven leader and administrator who has successfully led his State in several health care and welfare reform initiatives. That is important because the country faces several health care challenges: reducing the number of uninsured; ensuring that people, especially those with pre-existing

medical conditions, have access to affordable health coverage; and addressing the growing financial problems facing Medicare and Medicaid.

The country needs a strong, innovative leader who has the patience to listen to others about how to effectively address our health care challenges and motivate the department, the health care community, and State and Federal elected officials to adopt legislation and best practices that will solve the problems.

We at the Council believe that Governor Leavitt is the right person at the right time for a very big job, and we encourage you to approve his nomination in a timely manner.

Faithfully,

MERRILL MATTHEWS, PH.D.,
Director, Council for Affordable Health Insurance.

FEDERATION OF AMERICAN HOSPITALS TM,
WASHINGTON, DC 20004–2604,
January 14, 2005.

Hon. MICHAEL B. ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. CHARLES GRASSLEY,
Chairman,
Committee on Finance,
U.S. Senate,
Washington, DC 20510.

Hon. MAX BAUCUS,
Ranking Member,
Committee on Finance,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMEN AND RANKING MEMBERS: The Federation of American Hospitals is pleased to support strongly the nomination of Governor Mike Leavitt as Secretary of the Department of Health and Human Services (HHS). Governor Leavitt will be a wonderful addition to the President's cabinet, and the Federation urges quick approval of his nomination.

Governor Leavitt's demonstrated leadership and organizational skills, his vision, and his public policy expertise in health care make him exceptionally qualified to lead HHS. In addition, his ability to work with diverse groups and across party lines paired with his congenial manner qualify him as an outstanding choice to serve as HHS Secretary, particularly when considering the often contentious issues before the Department.

America's investor-owned hospitals know Governor Leavitt as a champion for constructive and thoughtful leadership. Again, we commend him and encourage the committees and the Senate to rapidly approve his nomination.

With warm regards,

CHARLES N. KAHN III,
President.

GALEN INSTITUTE,
ALEXANDRIA, VA 22320,
January 16, 2005.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR KENNEDY: I am writing to express strong support for President Bush's nomination of Governor Michael O. Leavitt to serve as Secretary of the Department of Health and Human Services.

Governor Leavitt has demonstrated his extraordinary leadership abilities as a governor and as Administrator of the Environmental Protection Agency, abilities that will be essential in managing a department as large and with as many responsibilities as DHHS.

Serving as a governor his given him valuable experience with key programs managed by the department. For example, he demonstrated both skill and creativity in implementing the State Children's Health Insurance Program. And he has been a leader in developing new ways to extend health coverage to the citizens of Utah through Medicaid waivers. Those skills will be invaluable in advancing President Bush's health policy agenda to provide health insurance to millions of uninsured Americans and to make coverage more affordable and accessible.

Governor Leavitt will serve the Department and the Nation well, and I strongly urge the committee to recommend to the U.S. Senate his confirmation as Secretary of Health and Human Services.

Sincerely,

GRACE-MARIE TURNER,
President.

January 19, 2005.

Hon. CHARLES E. GRASSLEY,
Chairman,
Committee on Finance,
U.S. Senate,
Washington, DC 20510.

Hon. MAX BAUCUS,
Ranking Minority Member,
Committee on Finance,
U.S. Senate,
Washington, DC 20510.

Hon. MIKE ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. EDWARD M. "TED" KENNEDY,
Ranking Minority Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN GRASSLEY, SENATOR BAUCUS, CHAIRMAN ENZI, AND SENATOR KENNEDY: We strongly support the confirmation of current EPA Administrator Michael Leavitt for U.S. Secretary of Health and Human Services. As former colleagues, we have all worked with him in a bipartisan manner and found him to be an individual of great intelligence, honesty, and integrity, Furthermore, be has a thorough understanding of both welfare and Medicaid, which are two programs of major importance to our Federal-State partnership.

We urge your committees to support Governor Leavitt's confirmation and look forward to a quick vote by the Senate.

Sincerely,

GOVERNOR MARK R. WARNER,
Virginia.
GOVERNOR JENNIFER GRANHOLM,
Michigan.
GOVERNOR THOMAS J. VILSACK,
Iowa.
GOVERNOR JIM DOYLE,
Wisconsin.

HEALTHCARE LEADERSHIP COUNCIL (HLC),
WASHINGTON, DC 20004,
January 17, 2005.

Hon. MICHAEL B. ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

DEAR CHAIRMAN ENZI: On behalf of the members of the Healthcare Leadership Council—chief executives of the Nation's premier health care companies and institutions—strongly urge you to support President Bush's nomination of Michael Leavitt to serve as Secretary of the U.S. Department of Health and Human Services,

Governor Leavitt is a sound choice to serve as HHS Secretary and has the skills and experience to serve the Nation well in this challenging position.

Governor Leavitt is an innovator. As governor of the State of Utah and as chairman of the National Governors Association, he was a strong advocate for giving States more creative flexibility in using Federal funds to better serve the health needs of their citizens. At a time when we must strive to make health insurance coverage more accessible to the tens of millions of citizens who are without it, Governor Leavitt's openness to new ideas and his determination to meet the health care heeds of the American people are welcome qualities.

He has a reputation as a pragmatic consensus-builder. This, too, is a welcome characteristic at a time when Washington, all too often, finds itself gridlocked on critical health care priorities. We need progress on issues ranging from the uninsured to health information technology dissemination to medical liability reform and we believe Governor Leavitt can be effective in finding common ground on these matters.

And, finally, Governor Leavitt has established himself as a strong manager, both in Utah and at the Environmental Protection Agency. This is no small credential for someone who will assume the reins of an institution as large and complex as HHS. And, as we move toward full implementation of the Medicare Modernization Act, a strong administrator at the HHS helm is a necessity.

In short, we believe that President Bush has made the right choice for a cabinet position of extraordinary importance and we encourage you to vote for Governor Leavitt's confirmation.

Sincerely,

MARY R. GREALY,
President.

CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,
WASHINGTON, DC 20062–2000,
January 12, 2005.

Hon. MICHAEL B. ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN ENZI: The U.S. Chamber of Commerce, the world's largest business federation representing more than 3 million businesses of every size, sector and region, strongly supports the nomination of Mike Leavitt to be Secretary of Health and Human Services.

Mike Leavitt has an exemplary track record for addressing the issues of healthcare access and affordability as the former Governor of Utah. As the Administrator of the Environmental Protection Agency, he worked diligently to bring all sides together and address the public health risks posed by emissions in a manner that cleaned the air without disrupting the economy.

The Chamber looks forward to working with the nominee in implementing the Medicare Modernization Act, particularly as it pertains to retiree health benefits, in advancing proposals making health coverage more affordable and accessible to all Americans, and in improving the safety and efficiency of our Nation's health delivery system.

We urge the committee's quick approval of this nomination and favorable recommendation for confirmation by the full United States Senate.

Sincerely,

R. BRUCE JOSTEN,
Executive Vice President,
Government Affairs.

NATIONAL ALLIANCE FOR HISPANIC HEALTH,
WASHINGTON, DC 20036–1401,
January 14, 2005.

Hon. MIKE ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, D.C. 20510–6300.

DEAR SENATOR ENZI: On behalf of the membership of the National Alliance for Hispanic Health (the Alliance), I am pleased to offer our full support for the swift confirmation of Mike Leavitt as the next Secretary of Health and Human Services. The Alliance is the Nation's largest and oldest organization committed to improving the health of Hispanics. Alliance members reach over 12 million Hispanics every year through the provision of direct services.

The Alliance worked with Administrator Leavitt when he was Governor of Utah and Chairman of the Western Governor's Association (WGA). As a founding board member of the Patient Safety Institute (PSI), the Alliance witnessed first hand then-Governor Leavitt's work with WGA to move forward new technology to realize the benefits of electronic patient health information. We look forward to his leadership on this issue as Secretary of Health and Human Services.

Our Utah-based community organization members describe Mike Leavitt as an effective advocate for Hispanic issues who has also been very supportive in the health arena. They describe him as a listener and quick learner who tempers his search for solutions with his knowledge, insight, and commitment to balance. For example, when he established his health policy commission in Utah he made sure that the group was diverse and included strong community advocates. Most impressive was his work with the health community to be proactive with the Children's Health Insurance Program (CHIP).

We are fortunate to have a person of the caliber and commitment of Mike Leavitt in public service. Our Nation's health system will benefit from his stewardship and the Alliance looks forward to his confirmation.

Sincerely,

JANE L. DELGADO, PH.D., M.S.,
President and CEO.

REPUBLICAN GOVERNORS ASSOCIATION,
WASHINGTON, DC 20004,
January 13, 2005.

Hon. MIKE ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510–6300.

Hon. EDWARD KENNEDY,
Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

DEAR CHAIRMAN ENZI AND SENATOR KENNEDY: We are writing to express our strong support for Administrator Mike Leavitt to be the next U.S. Secretary of Health and Human Services.

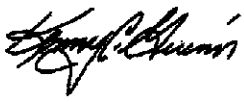
As Governor of Utah, Administrator Leavitt improved health care in numerous ways. His work to enact the Children's Health Insurance Program (CHIP) in Utah helped reduce the uninsured rates for children to its lowest point ever. His administration worked to increase the number of Utahans with health insurance by 400,000 and raise immunization rates by nearly 75 percent. He also was a leader in using technology to enhance the quality of health care and reduce costs.

Mike Leavitt was chosen by his gubernatorial colleagues to lead numerous organizations during his time as Governor. In those roles, he was a critical voice in the national discussions on the reform of Medicaid and welfare and in the crafting of CHIP. He was chosen for these leadership positions because of his command of the issues, his bipartisan temperament and his ability to listen to all sides and fairly synthesize different viewpoints.

His reputation for seeking consensus has served him well as EPA Administrator. We believe that this leadership style will be put to good use in working with the country's Governors toward the implementation of the permanent Medicare prescription drug benefit in 2006, improving the Medicaid program, ensuring an adequate supply of vaccines, holding the line on health care costs and other important health care causes.

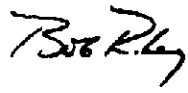
For his record of leadership, his steadiness of purpose and ability to get results, we heartily endorse Administrator Mike Leavitt to be the next Secretary of Health and Human Services.

Sincerely,

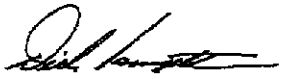


Kenny C. Guinn
Governor of Nevada

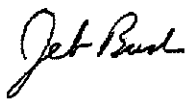
Mitt Romney
Governor of Massachusetts



Bob Riley
Governor of Alabama



Dirk Kempthorne
Governor of Idaho

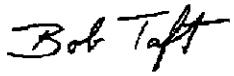


Jeb Bush
Governor of Florida

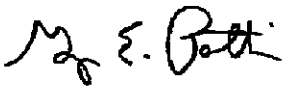
Mike Huckabee
Governor of Arkansas

Arnold Schwarzenegger
Governor of California

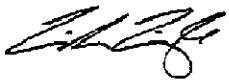
Bill Owens
Governor of Colorado



Bob Taft
Governor of Ohio

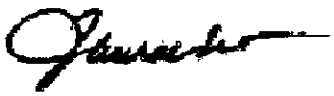


George E. Pataki
Governor of New York



Linda Lingle
Governor of Hawaii

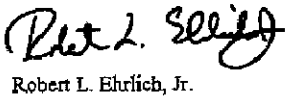
Rick Perry
Governor of Texas



Felix P. Camacho
Governor of Guam

Ernie Fletcher
Governor of Kentucky

M. Jodi Rell
Governor of Connecticut

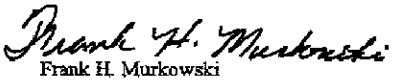


Robert L. Ehrlich, Jr.
Governor of Maryland

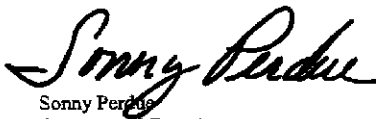
Haley Barbour
Governor of Mississippi

Matt Blunt
Governor of Missouri

Donald L. Carcieri
Governor of Rhode Island

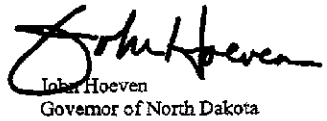


Frank H. Murkowski
Governor of Alaska



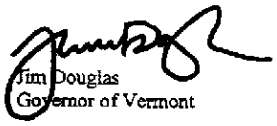
Sonny Perdue
Governor of Georgia

Tim Pawlenty
Governor of Minnesota

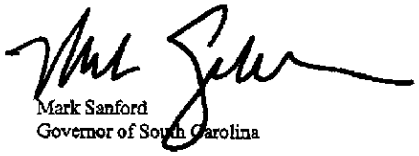


John Hoeven
Governor of North Dakota

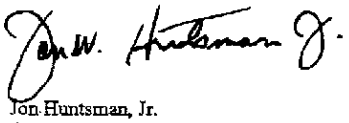
M. Michael Rounds
Governor of South Dakota



Jim Douglas
Governor of Vermont

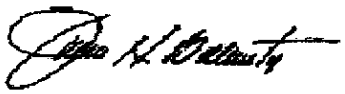


Mark Sanford
Governor of South Carolina



Jon Huntsman, Jr.
Governor of Utah

Mitch Daniels
Governor of Indiana



Juan N. Babauta
Governor of the Commonwealth
of the Northern Mariana Islands

NATIONAL ASSOCIATION OF HEALTH UNDERWRITERS (NAHU),
ARLINGTON, VA 22201,
January 17, 2005.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR KENNEDY: On behalf of the National Association of Health Underwriters and our entire Board of Trustees, I would like to wholeheartedly support the nomination of Governor Mike Leavitt for Secretary of the Department of Health and Human Services. Our Utah chapter has worked with Governor Leavitt extensively on health issues of all kinds and has given us their strongest vote of confidence in his knowledge, strength of character, and ability to get things done.

One of the most critical concerns in selecting the right person to lead a government agency as large as the Department of Health and Human Services is the ability not only to personally communicate well, but the ability to find ways to facilitate that type of communication with others both within the agency and among the citizens the agency serves. While governor of Utah, Governor Leavitt's ability to strategize effectively on technology resulted in an e-government initiative that made more than 110 State Government services available over the Internet.

Governor Leavitt has also shown himself to be an effective leader and communicator within organizations such as the National, Western, and Republican governors associations. He has been repeatedly chosen by his peers to lead them, and that

same leadership ability also resulted in Utah being recognized six times as one of America's best-managed states.

Our NAHU leaders in Utah know firsthand that Governor Leavitt's health care experience will result in innovative ideas being proposed and implemented. In 1994, Governor Leavitt proposed a comprehensive incremental approach to health care improvement that has resulted in 400,000 more Utahans having health insurance than did before, better use of the children's health insurance program, and improved immunization rates, all while decreasing the per capita cost of health care in his State to 25 percent below the national average. Certainly these types of skills are just what is needed at the Department of Health and Human Services.

We are confident that the Senate will recognize the tremendous potential Governor Leavitt has to offer and we look forward to working together with him and the Senate HELP Committee to improve access to affordable health care for Americans from coast to coast. Should you need any additional information or if we can move this process forward in some other way, please let me know. I can be reached at (703) 276–3806.

Sincerely,

JANET TRAUTWEIN,
Vice President of Government Affairs.

NATIONAL ASSOCIATION OF MANUFACTURERS (NAM),
WASHINGTON, DC 20004–1790,
January 6, 2005.

Hon. MICHAEL B. ENZI,
Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510–6300.

Hon. EDWARD M. KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510–6300.

DEAR CHAIRMAN ENZI AND RANKING MEMBER KENNEDY: On behalf of the members of the National Association of Manufacturers (NAM), the Nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 States, I write to express our strong support for the nomination of former Utah Governor Michael Leavitt to serve as Secretary of Health and Human Services.

Governor Leavitt is superbly qualified to serve as the Nation's Secretary of Health and Human Services (HHS). President Bush has chosen a leader who has been a successful manager of complex organizations like the State of Utah and the EPA. Governor Leavitt understands well the importance of building a more affordable health care system and the impact of health care costs on America's economic competitiveness in a challenging global economy. As Governor, I worked closely with Governor Leavitt on Medicaid and Welfare reform. Governor Leavitt was one of the lead Governors in the National Governors Association during the historic reforms of 1995–96. I know first-hand that he is a creative problem-solver who excels at innovation and management.

Governor Leavitt's leadership will be critical on the myriad complex issues before HHS, including deploying health information technology, promoting disease prevention and management and securing America's food and drug needs. He is the right choice at the right time to lead our Nation's health and human services agenda.

I hope that you will act promptly and favorably upon Mike Leavitt's nomination. If there is any way that the NAM can be of assistance to you, please do not hesitate to contact us.

Sincerely,

JOHN ENGLER,
President and CEO.

SAFE FOOD COALITION,
WASHINGTON, DC 20036,
January 14, 2005.

Hon. MIKE ENZI,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR ENZI: On behalf of the diverse group of Americans we represent, the Safe Food Coalition respectfully requests that you submit the attached questions to EPA Administrator Mike Leavitt to answer during his confirmation hearing as U.S. Secretary of Health and Human Services scheduled for Tuesday, January 18, 2005.

Thank you for considering our request on this very important issue. If you have any questions please respond directly to Ken Kelly at (202) 332–9110 ext. 319 and he will share your response with the organizations below.

Sincerely,

CAROL TUCKER,
Foreman, Consumer Federation of America.
CAROLINE SMITH DEWAAL,
Center for Science in the Public Interest.
KAREN TAYLOR MITCHELL,
Safe Tables Our Priority.
TONY CORBO,
Public Citizen.
TOM DEVINE,
Government Accountability Project.
ALISON REIN,
National Consumers League.
SALLY GREENBERG,
Consumers Union.

QUESTIONS OF THE SAFE FOOD COALITION FOR GOVERNOR MIKE LEAVITT

Modernizing Food Safety Laws

The National Academy of Sciences has said that food safety and quality in the U.S. is governed by a fragmented and overlapping system. It is based on laws, several of which were adopted in 1906, which means they are nearly 100 years old.

Question 1. Given how much the food industry has changed in the last 100 years, do you think that the food laws should be modernized to address new issues and hazards, like food borne pathogens, mad cow disease and genetically modified food?

Mandatory Recall

Currently, the Food and Drug Administration (FDA) does not have mandatory authority to recall contaminated food products. FDA must rely on voluntary cooperation by food companies to get contaminated food out of supermarkets, restaurants, and consumers' homes. FDA identified 3,248 recalls of non-meat and poultry foods from 1986 to 1999 and GAO identified nine instances during that time where companies delayed compliance with an FDA recall request.

Question 2. Do you think that FDA should have mandatory recall authority in order to protect American, consumers from unintentional contamination by food that is imported into the country?

Bioterrorism

The outgoing Secretary of Health and Human Services Tommy Thompson recently stated that "I, for the life of me, cannot understand why the terrorists have not attacked our food supply, because it is so easy to do." Secretary Thompson's concerns seem justified: Since 1994, food imports have grown five-fold to six million food import shipments, but the Food and Drug Administration (FDA) inspects only around 2 percent of these shipments. In addition, FDA does not have mandatory authority to recall contaminated food that it regulates.

Question 3. How would you improve FDA's oversight to imported food? For example, do you support the allocation of additional inspectors to the FDA in order to bolster food inspections at ports of entry in order to protect American consumers from the threat of both intentional and unintentional contamination of the U.S. food supply?

Question 4. Do you think that FDA should have mandatory recall authority to protect consumers from contaminated food that is distributed around the country?

Feed Ban

On January 26, 2004, HHS Secretary Tommy Thompson and then-FDA Commissioner Mark McClellan held a press conference to announce a new interim final rule that would tighten the feed regulations for bovines as a strengthening of the firewalls against bovine spongiform encephalopathy (BSE). This rule was to prohibit mammalian blood, poultry litter and plate waste as feed ingredients for ruminant animals. It would also require animal feed manufacturers to maintain segregated production lines to ensure that ruminant feed is not contaminated. A year later, this interim final rule has not been issued and none of these loopholes have been closed, leaving American consumers vulnerable to mad cow disease.

Question 5. What actions will you take to ensure that the measures announced by Secretary Thompson and FDA Commissioner McClellan are implemented immediately?

Trade With Canada

Two additional cases of mad cow disease have been identified in Canada in the last 2 weeks. In a recent letter sent by Senator Kent Conrad and Congressman Henry Waxman to USDA Secretary-designate Mike Johanns, they quoted from recent FDA "import alerts" and found that over the past 15 months, 17 Canadian feed companies have been cited by FDA for not meeting our current bovine feed regulations.

Furthermore, the Vancouver Sun on December 16, 2004 published an investigative report in which it cited Canadian Food Inspection Agency documents that showed seven Canadian feed mills with "major non-compliance issues." Three mills failed to "prevent the contamination of ruminant feeds with non-ruminant feeds" and in one of these cases the contaminated feed was actually consumed by other cattle.

Question 6. In light of these findings, do you believe that it is wise for the United States to resume beef and cattle trade with Canada at this time?

Anti-Microbial use in Animals

Anti-resistant strains of toxic pathogens, like Salmonella Super 9, have been increasing in recent years. Many scientific groups, like the CDC, cannot form valid risk assessments without information from drug companies on anti-microbial use of their drugs in animals, but current disclosure restrictions thwart real attempts to improve or design appropriate preventive measures.

Question 7. What course will you follow in getting drug companies to release information on anti-microbial use in animals? Are you willing to work towards building more open disclosure policies for all levels of animal production?

Traceability

Recently, departing Secretary of Health and Human Services Tommy Thompson made alarming comments regarding our food supply, claiming that it was vulnerable to attack by terrorists. Currently, there is no uniform traceability system in place for meat and poultry (USDA) and other contaminated foods (FDA) that would enable an effective and timely recall. Without a traceability system in place, it is almost impossible to trace contaminated food, both backwards to the source and forward through its distribution into the marketplace, allowing timely notification to the public.

Question 8. In the absence of uniform traceability, if a bioterrorism attack were to occur within our food supply, how does the government intend to respond? Should the government be developing traceability regulations that would result in contaminated food being recalled more effectively and completely, and which would include providing the public with complete information in a timely manner?

The CHAIRMAN. Governor Leavitt, proceed.

STATEMENT OF MICHAEL O. LEAVITT, OF UTAH, NOMINATED TO BE SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. LEAVITT. Chairman Enzi, thank you very much, and Senator Kennedy, for your graciousness. Leader Frist, thank you, and members of the committee. May I say that my heart requires that I express appreciation—appreciation to the President for his con-

fidence, appreciation to this committee for the graciousness with which I've been received as I have had a chance to move about and get acquainted with each of you, appreciation of the committee staff on both sides of the aisle who have been extraordinarily helpful in being able to go through the process that is necessary, an advise-and-consent constitutional process.

I would also like to express directly my admiration for Secretary Tommy Thompson. Tommy Thompson is a man who was a friend of mine while we were Governors. We served together not only as Governor, but he was a friend of the State of Utah while he was Secretary of HHS, allowed and empowered a number of important innovations and helped us solve problems. I believe America is stronger as a result of his service. I think the Department of HHS is stronger. People at HHS love Tommy Thompson. He is well respected on Capitol Hill, and I understand why. I want to pledge to him and to you that I will build on the legacy that he has built.

I would also very much like to acknowledge and express appreciation for the sentiments of my friends Senator Hatch and Senator Bennett, and the others who have expressed support for my confirmation. Their expressions this morning are warming impressions of a friend as well as professional colleagues, and I deeply appreciate it.

Mr. Chairman, I have prepared and submitted a written statement. In the interest of time and with an anxiousness to get to your questions, I am going to submit that and ask it be included in the record. But I would like to just cover, if I could, a few observations about the things I believe, about the vision or the feelings I have for the mission of the Department, and perhaps some of the things that we will need to face together.

First of all, let me say that I believe public service is a trust, and the most important thing I believe I can say to you today is that I give you my commitment that I will conduct that trust with fidelity.

I would also like you to know that I believe that this Nation has a responsibility to care for the truly needy, but it is also our generational responsibility to foster and to teach self-reliance. Self-reliance is a prerequisite of freedom and of prosperity.

I would like to also acknowledge the deep belief I have in the mission of the Department of Health and Human Services. It is clear to me that when families gather around their table at night that in this Nation they are able to do so with confidence knowing that their food is protected and safe. We live in a nation that when we awake in the middle of the night and administer medicine to a child, we do so with the confidence that it is safe.

I would also like to acknowledge the profound importance I think that this Department has on the administration and the development of health care policy in this country. It affects us all from the moment we enter this life until the moment we leave.

I am also quite conscious and feel very sensitive about the importance this Department plays in allowing us to meet our most noble aspirations as a society to care for those who are in need, the welfare of families, the health of families, and the ongoing capacity for us to assure that the truly needy in our society are, in fact, cared for.

In the course of the last several years, we have become more conscious of a new role that HHS plays, and that is its new important role in the fight for a safe homeland.

I would like to just, if I could, review a couple of the subjects that I know we will want to talk more about and that I feel confident that we will deal with over the course of our time if I am successful in my nomination and confirmed. The first is Medicare.

May I just say that successful implementation of the Medicare Modernization Act will be the main event at HHS in the year 2005. The time frames are short. The expectations are high. The interest is wide. The implications are long. There will inevitably be flaws, but we will not fail.

Senator Kennedy and others mentioned the reauthorization of welfare. I believe this is an American success story. What we have accomplished in the last 6 years is something that must be continued and improved upon, and I look forward to working together with all of you to see the reauthorization of this important program.

Medicaid. I believe Medicaid is a vital program. I believe it is a remarkably important means by which we serve the poor in this country. But it is not meeting its potential to do good in the lives of the poor that it can. I mentioned to one of you in a meeting that I had with you privately in your office, when asked what it was about this responsibility that appealed to me, I reflected that some 6 years ago or 7 years ago, I appeared many times before this committee and others when we were working on welfare reform and Medicaid. We succeeded, I believe, well with Medicare—rather, with welfare. We did not succeed on Medicaid, and I vowed if I ever had a chance to work on it again, I would. And I look forward to working with you to find ways in which we can serve this very important population in ways that will meet its full potential.

I would also like to recognize the importance of protecting three very important American brands: the FDA, the CDC, and NIH. Those I refer to as "brands" because a brand is a promise. It is a reputation. And it is clear to me that the American people depend on that promise. And we need to protect the integrity of those American treasures.

Large-scale discussions in my mind are beginning to grow on the whole subject of health care policy and how we deliver it. I welcome it. That discussion needs to be bold and it needs to be transformational, and we start with medical liability, something that badly needs to be improved.

I will also recognize this morning in my introduction the role I believe the United States of America has in influencing the rest of the world as a good humanitarian voice.

Now, Mr. Chairman, when I entered public service, I adopted three goals, perhaps consistent with our Western roots: I committed that I would leave it a better place than I found it, that I would plant seeds for a future generation, and that I would give it all I have. It is that pledge I leave with you today and look forward to interacting with you on the issues I have spoken of and many others that I am sure you will raise today and in the future. I look forward to an opportunity.

Thank you.

[The prepared statement of Mr. Leavitt follows:]

PREPARED STATEMENT OF THE HONORABLE MIKE LEAVITT

Good morning Mr. Chairman, Senator Kennedy, and members of this committee. Thank you for inviting me to discuss my nomination to be Secretary of Health and Human Services.

I would like to begin by expressing my immense admiration for Tommy Thompson. We have been friends for many years, but my admiration is broader than just friendship. I admired his leadership as Governor of Wisconsin. The two of us worked together on many of the issues we will talk about today. He also brought an aggressive agenda to HHS, and his 4 years at the helm have made America healthier and safer.

Consider: Medicare is providing more comprehensive care to more American seniors than ever before. HHS is better prepared than ever to respond to public health emergencies. More children receive immunizations and health care, and fewer use drugs. The Food and Drug Administration is inspecting seven times as much imported food as it did 4 years ago. And, thanks to the leadership of President Bush and Secretary Thompson, the United States leads the struggle against AIDS around the world.

Tommy has earned the affection and respect of the people of HHS, and I pledge to him and to you that, if confirmed, I will build on his legacy.

I have enjoyed every stage in my career, from business, to being Governor of Utah, to protecting the environment as Administrator of EPA. Now, President Bush has asked you to confirm me as Secretary of Health and Human Services. I want to thank him for his confidence and thank you for assessing my fitness to serve.

As a prelude to answering your questions it may be helpful if I tell you what I believe, what issues and opportunities I see confronting our Nation, and how I view the Department of Health and Human Services.

I believe conducting the public's business is a sacred trust. I pledge that I will serve with fidelity and full effort.

I believe collaboration trumps polarization every time and that solutions to complex problems have to transcend political boundaries.

I believe that information technology is challenging old institutions, bridging great distances, and giving people more control over their own lives. To survive, governments will have to be more flexible and more competitive.

I believe market forces are superior to mandates. People do more, and do it faster, when they have an incentive to do the right thing.

I believe we should reward results, not efforts. Our focus should always be the outcomes we are striving to achieve.

I believe that to change a nation, you have to change hearts. And you change hearts through education and example.

I believe government must care for the truly needy and foster self-reliance and personal charity. Helping others is good for the soul. Government can augment this compassion and provide services, but it can never replace the love that makes us help each other.

I expect the Department of Health and Human Services to achieve our Nation's noblest human aspirations for safety, compassion, and trust.

When we gather our families for dinner at night, we rely on HHS to ensure the food we put on the table is safe.

When we are alone at night caring for a sick child, we trust HHS to ensure that the medicine we give her is effective.

Our poor, disabled, and elderly have health insurance because this Nation has made it a priority; another powerful stewardship that has been given to HHS.

The Department of Health and Human Services helps to strengthen marriages and families, protects children, and fights disease. For example, we are often called upon to protect neglected and abused children. But we can never replace the love of a parent.

And if, God forbid, terrorists should ever unleash a biological agent on American soil, we would rely on the dedicated men and women of HHS and the plans they have developed already to stop the disease in its tracks and protect Americans.

We all know that HHS spends nearly one out of every four dollars collected by the Federal Government in taxes. I am humbled by the prospect of shouldering that responsibility.

I would like to thank the members of this committee for the kindness you showed me as I visited your offices. Our conversations have been helpful as I contemplate this task. One of you said, only partly joking, "Why would you want a hard job like that." There are so many reasons. Let me mention a few, beginning with welfare and Medicaid.

Welfare Reform

In the late 1990s, in my role as Chairman of the National Governors Association, I worked closely with Congress and other governors in building the federal-state partnership we called welfare reform. We can all be proud of this dramatic American success story. We set a tone of compassion for this country by caring for those in need and fostering self-reliance. Now I look forward to working with you to ensure that welfare reform is reauthorized and improved.

Medicaid

During the same period, Congress worked hard at reforming Medicaid, but ultimately failed. I vowed then that if the opportunity ever arose again, I would seize it. Delivering health care to the needy is important, but Medicaid is flawed and inefficient. We can do better. We can expand access to medical insurance to more people by creating flexibility for our State partners and transforming the way we deliver it.

Medicare

When you and your colleagues approved the Medicare Modernization Act, Mr. Chairman, that was a great achievement. And you asked us to implement the Medicare prescription drug benefit on January 1, 2006. This is a great challenge.

I have no illusions about the size of the task. It is immense. But I recognize that the President and the Congress made a solemn

commitment to America's seniors. I have the responsibility of delivering on that commitment. Our work will not be without flaw, but we will not fail.

Global

This Nation's compassion is not limited to America. We live in a prosperous country. And our prosperity is not only a blessing—it's also an obligation. While the world sometimes envies or resents us, it always respects us. And when we do the right thing, others emulate our example.

In international health, one of our Nation's greatest strengths is our considerable convening power—it's our ability to inspire, to set an example, and to call upon the best knowledge, experience, and resources, from individual experts, private institutions, and government agencies.

I resolve to use this convening power to meet our obligation as human beings to improve health and well-being. We will reach out to reduce suffering, to promote understanding, and to inspire compassionate action.

FDA, NIH, and CDC Brands

HHS is the trustee for a number of our Nation's most treasured brands. A brand is a promise. Over decades, the dedicated scientists and researchers of HHS have earned the public's trust, especially in three brands: FDA, NIH, and CDC. To millions of people, these brands are seals of quality, safety, and best in the world research. If they lost their reputations, they would take years to recover. HHS always needs to keep in mind the ethical implications of its decisions, to ensure that Americans can be proud, not only of the Department's scientific expertise, but also of the moral judgment of its leaders.

At FDA, our goal must be to inform consumers about risks and benefits. Our foundation must be sound science. Our motto must be independence.

At NIH, we must march forward with life-saving research, and always hold the scientists, universities, and laboratories accountable for results.

At CDC, our guiding focus must be disease prevention and control, sharing generously the best health and safety information in the world.

Liability

Most doctors make a sincere effort to do a good job, but medical errors do occur. People who are harmed by medical errors absolutely deserve prompt and fair compensation. Unfortunately, the capricious liability system that prevails in many States helps no one. Senators, I look forward to working with you to pass comprehensive medical liability reform.

Twenty-First Century Health Care

Most broadly, Americans deserve the health care of the 21st century. We've earned it. That includes modern medical technology. Modern information technology. And modern, consumer-focused delivery systems.

I see a world that is rapidly moving toward personalized medicine. People will own their own health savings, health insurance, and health records.

I see a world in which a doctor can write a prescription on a handheld device and transmit it to the patient's pharmacist, who can start filling it before the patient leaves the doctor's parking lot—and with less chance of error or delay.

I see a world where doctors heal our loved ones when they are sick, but focus more of their energies on keeping them well in the first place.

I see a world where good health care makes America more productive, not less competitive.

And I see a world where premier health research serves the betterment of mankind.

Conclusion

Mr. Chairman, I have always had three goals in public service. I followed them as Governor of Utah. I've followed them as Administrator of EPA. And I will follow them as Secretary of Health and Human Services.

The first goal is to leave things better than I found them.

The second goal is to plant seeds for future generations.

And the third goal is to give it all I have.

I promise to work with this committee in a responsive and transparent manner so we can do just that.

Thank you for your attention, Mr. Chairman. I look forward to answering your questions.

The CHAIRMAN. Thank you very much. I appreciate the brevity of your statement and want to assure you that your full statement will be a part of the record. I would also say that our prayers are with your wife for a speedy recovery and for your children who are flying in for a safe arrival.

Mr. LEAVITT. It is just an isolated epidemic of the flu in the Leavitt family. I am hopeful I can demonstrate my prowess as head of health, in my home at least, and get her better.

The CHAIRMAN. So I will not have to ask you any questions about vaccines because you will have a specific interest in that.

I did mention some front-page issues that are up, and one of those is the FDA's drug approval process, and I am sure you will be reviewing the authority and the resources of FDA.

How can we best work with you to ensure that the FDA has the proper authority and sufficient resources to perform the regulatory function that we have assigned to them in an effective and timely manner?

Mr. LEAVITT. Senator, I have become increasingly aware, as I know you and other members of the committee have, on the constant tension that exists between our desire to have innovation and speed to market and safety. Those are intuitive to all of us on both sides and create a natural tension. It will be finding the balance and working together to find ways to expedite innovation, but at the same time being able to protect it. I recognize that there are many, many issues still remaining. I look forward to working and working through with both those who manufacture and those who are responsible to assure their safety that we can do so.

The CHAIRMAN. Well, I hope that America realizes that a successful clinical trial does not guarantee the safety of a drug through the life of the drug. Some rare but serious side effects do not show up until after the drug is in wide circulation. What role should the FDA play in identifying these problems once a drug is on the market?

Mr. LEAVITT. Senator, I believe we are moving into a remarkable and powerful new era in medicine and particularly in prescription drugs. I would refer to it as a personalized—an era of personalized medicine where we will have the capacity in the future to determine the effect of drugs not just on broad populations but on specific cohorts and specific phenotypes among populations of human beings.

This will require a focused, disciplined review over time of the basic constructs and standards to which we hold ourselves. It is an exciting thing and part of a larger personal vision that I think this country can have of where we begin to focus our medicine not on institutions and not on broad populations but on people and on individuals and the way things can affect them directly. The treasures that have been unlocked in genetic research are very exciting and will change the way we look at matters at the FDA as well as in our broad policies that will need to be visited by this committee in a broad public debate.

The CHAIRMAN. Thank you. I want to shift the focus just a little bit. I know that you have been the cyber Governor and have a huge interest in information technology. Last year President Bush announced an ambitious plan to assure that every American has electronic health records, and he called on Secretary Thompson to appoint the first ever National Coordinator of Health Information Technology. I applaud the President for this emphasis on increasing the use of information within our health care system, and Senator Kennedy and I are intensely interested in doing some things to expedite that.

What are the next steps that Congress and HHS should take to make the vision of robust health care IT a reality?

Mr. LEAVITT. Senator, I share with you the day—a vision of the day when a physician will write a prescription on his personal hand-held electronic device, that it will be transmitted electronically to the patient's pharmacist who will be filling it before he leaves the parking lot of his doctor's office, and the health record will immediately be part of the permanent record that that person takes with them when they go to the next doctor's office for whatever purpose. I see that as having enormous—just as a symbol of the enormous amount of potential that we have in technology to streamline and make efficient the whole system of medical delivery. When you consider that medical services now approximates 15 percent of the gross national product of this country, this is not just a function of better health care; it is also a matter of economic competitiveness.

I believe that the area of interoperability of systems, of being able to sort through the very difficult, complex, and sometimes thorny issues related to personal privacy and related to assuring that those records are not used improperly will be among the most

important work that this committee can do in order to facilitate that discussion and that promise.

The CHAIRMAN. Thank you. I am going to shift focus once again to Medicaid because I know of your great work on that in Utah. A longstanding concern of mine has been that there are adults and children that are not enrolled, so they wind up in that 43 million Americans that are uninsured, but really they are just unenrolled. What do you think are the reasons for this? And do you believe there is anything we can do to rectify that situation?

Mr. LEAVITT. Senator, I do. I feel passionately there are things we can do to remedy that.

When I became Governor, only 86 percent of our children had access to health insurance. Now virtually every child has access, but 94 percent have health insurance. The CHIP program, SCHIP program, has been a great success in our State and other States. Some things have been revealed there to me that give me great promise.

For example, many worried that we would not be able to reach enrollment online among that population. In our State, over 50 percent of our enrollees or nearly 50 percent have enrolled online. We have also been able to reach into our rural populations with that program. We have used our schools as a method of being able to approach and find those who needed it. It is simply a matter of finding them and helping them, making it easy and helping them understand.

The CHAIRMAN. Thank you.

Senator Kennedy.

Senator KENNEDY. Thank you.

Welcome, Governor I join you in your the great support for the SCHIP program. I acknowledge the excellent leadership of my friend and colleague, Senator Hatch, on that program.

Just a quick note and I want to keep moving. There was a billion dollars that was returned last year that was not used in the SCHIP program. There is a need in that program. In the past when we had money that is returned, we have had a bipartisan effort, which we do have now in the Congress. The administration has been somewhat slow in giving us their judgment, whether they would support returning those funds to SCHIP as they have in the past, and I would hope maybe we could work with you on this. I do not know whether you have a view on this now. If it is not going to be encouraging, I would rather not hear it.

[Laughter.]

But if you are open on it, if we could work with you on it, there is a strong bipartisan effort to try and restore the funds to get other children covered.

Mr. LEAVITT. Senator, I am very optimistic about the sense of value that exists in SCHIP, and I know that there is an ongoing budget discussion that will be conducted between Congresses.

Senator KENNEDY. Just to pick up what the chairman said—about IT. I am continually impressed with an article out of the New England Journal of Medicine. I had not planned to bring this up here, but since you mentioned, since our chairman did. This is the data from the Latter Day Saints Hospital, and it shows what has happened with improved IT: better outcomes such as drug doses of medicine per patient, stays in the ICU, cost per patient,

mortality when this is replicated in system after system. We need it in terms of interoperability, better quality care, saving resources—although we may dispute how those resources ought to be allocated. But let us get about it. I would love to continue that conversation with the chairman, and we talked about that in the past, but I thank you for your strong interest in it.

If I could get to Medicaid. We know what we are facing in terms of the 50 million Americans depending on Medicaid for their health care. It is the poorest of the poor. The number of Americans living in poverty has grown by 8 million in the last 4 years. We have about 800,000 more children that are living in poverty. We see, in spite of increased need, that 38 States have cut the Medicaid eligibility, 34 States have cut the Medicaid benefits. Many States have not recovered from the recession's impact on their revenues, and we hear that the administration is planning to cut Federal support of Medicaid. My own view of this is that it would be a move in the wrong direction. You are a former governor. Do you think it is time that we ought to be cutting Medicaid?

Mr. LEAVITT. Senator, I have been one of those States who have been in a situation of very difficult budget circumstances, and it has always been my belief that we can expand the number of people that we serve with available resources. I have seen that happen many, many times, and I believe our focus should be to take what is available and expand the number of people who are provided with care.

Senator KENNEDY. I agree. No one differs as long as the people that need the help will receive the help, and it will be quality help, if that is what you are saying, and doing it more efficiently and effectively. But if you come to the point where you are going to have a reduction in services, if you cannot stretch it out, I would imagine you would be concerned about that.

Mr. LEAVITT. Senator, my purpose, if I am confirmed as Secretary, will be take the resources that are available to us and make certain that we are serving with basic quality health care the broadest population possible. It is clear to me we can serve a broader population if we allow the States greater flexibility to use those resources to make sure that they are devoting the resources, that they are putting up real dollars, making real commitments, and that we are too, and doing it in the most efficient way possible.

Senator KENNEDY. I want to move on. There are increased sorts of demands in terms of numbers of needy people on Medicaid. I am all for getting a better bang for our dollar, but I think there is real concern about whether we are going to be squeezing and denying health benefits, which would be unfortunate.

Let me move to Head Start. It has been an extraordinary success. We are going to be reauthorizing it. We are always interested in how it can be strengthened. We are always interested in how it can be tied on into the No Child Left Behind Program more effectively. We have 38 States now that have even gone into pre-Head Start programs. But Head Start works, and there are many of us who think that since it does work why we should be trying to limit it. We have enough challenges out there for different kinds of undertakings that are not working. I am just interested in your view on that program, on the Head Start, and any comments that you

wanted to make on the block grant, maintaining services or anything else expanse that you want to address.

Mr. LEAVITT. I share with you the belief that Head Start works. I share with you that it serves a very important preschool population and others. I share with you the view that we can improve its effectiveness by better coordination with other existing State programs.

Senator KENNEDY. My time is up, Mr. Chairman.

The CHAIRMAN. Would you like to ask another question?

Senator KENNEDY. I will wait till I get a second round. Thank you.

The CHAIRMAN. Senator Frist.

Senator FRIST. Thank you, Mr. Chairman.

Health care disparities, I continue to be troubled by the obvious disparities in our health care system, the gaps that this committee will hopefully continue to focus on aggressively over the next Congress.

Just last week the Office of Minority Health of the CDC reported that nonHispanic blacks bear a disproportionate burden of disease, whether it is injury, death, morbidity, or disability. In the CDC's report, just as an example, nonHispanic blacks who died from HIV disease had approximately 11 times as many age-adjusted years of potential life lost before age 75 years—that is on a per hundred thousand population basis—than did nonHispanic whites. Non-Hispanic blacks also had substantially more years of potential life lost than nonHispanic whites for homicide, nine times as many I believe. Stroke was three times as many. Perinatal diseases, it's either three to four times as many, somewhere in that range. The report documents disparities one after another. The documentation phase is not over because it is very important to do, but now is the time for action and for solutions. I appreciate the administration's commitment to reducing these disparities, the social disparities, the socioeconomic disparities, the racial disparities, the geographic disparities that plague our health care system and result in these very disappointing gaps.

I have cosponsored legislation, bipartisan legislation entitled "Closing the Health Care Gap Act." I think we need to continue to work together to eliminate these disparities. My question focuses on that. As Secretary, what actions can you take to build upon the administration's record during the past 4 years and work toward a day when such disparities will truly be eliminated?

Mr. LEAVITT. Senator, I share your concern and your feeling of inequity when I see that health outcomes are different, both in a defined way, and predictably among certain groups of people, particularly ethnic differences. I would mention two or three things. The first is best practices. The use of technology to assure that best practices can be deployed across the board at every hospital when they are known, and that is a function of technology and providing a means by which best practices can in fact be delivered. Second would be the disparities that exist in health coverage. I mentioned earlier my belief that we can serve more of those who are currently uninsured with the resources that we are currently devoting. I passionately believe that.

I will use again SCHIP as an example. One of the brilliant things that I believe that Congress did in writing SCHIP was to give the States the capacity, if they chose, to develop their own plan, both benefits and administration, as opposed to requiring them to fall under Medicaid. In my State—we were one of 13 who did so—and we were able to provide basic health care, the same health care essentially that my children received while I was governor, for nearly 30 percent more people than if we had had them on Medicaid. That to me demonstrates that we can deliver basic health care to more people using the same resources. Many of them fall into the categories that you have spoken of, either because of their geographic location or their ethnicity.

Senator FRIST. Thank you, Governor. I think what you pointed out in terms of the flexibility required, that not all populations are the same. We used to think of health care disparities as just being straight out racial inequities, disparities, which is a huge and important component, but part of it is socioeconomic. I think of the Appalachian Mountains in Eastern Tennessee, and every State is a little bit different. I just want to encourage both this committee, in working with you, with your leadership, to make real progress on these issues.

I have been in the Senate now 10 years and very early on we had to define those disparities. Now I feel like we have them defined, and now is the time, through an approach such as you mentioned, first of all recognizing the emphasis, providing the appropriate resources, and as you said, having the flexibility of being able to go to different areas, targeting different populations, and adjusting accordingly. Thank you, Governor.

Mr. Chairman, thank you.

The CHAIRMAN. Senator Alexander.

Senator ALEXANDER. Thank you, Mr. Chairman. I am glad to be here to say how proud I am of Governor Leavitt's nomination. I have made a habit for the last 30 years of watching governors in other States, and there have been a handful of what I would call transformational governors, those who have understood their State's uniqueness and celebrated that and found ways to actually change and improve it to transform it. Governor Dupont was one of those, Governor Engler, Governor Thompson was one of those, and Governor Leavitt was one of those. I think for him to come to this Department at this time, especially when the Medicaid challenge is going to require finding ways to take the available resources and give States as much flexibility as possible, and meet the needs, entrusting them to do that is very important. Understand that at governors' meetings, people do not sit around and talk about, "I can do it worse than you can do it." They sit around and talk about it and say, "I can do it better than you can do it." That is what the competition does.

So, I am delighted you are here. I want to thank you for your work with the Environmental Protection Agency and for your efforts to pay attention to the air pollution we have in the Great Smoky Mountains of East Tennessee. You have taken some steps which I hope will take us even further.

I want to ask these questions. You have talked some about the States, and I have confidence that you will pay attention to the

States. Senator Frist and I are very aware of what is happening in Tennessee. When I left the governor's office in 1987, 51 cents out of every State tax dollar was being spent on education, 14 cents on health care. Today it is 40 cents on education, instead of 51, and 26 cents on health care, going up. We are not going to have any first class universities or excellent schools in our State if the State cannot afford to fund them. So the governors need that flexibility.

I want to move on to another area that you have had some background in in your work as Chairman of the National Governors Association, and that is to look at early childhood education, early education. In another hearing with Dr. Condoleezza Rice this morning, it was pointed out that her parents, in the segregated town of Birmingham, made sure she had music lessons from the day she was 3-years-old, and they recognized her talent. There are 69 Federal programs already existing which spent 18 to 21 billion dollars other than Medicaid on behalf of early education for children, and several of those are in your Department. Those are programs that, not just Head Start, which we often talk about, but the Child Care and Development Block Grant is another one of those programs. The programs that you have in your Department, although there are only six, are 15 of the 18 to 21 billion dollars that have to do with early childhood education.

So what I would like to do, working with the chairman, is to use our oversight responsibility in this committee, and take a look at the Federal dollars that we are already spending on early childhood education, and find out where we are spending it well, where there may be gaps, and then report to the full committee and to the Congress about what else we need to do.

What are your thoughts on what you might do in your new position when you are confirmed to help Senator Enzi, Senator Kennedy, me and other members of this committee, to take a look at the dollars we are already spending on early childhood education and suggesting to us where needs exist and how we might be able to improve that through legislation?

Mr. LEAVITT. Senator, I have strong feelings, as I know you do, about the importance of dealing with this problem and dealing with it soon, because there are generations of children who are not being as well served as they could by a proliferation of programs. We do make a substantial investment in this country. As you suggest, maybe it should be greater, maybe it is adequate, but it is not as well coordinated as it should be. The number of programs—I will use in my own State—that do not coordinate, many of them serving the very same children. I would simply say providing the flexibility so that there could be on a State-by-State basis a commitment for better coordination and delivery of services in a fashion that looks at the whole child and not simply programmed needs.

Senator ALEXANDER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Burr.

OPENING STATEMENT OF SENATOR BURR

Thank you Mr. Chairman, it is a pleasure to be here today for this committee's second nomination hearing of the year.

Mr. Leavitt, thank you for being here. I am aware of your impressive work as the Governor of Utah and, more recently, as the Administrator of the Environmental Protection Agency. Under both jobs you demonstrated an excellent ability to manage and improve the lives affected by your position. We will be fortunate to have you as our Secretary of the Department of Health and Human Services.

As you are aware from your tenure as the Governor of Utah, the issues you will be responsible for at the Department of Health and Human Services are broad and complex. Our Nation's health care system is at a critical point and decisions by HHS will determine our path and the wellness of Americans in the coming century.

I sincerely believe that without cures for several chronic diseases, including diabetes, and a serious focus on preventative health care, we will not be able to stop our health care delivery system from hitting a brick wall. As a government, we must not pass laws or create an environment that hinders medical device and pharmaceutical research on new technology and medication, which can greatly impact quality of life. It is only through that important work that the world will be able to cure diseases that we currently can only treat as chronic conditions.

As a government, we must also help every American access affordable health insurance. But it needs to be smarter health insurance than what is currently available to most Americans. Smarter health insurance would allow individuals to be true participants in accessing and managing their health care needs. Individuals would be more knowledgeable and they would see the long-term benefit of preventative care; not only with their family budget in mind, but from a quality of life perspective.

Depending on individuals' situations, sometimes community health care centers are the best health care access point. I am very proud of North Carolina's community health care centers and as a Member of Congress I worked hard for the last 10 years to provide community health centers with necessary resources and assistance. Not only should the President continue his push for more community health centers, but he should also encourage existing centers to follow Greene County, NC's lead and implement electronic medical records and telemedicine capabilities throughout community health center networks.

These are very broad, but important goals. While we strive to reach these goals, we must also deal with the day-to-day threats faced by this country. Outgoing Secretary Tommy Thompson did an excellent job jumpstarting bioterrorism preparedness at HHS. I will look for you to continue his dedicated work in that area. The only way we can continue to work on our long-term goals for this country's health care system is if our Nation stays safe and secure from bioterrorism threats.

Mr. Leavitt, I look forward to asking you some questions and working with you in the future.

Senator BURR. Thank you, Mr. Chairman.

Governor, welcome.

Mr. LEAVITT. Thank you.

Senator BURR. And indeed a thanks to you for your commitment to public service, for the incredible leadership you showed at EPA, and most importantly for the creativity to problem solving, not only

that you showed as governor, but in the administration. It is, I am sure, not easy to say no when the President calls, and I think that your commitment to do this shows how wise the decision was by the President in seeking you to come to HHS.

My first opportunity to meet you was in 1995 when you testified in front of the Energy and Commerce Committee. At that committee hearing you talked about States needing more control over Medicaid. Let me ask you, today do you still believe that that is the case?

Mr. LEAVITT. Senator, I have deep, and I believe well-informed views that it is even more true today. We continue to see Medicaid escalate as a function of American investment. It is broadly now known, but I will say it for emphasis, that this year our expenditures on Medicaid will exceed our public expenditures in States on education. When I became governor 12 years ago, that was not even close. But our expenditures continue to rise, and our capacity to meet other demands continues to diminish.

I believe we have substantial obligation to care for the poor, but I believe that we can expand the number of people who are served with quality basic care by allowing additional flexibility and assuring that we have a partnership where both partners are putting up real, making real commitments and using real dollars to fund them. This is an important part of what I believe will become the larger medical debate in this country over the next couple of years. We could and should use Medicaid as part of a transformation movement in the delivery of health care generally.

Senator BURR. I certainly agree with you, and I think members would not serve on this committee if there was not a passion for health care, and I am sure you would not be at HHS if there was not also a passion on your part.

A personal concern is that we are moving from what has been up till this point a debate about affordability, and that the lack of solutions on our part means that we will very quickly be faced with an accessibility problem from the provider standpoint. We will feel it first in the rural markets and then it will spread to the urban markets.

Let me shift if I could over to SCHIP and follow up on Senator Kennedy's inquiry. When we wrote SCHIP it was the intentions of that legislation that States that did not use their allocation, that that money would then be freed up for the States that had fully implemented the money that they had available. North Carolina would have been the beneficiary of additional funds because we did an excellent job at SCHIP enrollment. I am not asking you to be a prophet as it relates to the budget or to the disposition of this money. But are we at a situation where States who do excel should have an incentive to grow the population even bigger?

Mr. LEAVITT. As you suggest, Senator, there is an ongoing budget discussion about what the disposition of those dollars should be, and I am going to leave that between the Congress and the White House. I will tell you this: that whatever amount of money is allocated to SCHIP, I can assure you it is having a profound and important impact, and to whatever extent HHS has an opportunity to administer money, we will assure that it is done in a way that will

reach out, find those populations of children and provide them with basic health care.

Senator BURR. Thank you. Last question. Senator Alexander talked about the academic institutions and their need to stay vibrant. One of the areas that is beneficial across this country today is the extramural research dollars that come out of NIH. Tell me if you can, do you see a growth in the extramural side versus the intermural side at NIH, and which is more beneficial to the long-term breakthroughs in this country?

Mr. LEAVITT. Senator, I do not know the answer to that. We were dealing with that same question at the Environmental Protection Agency, who has an extended research and laboratory capacity, and the issue was should we do it inside or do it outside, and it was clear to me that there needed to be a healthy dose of both. The balance of it at NIH is not something I am in a position to make a knowledgeable suggestion on, but I am very well acquainted with the pressures, the debates and the tension, and I feel some confidence, if confirmed, that I will be able to work through that with you.

Senator BURR. Thank you, Governor.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Isakson.

Senator ISAKSON. Governor, welcome.

Mr. LEAVITT. Thank you.

Senator ISAKSON. I have to tell you, last night when I got on the airplane about 8:15 to fly to Washington, much to my surprise, I sat next to the former director of the Department of Medical Assistance in Georgia, an old friend of mine, Russ Towles, who in the course of the conversation I told him where I would be at 10 o'clock. He said, "Well, you tell Governor Leavitt that he is the best choice the President of the United States could have possibly made." He is a big fan.

Mr. LEAVITT. Thank you.

Senator ISAKSON. Because he said that, and it gave me a great opening, I decided I would ask him, "Well, if you could ask the Governor any question, what would you ask him?" And he was very complimentary of what we did in the Prescription Drug Medicare Modernization Bill, but he asked the question, in Medicaid there is a rebate program on pharmaceuticals based on volume. As you implement through this year the prescription drug plan for Medicare beneficiaries, can we do the same thing?

Mr. LEAVITT. Senator, that is a well-informed question, and one that I am not sure, given the limited exposure that I have had at HHS on the nature of it on this side of the equation, that I am in a position to really knowledgeably respond to. I will tell you that, again, as a question we referred to earlier, these are tensions I am very well acquainted with, having dealt with them as governor, and my experience has been there is a balance that has to be found. We have to provide means by which we can create both the incentives necessary and the economic structure for continued innovation. At the same time people deserve to have safe pharmaceuticals, to have them delivered in an innovative way, and to do it. I would seek balance. I do not think I can give you an answer

beyond that. I am just not well acquainted enough yet with the issue.

Senator ISAKSON. Well, as you work on it, I will be happy to work with you. I supported the program. I think it is a brilliant move in terms of the future of health care pharmaceutical coverage for seniors. In the long run they actually save us money over the higher cost of hospitalization and more intensive care.

Second, as Governor of Utah your use of technology was nothing short of tremendous, in distance in your education department, which I am familiar with, and other areas. I want to go back to what Senator Kennedy said and Chairman Enzi, talking about health information and using technology. It seems to me that as we have spiraling costs of health care, one of the embedded costs that is growing is the paperwork cost and the redundancy of doing the same thing over and over again almost to the level of insanity.

I mean I recently made two trips to the doctor, and it is after January, so I filled out health information forms ad infinitum, which could have been available on a health ID card that could be just as secure as my ATM card. And I know you indicated earlier, and I want to applaud you for it, we need to work as far as we can. That is one component of the cost of health care, that it seems to me we could foster quickly to help bring down some of the costs and actually improve the qualify of both information and care for those who receive it.

Mr. LEAVITT. Senator, I have heard estimates that range as high as 20 percent, that there could be 20 percent additional efficiency, and I believe them. It is everywhere I look in the health care delivery system. I do not think there is a person on the planet who has not dealt with a health care issue.

Last night I was looking through a medical bill of mine on a medical device that I bought in July, and I have, first of all, found that the health insurance company was charged $900 for this device. I could have bought it online, the same device and the same person for $400. We have been going back and forth.

There is a more efficient way to do this, and it all comes down to technology and coming up with interoperable systems. This is a problem that the entire economy is going through. We have come through a period of industrialization. We have gone through the information age. We are now moving into the age of interoperability. We have learned to make machines work together. Now it is can we get the people to work together? Can we find systems from Government agencies and private providers and hospitals and physicians, and cause them to work together in a way that will create that efficiency?

This is a complex, demanding problem, and I believe there is an entirely new set of skills that we are having to learn as a society, but the efficiencies are there to gather. I believe we can and must pursue it because it is not just a function of good health care. It is a matter of economic competitiveness as a nation when 15 percent of our entire gross national product is being consumed in health care services. Unless we are able to do it efficiently, it could become a drag on our productivity as opposed to the boost that it can be.

Senator ISAKSON. Thank you very much.

My time is up, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Hatch.

Senator HATCH. Thank you, Mr. Chairman.

Governor Leavitt, as you are well aware, Utah is a State where we have tremendous capacities in health care, medical device companies, pharmaceutical companies, and many, many dietary supplement companies as well.

There are some in this town who believe that supplements are unregulated, which I hope you know is absolutely not true. We gave more power under the Dietary Supplement Health in Education Act than previously existed to the FDA. Now, many also believe that you will go easy on supplements because of our home State connection, which I also believe is not true; I believe that you will implement the law as it should be implemented. That is my understanding.

Mr. LEAVITT. Senator, your assumptions are correct.

Senator HATCH. The law in this area is tremendously complicated, and I will not put you on the spot today by trying to pin you down on anything. I just want to note that the past two commissioners and the acting commissioner, I believe, agree with me and Senator Harkin, that the law is adequate to take care of those supplements that may pose a concern, be it a safety concern or one related to labeling or content.

Now, when you come on board, it would be well if you could speed up the Good Manufacturing Practice Guidelines that we approved well over 10 years ago, or I should say were authorized by law over 10 years ago, and which have been held up for several years. I think it is critical to that industry that this organization that you are going to head take care of that. I believe they are almost ready to be published now.

But on a more general note, I wanted to put these concerns on record, and I will be asking for your viewpoint in coming months as you assume the reigns of HHS, but if you want to make any comments now, we would love to hear them.

Mr. LEAVITT. Senator, I think your statements approximate my own views. It is clear to me that we have an obligation to assure safety, but at the same time to provide innovation and choice. And while my approach will be rigor, I also recognize the value that is there and the fact that much thought has been given to it, and I will look forward to working with you.

Senator HATCH. Thank you. Well over 10 years ago, I think Senator Kennedy and I passed the FDA Revitalization Act, which was to create a central campus for FDA with State of the art equipment and a place where we could attract some of the top scientists in the world to come and help us with this very, very important organization that handles upwards of 25 percent of consumer products in America. December of 2003 we dedicated the first building. We now have FDA and some 30 plus buildings all over this area. Some of them are converted chicken coops, and without the best equipment in the world and so forth, I am asking you to really push the revitalization act. I think had we immediately started when we passed the bill, it probably would have cost us a billion dollars. I think it is now estimated to cost us about $3 billion. But the importance

of that is to be able to reduce the safety and efficacy time at FDA so that drug prices will come down, while giving the people at FDA the very best tools and facilities to administer the programs.

So I am hopeful that you will be one of the most dynamic pushers of this, and I do compliment Tommy Thompson for the work he has done not only here but in other areas as well. But I would appreciate your help on that.

Mr. LEAVITT. Thank you, Senator. I will look forward to working with you and others on it.

Senator HATCH. Thank you. As one of the original authors of the Ryan White CARE Act, I am interested in what direction the Agency will be taking on domestic and international AIDS policy. So this is also an area that I know you are going to get into and I know that you can play a dramatic and I think constructive role in this particular area. Our country is the leading country in the world in trying to resolve these dilemmas, and hopefully we can live up to what the President said we would do for the rest of the world.

There are so many other questions I have, but I will wait until the second round before I ask them. Thank you so much.

Mr. LEAVITT. Thank you, Senator. I will just comment that I am aware of the President's commitment to invest up to $15 billion, and I know both his commitment to do it and his intent to see it carried out.

The CHAIRMAN. Senator Gregg.

Senator GREGG. Thank you, Mr. Chairman.

Governor, I greatly appreciate your public service. It has been extraordinary for many, many years. I do have a number of specific questions I would like to ask you. I will start with the FDA Commissioner. FDA is regrettably an agency that has had some serious issues recently. It has always been a premier agency in this Nation, something that the American people can take great pride in. When they walk into a grocery store or a drug store, the products that they get are protected and the FDA has played the major role in doing that.

Since it is an agency in crisis, can we expect to get an FDA Commissioner nominee up here before the end of this month?

Mr. LEAVITT. Senator, I share with you the view that the Agency needs permanent leadership, and if confirmed, I give you my commitment I will press hard to see that that slot is filled on a permanent basis rapidly.

Senator GREGG. Does that mean before the end of the month?

Mr. LEAVITT. As you know, that is a decision the President of the United States makes, and what you have is a commitment from me that I will do all I can to see that it occurs, and it is my sense that it will happen soon.

Senator GREGG. Obviously, we are facing a difficult budget situation. The Medicare Modernization Act has been passed. When it was proposed it was stated that the drug component of that would be a $400 billion item over 10 years. The majority—not the majority, but the plurality, the most significant element of that spending actually goes to subsidize corporations, the purpose of which is to keep them from shifting their drug burden over to the public sector. It is now estimated as a result of anticipated usage of that sec-

tion of the bill by the administration actuary, that the drug program will cost approximately $555 billion. That is an increase of almost 40 percent, and I suspect it is an underestimate, even though the program is not even in place yet.

I am wondering if the administration will be sending up to us directions as to how to bring that program in line with the original $400 billion estimate, or is it the administration's position that $532 billion, which is what the administration actuary actually estimated this to be, is a reasonable number now, and $400 billion is no longer the cost of the program over 10 years?

Mr. LEAVITT. Senator, I suspect if I am confirmed I will have an opportunity to answer that question in a more informed way than I can today, given the fact that I was not part of that discussion, nor have I been part of their discussions on forward-leaning budgets. I do not know the answer to it.

But I am aware of the responsibility to implement the program. As I indicated earlier, it will be the main event at HHS during the year 2005. The expectations are very high. The timeframes are very short.

Senator GREGG. Let me just cut in. My time is limited. Do you expect to implement this program within the price that was estimated for the Congress, which was $400 billion, or do you expect this program to exceed that number, as estimated by your actuaries?

Mr. LEAVITT. Senator, I am just not in a position at this moment to know because I have not had briefings on the estimate that was made originally. I am aware of the controversy. I am aware of the fact that the cost estimates have changed, but I am simply not in a position at this moment to know because I have not been at HHS. When I do, I will be very happy to be responsive to your question.

Senator GREGG. Well, let me ask you another way. Would it be your intention to implement it under the terms as it was passed, or would it be your expectation to exceed the original number of $400 billion?

Mr. LEAVITT. It has been my practice as a manager to operate within my budget.

Senator GREGG. That would be great. That is exactly what we need in that area.

There is another element of that bill which is sort of interesting, which is that it did not allow the Federal Government to negotiate prices with drug companies, something that the Veterans Administration is allowed to do, something that the State of New Hampshire is doing. I do not know if Utah has that program. Do you believe that the Federal Government should be able to negotiate drug prices to benefit seniors under this Medicare program?

Mr. LEAVITT. I believe that the best way in which to keep drug prices competitive is to have a rigorous and active market, and that the best negotiation would be between those who are providing coverage and those—rather, those who are providing the care, and those who are manufacturing it. I am aware that there are cases in which the National Government, in the case of the Veterans Administration and other situations, or in some cases State Governments, are the providers of the care, and in that case it is an ap-

propriate thing for them to be negotiating. I do not believe it is a good role for the National Government to be providing as the setter of prices, and there are ways in which I believe if we become the so-called negotiator of prices, we are actually setting prices, and I think a market does a better job of doing that.

Senator GREGG. Thank you.

The CHAIRMAN. For our second round of questions, I know that you have a rural State and that you recognize that Wyoming probably has the smallest population in the United States, and I am concerned about the HHS grants. Our population is so small that the dollars wind up correspondingly small, and by the time we take care of the regulation and the administration necessary for the regulation, we do not have much left to provide any of the assistance, and I would like to see much greater administrative flexibility for rural grant recipients, and I am hoping that you will work with me on that as we get into legislation and as you can do it administratively.

Mr. LEAVITT. Senator, you will find me to be sympathetic with that view.

The CHAIRMAN. Thank you. I also have some concerns, as I am sure everybody does, over what the medical liability crisis can add to medical costs and the ability to have access and quality programs. I have drafted a bill that provides for some other mechanism, such as an early offers, demonstration program, and some special courts demonstration program, and I hope you will take a look at that. And as I mentioned before, I hope you will hold some informal sessions with members of the committee that are willing to take the time to sit down and discuss some of these things so that we can come up with the best plan possible.

Mr. LEAVITT. This is a subject on which I both have experience and passion, and I know that the President has set this as one of his most important priorities, and I will look forward to being a participant in that conversation.

The CHAIRMAN. Thank you.

Senator Kennedy.

Senator KENNEDY. Thank you, Mr. Chairman.

Governor, I listened carefully to these questions of Senator Isakson and Senator Gregg about negotiating these costs in price, and this is a hornets nest. We have a very divided Senate on this. We have seen, as you pointed out, in the Veterans Administration where we have seen dramatic reductions in terms of the costs as compared to others. Many of us believe that Medicare ought to be able, or you ought to be able to at least be involved in those kinds of negotiations for the benefit of the seniors to lower prices. That is for a different time, to debate that. Negotiating rebates is an authority that the Secretary does not have at this time that many of us believe you should have in order to lower costs.

I appreciate the mentioning of the AIDS relief at $15 billion. I appreciate you mentioning that. I hope you will look again at what percent of that $15 billion is being used to pay for generic drugs and what percent is being used for the high cost drugs. You will find out that because of the influence of the drug companies, that the greatest percentage is the higher cost drugs. Many of us believe that they could have greater kinds of impact in terms of peoples

lives with generic drugs. That is a policy issue I know you will want to visit with. I do not want to get into that at this time.

I want to underline the importance of a new Director for FDA. The last 4 years we have had one Director, Mark McClellan, who was superb. But it has been vacant. We have had an Acting Director. That is not right for that Agency. I mean my State, like other States, has a very active and involved pharmaceutical industry and a biotech-industry, and they as you would well understand, want to be able to get decisions that are going to be lasting and effective so that they can plan, and they just cannot get that. And I join with Senator Gregg in urging that we get that position filled. There are a number of enormously gifted and talented people outside the industry that can do the job and have our confidence, and I hope that that can be done.

I listened to my friend, Senator Hatch, talk about the diet supplements, and I know his strong view about it, except we have had the experience of ephedra that was taken off the market but it took a long time to get that off, and it was a real health danger, so having the top person over there at FDA to be able to do the job is important. The bill is quite specific, as Senator Hatch pointed out, but there are issues that are involved in it.

I want to just cover two issues very quickly. One is affecting my State and that is LIHEAP. We have 671,000 families in Massachusetts eligible for LIHEAP, and only 146,000 families receive LIHEAP funding, so this is about 1 in 5 families that are receiving it now. Massachusetts used up the entire $7 million released in December. We only had enough to cover about 20 percent of the estimated families without emergency funds, and there is no help now for anyone. There is wind chill of 2 below in Massachusetts, been there, well, for the last 4 days. There is $200 million in LIHEAP emergency funding at HHS, and I would hope that—we are going to do all we can to get you into that office, and I would hope at least you would look at this, not just for Massachusetts but for other hard-pressed areas. We have a number of States.

Mr. LEAVITT. Thank you, Senator. That is both noted, and I will follow on it, and give you what response——

Senator KENNEDY. If you can, as an early priority because it is a real priority here.

Just finally, we had talked about what you had done on the welfare in Utah. Utah's program is flexible in dealing with a number of barriers. Treatment services count as TANF participation. Mental health and substance abuse. Counselors are available in TANF offices for short term counseling, or for long-term treatment concurrent with employment. Some have disabilities, others are caring for sick children. You have had really important flexibility in responding to enormous human needs. I am wondering whether this would be your position, to support those kinds of efforts in our deliberation of this bill when it comes before the Senate? I know the administration is going to speak to this, but I would be interested in your own experience about the effectiveness of the programs and what you might hope would be in legislation that we would consider along these lines.

Mr. LEAVITT. Senator, I will just say that I have had occasion as Governor to sit at the table with a person being counseled and to

work through the entire process with them. I know that it is a process of essentially helping a person put their life back together. In most cases it has been a hardship and they have some short-term problems they have to deal with, and often it is a matter of doing something simple.

I remember one case where we, rather than put them on to the whole program, we just needed to provide them with some steel-toed shoes and help them with some other kinds of things that otherwise would not have been—under the old program we would have had to put them on welfare for several months, but we were able to solve the problem. They went to work, and it was a good thing for them. So I found flexibility in dealing with the individual needs is a very important part, and I would hope we could preserve that and what I think is a great American success story.

Senator KENNEDY. May I have one last one? My time is up, and I thank the Chair. On the flexibility in the waiver, we have had now with the changing of the administration—Massachusetts had a waiver for the last 8 years on Medicaid. We have saved Medicaid $1.8 billion. It was always used for health care issues—Medicaid. Governor Romney has been down seeing Thompson. That part has been worked out, and as a result of it, our Governor is going to have a lot less flexibility than he would have had previously.

So I know this point that has been made here in terms of the flexibility, we have seen in our own State where we have had the waiver and it has been done under Republican and Democratic Governors, been done very, very effectively in terms of the purposes of Medicaid and the savings that have been provided. So you are going to have a different kind of framework to operate in, but I just wanted to add that.

I thank the Chair very much for his indulgence.

The CHAIRMAN. Thank you.

Additional questions, Senator Isakson.

Senator ISAKSON. Just one, and a comment. One of the largest contributors to the rising cost of health care for those who are covered in terms of the cost of their insurance and their co-payment is the rising cost of the uninsured. The CHIP program—and you did a great job in reaching out to get those children insured who were a large number of the uninsured in Utah. But do you have any suggestions as to what you would recommend or think we ought to focus on to try and increase the number of insured and decrease that burden on the number of those who are insured and paying at higher rates?

Mr. LEAVITT. Senator, I do have, and I want to describe something for you that I do not intend to imply as a solution on a national basis. But it troubled me greatly that we had 400,000 people in our State who did not have any health care insurance at all. In my State, if you want to have the richest health benefit program, you will go to Medicare. It is about 143 percent in terms of benefits of what a person would earn if they went to work at a car dealership or a mill. If you want the second richest, you go to Medicaid. It is about 139 percent. Or at least those were the percentages when I was dealing with this.

We went through a period of time, a very difficult period, like most States, where we were simply pressed to balance our budget,

and we actually had to reduce benefits for vision and dental on a small population of our Medicaid recipients. I noticed today in the paper that the new Governor has money now, and he is going to go put those back, and I am glad for that.

But at the same time, we concluded what if we were to have that program on Medicaid not be 139 percent richer but what if it were only 125 percent richer and we were to take those dollars and provide a benefit to people who are without coverage at all. I got a waiver from HHS. We now have 18,000 families who are working at one or two or three jobs, who had no health insurance, who now have it. We took the same dollars. We provided them with health care, frankly, that was not the kind of health care we would aspire to have them receive. But they have health care. They have basic health care. We used our community health centers to provide it, created a policy that provided preventative care, basic health care. The community got together. It was a very solid success, and we are learning from that.

So I do not represent it to be the wave of the future. I simply just hold it out to be what it was: an effort on our part to take limited resources and to provide basic health care to all of those who don't have it.

Senator ISAKSON. Well, it is a good example of why you are the appointment of the President, too. It is thinking outside the box, and I appreciate that.

I just have a comment, Mr. Chairman, and that is, you cannot come from Georgia and talk to the future Secretary of Health and Human Services without thanking him for acknowledging CDC's brand and making the statement that the Congress and the President during the last 4 years have done a remarkable job in funding the new construction, the laboratory work, and the hardening of what is really the world's public health asset. And I appreciate very much your acknowledging that, and I look forward to working with you to continue to grow CDC and its capability and its reach around this country and around the world.

Thank you very much.

Mr. LEAVITT. Thank you.

The CHAIRMAN. Senator Dodd.

Senator DODD. Well, thank you, Mr. Chairman. And, Governor, welcome. I apologize for being late. Dr. Rice is appearing two or three floors up before the Foreign Relations Committee, so it is one of those mornings where we are sort of scurrying back and forth. I apologize that I was not here for your opening comments.And I gather a number of my colleagues here already have gone into some detail, Mr. Chairman, on Medicaid funding and other questions, so I will rely on that record.

I should point out, Mr. Chairman, that my family, the side that I married into is a Utah family, and so I am very much aware of Mike Leavitt and his stewardship of that State. When I go out for family holidays, I am often called the third Senator from Utah. And those ten Democrats out there deserve a Senator.

[Laughter.]

My good friend Orrin Hatch likes to tease me about that.

Senator HATCH. We are very proud to have you. However, we could suggest some changes.

Senator DODD. I think now you could. I have suggested several for you along the way.

Senator HATCH. You have.

Senator DODD. Neither of us has had any success in that regard, I might point out. But I always enjoy going out to Utah and seeing my wife's family out there. So it is a pleasure to have you before the committee.

Let me raise a couple of questions. One, I mentioned my good friend Senator Hatch because one of my proudest moments in this body over the last quarter of a century occurred almost 20 years ago, when Senator Hatch and I, along with many others, initiated the concept of the Child Care Development Block Grant, which was a revolutionary idea in its time to try and assist working families particularly who were struggling, as you have just pointed out, many of them single parents, or intact families with both people working trying to make the economics work, with young children, and the importance of having a quality, safe, available child care structure that would allow them to be able to do what they had to do and know that the individuals they care most about, their children, would be under safe quality conditions.

But we have had an awful problem over the last number of years in the freezing of funds, and as a result we now have some 600,000 children who are on waiting lists all across this country waiting to get into a decent child care setting. Too often the parents are relying on the worst of circumstances for these kids, and we need to do something about it, clearly, as we move forward on welfare reform. And you will be asked to play a major role in that.

And so what I would like to ask you this morning—I do not expect you to lay out anything in detail at this point, but we need to sit down, if you could, with those of us up here who have worked on this issue over the years—and, again, I want to thank my colleague from Utah. He was just invaluable to understanding this issue early on, the importance and the role that we could play at the national level of being supportive of our States and our families in this regard. But we need to sit down—if we are going to move forward on a welfare reform bill, we cannot have the working poor being pitted against those on the welfare rolls when it comes to getting this kind of support. If we end up reducing the child care assistance for the working poor only for those who would be on the welfare rolls, then we are going to find the working poor tumbling back into the rolls of the very people we have been trying to move out of that system into working relationships.

So I would hope that we could sit down soon, if we could, with you and see if we cannot get some movement on unfreezing these funds, in my view, and providing some additional assistance as we move forward. And I wonder if you might share some overall comments on that point.

Mr. LEAVITT. I would be happy to, Senator. I had the privilege, as you have indicated, of serving as Governor during a period when welfare reform was enacted. When I began as Governor, we had just under 20,000 families that would be considered on welfare. When I left, there were about 7,000. During the more difficult times, we saw that edge up, as we should, because more people needed help.

But it was clear as we went through that process of helping people realign their lives that it was unrealistic to send a mother, a single mother with two or three children, off to work without the capacity for her to have high-quality care for her children. It was not in our interest or hers or the children's.

The good news here is that we have accomplished much. We have been able to reduce the number of cases that we are dealing with in the country. There are fewer people who are in that circumstance than were before, and I feel optimistic that we can find a solution to this because I think the principle is sound. People need good-quality child care. The question is how do we provide it. I would add my experience has been when you sit down with people and actually get down to it, you just need the flexibility to find a solution to their problem.

Senator DODD. The affordability issue obviously is critical. I do not need to tell you. Now, per child it costs, and I am not exaggerating when I tell you this, between $6,000 and $10,000 per child per year. And you start with people of incomes of $20,000, $25,000 a year trying to hold on to those jobs with two kids, you do not have to have a Ph.D. in mathematics to know it just does not work. So that is a critical constituency. And I hope you will work with us and not only ensure that child care is more affordable but also that low income parents have access to quality care. It is very, very important.

The drug safety issue has received a lot of attention. Again, I gather, Mr. Chairman, we haven't spent a lot of time on this issue, again a subject matter I know my friend from Utah has a lot of interest in, but a lot of stories over the last few weeks about the FDA and drug safety. We know of these patients who have been hurt or killed by widely used pain medication. We have heard those stories recently.

Several of us in Congress are considering legislation to reform the Food and Drug Administration's approach to drug safety and ensure the results of clinical trials are made public. I wonder if you might comment, particularly on the last point dealing with the public information, making available to the public about these clinical trials and public safety.

Mr. LEAVITT. I believe that the process of Government ought to be conducted in the most transparent possible way, and when it comes to drug safety, people do have a reason to expect safety. We want it also to be—for industry and for Government to be innovative. We want to have access. We want to have independence in assuring that it is.

I recognize the tension that exists perpetually, intuitively between wanting innovation and speed and at the same time wanting safety. And sometimes those conflict. It is a function of finding balance and getting better at it.

Senator DODD. Well, I represent a significant number of companies in my State, some 35,000, 40,000 people in Connecticut are employed in the pharmaceutical industry, and they are tremendous companies and they do a wonderful, wonderful job in many, many ways. And it is also a great source—we have a tremendous imbalance in trade, and our pharmaceutical industry contributes significantly to U.S. exports.

One of the reasons they do is because that stamp on it, FDA approved, means so much all over the globe. That Good Housekeeping Seal of Approval that these products are effective and safe has been tremendous, first of all, on a human level very important, but also economically. It is really important we get this right early. If we end up with a reputation that this very important agency is no longer reliable, I think it would do great, great damage to a very important industry in this country.

Now, I see time is—well, I have a couple more questions, and I will be glad to wait until my colleagues go around, if that is the way you are doing this. Are you, Mr. Chairman?

The CHAIRMAN. Yes.

Senator DODD. Fine. I will come back.

Mr. LEAVITT. Mr. Chairman, could I just make one brief response?

The CHAIRMAN. Yes.

Mr. LEAVITT. I referred earlier to FDA and CDC and NIH as important brands. A brand is a promise, and if we ever lose the value of that brand, the American people lose a great treasure.

Senator DODD. You bet.

Mr. LEAVITT. And I see the guarding of the integrity of those brands as a fundamental part of this responsibility.

Senator DODD. Thank you.

The CHAIRMAN. Senator Hatch.

Senator HATCH. Thank you.

Governor Leavitt, one issue that I think all of us are deeply interested in—I certainly am—you know, is building up our Nation's defense, especially against biological and radiological weapons. Last year the Senate Judiciary Committee, which I chaired at the time, and the HELP Committee, this committee, held a joint hearing on how the 2003 bioshield law may be improved upon and what Bioshield II needs to have included.

Now, we need to encourage rather than discourage pharmaceutical and biological companies to develop products to help us combat bioterrorism. Unfortunately, current policy discourages companies to develop these products. I think this has to change. We have got to make headway in this area, and knowing you, I am sure that you are the guy who can help do this—not that people at HHS have not been trying.

I want the Department to work with us in developing policy to address these very serious concerns, so I am hopeful that we can work together to do this. I am working currently on legislation with regard to this with my good friend, Senator Lieberman from Connecticut. And so we would appreciate your assistance on this.

I also want to thank my colleague from Connecticut, Senator Dodd, who has been such a great leader on this committee, for his kind remarks about me. It is a privilege to be back on this committee and to work on some of these issues that I have taken such an interest in. And I have to say for everybody, I know you as well as anybody knows you, and I know what a great policy person you are and how much you really do care about getting things right and working them through. It is a tremendous ability that not too many people have. But you do, and I think you were recognized as one of the great Governors in this country, as you should have

been. And I know that you have done a tremendous job over at EPA, which is almost an incomprehensibly difficult job, especially for a Republican, to do. And I think virtually everybody has given you credit for doing that, and with aplomb and with dignity and with fairness.

Now, what I hope is that this committee will put Governor Leavitt out quickly so that he can get busy and do some of the things we all know he can do. And we have got to be very much concerned about helping you. And I think this committee will be, and I have been really pleased with the nice way you have been treated here today by members of the committee.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Gregg.

Senator GREGG. Governor, have you had a chance to spend any time—and I can understand if you have not, just moving over—on this whole issue of how we revitalize the vaccine industry in America? The whole concept of Bioshield was that we needed to prepare ourselves for a biological attack, and we have no significant domestic vaccine industry because most of our vaccine industry had been pushed out of business by basically trial lawyers. And so to try to create such an industry, or at least incentivize people to move into this area, we passed Bioshield I.

We have now seen the flu vaccine problem, which shows that if you rely on a single supplier, whether domestic or international—but obviously international raises issues, too—you have got serious problems. And I am wondering how you are viewing this issue of how we get, first, our domestic vaccine business up and running, an enterprise up and running, what we need to do beyond Bioshield I; and, second, how we expand, for example, the flu vaccine purchasing process so that we use the Canadian vaccines that are available and other international vaccines that are available and not find all our eggs being in one basket as they were?

Mr. LEAVITT. Senator, this was an obvious area of interest to me given the fact that we are moving into the flu season and the prospect and the potential of being confirmed. Just a couple of observations.

One, we cannot expect that we will have people stepping up to manufacture unless there is a market. There needs to be a market. Sometimes it may need to be the Federal Government to make certain that there is a market.

Second, despite the fact that there has been substantial work on the liability issues by the Congress, I suspect by this committee, it is also clear to me that there remain some issues that need to be resolved. This is a very serious problem and one that in my judgment needs to be dealt with and dealt with promptly.

Senator GREGG. Do you have any thoughts about whether we should look for other suppliers from other countries besides just the one we were using for the flu vaccine, such as Canadian suppliers?

Mr. LEAVITT. My thoughts have not matured to the point that I could express them adequately or properly. I am aware of that as a possibility. I am working to gather the information necessary to form a viable opinion. I look forward to an opportunity to talk with you about it.

Senator GREGG. There is a bill bouncing around the Congress right now, which, again, you may not have had time to get up on, called the Patient Safety Act, which is essentially an attempt to give—which passed out of this committee unanimously, passed the Senate, was held up in the House on an ancillary issue which had nothing to do with patient safety. Are you familiar at all with that bill?

Mr. LEAVITT. By title.

Senator GREGG. OK. Well, anyway, I would hope that you might have a chance to take a look at it at some point and see if we could not encourage its passage. It will allow hospitals and doctors to exchange information more efficiently, which is a key part of this whole process of getting health care delivered more effectively, and we hope that we can restart it in this Congress in a prompt way.

Again, I thank you for your willingness to participate in public service the way you have. It is extraordinary, your career is extraordinary, and we are very lucky to have someone like you being willing to take this position on.

Mr. LEAVITT. Thank you, Senator. Could I just respond with respect to the issues related to the extent—or the supplying of information and interoperability issues. I do believe those are issues that we will have to work together to resolve, because much of the efficiency, much of the protection we seek can be hampered until we are able to work through those very thorny issues.

Senator GREGG. Well, you are absolutely right, and this bill takes a fairly significant step forward in that exact area in that it allows hospitals and doctors to exchange information without putting the patient's information or the patient at risk and do so in a way that gets around the competition issues, which we have had problems with the antitrust issues, and protects the doctors and the hospitals from arbitrary lawsuits which would be brought as a result of an exchange of that information. And that information will lead to a more efficient delivery of service, and what it most importantly will lead to is less medical errors, hopefully.

Mr. LEAVITT. Yes.

Senator GREGG. Which is very important. That is why this committee passed it unanimously. That is why the Senate passed it on, I think, a voice vote. We are still wondering why the House has not passed it.

The CHAIRMAN. Senator Dodd.

Senator DODD. Thanks, Mr. Chairman. Just a couple of quick other questions that I would just like to raise, if I may.

We pay a lot of attention obviously to drug abuse among young people. The largest killer among these kids, though, when it comes to substances, is alcohol, underage usage of alcohol. The numbers are just staggering. About 7,000 kids under the age of 16 today will take their first drink, and for many of them it becomes a serious problem. In fact, we lose over 4,000—close to between 4,000 and 5,000 young people every year in deaths related to alcohol in this country.

Well, in 2003, the Institute of Medicine released a study called "Reducing Underage Drinking: A Collective Responsibility," that laid out the national problems presented by the consumption of alcohol by youth and established a multitiered national strategy to

reduce underage drinking's toll. Sadly, there has been very little progress on this at the Federal level in instituting this important report's recommendations, and I do not expect you have had a chance necessarily to become familiar with these recommendations, but I would urge you to do so, if you could, so that we might begin to talk about establishing national policy in this area.

I have had countless meetings with people from the alcoholic beverage industry, and I must say many of them are fully supportive of what we are trying to do in coming up with some intelligent responses to this, including how they advertise. And we all know the First Amendment issues, and the industry has as a matter of its own decision refrained to a large extent from advertising, at least on television and other places. But, nonetheless, we have seen some real problems with some of the efforts. Again, just watching any major sporting event and you watch the advertising that comes on, too often you see exactly what age group they are appealing to when they are using Play Stations to advertise beer and so forth, as one industry did. They have stopped it, by the way, but they certainly did for a while. You get a clear indication of the age group they are trying to appeal to.

There have been some very good recommendations in these reports. Some of them may be a little more than the administration and others may want to accept, but I think there are some good ideas, and I would really urge you to take a good look at this early on and see if we cannot take some good steps. I think you will find a lot of cooperation up here. The American public cares about it. Considering the loss of life, the damage, the illness, the permanent damages to those who don't lose their lives is just overwhelming. And so I would urge you to become involved in it as early as you can. I don't know if you want to make any particular comment.

Mr. LEAVITT. Well, I would just comment that you indicated early you have spent a fair amount of time in Utah, and as a result you would know that that is a State that takes this issue quite seriously.

Senator DODD. Well, good. We hope you will do that.

This last one I want to raise with you is, again, an issue that there is nothing like a personal experience, I suppose, to bring your attention to an issue. Three years ago, my wife and I had our first child and discovered when she was born that there were only about eight newborn screening tests available in the State of Virginia where she was born. Only one State provided testing in 32 areas, which was the State of Massachusetts at the time. We passed legislation to try to increase support for additional newborn screening for these newborns given, again, the problems that can emerge very, very quickly with these kids.

There has been a report that has come out from the Committee on Heritable Disorders and Genetic Diseases in Newborns and Children—it is going to release a report, I should point out, recommending that all States test for 29 disorders in these infants. We have had hearings in this committee, very compelling hearings, where parents have come forward and said had there just been some of those tests—they are very inexpensive to do, but we need some additional cooperation. The States would like to do a lot more in this area. Some of the equipment necessary is not inexpensive,

but the cost of not doing it, I do not need to tell you, is overwhelming when you look at children experiencing lifelong disorders that require millions of dollars being spent in some cases.

So it is another one of these areas that, again, I do not expect you necessarily to be deeply familiar with the subject matter, but it is one where we can, with a small amount of effort, make a huge difference for people. And I would urge you to take a look at this, and your staff, and see if we cannot sit down and maybe talk about some ideas and how we promote this expanded use of newborn screening.

Mr. LEAVITT. Thank you.

Senator DODD. Mr. Chairman, I thank you. I have taken a little more time, and I appreciate it.

The CHAIRMAN. Thank you very much.

I want to thank all the members of the committee for their participation. I want to thank Secretary Leavitt for his straightforward answers and wealth of knowledge that he brings to this job and the willingness to go through two of these nomination hearings. We are not the primary committee, as I explained before. As a result, the record will remain open for 10 days or until the Finance Committee takes action, whichever is less. And we will be polling the members of this committee on an appropriate question for our advice and consent.

With that, this hearing is adjourned.

[Additional material follows:]

ADDITIONAL MATERIAL

RESPONSE TO QUESTIONS OF SENATOR BINGAMAN

The Uninsured

Question 1. The uninsured rate has increased from 40 million to 44 million people during the past 3 years. To put that in prospective, that is equivalent to having every single person go from full health coverage to nothing in the following places: Milwaukee, Wisconsin; Memphis, Tennessee; Tuscon, Arizona; Albuquerque, New Mexico; Miami, Florida; Pittsburgh, Pennsylvania; Des Moines, Iowa; and the entire State of Montana. What steps will you take to reduce the number of uninsured Americans, especially low-income pregnant women, children, or those with chronic illnesses?

Answer 1. My experience as Governor taught me that there is no one-size-fits-all solution to reduce the number of uninsured Americans. Simply expanding eligibility for government programs may in fact overlook market based solutions for the working uninusred. The Covered at Work program is an example of a public-private parternship to help low-income working families access the health insurance that is available to them through their employer, but may be out of reach due to the expense. The program provides subsidies for up to 6,000 Utah residents who are not eligible for Medicaid but also struggled to meet their share of the expense for employer-sponsored insurance. I very much look forward to working with you and the Congress to advance the President's multi-faceted approach to reducing the number of uninsured. As you know, the President is committed to making quality health insurance more affordable and more accessible for millions of American working families. The President's plan will help reduce the rising cost of health care; provide new and affordable health coverage options for all Americans; and provide not just a government program, but a path to greater opportunity, more freedom, and more control over your own health care and your own future. For low-income families, the proposal includes refundable tax credits to enable families to buy coverage. It also includes $4 billion in Federal grants to States to establish purchasing pools—or to expand existing pools—where people could use their tax credits to buy coverage. In addition, he's proposed to allow tax credit recipients to divide their assistance between a premium subsidy and a government contribution to a health savings account. This account, which they could use to pay routine medical expenses and to save for future health care needs, would belong to them, not to the government. These and other proposals would help reduce the number of people who lack health insurance coverage.

Healthcare Workforce

Question 2. With 76 million baby boomers aging upward and the average lifespan continuing to increase, the aged 65 and over population is expected to double over the next 30 years. Our society currently faces significant health care workforce shortages. What strategies and actions do you foresee that will help to ensure an adequate number of providers who are fully-trained and capable of meeting the health care needs of an aging population, now and in the future?

Answer 2. By continuing to focus on the problem of maldistribution of health professionals across the country, we will help ensure that the aging population has access to the health care they need. As you are aware, HHS administers a successful program that specifically addresses this issue ? the National Health Service Corps (NHSC). This program provides financial incentives, through scholarships and loan repayments, to health professions students and providers who agree to serve in underserved areas. This program has supported more than 24,500 health professionals committed to service to the underserved, and approximately 6 million people now have access to care from NHSC clinicians. HHS also continues to expand the Community Health Center program to ensure that affordable health care is available in underserved areas across the country.

There continues to be a serious shortage of nurses across the United States and a shortage of nursing faculty that is limiting the number of students that can be admitted to schools of nursing. HHS administers several programs that specifically focus on alleviating this nursing shortage, including comprehensive geriatric education to prepare nursing personnel to care for the aging population. Funding for these activities has increased by 75 percent since fiscal year 2001.

The Department's efforts to ensure an adequate supply of health care providers are guided by studies carried out by the National Center for Workforce Analysis. This center continues to conduct studies that help develop strategies to meet the

health workforce needs of an increasingly diverse and aged population. Over the past two decades, HHS has invested over $6 billion in general health professions training grants. HHS is in the process of compiling detailed information on the effectiveness of these health professions programs and we will be sure to share that information with your committee when it is available.

Question 3. Would you support a study examining the role of U.S. medical schools in meeting the physician needs within the country?

Answer 3. I understand your concern about the lack of growth in the number of students graduating from medical schools in the United States and the increasing dependence on foreign medical schools in the training of American medical students. The Department will continue to monitor and evaluate the impact of the health professions programs and the state of the health care workforce in general. From what I understand, the fiscal year 2005 appropriation did not include funds to support such a study, but if I am confirmed as Secretary, I will stand ready to work with you to evaluate this situation.

NIH

Question 4. The scientists and researchers at the National Institutes of Health (NIH) are responsible for cutting-edge medical breakthroughs that are improving the lives of Americans every day. Unfortunately, the value of their research has on occasion been called into question outside of the agency. As Secretary of the Department Health and Human Services, would you continue to support the peer review process for NIH grants whereby researchers work is evaluated by their fellow scientists?

Answer 4. Yes. The peer review process is the essential ingredient that protects the integrity and value of research supported by NIH.

Plan B Emergency Contraception

Question 5. Last December, the FDA's Independent Expert Advisory Committees overwhelmingly recommended approval of the Plan B OTC application with a 23-4 vote. The committees were, however, unanimous in their determination that Plan B is safe enough for over-the-counter use, and that there is no data to show that Plan B leads to substitution of EC for other methods of contraception. Despite the Advisory Committees' review of hundreds of studies on Plan B, and that recent research, including a JAMA study, continues to support the committees' original favorable recommendation, the FDA denied Plan B OTC status and overrode the overwhelming scientific evidence. Why has the FDA delayed approval of this drug?

Answer 5. As you know, the FDA previously denied an application to change this drug to over-the-counter status. I understand that FDA did not approve a switch of this prescription drug to OTC status on the first review of the application for two reasons. First, the sponsor did not provide adequate data to support the conclusion that young adolescent women can safely use Plan B for emergency contraception without the professional supervision of a licensed practitioner. Second, a proposal from the sponsor to change the indication requested in their application to allow for marketing of Plan B as a prescription-only product for women under 16 years of age and allow non-prescription marketing to women 16 years and older was incomplete and inadequate for a full review.

In July 2004, Barr Laboratories resubmitted their application after FDA determined it could not approve Barr's initial application based on the information submitted by the company. The Agency currently is reviewing the resubmitted application.

Indian Health Service

Question 6. Despite double digit growth in health care spending in both private and public sectors, the Administration's fiscal year 2005 budget submission for IHS includes just $45 million, or a 1.6 percent, increase. This follows a 3 percent increase in fiscal year 2004 and a 2.5 percent increase in fiscal year 2004—none of which covered even basic medical inflation. The result has been a dramatic decline in spending power for the Indian Health Service (IHS) during the Administration's term in office.

Consequently and not surprising, this disparity in funding translates into severe health disparities for Native Americans. For example, life expectancy is six years less than the rest of the United States citizens. Tuberculosis rates are four times the national average. Complications due to diabetes are almost three times the national average and death rates exceed the Health People 2010 targets by 233 per-

cent. Infant mortality rates are 1.7 times higher than the rate for white infants. These figures are both shocking and unacceptable. What will you do to address the health disparities faced by Native Americans?

Answer 6. Over the last 40 years, there have been significant health improvements among Indian people related to control of infectious diseases, expanded access to primary health care, and fundamental community infrastructure such as safe drinking water. Today, injuries, chronic diseases and behavioral related diseases such as alcoholism, substance abuse and mental health have emerged as leading challenges in Indian communities. One of the keys to addressing these problems is ensuring access to health care. I look forward to working with Congress and the Indian Health Service, which plays a key role for the Department of Health and Human Services in providing access to care to American Indian and Alaska Native communities, to address these issues and reduce and eliminate health disparities. In doing so, it is critical that the IHS identify and collaborate with outside organizations with the capacity, capability, and interest to assist in addressing these diverse health problems. The IHS has developed partnerships and collaborations with other Federal Government agencies as well as academic, professional and other non-governmental partners. These partnerships cover a broad array of programs, including on health promotion and disease prevention.

Question 7. The Indian Health Care Improvement Act is critical for providing health care services to 1.6 million federally-recognized Native Americans through IHS, as well as Tribal and urban Indian health programs, and has been pending before the Congress for far too long. Will you work to push for reauthorization of the Indian Health Care Improvement Act (IHCIA)?

Answer 7. Over the last 40 years, there have been significant health improvements among Indian people related to control of infectious diseases, expanded access to primary health care, and fundamental community infrastructure such as safe drinking water. Today, injuries, chronic diseases and behavioral related diseases such as alcoholism, substance abuse and mental health have emerged as leading challenges in Indian communities. HHS, working through the Indian Health Service, has a key role to play in working with American Indian and Alaska Native communities to improve health conditions through improved access to quality health care services, enhanced health care promotion and disease prevention, and focuses on new and emerging health issues facing these communities. The reauthorization of the Indian Health Care Improvement Act, which Congress was unfortunately unable to complete last year, could further support the efforts of HHS and IHS in these endeavors. As Secretary, I look forward to examining any reauthorization proposals and hope to work with Congress on these critical issues.

Mental Health

Question 8. In July, 2003, President Bush's New Freedom Commission on Mental Health completed its final report. Describing the country's mental health system as one in "shambles," the Commission documented the crisis:

- In the United States, suicide claims approximately 30,000 lives a year.
- In the United States, about 2/3 of people with mental illness are unemployed.
- In 2001, parents were forced to place more than 12,700 children in the child welfare or juvenile justice systems in order to get them mental health treatment.
- More than 750,000 people with mental illnesses will end up in jails or prisons over the coming year, most of them for nonviolent offenses related to their mental illness.
- And worldwide, mental illness is the leading cause of disability worldwide, accounting for nearly 25 percent of all disability across major industrialized countries.

Notwithstanding the urgency, the President has never endorsed the Commission's Report or even acknowledged its existence. Nor has HHS issued an action plan for implementing the Commission's recommendations. What is the status of the Department's work on this issue? Will you make mental health policy a priority?

Answer 8. The President's New Freedom Commission on Mental Health's report, issued in July 2003, called for profound change and transformation of the current system, recommending new service delivery patterns and incentives to ensure that every American with mental illness has easy access to the most current treatments and best support services.

The Substance Abuse and Mental Health Services Administration (SAMHSA) was tasked by the Department to review the Commission's report and to lead the development of an Action Agenda for that transformation to create a more recovery-focused mental health services delivery system. An executive team at SAMHSA-along with senior staff from six Federal departments and the Social Security Administra-

tion-are working collaboratively to conduct a thorough review and assessment of the Report.

A hallmark of the Action Agenda is the unprecedented collaboration and partnership across the Federal Government to work together and make every effort to keep consumers and families at the center of care. I look forward to working with you to continue this excellent effort.

Question 9. Perhaps the most significant finding in the report is the recognition that the service system is hopelessly fragmented and uncoordinated across multiple, disconnected programs, including those related not only to mental health specifically, but also public health and health care financing, housing, employment, rehabilitation, criminal and juvenile justice, substance abuse, education, and child welfare. In response, the Commission recommended that the relevant departments—HHS, the Social Security Administration, Justice, Veterans Affairs, Education, HUD—align their programs to improve access and accountability for mental health services. [Commission Recommendation 2.3, page 37]. Will you work for White House leadership on mental health and implementation of the Commission's recommendations?

Answer 9. As stated before, the Substance Abuse and Mental Health Services Administration (SAMHSA) was tasked by the Department to review the Commission's report and to lead the development of an Action Agenda for that transformation to create a more recovery-focused mental health services delivery system. An executive team at SAMHSA—along with senior staff from six Federal departments and the Social Security Administration—are working collaboratively to conduct a thorough review and assessment of the Report. A hallmark of the Action Agenda is the unprecedented collaboration and partnership across the Federal Government to work together and make every effort to keep consumers and families at the center of care. The result has been commitment for a true Federal Action Agenda that is informed by the final report of the New Freedom Commission and aligned with the President's priorities.

I understand that an announcement from the Substance Abuse and Mental Health Services Administration on the availability of these funds and how to apply will be issued in the near future. The purpose of these grants is to help States overcome fragmentation by pulling together State government offices and engaging multiple systems of care together in a coordinated manner to focus on improving outcomes for adults with serious mental illness and children with serious emotional disturbance.

Obesity

Question 10. Overweight and obesity are major risk factors for heart disease and stroke, two of the top three leading causes of death in the United States. There have been many alarming reports about the rate at which Americans are becoming obese. A Surgeon General's report has called this problem an epidemic. Recent estimates indicate the direct medical cost attributable to overweight and obesity is $78 billion dollars annually. And approximately half that amount, about $40 billion, is paid for with public dollars through the Medicare and Medicaid programs. We must prevent Americans, and especially American children, from becoming overweight. What do you think is the role of the Secretary of Health and Human Services in getting the problem of obesity and the related costs under control?

Answer 10. Seven of nine of the major causes of death in the United States are caused by chronic diseases. The underlying causes of these diseases are often behaviors that can be successfully modified thereby reducing illness and death. Three factors—lack of physical activity, poor nutrition, and tobacco use—are major contributors to the Nation's leading killers; heart disease, cancer, stroke, chronic obstructive pulmonary disease and diabetes. Too, the prevalence of overweight has more than doubled in children and tripled in adolescents; indicators suggest that diabetes too is increasing among children. This is particularly troubling given obesity is a comorbidity factor leading to significantly increased risk of death due to cancer, heart disease and diabetes.

In June 2002, President Bush launched the *HealthierUS* initiative to utilize the combined expertise of the Federal Government to help Americans live longer and healthier lives through simple changes in their everyday lives. The four pillars of the *HealthierUS* initiative are: 1) be physically active every day; 2) eat a nutritious diet; 3) get preventive screenings; and 4) make healthy choices concerning alcohol, tobacco, drugs and safety.

HHS is currently engaged in a number of key activities, two of which are listed below. I look forward to examining what has been done and what is underway, and working to continue this tremendous progress.

Current Activities:

• *Steps to a HealthierUS* Initiative (Steps). Steps specifically targets diabetes, asthma and obesity. In fiscal year 2003 Steps funded 23 communities. In fiscal year 2004 the program awarded $44 million to help 16 additional communities develop action plans to implement programs that promote disease prevention and health; the total number of funded communities is 40. Steps also received $1.5 million to fund one national program, YMCA's Activate America. Fiscal year 2005 appropriations budget for Steps is approximately $47 million.

• National Coverage Decision—Earlier this year, HHS announced a new Medicare coverage policy that would permit Medicare to cover anti-obesity interventions if scientific and medical evidence demonstrate their effectiveness in improving Medicare beneficiaries' health outcomes. The new policy removes language in the Medicare Coverage Issues Manual stating that obesity is not an illness, allowing Medicare to determine if specific obesity-related treatments should be covered by Medicare.

Nutrition and Dietary Concerns

Sodium

Question 11. Research over the last half-century has demonstrated that high-sodium diets (due mostly to the salt in packaged and restaurant foods) are a major cause of high blood pressure. For the past quarter-century, *Dietary Guidelines for Americans,* which is published by USDA and HHS, has advised consumers to consume less sodium. Notwithstanding that advice and similar advice from the National Institutes of Health and the National Academy of Sciences, Americans' consumption of sodium has not decreased, but increased. Though mandatory nutrition labeling, begun in 1994, on packaged foods has been useful to millions of people, it has had little apparent effect in reducing Americans' average sodium intake, according to HHS's National Health and Nutrition Examination Surveys (NHANES) in 1988–94 and 1999–2000. In 1994, the National High Blood Pressure Education Program (part of the National Heart, Lung, and Blood Institute) said that "it is critical that the food industry reduce (or continue to reduce, in some cases) the content of sodium in generally available processed foods." The NHBPEP has said that reducing sodium levels could save tens of thousands of lives per year. However, judging from current trends, the goal in HHS's Healthy People 2010 (published in 2000) of increasing the percentage of people consuming 2,400 mg or less of sodium per day from 21 percent to 65 percent will never be met. What will you do to reduce the sodium content of packaged and restaurant foods and reduce the incidence of high blood pressure?

Answer 11. I believe that HHS has done a tremendous job in focusing public attention on the issues relating to wellness, prevention and obesity, and that these efforts are bearing fruit. As part of these efforts, HHS has been able to work collaboratively with outside stakeholders, including the food and restaurant industry, to make important progress. An example of this is the improved nutritional labeling information that is available through many restaurants. I hope to continue this collaborative approach and work with all interested parties to improve the health of the Nation.

Trans Fat in Partially Hydrogenated Vegetable Oils

Question 12. Trans fat in partially hydrogenated vegetable oils is a major public health problem because it promotes heart disease. In July 2002 the Institute of Medicine ("IOM") of the National Academy of Sciences concluded that the consumption of Trans fat is at least as unhealthful as the consumption of saturated fat and that consumption of trans fat in any amount increases the risk of heart disease. In December 2003 the IOM concluded that it is feasible to exclude from the diet trans fat from partially hydrogenated vegetable oil.

In April 2004 the Nutrition Subcommittee of the Food and Drug Administration ("FDA") Food Advisory Committee concluded that trans fat is more conducive to coronary heart disease than is saturated fat. In August 2004 the Dietary Guidelines Advisory Committee reported to Secretary Thompson and Secretary Veneman that consumption of trans fat from both partially hydrogenated oils and meat and dairy products should be limited to one percent of total calories. Do you believe that it would promote the public health if partially hydrogenated vegetable oils were eliminated from both packaged and restaurant foods? If so, what steps will you take as Secretary to bring this about?

Answer 12. Saturated fat, *trans* fat and cholesterol intake are associated with risk of cardiovascular disease. As indicated in the *Dietary Guidelines for Americans,* controlling the intake of all three of these lipids is important for managing health risk. In response to FDA's rule that *trans* fat must be on food labels by January 2006, the food industry has taken significant steps to lower the *trans* fat content of food products. These steps include the development of products that can replace partially hydrogenated oils as well as improvements in the hydrogenation process to prevent formation of *trans* fatty acids. During this transition in product formulation, it is important that the reduction of *trans* fat from certain oils not be achieved simply by switching to fats that are high in saturated fatty acids but by development of healthier alternatives to these fats. FDA is currently reviewing proposals for making claims about the *trans* fatty acid content of foods, and once finalized such claims could provide additional incentives to the food industry to lower the trans fat content of certain foods. If confirmed, I will work to advance these initiatives to address health concerns associated with the use of partially hydrogenated vegetable oils in packaged and restaurant foods.

Food Safety

Question 13. The safety and quality of the U.S. food supply is governed by a fragmented and overlapping system. That system is based on more than 30 laws, over 50 inter-agency agreements, and administered by 12 agencies. These agencies work to ensure basic food safety, address human and animal nutrition, deal with naturally-occurring food borne pathogens, protect the environment, monitor the incidence of disease, and develop effective research programs. President Bush, former Secretary of Health and Human Services Tommy Thompson and Homeland Security Director Tom Ridge all have publicly discussed combining Federal food-safety responsibilities into a single agency. Do you support consolidating food safety authority by modernizing food safety laws and creating a single agency responsible for protecting the American food supply?

Answer 13. As you know, in 2002, President Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act) which gave FDA new authorities to ensure the safety of the food supply. I believe the current food safety system is working. The American food supply continues to be among the safest in the world. Federal agencies with food safety authorities are working together effectively. As Secretary, I will continue to support this enhanced cooperation among all of our food safety partners that can increase the effectiveness of our food safety system.

Question 14. How would you improve FDA's oversight of imported food?

Answer 14. Through the authorities under the Bioterrorism Act, FDA was recently equipped with significantly enhanced tools to ensure the safety of the food supply. If confirmed as Secretary, I plan to work to ensure that FDA is effectively using the ample authorities recently enacted by Congress relating to imported foods. These authorities include requirements that prior notice of imported food shipments be submitted to FDA. FDA is currently receiving about 30,000 advance notices per day. FDA uses this information to make risk-based decisions about the admissibility of imported food shipments before the food may proceed into commerce. To implement the Prior Notice requirement, FDA established and staffed the Prior Notice Center, a first-of-its-kind activity which operates on an around-the-clock basis to accommodate the global economy.

The Bioterrorism Act also requires that the owner, operator, or agent in charge of a domestic or foreign facility to register with FDA. Now, for the first time, FDA has a roster of foreign and domestic food facilities, allowing timely notification and response in the event of a food safety threat.

The Act also requires that records be created and maintained to enable FDA to determine the immediate previous sources and the immediate subsequent recipients of food. In the event of credible threats of serious adverse health consequences or death to humans or animals, this requirement will enable FDA to identify the source of the contamination and to remove adulterated food from commerce, thus preventing foodborne illnesses and deaths.

The Bioterrorism Act also contains authority to order the administrative detention of food if there is credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals.

With these new tools, FDA can continue to improve its oversight of imported food.

In addition to those protections discussed above, FDA and U.S. Customs & Border Protection (CBP) signed a Memorandum of Understanding (MOU) in December 2003

that allows ORA to commission thousands of CBP Officers in ports and other remote locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This agreement provides a contingency plan to assure adequate regulatory coverage at the 300 ports through which imported food may be offered for entry into domestic commerce. Moreover, to ensure prompt access for specified analytical testing of imported foods at U.S. ports of entry, FDA and the U.S. Army's Edgewood Chemical Biological Forensic Analytical Center designed, constructed, and equipped two mobile laboratories. FDA is now deploying these labs and will soon start operation.

In tandem with those protections discussed above, FDA continues to improve its food import program. This continuing improvement effort focuses on evaluation of risk associated with imported food shipments based on several factors: the source(s) of a finished product, intelligence information gathered from both foreign and domestic sources, adherence to good manufacturing practice requirements, the compliance history of all of those entities involved in the distribution chain, and shipping conditions. This risk-based approach will enhance FDA's effectiveness and efficiency by enabling FDA to target shipments for further investigation and/or testing and will complement FDA's traditional examination activities at the border.

Question 15. Do you think that FDA should have mandatory recall authority to protect consumers from contaminated food that is distributed around the country?

Answer 15. It is my understanding that FDA has authority under the Federal Food, Drug, and Cosmetic Act to remove a violative product from the market by using its seizure authority. In addition, in 2002, President Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act) which gave new powers to FDA to administratively detain foods for which there is credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. This domestic authority is coupled with the authority to detain imported foods at ports of entry for a period of time sufficient to ensure their compliance with FDA standards and safety. FDA has been working hard to implement these and other provisions of the Bioterrorism Act.

Effects of Nuclear Weapons Testing

Question 16. The Radiation Exposure Compensation Act makes available modest compensation to some downwinders in some high-fallout counties in Utah, Nevada, and Arizona. Since passage of RECA, a 1997 National Cancer Institute report found that US atmospheric nuclear testing exposed nearly everyone who lived in the US in the 1950s and early 1960s to radioactive fallout. People who lived in many counties in Idaho, Montana, North Dakota, South Dakota, Kansas, Nebraska, Iowa, Missouri, and Arkansas were severely exposed. Will you support just redress for additional people who have been made sick from fallout by expanding RECA coverage?

Answer 16. Thank you for your continued support for the RECA programs and your focus on using the best science possible in the administration of these programs. As the former Governor of Utah, this is an issue with which I am very familiar. As you know, the Department of Justice administers the Radiation Exposure Compensation Program, which provides compassionate compensation to individuals, or their beneficiaries, who contracted certain cancers or other serious diseases as a result of their exposure to radiation from U.S. nuclear testing and uranium mining. Since 1990, when the RECA legislation was enacted, coverage has been expanded based on available scientific information. The Department of Energy also administers a program that provides benefits to Department of Energy employees and contractors who have been approved for an award under RECA.

Through HHS, individuals in Utah, Colorado, New Mexico, and Arizona have access to cancer screening, early detection, medical referrals, education, and assistance with compensation claim documentation. This program, the Radiation Exposure Screening and Education Program, provides grants to six health care organizations in these States. HHS is also overseeing a research project by the National Academies' National Research Council on whether other classes of individuals or additional geographic areas should be covered under RECA, and on how services can be improved based on the most recent scientific information. The report is expected to be delivered to Congress this summer.

Question 17. Following release of the 1997 NCI study, the Senate Appropriations Committee asked the Department of Health and Human Services (HHS) to conduct an initial assessment of the feasibility and public health implications of a study concerning the health consequences to the American population of radioactive fallout from nuclear weapons testing. In 2002, HHS transmitted to the Senate Appropria-

tions Committee a progress report and an extensive, two-volume draft Feasibility Study. The draft was also sent to the National Academy of Sciences Committee on Assessment of CDC Radiation Studies, which released a report in February 2003. Despite repeated requests HHS has not released the Feasibility Study. Will you work to expedite release of the final Feasibility Study, which we understand has been complete for some time?

Answer 17. Yes, if I am confirmed, I will ensure that the release of the final report will be expedited. HHS transmitted to the Senate Appropriations Committee a progress report and draft report in 2002. The draft report was also posted on the CDC website for public comment and was sent to the National Academy of Sciences for review. The NAS Committee issued a report in February 2003. CDC and NCI have been working together to carefully review and respond to all comments from NAS and the public. Because of the length and complexity of the report, making and reviewing the changes have been quite time consuming. However, the basic technical content and findings have not changed since the draft report was published. The final report will present little information that was not already available to the public in the draft report.

Question 18. One of the key obligations growing out of the 1997 NCI study was to inform people exposed to radioactive fallout and their health care providers of the potential health impacts. But HHS has done very little in this regard. What will you do as Secretary of HHS to insure that people exposed to high levels of radiation without their knowledge first are informed about their potential exposures and health consequences and second that they receive adequate health care?

Answer 18. As the former Governor of Utah, this is an issue with which I am very familiar. As you know, HHS administers a community grant screening and education program, the Radiation Exposure Screening and Education Program, which provides access to cancer screening, education, and medical referrals. The program, administered by the Health Resources and Services Administration (HRSA), provides grants to six health care organizations in Utah, Colorado, New Mexico, and Arizona. These organizations screen for the early warning signs of cancer, provide medical referrals, educate individuals on prevention and treatment of radiogenic diseases, and assist with compensation claim documentation. HRSA also oversees a research project by the National Academies' National Research Council on whether other classes of individuals or additional geographic areas should be covered under RECA, and on how services can be improved based on the most recent scientific information. The report is expected to be delivered to Congress this summer.

In addition to this grant program, HHS has developed extensive information for individuals about assessing their risk for thyroid disease—which is the most important harmful radioactive material and can lead to thyroid cancer—and what to do if they are concerned about this possibility. If I am confirmed, I will stand ready to work with you to ensure that these and other HHS activities continue to educate and treat people exposed to high levels of radiation.

The Safety of Dietary Supplements

Question 19. Do you believe that the current law regulating the safety of herbal dietary supplements is adequate? Do you think that it would be useful to commission the National Academy of Sciences to review the safety and efficacy of dietary supplements?

Answer 19. In November 2004, FDA published a regulatory strategy that lays out the Agency's direction in implementing all the provisions of the Dietary Supplements Health and Education Act (DSHEA). The strategy is designed to give consumers a higher level of assurance about the safety of dietary supplement products and the reliability of their labeling, as well as to improve the transparency, predictability, and consistency of the Agency's scientific evaluations and regulatory actions to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. The Agency will continue its ongoing efforts of monitoring and evaluating product safety, ingredient safety, and product labeling, as well as ensuring product quality. Recently, the Agency took action on ephedrine alkaloid-containing dietary supplements because they present an unreasonable risk of illness or injury. The courts are now reviewing this decision.

In 2001, FDA funded an Institute of Medicine/National Academy of Sciences (IOM/NAS) study on the safety evaluation of dietary supplements. FDA considered this report, along with other information, in developing the initiative for full implementation of DSHEA. The NIH has recently funded an IOM/NAS study on complementary and alternative medicine. In light of this recent study, we do not believe that another study would provide additional benefits to the Agency.

Underage Drinking Legislation (STOP Act)

Question 20. As Secretary, what would you do to elevate underage drinking prevention as a national public health priority? Would you include an underage drinking prevention initiative in your fiscal year 2006 or 2007 budget request?

Answer 20. Under Secretary Thompson, SAMHSA convened the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD), that is made up of representatives from the Office of the Surgeon General, the Centers for Disease Control and Prevention, the Administration for Children and Families, and the Office of the Assistant Secretary for Planning and Evaluation, the National Institute on Alcohol Abuse and Alcoholism, the Department of Justice/Office of Juvenile Justice and Delinquency Prevention, the Department of Education/Office of Safe and Drug Free Schools, the Department of Transportation/National Highway Traffic Safety Administration, the Office of National Drug Control Policy, the Department of the Treasury, the Department of Defense, and, ex officio, the Federal Trade Commission.

The Department, in consultation with the ICCPUD, is to develop a comprehensive Federal plan for addressing the issue of underage drinking. An interim plan has been submitted to Congress for their consideration. The interim plan includes the following three goals:

Goal 1: Strengthen a national commitment to address the problem of underage drinking.

Goal 2: Prevent underage drinking and its negative consequences.

Goal 3: Use research, evaluation, and surveillance to improve the effectiveness of programs and policy designed to reduce underage drinking.

These are important goals, and I look forward to working with you to help achieve them.

Fetal Alcohol Syndrome Prevention

Question 21. Would you support the re-issuance of a Surgeon General's advisory on the dangers of drinking during pregnancy?

Answer 21. On 4 December 2004, the Surgeon General released an updated advisory on the dangers of drinking during pregnancy. This advisory updates the one issued in 1981 to reflect scientific evidence amassed since that time on trends in alcohol use among pregnant women and the consequences of prenatal alcohol exposure.

RESPONSE TO QUESTIONS OF SENATOR CLINTON

Kinship Care/Child Welfare

Question 1. As you well from your experience as Governor, there has been a significant rise in the number of children living in kinship care arrangements—living with their grandparents, aunts, uncles, siblings or other relatives because their parents are unable to care for them. You oversaw the establishment of Utah's subsidized guardianship program to support these families. Today that program is serving about 117 children. We think this is a terrific model—one that should be supported through the Federal Government's foster care system. But as you know, States may not use their Title IV-E funds to assist kinship care families, and HHS has not granted a State waiver for this purpose since President Bush took office. Senator Clinton has introduced legislation with Senator Snowe to expand the uses of IV-E to include subsidized guardianship arrangements.

Can we count on your support of this proposal as we reauthorize Title IV-E?

Answer 1. Thank you very much for your comments on Utah's guardianship program. I am extremely proud of the work we did in Utah to strengthen our foster care program. I understand that HHS recently approved a waiver for one State to fund kinship care and that there are others in process. However, I am a strong proponent of maximum State flexibility and believe the President's Child Welfare Program Option provides a much better approach for supporting State innovation than the existing waiver process.

Under the President's proposal, States would be offered the opportunity to receive their foster care funding as a flexible grant to develop a seamless child welfare system that supports a continuum of services to families in crisis and children at risk. States that choose the option would be able to use the funds for foster care payments, prevention activities, permanency efforts (including guardianship) and administrative and other service related child welfare activities.

I strongly urge you to support the President's proposal and look forward to working with you on this key legislative initiative to support innovation and strengthen child welfare programs and the critical services they provide to this vulnerable population.

Family Planning

Question 2. As you know, Title X is the cornerstone of our Nation's family planning program. For millions of low-income women it is the only access to healthcare they have. It is also cost effective—saving three dollars in Medicaid costs for every dollar expended. Yet, the Title X appropriation has lost significant value since the early 80s. If the program had only kept pace with inflation—experience no increase at all—since 1981, the funding level would be double what it is today. Can we count on you to strongly support Title X by increasing the budget proposal for Title X funds?

Answer 2. Title X, as you pointed out, has a long history of providing family planning services and there were considerably fewer family planning options for low-income women when the program was created 35 years ago than there are today. For example, in 1970 very few States had dedicated funds for family planning. Since then, however, virtually all States have committed resources to help women plan for healthy families. In addition, the growth of more avenues of support in the Federal and private sector have made it possible for many, many more low-income women in the United States to have access to free or affordable family planning services.

Title X funding itself has increased from $162 million in 1981 to its current level of more than $280 million. In addition, the Maternal and Child Health Block Grant programs and Community Health Centers are among the new resources though which low-income women can and do receive subsidized care. By far the largest expenditures for family planning services, however, are made under the Medicaid program and, in particular, the Medicaid waivers granted to States to provide family planning assistance. In 2004, over $810 million in Federal funds were expended for fee-for-service family planning services under Medicaid. With the expansion of Medicaid waivers, more women than ever are able to have access to family planning services. We need to continue to access program effectiveness and determine how we can best serve our target population with the resources at our disposal.

As the Nation's healthcare funding continues to change, I am committed to ensuring that low-income women and men continue to have access to basic family planning services and care, including those services necessary to prepare for planned, healthy pregnancies. I am sensitive to the need for both fiscal discipline and the assurance that we are meeting our current program funding obligations. As Secretary, I will work very hard to ensure that women are able to receive adequate access to necessary services.

Plan B

Question 3. We are am deeply concerned that the FDA's process for determining over the counter status became politicized during the "Plan B" application process. The FDA's own advisory committee voted 23–4 in December of 2003 to approve Plan B for over-the-counter status. The panel also unanimously agreed that Plan B is safe for use in the non-prescription setting and unanimously rejected the claim (voting 0–28) that use of Plan B leads to substitution of emergency contraception for the regular use of other methods of contraception. Over 70 organizations, including the American Academy of Pediatrics and the American Associations of American College of Obstetricians and Gynecologists, have recommended that it be available over the counter.

What principles do you believe should guide the FDA when it makes decisions about what drugs may be available over the counter? Under what circumstances do you believe it is appropriate for the FDA to override such strong scientific evidence in making such decisions?

Answer 3. As you know, the FDA previously denied an application to change this drug to over-the-counter status, because the supplemental application did not meet the criteria for approval in that it did not demonstrate that Plan B could be used safely by young adolescent women for emergency contraception without the professional supervision of a licensed practitioner.

I understand that the sponsor has subsequently submitted a new application, and that the application is being reviewed by the scientists at FDA—and that action is due on this application soon.

Head Start

Question 4. I understand HHS is moving forward with its plan to test every four-year-old in Head Start via the National Reporting System. As you know, many childhood development experts have raised concerns about the NRS. On February 28, 2003, a number of experts sent a letter to senators expressing their concerns about the implementation of the NRS. In an October 28 joint press release, Dr. John Meier, Ph.D., Dr. Lonnie Sherrod, Ph.D., and Dr. Susanne A. Denham, Ph.D., respected professors and researchers in the field of early childhood, suggested that the proposed outcomes are too rigid and that the National Academy of Sciences (NAS) should have the "flexibility to design both the test (or tests) and the outcome standards." They also believe it be detrimental to tie any type of program funding to the outcomes of this test. Can we have your assurance that the NRS will never be used to make decisions about which programs receive funding? What plan does HHS have to ensure that children with special needs and those from Limited English Proficient households will be assessed using measures that are appropriate? Have HHS made progress in identifying and training LEP individuals to administer the NRS to children from LEP households?

Answer 4. I share the President's commitment to accountability and to measuring the outcomes of program efforts, including the Head Start program. We must do a better job of determining how well Head Start children across the country are being prepared for academic success once they enter school and the National Reporting System (NRS) is critical to this effort.

The results will be useful in planning new approaches for strengthening Head Start program quality and effectiveness. The information also can be used to identify common national, regional and local needs for training and technical assistance as well as help in identifying programs that are unusually effective in promoting children's progress. However, it is my understanding that there are a number of ways in which Head Start programs are monitored and evaluated, and I can assure you funding decisions for Head Start programs will not be based solely on the information in the NRS.

I understand your concerns about the needs for sensitivity in assessing children with special needs and those from Limited English Proficient households. It is my understanding and expectation that appropriate and required adaptations will be made to allow special needs children to fully and fairly participate in the NRS assessment. Currently, the child assessment is available in both English and Spanish and only trained and certified assessors, including those fluent in Spanish, will be used. Given the wide and ever-increasing diversity of Head Start children and families, I look forward to reviewing the recommendations from the newly formed advisory Committee on Head Start Accountability and Educational Performance Measures on this specific issue as well as other Head Start questions of accountability.

Medicaid

Question 5. New York State has the second highest Medicaid population in the Nation, and the Medicaid program ensures that millions of New Yorkers are able to access crucial health care services. I would like to stress the importance of preserving such benefits, and I was pleased to see that in your opening statement, you recognized the importance of providing access to care for our Nation's poor, elderly and disabled populations. I have specific questions about your views on some of the possible proposals for Medicaid reform.

In 1997, you were one of the architects of the National Governors Association's Medicaid reform package. In that package, you opposed placing Federal spending caps upon the Medicaid program. However, the Administration has stated that it favors such a proposal. What is your current position on Federal Medicaid spending caps, and how do you propose to offer States fiscal relief from rapidly increasing Medicaid costs?

Answer 5. The Administration has not proposed to block grant the program. It is committed to maintaining the entitlement of mandatory populations to mandatory services. At the same time, I believe that States can be given more flexibility to extend health insurance coverage to more low-income individuals and families.

Question 6. As part of your Medicaid reform package in Utah, you cut benefits for recipients in order to expand the program to cover low-income uninsured individuals. Yet the expanded program failed to provide comprehensive coverage and did so through a model in which Federal and State dollars were used to subsidize private insurance companies. How will you increase the flexibility given to States within Medicaid while ensuring that there remains an adequate benefit package that is so desperately needed by so many Medicaid recipients?

Answer 6. First and foremost, I believe strongly that waivers provide States with the flexibility to implement innovative ways to extend health coverage to more people. This is a goal we should all support. The waiver that I implemented in Utah did not make any changes to the benefit for mandatory populations. Instead, the waiver expanded preventive and primary care coverage to an additional 25,000 uninsured adults. To do so, a $50 enrollment fee was instituted, but with exemptions for vulnerable optional populations (including the elderly, blind, disabled, children and pregnant women).

States are not required by the Medicaid law to cover optional populations, yet hundreds of thousands of people in this country—who would otherwise be uninsured—now have access to healthcare because States have been granted modest flexibility in designing and implementing Medicaid expansions. I simply disagree with the suggestion that the better policy would be to leave all of these people without any health care.

Information Technology and Health

Question 7. As governor of Utah, you were a pioneer in efforts to increase efficiency through the use of interoperable information technology systems within the State government. During your testimony before the HELP Committee, you reaffirmed your interest in using information technology to improve the quality of care and reduce overall health care costs. However, the Office of Healthcare Information Technology within HHS did not receive any funding in the recent omnibus appropriations bill.

As Secretary, how will you support the efforts of the National Coordinator for Health Information Technology and work with Congress to provide increased access to and use of information technology in healthcare? In addition, how do you plan to promote and implement health care information technology as a tool for improving overall healthcare quality?

Answer 7. The President believes that better health information technology is essential to his vision of a health care system that puts the needs and the values of the patient first and gives patients information they need to make clinical and economic decisions. I believe that the Federal Government can play a critical role in encouraging and facilitating the adoption and use of health information technology, and I am keenly interested in this issue. Innovations in electronic health records and the secure exchange of medical information can help transform health care in America—improving health care quality, preventing medical errors, reducing health care costs, improving administrative efficiencies, reducing paperwork, and increasing access to affordable health care. The goal is to encourage widespread private adoption of health it without heavy-handed regulation or upheaval in the health care sector. HHS is currently undertaking efforts in four areas identified under its strategic framework—informing clinical practice, interconnecting clinicians, personalizing care, and improving population health—and we should and will continue these efforts. I look forward to the opportunities that lie ahead in the area of health information technology, and will work with Congress in that process.

HIV/AIDS and Ryan White Funding

Question 8. There are over 900,000 people in the United States who are infected with HIV/AIDS. New York State has borne the brunt of this epidemic, and has had both the highest cumulative number of total AIDS cases and the highest number of new AIDS cases in 2003. I cannot stress the importance of Ryan White funding to people living with HIV/AIDS in New York, many of whom are poor, disabled, uninsured, or underinsured. The dedicated funding stream provided by this bipartisan-supported law allows people living with HIV/AIDS to access services that are not covered under the Medicaid or Medicare programs. While the President has already announced his support for reauthorization, I would like to gain a greater understanding of your commitment to the Ryan White program, and the priority that this reauthorization will have within your agency. Specifically:

How will you ensure that the epidemiological profile of the epidemic, which shows that New York City is one of the epicenters of this epidemic in the United States, is adequately reflected in funding?

Answer 8. Thank you for your support for the Ryan White CARE Act. I understand your concern for the people of New York who are living with HIV and AIDS. The Administration continues to finalize its assessment of the successes and drawbacks of the current Ryan White CARE Act (RWCA) statute. Through the reauthorization process, there are opportunities to strengthen the various RWCA programs and to make them more effective. Treatment for people living with HIV/AIDS has changed significantly since the last RWCA reauthorization. If I am confirmed as

Secretary, I will work hard to ensure a successful reauthorization. As I am sure you are aware, the President laid out the principles that will be used in guiding this process: (1) focus Federal resources on life-extending care and a core set of clinical services, (2) provide greater flexibility to better target resources to address areas of greatest need, (3) encourage participation of any provider, including faith based and community organizations, that show results, recognizing the need for State and local planning, and ensuring accountability by measuring progress.

With regard to ensuring that funding adequately reflects the profile of the epidemic, the President's second reauthorization principle is to ensure that the Secretary has greater flexibility to target resources to areas of greatest need. This will be an important aspect of any reauthorization discussions. As you know, RWCA grants that are distributed by formula are currently based on estimated living AIDS cases. Under the formulas for Title II grants to States and Title I grants to Eligible Metropolitan Areas, New York State and New York City have each received over $1 billion between 1991 and 2004. The Institute of Medicine (IOM) issued a report in 2003 that examined whether States' HIV surveillance systems could provide adequate and reliable information on the number and demographic characteristics of cases of HIV infection on which to base RWCA formula grants. The study considered issues of State capability, comparability of data across jurisdictions, whether HIV data would be a more accurate measure of disease burden, and whether material variation and equitable allocations would result. While the IOM supported Congressional intent to incorporate data into the allocation formulas that reflect the evolving needs of the epidemic, their overall finding was "that States' HIV reporting systems are neither ready nor adequate for purposes of the Ryan White CARE Act allocation." Therefore, Secretary Thompson concluded that HIV data should not be used for purposes of making formula grants under Titles I and II of the RWCA, and that estimated living AIDS cases should continue to be utilized until such time as HIV data is judged to be useful. HHS will continue to work with States to support an HIV surveillance system that ensures the collection of such data.

Question 9. How will you ensure that Ryan White Funding is able to provide the appropriate mix of support and treatment services for the many conditions faced by people with HIV, including everything from homelessness to increased rates of Hepatitis C infection?

Answer 9. When the RWCA was originally enacted, people living with AIDS had little hope. Treatment focused on support services for people who were severely disabled and dying. Medical advances and new medications have enabled people to live longer, healthier lives and treatment has shifted toward helping people live with a chronic disease. At the same time, those entering care are more likely to be poor, minority, and have other complex issues, such as substance abuse and mental health issues. As we consider the successes and drawbacks of the current RWCA statute in the context of reauthorization, and discuss ways to make the program more effective, we will identify strategies that enable HHS to meet these changing needs and provide more flexibility to target resources to the areas with the greatest need.

EPA and Industry

Question 10. While you were serving as EPA Administrator, the agency was forced to suspend implementation of its Children's Environmental Exposure Research Study (CHEERS), a program partially funded by the American Chemistry Council, in response to concerns over potential harm to participants. Opponents of the study are concerned that industry involvement would influence the methodology and outcomes of the study, and EPA has taken the step of re-examining the study's protocol in response to these charges. While I appreciate the responsiveness of the agency to these concerns, I am deeply concerned about the safety of research participants, as well as the children who would eventually be affected by the outcome of this study.

At HHS, similar concerns have been raised about the influence of private companies, particularly the pharmaceutical industry, upon the activities of HHS agencies. The recent withdrawal of Vioxx and the controversy surrounding side effects of pediatric antidepressant use have called attention to the industry's influence on the FDA drug approval process and the inability of the agency to guarantee the safety of these drugs after they are marketed to the public.

What actions will you take as Secretary to ensure that the FDA operations are not influenced by drug company financing, and how will you guarantee the safety of drugs after they become available on the market?

Answer 10. If confirmed, I will work to ensure that FDA performs its important statutory responsibility to monitor the safety of approved drugs. The enhanced post-marketing surveillance provisions in the Prescription Drug User Fee Act provide new tools and opportunities to accomplish this goal.

EPA and the Safety of Nuclear Workers

Question 11. The Energy Employees Occupational Illness Compensation Act (EEOICPA) was passed by Congress in 2000. This law is intended to compensate former nuclear weapons workers whose illnesses were caused by exposure to radiation during weapons production-related activities. This program is extremely important to my constituents, as a considerable amount of this work was performed in New York during the 1940s and 1950s. Under EEOICPA, the Secretary of HHS has significant direct responsibilities, as does the National Institute for Occupational Safety and Health (NIOSH). One of the direct responsibilities of the Secretary under EEOICPA is to act on recommendations of the Advisory Board on Radiation and Worker Health. And the next several months, the Advisory Board will be forwarding to the Secretary of HHS a set of recommendations about the Bethlehem Steel site in Lackawanna, NY. Hundreds of claimants who worked at the Bethlehem Steel site have been waiting for years to have their claims considered fairly, which will depend in part on your reaction to Advisory Board's recommendations.

If confirmed, will you act promptly on these recommendations after you receive them? In addition, if confirmed, will you work with me to address concerns about implementation of the program by NIOSH as they arise?

Answer 11. NIOSH responsibilities under Energy Employees Occupational Illness Compensation Program Act of 2000 had to be fulfilled before NIOSH could begin processing claims. NIOSH had to hire staff, establish procedures and promulgate three rules to create the process and systems to run the program; a backlog was created because the program was receiving claims before processes were in place.

As of January 20, 2005, NIOSH has completed more than 50 percent of the claims from New York and nearly 40 percent of all claims received from the Department of Labor. In addition, the promulgation of the Special Exposure Cohort rule in May 2004 will speed determination of claims for which it is not possible to perform a dose reconstruction with sufficient accuracy. NIOSH will continue to strive to improve its performance.

World Trade Center Expert Technical Review Panel

Question 12. While you served as the Administrator of the Environmental Protection Agency, we worked together to form and launch the World Trade Center Expert Technical Review Panel. I appreciate the attention that you gave to this important issue during your time at EPA. As you know, the Department of Health and Human Services is represented on the panel. As its work continues in 2005, the panel will shift its focus to examining the health consequences of exposure to contamination released from the collapse of the World Trade Center. I believe that HHS is uniquely suited among the Federal agencies represented on the panel to address these issues.

Will you work with me to strengthen the role of HHS on the panel to help ensure that the panel addresses these issues in a timely and comprehensive manner?

Answer 12. As Secretary of HHS I would continue the commitment I made as Administrator of EPA to the important work of the World Trade Center Expert Technical Review Panel. As you know, the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, and the National Institutes of Health are working in collaboration with other public and private entities, such as the New York City Department of Health and Mental Hygiene, and academic and health care institutions, many of which also are represented on the Panel, on projects relating to the health consequences of exposure to contamination released in the World Trade Center disaster.

Food Safety

Question 13. Listeria monocytogenes is the most virulent of foodborne pathogens, killing 20 percent of those infected, with pregnant women and their unborn children being particularly susceptible. While the U.S. Department of Agriculture (USDA) and HHS had publicly committed in 2000 to reducing the rate of listeria poisoning by half by 2005, the deadline for this halving has since been pushed back to 2010. Will you reinstate the goal of halving the Listeria food poisoning rate by the end of 2005, rather than 2010?

Answer 13. The goal has always been stated in the Healthy People 2010 document as a 50 percent reduction in illness attributed to Listeria monocytogenes by 2010. In FDA's Listeria monocytogenes Action Plan document, FDA stated its own goal would be to achieve this reduction by 2005. The baseline for calculating the reduction is 0.47 illnesses per 100,000 population with the goal of 0.25 illnesses/100,000. My understanding is that we are on target for reaching the 50 percent reduction with a current incidence rate of 0.26 illnesses per 100,000 population.

Question 14. The FDA is given the mission of ensuring the safety of our food supply, and I was pleased of hearing of your commitment to maintaining the FDA brand. However, I am concerned about the manner in which the FDA is handling the threat of bovine spongiform encephaly (BSE), several cases of which have emerged recently in Canada. Both Secretary Thompson and former FDA Administrator Mark McClellan have affirmed the importance of FDA action in regards to the contents of bovine feed. However, the USDA, which is not charged with ensuring the safety of our food, has largely taken the lead on this issue. What specific FDA action will you take to remove the threat of BSE-contaminated cows from our food supply, and how will you work with USDA to strengthen the regulations in this area?

Answer 14. On July 14, 2004, FDA published an Interim Final Rule, effective immediately, banning use of specified risk materials (SRMs) and other prohibited cattle materials in all FDA-regulated foods and cosmetics. Prohibited cattle materials include SRMs from cattle 30 months of age and older, small intestine of all cattle, materials from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef—these are the cattle materials at highest risk of containing prions. The FDA foods regulation parallels the USDA Interim Final Rule, also effective immediately, for meats and meat products. The agencies cooperated in the development of these documents and continue to cooperate to maintain a harmonized U.S. food safety policy for BSE.

Both the FDA regulation covering foods and cosmetics and the USDA regulation covering meat and meat products augment the preventive measures already in place to reduce or eliminate the threat of BSE in the U.S. and in the U.S. food supply. These measures include FDA's 1997 regulation that prohibits, with some exceptions, the use of protein derived from mammalian tissues in feed for cattle and other ruminant animals—the basis of the agency's efforts to prevent the spread of BSE in U.S. cattle. They also include the import prohibitions imposed by USDA/APHIS.

Science and Ideology

Question 15. The National Academy of Sciences recently issued a report on how the Administration screens nominees for advisory panels in areas of science and technology. Specifically, the report recommended the following:

"When a Federal advisory committee requires scientific or technical proficiency, persons nominated to provide that expertise should be selected on the basis of their scientific and technical knowledge and credentials and their professional and personal integrity. It is inappropriate to ask them to provide nonrelevant information, such as voting record, political-party affiliation, or position on particular policies."

How will you ensure that scientific expertise, rather than political views, is the crucial factor in determining whether a candidate is qualified for an advisory panel?

Answer 15. Although I have not had an opportunity to review the report you cited, I believe that scientific expertise is critical to ensuring appropriate input on scientific advisory committees, and I will work to ensure that HHS advisory committees are appropriately assembled.

Mental and Behavioral Health

Question 16. What do you see as the role of mental and behavioral health services in federally supported health care programs?

Answer 16. In its report entitled "Achieving the Promise: Transforming Mental Health Care in America" issued in July of 2003, the President's New Freedom Commission on Mental Health established six goals as a foundation for transforming mental health care in America. The first goal was that "Americans Understand that Mental Health Is Essential to Overall Health." In its discussion of that goal, the Commission discussed what a transformed mental health delivery system would look like. Part of that discussion included the following passage:

Effective mental health treatments will be more readily available for most common mental disorders and will be better used in primary care settings. Primary care providers will have the necessary time, training, and resources to appropriately

treat mental health problems. Informed consumers of mental health service will learn to recognize and identify their symptoms and will seek care without the fear of being disrespected or stigmatized. Older adults, children, and adolescents, individuals from ethnic minority groups, and uninsured or low-income patients who are treated in public health care settings will receive care for mental disorders.

The Substance Abuse and Mental Health Services Administration (SAMHSA) was given lead responsibility for preparing a response to the Commission's findings and recommendations. An Action Agenda was prepared after consultation with 15 different Federal agencies. The Action Agenda is expected to be released shortly.

Incorporated in this agenda are goals for integrating behavioral health care into the primary health care system to provide greater access to quality mental health care in keeping with goal 1 of the Commission Report.

I look forward to sharing the Agenda with Congress as soon as it is released.

Question 17. How can we ensure that the Medicaid waiver process does not undermine critically needed mandatory mental health services, such as those provided through Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)?

Answer 17. In general, I believe that EPSDT is a very important benefit that must be preserved and protected for the most vulnerable children—those with disabilities and those in families at the lowest income levels. I also believe strongly that waivers provide States with the flexibility to implement innovative ways to extend health coverage to more people. This is a goal we should all support.

Flu Vaccine

Question 18. As you are well aware, our Nation recently suffered its third flu vaccine shortage in four years. In order to forestall such shortages, I have asked Secretary Thompson and HHS to implement some of the recommendations of the Government Accountability Office (GAO) regarding flu vaccine development and distributions. I would like to know what measures you will take to ensure an adequate and safe flu supply, in particular:

How will you develop a flu vaccine supply cushion, or otherwise enable the Government to stockpile flu vaccine in case of emergency? In what ways will you work to encourage increased research of alternative vaccine production methods at the National Institutes of Health? How will you improve the CDC's ability to track and distribute vaccine throughout the United States in times of shortage? How will you improve the ability of the FDA to expedite approval and safe importation of excess flu vaccine from other nations? What are your plans for encouraging drug companies to enter the flu vaccine market?

Answer 18. Preparation for the annual flu season has been a priority at HHS. I will ensure that it continues to be a priority. I believe that the CDC and FDA have successfully taken great strides toward responding to an unforeseeable shortage of vaccine, through the creation of tools to help States identify additional vaccine, through the identification and purchase of additional vaccine under an investigational new drug (IND) application, and through effective public communication about the prioritization of high-risk groups who should receive the available vaccine. Looking forward to the future, we will continue to work with vaccine manufacturers to encourage them to bring their vaccine for licensure and sale in the United States, as well as taking longer-range steps to encourage the development of a domestic vaccine supply, to ensure appropriate supplies of influenza vaccine.

Pediatric Rule

Question 19. In 1998, the FDA adopted a "Pediatric Rule" that required drug manufacturers to provide guidelines for the safe use of their products by children. In order to codify the FDA authority to require such action on behalf of companies, several of us from the HELP Committee introduced the *"Pediatric Research Equity Act of 2003,* which has now become law. This law strengthens the FDA's power to ensure that drugs that are marketed for pediatric populations are safe for use in those populations. In February 2004, I sent a letter to Secretary Thompson asking him how he planned to implement the Pediatric Rule after concerns were raised in regards to the safety of antidepressant use in children. I would like to learn about your position on these issues as well. Specifically:

How can we further improve the FDA's current statutory authorization to strengthen the safety and efficacy of pediatric drugs?

Answer 19. The Pediatric Research Equity Act of 2003 and the Best Pharmaceuticals for Children Act of 2002 have provide FDA with valuable tools to ensure the development of information on the safe and effective use of pharmaceuticals

products in pediatric populations. I hope to more closely review these if confirmed as Secretary

Question 20. What steps do you plan to take to ensure that clinical trial information resulting from pediatric studies will be available to the children and families who would greatly benefit from such access?

Answer 20. FDA is committed to including appropriate information related to the safe and effective use of drugs in pediatric patients in approved drug labeling. In addition, when pediatric studies are submitted to FDA as part if the pediatric exclusivity program under the Best Pharmaceuticals for Children Act of 2002, within 180 days, the agency publishes on the web (<http://www.fda.gov/cder/pediatric/Summaryreview.htm>) a summary of the medical and clinical pharmacology reviews of the pediatric studies. In addition, when pediatric-specific changes are made to drug labeling as a result of studies conducted for pediatric exclusivity, FDA highlights these changes on its pediatric web-site at http://www.fda.gov/cder/pediatric/labelchange.htm.

Open Access

Question 21. This past fall, NIH released a draft rule to improve access to federally funded research literature. While I have supported the concept of open access throughout this process, I think it is very important that a deliberate and inclusive process is pursued to ensure adoption of a policy that thoughtfully considers and appropriately addresses the views of all those affected by it.

What will you do to ensure that this is the case, particularly in light of suggestions that the delay of an announcement about the final rule was designed to postpone any controversy over this issue until after your confirmation?

Answer 21. I am not familiar with the details of the proposal, or of where NIH stands as it works to finalize the proposal. Nonetheless, in general, I believe that encouraging transparency and a public dialogue in managing the taxpayer's investments at NIH are critical steps to ensuring that the trust Congress has shown is maintained.

Comparative Effectiveness

Question 22. Comparative Effectiveness studies were included in the final Medicare prescription drug law based on an amendment that Senators Johnson and Bingaman joined me in offering during debate on the bill. In December, AHRQ released its initial list of priorities for this work.

In light of recent concerns over post approval drug safety, what will you do to ensure that comparative effectiveness research is used to help address this critical issue?

Answer 22. As you know, the MMA directed HHS to take important new steps with regards to the comparative clinical effectiveness of prescription drugs and other therapies. However, the MMA did not include appropriations for these efforts. Accordingly, AHRQ and CMS have taken steps to move forward as quickly as possible within those constraints. This research is a priority for both AHRQ and CMS, and I look forward to working with you as HHS moves forward on this.

RESPONSE TO QUESTIONS OF SENATOR DODD

Ryan White CARE Act—Title IV

Question 1. The highly effective approach of family-centered care, as practiced by grantees under Title IV of the Ryan White CARE Act, is a model of efficiency that provides comprehensive medical and support services to women, children, youth and families affected by HIV/AIDS. Across the country, more than 53,000 people are served by 91 programs, including specialized programs for HIV-positive adolescents and youth. It is a critical program that must be maintained. If you prioritize the reauthorization of the Ryan White CARE Act? Will you support maintaining Title IV as an independent program that emphasizes the importance of "family-centered" care? The past two fiscal years have brought cuts to Title IV, despite its burgeoning caseload. Do you support funding increases for Title IV? The HIV epidemic is growing among young people in the United States, yet primary HIV prevention programs at CDC targeting youth have been cut in recent funding cycles. Do you agree we need additional resources for CDC's HIV prevention programs for young people?

Answer 1. Thank you for your support for the Ryan White CARE Act, which provides for the treatment of over 500,000 individuals living with HIV/AIDS in the

United States. The Administration continues to finalize its assessment of the successes and drawbacks of the current Ryan White CARE Act (RWCA) statute. Through the reauthorization process, there are opportunities to strengthen the various RWCA programs and to make them more effective. Treatment for people living with HIV/AIDS has changed significantly since the last RWCA reauthorization. If I am confirmed as Secretary, I will work hard to ensure a successful reauthorization. I would expect that the structure of the RWCA Titles may be part of the discussion during the reauthorization process. As I am sure you are aware, the President laid out the principles that will be used in guiding this process: 1) focus federal resources on life-extending care and a core set of clinical services, 2) provide greater flexibility to better target resources to address areas of greatest need, 3) encourage participation of any provider, including faith based and community organizations, that show results, recognizing the need for State and local planning, and ensuring accountability by measuring progress. The President's budget will be delivered to Congress next month and will include continued funding for all Titles of the Ryan White CARE Act.

As for HIV prevention programs at CDC, this is a high priority for HHS and CDC and is reflected in the ongoing funding of State and local health departments, community based organizations, and school health programs. Much of the funding provided to State and local health departments, as well as community organizations, for HIV prevention efforts is directed towards programs serving youth and young adults. HHS encourages community organizations serving youth to work with their health departments to determine the best way to meet the HIV prevention needs of young people in their communities. If I am confirmed, I will stand ready to work with you to ensure that these programs continue to help at-risk youth to stay healthy, reduce their risk, and remain free of HIV infection, and to help young people already infected with HIV to access the care, treatment, and support they need.

Pediatric Devices

Question 2. Governor Leavitt, as you may know, for almost the past decade, this committee has taken the lead in ensuring that the drugs children need are tested specifically for their use. Beginning with legislation enacted in 1997 which created incentives for pediatric studies (authored by myself and Senator DeWine) and continuing through legislation enacted in 2003 requiring pediatric testing of certain drugs (championed by myself, Senators Gregg, Kennedy, DeWine, Clinton, and others) we have been working hard to ensure that children have the same assurance of drug safety and efficacy that we expect as for ourselves as adults.

As we're beginning to learn, however, this problem isn't confined to drugs. Like with drugs, where for too long we assume that children were small adults and could just take reduced doses of adult products, we're finding that many essential medical devices used extensively by pediatricians are not designed and sized for children's special needs. Because the number of children needing a particular device is often quite small, there's simply little financial incentive for manufacturers to make pediatric appropriate devices. As a result, health care providers are forced to use adult devices "off-label" without a clear understanding of the risks involved or to use older, less optimal, or more invasive interventions. Pediatricians tell us that the development of cutting-edge medical devices suitable for children's smaller and growing bodies can lag 5 or 10 years behind those for adults.

In my view, this is an issue that demands our attention. As technology for prolonging and saving lives continues to advance at a rapid pace, children are at risk of being left further and further behind. It is my strong hope that this year we can come together on bipartisan legislation to ensure that children are not an afterthought when it comes to life-saving medical devices.

Governor Leavitt, I would be very interested in your views on this issue. It would be my hope, if you are confirmed, that we could work closely together on this very critical problem.

Answer 2. As you know, bringing pediatric medical devices to market can be challenging for a number of reasons. Children are often smaller and more active than adults, body structures and functions change throughout childhood, and children may be long-term device users—bringing new concerns about device longevity and long-term exposure to implanted materials. In addition, modifying an adult device for pediatric use may require significant re-designing of the device and re-tooling of the manufacturing process. Conducting clinical trials in children can also be more difficult due to the small patient population and the variation within the population. I believe it is critical that we work with FDA to encourage and support the development and availability of safe and effective pediatric medical devices, and hope to work with you in this area.

Medicare Modernization Act Implementation

Question 3. The new Medicare Part D prescription drug program will begin in January 2006. To succeed, Medicare beneficiaries must receive specific information regarding the plans available to them. The information must be mailed to beneficiaries and include the drug formularies in the plans available to each individual, what the co-payments will be for each covered drug, how to enroll, and the consequences of failing to enroll. Without this information beneficiaries cannot make an informed choice.

Please tell me what you plan to do in order to provide this information directly to each Medicare beneficiary. If you do not know at this time, please confirm that you will mail specific information to each beneficiary, that the information mailed will be particular to the options available to each individual and that the information will be detailed enough to allow the beneficiary to make an informed choice.

Answer 3. CMS will mail detailed comparison information about the new prescription drug plans to all beneficiary households no later than October 15, 2005, as required by the MMA, and will include the information in our annual Medicare & You handbook, which allows CMS to employ a tested production process and a trusted and recognizable communication vehicle to get this information into the hands of beneficiaries and help them make an informed choice. Handbooks have specific comparison information for each beneficiary's geographic area and the comparison data that is included is garnered from data that the plan itself submits to CMS and has the opportunity to preview before the mailing occurs. Additional detail will be available through the individual plans, www.medicare.gov and 1-800-MEDICARE.

Further to the implementation of the Part D program:

Question 4. What particular outreach efforts will be made for hard-to-reach populations, including those in nursing homes, those who are eligible for both Medicaid and Medicare, those who speak other than English as their first language, and those in rural areas?

Answer 4. Medicare's community-based outreach will work through the Social Security Administration (SSA) and other Federal agencies, States, employers, providers, pharmacists and other health care stakeholders to reach beneficiaries through the various networks where they obtain health care information. This local outreach will encompass the hard-to-reach Medicare populations including those in nursing homes, those who are eligible for both Medicaid and Medicare, those who speak other than English as their first language, and those in rural areas.

CMS will continue this local outreach through an expansive grassroots campaign to educate Medicare beneficiaries at the local level about the Medicare drug benefit. For example, CMS enhanced its partnership with the State Health Insurance Assistance Programs (SHIPs). HHS awarded $21.1 million in fiscal year 2004 and will award another $31.7 million in fiscal year 2005 to the SCHIPs, thereby reflecting the increased emphasis on one-on-one advice and counseling for Medicare beneficiaries. The SCHIPs are among the most effective resources in helping beneficiaries learn about the changes to Medicare and will be able to use the additional funds to equip local organizations with the tools needed to answer beneficiaries' questions. CMS will also support an expansive network of local, community based organizations to help educate and assist low-income beneficiaries who may otherwise be hard to reach.

Question 5. What additional funding will be made to the State Health Insurance Programs (SCHIPs) so that they will have sufficient resources to help older people and people with disabilities understand the new Part D program and make informed choices?

Answer 5. CMS has increased the funding for SCHIPs by awarding $21.1 million in fiscal year 2004 and will award another $31.7 million in fiscal year 2005 to the SCHIPs, thereby reflecting the increased emphasis on one-on-one advice and counseling for Medicare beneficiaries.

Global HIV/AIDS—Appropriate Pharmaceuticals for Pediatric Use

Question 6. Currently, few programs specifically target the treatment of children with HIV/AIDS in developing countries. One of the reasons for this is the lack of appropriate pharmaceuticals for their use. Children are not small adults and treating them that way jeopardizes their lives. With 2.5 million children infected with HIV around the world, it is essential that we have appropriate medications to treat them. How will you ensure that the HIV/AIDS drugs (both generic and brand name) being approved by the FDA expedited process will also include pediatric formula-

tions, as well as important dosing information needed for treating different age groups?

Answer 6. The pediatric exclusivity provision of the 1997 FDA Modernization Act and the subsequent 2002 Best Pharmaceuticals for Children Act have generated many clinical studies and useful prescribing information for many products, including several for the treatment of HIV infection. FDA has an HIV Written Request Template to facilitate the development of products. Following are a few examples of products that have been approved for treatment of HIV infection in children. These approvals resulted from studies submitted in response to a Written Request from FDA.

Ziagen (abacavir), Zerit (stavidine), Videx (didanosine), and Viracept (nelfinavir mesylate), in combination with other antiretroviral agents, are indicated for the treatment of HIV-1 infection in children. Use of Ziagen in pediatric patients aged 3-months to 13 years is supported by pharmacokinetic studies and evidence from adequate and well-controlled studies of Ziagen in adults and pediatric patients. Use of Zerit in pediatric patients from birth though adolescence is supported by evidence from adequate and well-controlled studies of Zerit in adults with additional pharmacokinetic and safety data in pediatric patients. Use of Videx in pediatric patients two weeks of age through adolescence is supported by evidence from adequate and well-controlled studies of Videx in adults and pediatric patients. Use of Viracept in pediatric patients from age 2 to age 13 is supported by evidence from adequate and well-controlled studies of Viracept in adults with additional pharmacokinetic and safety data in pediatric patients.

In addition, in March 2003, the Pediatric Subcommittee of the AntiInfective Drugs Advisory Committee, of the Food and Drug Administration, Center for Drug Evaluation and Research discussed the development of antiretroviral drugs in HIV-infected and HIV-exposed neonates younger than four weeks of age. The Advisory Committee supported the continued need for development of products for neonates.

These are just a few examples demonstrating FDA's commitment to the principle that product development should include pediatric studies when pediatric use of the product is intended. In addition, through efforts to make safe and effective antiretrovirals available for treatment of HIV across much of the developing world, we expect to reduce the number of children born with HIV infection and thus significantly impact global health.

If confirmed as Secretary of HHS, I will work to ensure that FDA builds on this strong record of review of HIV treatments suitable for children.

Mercury/Environmental Health

Question 7. The Environmental Protection Agency (EPA), under your leadership, is poised to finalize a regulation that would establish a market-based trading program for the regulation of mercury emissions from coal-fired power plants. The trading regime would reduce emissions from the industry overall, but would allow some plants actually to increase their mercury emissions. Unlike emissions of substances like carbon dioxide, mercury emissions are believed to have at least some local impacts. In addition, mercury is believed to be toxic to children.

Governor Leavitt, there is a growing body of evidence that environmental factors have a profound impact on children's health. I am concerned that your actions as EPA Administrator in regards to mercury suggest insensitivity to this issue. As Secretary of HHS, what would you do to protect children from mercury and other environmental hazards that cause conditions from asthma to impaired neurological development?

Answer 7. During my tenure at EPA, and especially during the development of the first-ever rule to regulate mercury emissions from power plants, I have been committed to protecting the public health of all citizens and the environment. To that end, I outlined five principles that provided a context for additional inquiry and help focused the Agency's deliberations as it moves toward the mercury final rule in March of this year. The protection of children and pregnant women from the health impacts of mercury were at the forefront of these five principles.

As you may know, we have coordinated the implementation of the cap-and-trade approach for regulating mercury from utility units with the Clean Air Interstate rule proposal (CAIR), which is designed to dramatically reduce and permanently cap the emissions of sulfur dioxide (SO2) and nitrogen oxides (NOx) in 29 Eastern States. We believe that a multi-pollutant approach to regulating SO2, NOx, and mercury from the utility sector provides a cost-effective and environmentally beneficial strategy for reducing air pollution from the sector.

As a general matter, a cap-and-trade system requires emissions reductions on a concrete timeline of declining caps, thus leading to continual reduction of emissions

and promotion of new technologies. Further, the largest emitters typically will be the first to reduce their mercury emissions and will generally achieve the greatest level of reductions. More specifically, it is my understanding that in implementing cap-and-trade programs in the past, we have not observed the creation of hot spots. Even so, the proposed trading programs provide legal mechanisms to ensure that should hot spots be identified, appropriate Federal and/or State actions are allowed to address them. Historically, EPA has seen the largest emitters attempt to control emissions sooner in a cap-and-trade program because of the economies of scale and the ability to bank allowances for later years. Thus, we believe such a program creates incentives for the utility sector to aggressively seek reductions in NOx and SO2, which ultimately provide early mercury reductions.

As Secretary of HHS I would continue the Department's commitment to safeguard the environmental health of children, through support of several ongoing programs to advance the scientific understanding of health impacts from exposure to hazardous substances, including mercury, and to protect children from exposure to environmental contaminants with potentially adverse health impacts.

RESPONSE TO QUESTIONS OF SENATOR HARKINS

Obesity Crisis

Question 1. Health care costs are skyrocketing and chronic conditions like obesity and smoking are major contributors. We have one of the best medical systems in the world to treat people but unfortunately it does little in terms of prevention. Obesity has become an epidemic in this country and is especially worrisome when it comes to children. The direct and indirect costs of obesity are more than $117 billion annually according to the Department you will now lead. Yet, there is no single Federal agency with the responsibility and authority to handle the crisis. While obesity is a complex public health problem, many agree that a comprehensive plan is necessary to combat the growing epidemic.

Do you envision creating a command and control center at CDC to develop a Federal game plan for preventing and controlling obesity and related chronic diseases like diabetes and heart disease? If not, how do you propose to address the Nation's obesity epidemic? How specifically will you work with other Federal agencies?

Answer 1. Seven of nine of the major causes of death in the United States are caused by chronic diseases. The underlying causes of these diseases are often behaviors that can be successfully modified thereby reducing illness and death. Three factors—lack of physical activity, poor nutrition, and tobacco use—are major contributors to the Nation's leading killers; heart disease, cancer, stroke, chronic obstructive pulmonary disease and diabetes. Too, the prevalence of overweight has more than doubled in children and tripled in adolescents; indicators suggest that diabetes too is increasing among children. This is particularly troubling given obesity is a comorbidity factor leading to significantly increased risk of death due to cancer, heart disease and diabetes.

In June 2002, President Bush launched the *HealthierUS* initiative to utilize the combined expertise of the Federal Government to help Americans live longer and healthier lives through simple changes in their everyday lives. The four pillars of the *HealthierUS* initiative are: 1) be physically active every day; 2) eat a nutritious diet; 3) get preventive screenings; and 4) make healthy choices concerning alcohol, tobacco, drugs and safety.

HHS is currently engaged in a number of key activities, two of which are listed below. I look forward to examining what has been done and what is underway, and working to continue this tremendous progress.

Current Activities:

• Steps to a *HealthierUS* Initiative (Steps). Steps specifically targets diabetes, asthma and obesity. In fiscal year 2003 Steps funded 23 communities. In fiscal year 2004 the program awarded $44 million to help 16 additional communities develop action plans to implement programs that promote disease prevention and health; the total number of funded communities is 40. Steps also received $1.5 million to fund one national program, YMCA's Activate America. Fiscal year 2005 appropriations budget for Steps is approximately $47 million.

• National Coverage Decision—Earlier this year, HHS announced a new Medicare coverage policy that would permit Medicare to cover anti-obesity interventions if scientific and medical evidence demonstrate their effectiveness in improving Medicare beneficiaries' health outcomes. The new policy removes language in the Medicare Coverage Issues Manual stating that obesity is not an illness, allowing Medicare to determine if specific obesity-related treatments should be covered by Medicare.

Parity Between Disease Prevention and Treatment

Question 2. As you know, the United States spends more than $1.5 trillion each year on health care. That figure has doubled over the past 5 years, and if current patterns hold, is expected to double again within 6 years.

The consequences of future increases are clear: More Americans will be left without access to health care, and more communities will suffer the closure of local hospitals and clinics. As a result, many Americans will forgo basic health maintenance visits, making it more likely that illnesses will go undiagnosed at early stages—a situation that will send health care costs spiraling even further.

In my view, one way to reduce the long-term burden of disease is to invest in preventing disease at the outset. This involves research to determine the best methods to convince Americans to adopt healthy lifestyles and grassroots programming to get the results of that research into our communities.

To what extent will you focus the efforts of the Department on population-based public health research and prevention programs such as that conducted by CDC and NIH?

Answer 2. I believe, as you do, that disease prevention is an important tool that we can use to reduce the long-term burden of disease. You raise an important question of focusing efforts in this area that I will consider carefully if confirmed as Secretary.

Question 3. A brief glance at the Department's budget proves that Federal resources are disproportionately skewed away from disease prevention and toward treatment of illness and disease. In 2003, Federal spending on health care programs run by the Centers for Medicare and Medicaid services totaled $414 billion. In 2003, federal spending on major disease prevention and health promotion programs totaled $42 billion, or just about ten 10 percent.

A greater investment in prevention will ultimately yield tremendous savings in human suffering and financial cost. Have you given any thought as to how you might make disease prevention a centerpiece of the Department's vast and diverse portfolio?

Answer 3. As you know, many of our Nation's leading health challenges are preventable diseases. Focusing efforts on prevention can pay key dividends. I know that the recently enacted MMA included important provisions in this area, and that prevention has been a growing area of focus for HHS. I look forward to carefully examining this issue more fully if confirmed as Secretary.

Need to Increase Access to Community Based Services for People With Disabilities and Older Americans

Question 4. We are currently spending approximately 70 percent of our long-term care Medicaid dollars on institutional settings and only 30 percent on home and community based services. There needs to be increased access to home and community based services so Americans with disabilities and older Americans can choose where they want to live and not be forced into segregated settings away from family and friends.

How will you expand the long term care system to assure no person is forced into a nursing home or other institution because of the lack of home and community service and support options? What policies will you propose?

Answer 4. I firmly believe that individuals who are able to receive long term care services and supports in the community have increased satisfaction, lower incidence of care neglect, lower incidence of adverse effects and health problems; and lower unmet needs. While community-based care is not for everyone, I support policy options to make the choice available to individuals with disabilities and the elderly population.

CMS is currently working with several States interested in using the 1115 waiver authority to develop long-term care systems that tighten the standard for institutional care while making home and community-based services more readily available. As States have developed effective ways to rebalance State long-term care systems, CMS is sharing that information with other States to enable them to rebalance their systems. As Secretary, I will work with States to use the flexibilities permitted in Medicaid to rebalance State long-term care systems.

Question 5. The Supreme Court ruled in the Olmstead case that people with disabilities have a right to services and supports "in the most integrated setting". What will you do as Secretary to assure that States are complying with the Olmstead decision and that Medicaid long term care funds are spent so people with disabilities have a choice to receive services and supports in the most integrated setting?

Answer 5. As Secretary I will ensure that the Department continues to take a leading role in carrying out the President's New Freedom Initiative, including its commitment through Executive Order 13217 to implement the Olmstead decision to ensure that individuals with disabilities receive services in the most integrated setting. The Executive Order commits the United States to a policy of community integration for individuals with disabilities and calls upon the Federal Government to work with States to implement the Supreme Court's decision in Olmstead v. L.C. As part of the Executive Order, the President directed the Secretary of HHS to coordinate the activities of other Federal agencies. This coordinated effort led to the production of Delivering on the Promise, a comprehensive compilation of the reports of nine Federal agencies outlining more than 400 specific steps the agencies will implement to support community living for the nearly 54 million Americans living with disabilities. The Office on Disability was created at HHS to coordinate the Department's commitments, and I will ensure that the Department continues to place these activities among its highest priorities. Additionally, OCR will continue to provide technical assistance to States as they continue developing comprehensive, effectively-working plans to integrate persons with disabilities into communities and to resolve voluntarily complaints filed by or on behalf of persons with disabilities.

Medicare

Question 6. Iowa ranks at the bottom of all 50 States on per beneficiary Medicare reimbursement, even though medical facilities in Iowa provide high quality care. While I understand that this is due in large part to the relative cost of performing these services, I am concerned that this reimbursement provides a disincentive for health care professionals to remain in the State. In addition, I am concerned that any further cuts in provider payments will make this situation untenable.

How do you plan to link Medicare reimbursement with quality services and outcomes?

Answer 6. Encouraging improved health care quality is a top priority of mine and of the President's. The Administration has promoted accountability for quality, creating incentives to collect data from Medicare providers on quality measures. I am intrigued by the possibility of approaches to link Medicare reimbursement to provider performance. While I certainly am not versed in the variety of ways that pay-for-performance could be incorporated into the Medicare and Medicaid payment systems, I am excited to be involved in conversations regarding the issue. If I were to be confirmed, I would expect the Department would continue to review this issue and I would want us to work with the provider and beneficiary communities and the Congress in doing so.

Question 7. Do you think, from the administration's perspective, in order to reduce the budget deficit in half in five years, that provider payments cuts will be part of any administration proposal to change Medicare? And, if so, what can be done to mitigate this problem for rural providers.

Answer 7. As you know, I have not been part of discussions on forward-leaning budgets, but I am aware of the sensitivities surrounding provider payments and the challenges that rural providers face and will be sensitive to those issues.

Dietary Supplements

Question 8. As an author with Senator Hatch of the Dietary Supplement Health and Education Act of 1994, I wanted to get your response to several questions regarding the regulation of dietary supplements. First, as you know, after many years of delay, final good manufacturing practices regulations are near completion. Can you assure me that these regulations will be published in the next 30 days?

Answer 8. If confirmed, I will look into the status of these regulations and work with FDA to see them completed as quickly as possible.

Question 9. Second, as you may know, DSHEA was passed unanimously by both the House and Senate. This unanimity of support reflected the Act's careful balance of maintaining consumer access to a range of healthful products, improving the quality and availability of reliable scientific information on supplements, and providing regulatory authority adequate to assure the protection of the public health. Do you agree with me that DSHEA provides an appropriately balanced regulatory structure when fully implemented and enforced? Or do you believe it should be amended to provide the Department with additional regulatory authority over the manufacture and sale of dietary supplements?

Answer 9. If confirmed as Secretary, I will carefully evaluate the need for any additional authority relating to this issue.

As you may know, FDA recently published a new strategy to strengthen its regulation of dietary supplements. FDA's strategy for dietary supplements outlines the steps it plans to take to continue implementing and enforcing the Dietary Supplement Health and Education Act of 1994 (DSHEA). The strategy sets forth a series of research and measures, including guidance, regulations, and science-based compliance and enforcement mechanisms.

The strategy focuses on three areas: monitoring and evaluating product and ingredient safety, ensuring product quality, and monitoring and evaluating product labeling. With this strategy, FDA hopes to improve the transparency, predictability, and consistency of the Agency's scientific evaluations of dietary supplement product and ingredient safety. The actions outlined in the strategy are also designed to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. FDA expects that this improved transparency will help engage stakeholders in the development of further measures to implement DSHEA.

RESPONSE TO QUESTIONS OF SENATOR JEFFORDS

Question 1. Last December, the FDA's Independent Expert Advisory Committees were unanimous in their determination that Plan B is safe enough for over-the-counter use, and that there is no data to show that Plan B leads to substitution of emergency contraception for other methods of contraception. Despite this determination by the Advisory Committees, the FDA denied Plan B Over-The-Counter status and overrode the overwhelming scientific evidence.

I am concerned that the FDA decision was based more on ideology than science. Governor Leavitt I am interested in what actions you would take to ensure that FDA decisions are based on scientific evidence and not political ideology?

Answer 1. I am committed to the principle that regulatory decisions should be based on the best scientific information that is available. As you know, the FDA previously denied an application to change this drug to over-the-counter status, because adequate data were not provided to support a conclusion that young adolescent women can safely use Plan B for emergency contraception without the professional supervision of a licensed practitioner.

I understand that the sponsor has subsequently submitted a new application, and that the application is being reviewed by the scientists at FDA—and that action is due on this application soon.

Question 2. In August of 2004, the Drug Enforcement Administration (DEA) forwarded a petition to reschedule marijuana to the Department of Health and Human Services (HHS). The DEA requested from HHS a scientific and medical evaluation of marijuana, upon which it would base its decision as to whether to reschedule marijuana. By law, the Secretary of HHS is required to conduct this evaluation "within a reasonable time."

As you may know, 10 States, including my home State of Vermont, currently allow for the medical use of marijuana, while the Federal Government does not. To address this discrepancy, the HHS evaluation needs to move forward. Governor Leavitt, can you work to ensure that this evaluation is completed by August 2005, 1 year after the request was received by HHS? If not, could you please explain what you would consider a "reasonable time" for this evaluation to be?

Answer 2. FDA is currently reviewing the scientific data and must conduct a scientific and medical evaluation of marijuana in accordance with the statutory criteria and make a recommendation to DEA. We will make every effort to complete the evaluation by August 2005.

RESPONSE TO QUESTIONS OF SENATOR KENNEDY

Medicaid

Question 1. At the hearing you talked about your desire to give governor's greater flexibility in Medicaid, so that they can cover more people. Covering more people is a laudable objective and additional resources to do it are essential, but flexibility that results in reduced services or coverage for the most needy and sickest members of our society is not desirable. Specifically, some who advocate increased flexibility have favored abolishing EPSDT services for poor children. EPSDT requires the coverage of medically necessary services for children even if those services are not normally covered under the State Medicaid plan. The children who benefit from this

rule are typically children with disabilities or special needs who need services that are not normally covered by a typical insurance policy.

Do you think that removing a guarantee of needed health services for poor children with serious disabilities is the right priority for our country?

Answer 1. EPSDT is a very important benefit that should be preserved and protected for the most vulnerable children—those with disabilities and those in families at the lowest income levels who meet the federally mandated eligibility groups in Medicaid.

Women's Health

Question 2. Congressman Henry Waxman recently released a report showing that the curricula used in the largest abstinence-only education program, and other federally funded programs are not reviewed for accuracy by the Federal Government. The report finds that over 80 percent of the abstinence-only curricula, used by over two-thirds of the Community Based Abstinence Education grantees in 2003, contain false, misleading, or distorted information about reproductive health.

It is essential to separate ideology from sound science and provide clear and accurate sex education for our children. What will you do to provide effective oversight of these programs and ensure accuracy and integrity of the sex education curricula?

Answer 2. I share your interest in the Community-Based Abstinence Education programs and the need to provide sound and medically accurate information to our Nation's youth. I also agree with the President that the only 100 percent sure way to prevent unwanted pregnancies and sexually transmitted diseases is sexual abstinence. I look forward to working with you on helping our Nation's youth make the best choices for themselves.

Question 3. Title X of the Public Health Service Act, the cornerstone our Nation's family planning program, serves 5 million women each year at more than 4,500 clinics across the Nation that are run by abroad range of local providers, including hospitals, health departments, and local non-profit agencies. Investments in contraception are among the most cost-effective health services. For every dollar spent on publicly funded family planning services, three dollars are saved in pregnancy-related and newborn care costs to Medicaid.

Despite the proven cost-effectiveness of family planning services, Title X has a very small appropriation of only $288 million, even though the program has an excellent track record of providing low income Americans with subsidized, confidential health care services such as pap tests, birth control, and screening and treatment for STDs and helps women to avoid over one million unintended pregnancies each year.

Can you give us your assurance that maintaining the integrity of Title X and its commitment to providing critical contraceptive and related services to low income women will be a top priority for you and the department?

Answer 3. I can assure you that I will require the highest degree of accountability and integrity from Title X, and other Federal programs that provide family planning, and that reducing health care disparities for minority populations and low income families will continue to be a priority for the department during my tenure as Secretary.

Public Health

Question 4. Two-thirds of Americans are overweight or obese, and the problem is growing, particularly in minority populations. Rates of obesity in children have doubled, and even tripled in some age groups over the past 20 years. As a result, children are increasingly developing diseases like diabetes and hypertension that used to be seen mostly in adults.

Last week, HHS and the Department of Agriculture released "Dietary Guidelines for Americans", which recommend eating more fruits and vegetables, low-fat milk, whole grains, and exercising more often. The guidelines specifically recommend limiting consumption of sugars and trans fats. However, as the report states, the publication is not aimed at the general public, unlike previous versions, and no funds are designated to promote the guidelines or disseminate the information to the public in useful ways.

What steps will you take to make the information in these guidelines available in ways that help people practice what the guidelines preach?

Answer 4. The Dietary Guidelines, based on the latest scientific and medical information, provides authoritative advice about how proper dietary habits can promote health and reduce risk for major chronic diseases. Consumer-friendly materials such as brochures and Web sites will assist the general public in understanding the sci-

entific language of the 2005 Dietary Guidelines and the key points that they can apply in their lives. To highlight those points, a consumer-oriented brochure accompanies the 2005 Dietary Guidelines. USDA's Food Guidance System also will serve as a tool to educate consumers on the Dietary Guidelines for Americans. The Food Guidance System, currently called the Food Guide Pyramid, is undergoing revision and will be released in the spring of 2005.

Question 5. The National High Blood Pressure Education Program at the NIH has said that the food industry must reduce the sodium content of processed foods because such reductions could save tens of thousands of lives per year by lowering high blood pressure. How do you intend to work with the food industry to reduce the salt in processed foods?

Answer 5. I believe that HHS has done a tremendous job in focusing public attention on the issues relating to wellness, prevention and obesity, and that these efforts are bearing fruit. As part of these efforts, HHS has been able to work collaboratively with outside stakeholders, including the food and restaurant industry, to make important progress. An example of this is the improved nutritional labeling information that is available through many restaurants. I hope to continue this collaborative approach and work with all interested parties to improve the health of the Nation.

Question 6. In a 2004 report on the labeling of sugars and other nutrients, the Institute of Medicine recommended that providing information to consumers about sugars or added sugars in the context of a total daily diet "should be an urgent consideration of the cognizant regulatory bodies." How do you believe the FDA should respond to this IOM recommendation?

Answer 6. The *2005 Dietary Guidelines for Americans* recommends that consumers limit consumption of added sugars in foods and beverages. The *Dietary Guidelines* present the concept of "discretionary calories" as a way for consumers to understand the amount of added sugars that could be incorporated into a healthful diet and also the concept of nutrient dense foods as a way to choose products that are good sources of nutrients compared to their calorie content. The Nutrition Facts panel of food labels provides consumers with information on the total sugars in a product and the ingredient list provides information on what is in a product, including ingredients that are sources of added sugars. FDA can help consumers respond to the recommendations in the IOM report as well as the *Dietary Guidelines* by educating consumers on how to use the Nutrition Facts panel and ingredient list to determine which foods are high in added sugars.

Question 7. The Centers for Disease Control released a comprehensive report on the state of health of African Americans, which outlined severe and pervasive disparities in health between African Americans and whites Americans. You mentioned that expansion of health insurance coverage would be one way to reduce health disparities. What additional programs and policies will you support to eliminate racial and ethnic disparities in health and health care? What work has been conducted or completed by the HHS Disparities Council in this area? Who are the members of the HHS Disparities Council?

Answer 7. We have experienced remarkable achievements in the health of this Nation. However, some Americans have not benefited equally. As you correctly indicate, it is well documented that racial and ethnic minorities, as well as some geographically and socio-economically disadvantaged populations, suffer a greater burden of illness and premature death in this country. These disparities in health are persistent, in some cases are widening, and are simply unacceptable. We must take action if we are to remain healthy, strong, and vibrant as a nation. I want you to know that disparities in health is a challenge that I have taken to heart.

The President and his Administration have made the elimination of health disparities in our country a priority, and I am also committed to making this happen. I intend to work with the Department's Health Disparities Council, which consists of senior representatives of each agency and staff division of HHS, to focus time and attention on ways to make sure communities of color and other disadvantaged populations have access to quality health care and are getting the very best health information. We will continue to expand on those efforts that have resulted in improved health outcomes as well as identify new approaches to closing critical health gaps.

Question 8. Approximately half the U.S. supply of flu vaccine is unusable because of manufacturing problems at a facility in Britain operated by the Chiron Corporation. I am concerned that FDA appears to have known of problems in vaccine production at the facility many months before it was shut down by the British regulatory agency, but took little action to correct the problems. To determine what ac-

tions FDA took or failed to take, I requested documents to show FDA's communications with Chiron regarding its production of flu vaccine. I was disappointed to receive only 229 pages of documentation, which included 26 pages that were blank or contained material, such as press releases, that were already in the public domain. Over 850 additional pages—more than 80 percent of the total relevant documents—were withheld and not released to me. That is the nature of the withheld documents and why have you deemed them to be "not releasable?"

Answer 8. Your request for documents relating to the suspension of Chiron Corporation's influenza vaccine manufacturing license by the United Kingdom's Medicine and Healthcare Products Regulatory Agency covered a very large volume of documents. I understand that FDA provided a partial response to your request on January 10, 2005.

The information redacted from the documents enclosed in the January 10 letter was commercial confidential and other privileged information protected from disclosure under the Freedom of Information Act (Title 5, United States Code section 552) and FDA regulations.

Question 9. What steps did the FDA take to monitor Chiron's production process after the delay in shipping due to contaminated lots in August 2003? Please describe in detail any inspections of the Liverpool plant and communication with Chiron employees and British regulators.

Answer 9. I believe that your question relates to contaminated lots identified in August 2004, not August 2003. On August 25, 2004, Chiron informed FDA that the company had discovered bacterial contamination in eight lots of final vaccine product for this year's flu season supply and advised that they were investigating the problem. They shared with FDA an overview of their planned investigation to determine root causes of the problem as well as their plan to retest all other lots produced. Chiron quarantined all influenza vaccine lots during its investigation, including those that had passed all required testing, and did not release any of the product.

In September 2004, FDA, CDC and Chiron scheduled weekly conference calls to discuss the status of the firm's investigation. Chiron stated to FDA that the company thought it had identified the cause of the contamination and that the contamination was confined to the identified vaccine lots. Nonetheless, FDA concurred with the need for Chiron to thoroughly retest all final lots, complete a thorough investigation of the manufacturing process and provide a complete investigation report to FDA. While the investigation was ongoing, Chiron informed FDA that results of the retesting were negative and that the company would submit its final investigative report to FDA during the week of October 4–8.

In late September, Chiron advised that it would substantially meet its obligations to supply influenza vaccine to the United States. On September 28, Chiron's CEO affirmed this in testimony to the Senate Committee on Aging when he stated: "As of September 27th, it remains Chiron's expectation that between 46 million and 48 million Fluvirin doses will be delivered to the U.S. market beginning in early October as compared to the 50 million doses projected in July."

FDA inspected the Liverpool, U.K. facility where this vaccine is produced in 1999, 2001, 2003, and 2004. Under Agency enforcement policy, FDA inspects U.S. licensed vaccine manufacturing facilities every two years. Please note that Chiron acquired the facility in July 2003 after FDA conducted the biennial inspection. During the 1999 inspection, FDA identified various concerns and, as a result, issued a warning letter regarding the Liverpool facility. The most significant issues identified in 1999 were the lack of validation for its manufacturing processes, including establishing proper limits for bioburden (including bacteria) and issues related to assuring sterility in the manufacturing process. During the 2001 and 2003 inspections, although FDA found that the company made improvements, we also made observations related to current Good Manufacturing Practice (cGMPs). In each case, FDA reviewed the corrective measures and plans in response to these deficiencies. If fully implemented, the company's plans appeared adequate to correct deficiencies identified at the facility.

1999 and 2001 Inspections

An inspection of the firm on July 13 through July 21, 1999, resulted in the issuance of a Warning Letter on October 21, 1999. The firm responded to the Warning Letter on November 15, 1999. A response review letter was issued to the firm on March 1, 2000, which included requests for additional information. The firm provided the additional information in a letter dated April 6, 2000. A second response review letter was issued to the firm on May 24, 2000, which included additional

comments and also stated that the adequacy of the firm's responses would be verified during the next inspection.

The inspection of Evans Vaccines Ltd., operating as a division of PowderJect Pharmaceuticals Plc., performed February 26 through March 9, 2001, was conducted in part as a follow-up inspection to the Warning Letter and as a routine CGMP inspection. As stated in the establishment inspection report (EIR) for this inspection, the firm's corrective actions taken in response to the Warning Letter were reviewed and evaluated and appeared to be adequate with the exception of the cleaning validation of a filtration unit. The cleaning validation was not complete and further studies were needed to assure the completeness of sterility test failure investigations.

The February 26 through March 9, 2001, inspection was classified voluntary action indicated (VAI). On March 9, 2001, a 31-item, Form FDA 483 was issued to the firm. The CGMP deviations included no data to support holding times, inadequate cleaning validation studies, failure to follow SOPs, inadequate failure investigations, inaccuracies noted in the Master Production Records, tubing used for transfer touching the floor, no SOP for Biological Product Deviations, inadequate validation for a vial filler, inadequate preventive maintenance program, inadequate validation for vial and stopper washing, process qualification for WFI system not reviewed and approved by the Quality Control Unit and testing to determine compatibility of equipment.

The firm responded to the Form FDA 483 items on April 20, 2001. The response stated corrective actions including the modification and enhancement of SOPs, purchasing of new equipment, enhancement of Quality Control Unit, and training/retraining of personnel. A response review letter was issued to the firm on July 19, 2001, which included comments and also stated the firm's responses appeared adequate and that the implementation and effectiveness would be verified during the next inspection.

The inspectional observations made during the February 26 through March 9, 2001, inspection were deviations from CGMP and were adequately addressed by the firm in the April 20, 2001, response.

2003

The inspection of Evans Vaccine, Ltd., operating as a division of PowderJect Pharmaceuticals Plc., performed June 2 through June 10, 2003, was conducted as a routine CGMP inspection. As stated in the EIR, the inspection disclosed that the firm had corrected most of the observations cited during the February 26 through March 9, 2001, inspection with the exception of the cleaning validation of a filtration unit, inaccuracies in the Master Production Records, validation for a vial filler, and testing to determine compatibility of equipment.

The June 2 through June 10, 2003, inspection was classified VAI. On June 10, 2003, a 20-item, Form FDA 483 was issued to the firm. The majority of observations cited during the inspection were regarding issues and lots manufactured in 2000, 2001 and 2002. The CGMP deviations included reprocessing of monovalent blends for 2001/2002 campaign lots without prior approval, inadequate failure investigations for 2000/2001 and 2001/2002 campaign lots, incomplete sterility failure investigations for monovalent blend pools for 2000/2001 and 2001/2002 campaign lots, deficiencies in product contact equipment compatibility, incomplete Biological Product Deviation (BPD) reporting, inadequate cleaning validation studies, failure to follow SOPs, deficiencies in filling room operations, inadequate validation of sanitizer efficacy, deficiencies in media fill simulations, and no documentation of adverse events for 2002/2003 campaigns.

The firm responded to the Form FDA 483 on June 27, 2003. The response stated corrective actions including a commitment to quality system improvements, an enhanced program to ensure consistency of application of CGMPS across all sites, ongoing global initiative for the company, incorporation of "Quality System Improvement Program" (QSIP), and the use of a U.S. consultant to assist the firm. In addition, the response stated that as of April 12, 2002, no reprocessing of monovalent blend lots had occurred for lots destined for U.S. market and committed to revising the SOP. Moreover, as stated in the firm's response and as the evidence collected during the inspection clearly showed, there was a steady decrease in bioburden level excursions from 2001 up to June 2003. This indicated that corrective actions taken as a result of the bioburden level excursions seemed to be effective.

A response review letter was issued to the firm on September 3, 2003, which stated the adequacy of the firm's responses would be verified during the next inspection.

The inspectional observations made during the June 2 through June 10, 2003, inspection were deviations from CGMP and were adequately addressed by the firm in the June 27, 2003, response.

2004

The inspection of Evans Vaccines Ltd., operating as an affiliate of Chiron Corporation, performed October 10 through October 15, 2004, was conducted in part as a follow-up to the MHRA flu vaccine license suspension and as a routine CGMP inspection. As stated in the EIR, the inspection disclosed that 5 out of the 20 observations made during the June 2003 inspection had not been adequately corrected which included inadequate failure investigations for 2000/2001 and 2001/2002 campaign lots, incomplete sterility failure investigations for monovalent blend pools for 2000/2001 and 2001/2002 campaign lots, deficiencies in product contact equipment compatibility, deficiencies in media fill simulations, and no documentation of adverse events for 2002/2003 campaigns.

The October 2004 inspection disclosed deficiencies in the control of bioburden in the manufacturing and production areas, which were not seen during the June 2003 inspection. The October 2004 inspection disclosed that over 50 percent of the monoblend pools used from March 2004 through October 2004 exceeded the firm's bioburden alert level. In addition, nine batches of final product were rejected for sterility failures, and four other batches of final product were rejected within two months, from September 2004 to October 2004, due to environmental excursions.

The October 10 through October 15, 2004, inspection was classified official action indicated (OAI). On October 15, 2004, a 14-item, Form FDA 483 was issued to the firm. The inspection resulted in the issuance of a Warning Letter on December 9, 2004. The CGMP deviations included failure to establish an adequate quality control unit, failure of the quality control unit to review records to assure no errors have occurred, or, if errors have occurred, that they are fully investigated, failure to follow written procedures applicable to the function of the quality control unit, and failure to establish, implement, and follow scientifically sound and appropriate specifications, standards, sampling plans, and test procedures.

The firm responded to the investigational findings by meeting with the FDA on November 9, 2004, and with a written response on November 13, 2004. Comments to the firm's response and requests for additional information were included in the December 9, 2004, Warning Letter. Chiron responded to the Warning Letter on January 7, 2005. The response is under review at FDA.

Communications With MHRA

On the morning of October 5, 2004, MHRA announced a three-month suspension of Chiron's license to manufacture influenza vaccine. FDA had no prior knowledge of the MHRA's intention to suspend the firm's U.K. license. MHRA's Chief Executive, Professor Kent Woods, indicated that MHRA did not have the legal authority to notify FDA about the suspension announced on October 5 until after MHRA instituted its administrative action. Dr. Woods has also stated that, "Contrary to some reported statements, MHRA, as the responsible regulatory authority in the United Kingdom, made the decision to suspend Chiron's license after an internal meeting on October 4 and first informed the company and the FDA of this decision on October 5. At the same time, we informed other drug regulatory authorities via an intergovernmental rapid information alert."

Upon learning of the MHRA's suspension, FDA communicated with both Chiron and the MHRA. While Chiron indicated to FDA that it believed it had satisfactorily addressed MHRA's inspectional findings and provided to FDA a copy of those findings and the company's response, MHRA expressed serious concerns about Chiron's vaccine stocks and the company's ability to assure the safety of the vaccine.

FDA will continue to work with Chiron and the U.K. government to ensure that the company corrects the deficiencies in the Liverpool plant so that it can eventually resume production of a safe and effective influenza vaccine. Subsequent to MHRA taking its action to suspend Chiron's license to manufacture influenza vaccine at the Liverpool facility, Chiron gave MHRA and FDA permission to discuss the issues related to Chiron that are considered confidential commercial, trade secret and proprietary. FDA is also working to implement an information sharing agreement with MHRA that would, among other things, permit advance communication on important issues.

Question 10. During the weekly telephone calls with Chiron in September 2003, did the FDA have the opportunity to review the actual data obtained from the re-testing of the lots? If so, what did the data show, and did it confirm Chiron's weekly statements that the re-testing indicated that they would be able to ship approximately 46 million doses in October?

Answer 10. On August 25, 2004, FDA investigators were on site conducting a prelicense inspection and were informed of the contamination of the vaccine. FDA inspectors met with Chiron's staff and reviewed the preliminary findings and the

approach that Chiron was taking to its investigation and retesting at multiple points in its process. FDA investigators in Liverpool faxed to CBER preliminary data and information regarding the scope and plans for the sterility failure investigation being conducted by Chiron. The results of these evaluations were needed and essential for any regulatory assessment. Chiron's investigation was in the earliest stage and, therefore, only preliminary information was available; however at the time the additional testing on other lots were negative. Chiron did believe it had identified the root cause for the contamination and that it was limited to the affected lots. FDA performed a comprehensive review of the retesting data during its October 10-15, 2004, inspection of the Liverpool facility. The retesting results were indeed negative; however, FDA's inspection found issues related to the adequacy of the statistical sampling plan used for the retesting. These findings, coupled with the other issues uncovered during the inspection, led FDA to conclude that it could not assure the safety of the vaccine.

Question 11. Were FDA officials aware of the Medicines and Healthcare Products Regulatory Agency's findings from their inspection of Chiron's plant in March 2004? If so, what actions did the FDA take to follow up on the British agency's concerns and ensure that Chiron improved their manufacturing conditions?

Answer 11. FDA was not aware of MHRA's March 2004, inspection at the time of the inspection. FDA recognizes the need to further strengthen mechanisms for real-time communication with our foreign regulatory counterparts. We are in the process of evaluating and expanding agreements so that this type of information so that government agencies can readily share such information in the future.

Food and Drug Administration

Question 12. The FDA has a special public trust to see that the medicines that American patients take are safe and effective. I am concerned that the Administration has not given the dedicated professionals at FDA the support and leadership they need to do the essential job that Americans count on them to do.

FDA must have the authority to require—not just to request—that drug companies complete post-approval studies to assure that drugs put on the market are safe and effective over the long haul for their actually conditions of use. And it's clear that the passive monitoring system that FDA now realizes on to monitor the safety of drugs after they are approved isn't good enough.

Will you work to give FDA the leadership, resources, and authority it needs to do its job? Will you work to see that FDA has the authority to and resources it needs for post-market studies and surveillance, and will you nominate a strong Commissioner who is free of ties to industry? What other measures will you propose to help FDA enhance drug safety?

Answer 12. I recognize that FDA has a special public trust to see that the medicines Americans take are safe and effective. I am committed to working with FDA to fulfill its mission to protect the public health by assuring the safety, efficacy, and security of human drugs; helping to speed innovations that make medicines more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and to improve their health.

Nominating an FDA Commissioner committed to the Agency's mission will be one of my top priorities.

On November 5, 2004, FDA announced a five-step plan to strengthen its drug safety program. Key among these steps is IOM study on FDA's drug safety system, with an emphasis on the drugs as they are actually used. These are important and ambitious steps designed to enhance drug safety. I will work to see that FDA proceeds with this five step plan and will consider additional steps that may further enhance drug safety.

Question 13. American pay 60 percent more for prescription drugs that the British or Swiss, two-thirds more than Canadians, 75 percent more than Germans, and more than twice as much as Italians. This is often for FDA approved drugs made by American companies in FDA approved plants. Do you think this is fair? What will you do about it?

Answer 13. In recent years the Administration has worked to make prescription drugs more affordable for U.S. consumers. FDA has taken steps to encourage greater generic competition and speed access to generic drugs as well as streamline the drug development and approval process. As Secretary of HHS, I will work with Congress to continue to address the high costs of health care.

Question 14. Secretary Tommy Thompson recently stated: "I, for the life of me, cannot understand why the terrorists have not attacked our food supply, because

it is so easy to do." Do you share Secretary Thompson's concerns, and if so, how do you propose addressing the problem?

Answer 14. I certainly share Secretary Thompson's concerns about the safety of the food supply. Ensuring the safety of the food supply has been a priority for Secretary Thompson, for the Administration and will be a priority for me. I do know that a great deal has been done in the past few years to improve security. For example, in 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response (Bioterrorism Act). This landmark legislation represents the most fundamental enhancement to FDA's food safety authorities in many years. FDA has been working hard to implement this important legislation. In addition to implementing the Bioterrorism Act, FDA has many other ongoing counterterrorism activities. However, we must continue to be vigilant in these efforts. Ensuring the full and effective continued implementation of the food safety regulations will be a continued priority of mine and of HHS.

Question 15. Do you believe that Congress should require manufacturers of dietary supplements to report serious adverse events related to use of their products to the Food and Drug Administration? Do you believe there are other steps FDA or the Congress should take to better enable the agency to remove unsafe dietary supplements from the market?

Answer 15. If confirmed as Secretary, I will carefully evaluate the need for any additional authority relating to this issue.

As you may know, FDA recently published a new strategy to strengthen its regulation of dietary supplements. FDA's strategy for dietary supplements outlines the steps it plans to take to continue implementing and enforcing the Dietary Supplement Health and Education Act of 1994 (DSHEA). The strategy sets forth a series of research and measures, including guidance, regulations, and science-based compliance and enforcement mechanisms.

The strategy focuses on three areas: monitoring and evaluating product and ingredient safety, ensuring product quality, and monitoring and evaluating product labeling. With this strategy, FDA hopes to improve the transparency, predictability, and consistency of the Agency's scientific evaluations of dietary supplement product and ingredient safety. The actions outlined in the strategy are also designed to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. FDA expects that this improved transparency will help engage stakeholders in the development of further measures to implement DSHEA.

Question 16. Medically valuable antibiotics are often used indiscriminately in animal agriculture to promote growth rather than to treat disease. This misuse gives rise to drug-resistant pathogens that can cause illness in people through contaminated food. FDA has taken some important steps to scrutinize the public health impact of this misuse of antibiotics by issuing guidelines for the evaluation of new antibiotics proposed to be used as feed additives. These guidelines, however, fail to address the public health concerns raised by antibiotics already on the market as feed additives. hat do you plan to do to protect the public from the danger of drug-resistant bacteria that result from the misuse of antibiotics in animal agriculture?

Answer 16. FDA is concerned about antimicrobial resistance and the use of antimicrobial drugs in food-producing animals. FDA agrees with the Government Accountability Office's recommendation that it is important to review animal drugs that are critical to human health and to collect antibiotic use data.

Guidance for Industry #152, "Evaluating the Safety of Antimicrobial New Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern," addresses the pre-approval safety assessment for new antimicrobial drugs intended for use in food-producing animals. This guidance also is used for re-evaluating currently approved veterinary antimicrobial drugs. FDA's Center for Veterinary Medicine (CVM) has finished the assessment for the growth-promoting uses of penicillin-containing antimicrobial drugs. CVM is currently in the process of re-assessing the growth-promotion uses of tetracycline-containing antimicrobial drugs.

In addition, CVM has re-evaluated the use of virginiamycin, a streptogramins used in five species of food-producing animals, for its potential to cause Synercid-resistant Enterococcus faecium in humans. FDA has posted the draft risk assessment on its CVM website. In addition, FDA published an announcement in the Federal Register on November 23, 2004, that the risk assessment was available and that FDA would accept comments for 60 days. FDA subsequently extended the comment period an additional 30 days to February 23, 2005. The draft risk assessment is available at: http://www.fda.gov/cvm/antimicrobial/SREF—RA—FinalDraft.pdf.

My understanding is that FDA can pursue a number of regulatory and administrative enforcement options if its reviews uncover a human health risk. Any new antimicrobial drugs with animal feed claims will be subject to review under the above-referenced guidance as well as review by FDA's Veterinary Medicine Advisory Committee.

Occupational Health

Question 17. The National Institute for Occupational Safety and Health in the Centers for Disease Control plays a pivotal role in protecting our Nation's workers and thus in safeguarding our Nation's public health. Last year's Omnibus Appropriations conference report concurred in Senate language directing that NIOSH's role must not be impeded or diminished through the CDC reorganization process.

As Secretary, what will you do to ensure, in keeping with Congress' direction, that (1) no funds or personnel are transferred from NIOSH to other parts of CDC, (2) NIOSH's current procedures and structure are preserved; and (3) the Director of NIOSH continues to report directly to the Director of CDC? Will you commit to these actions to ensure that occupational safety and health remains a top agency priority?

Answer 17. CDC will make no changes to NIOSH's current operating procedures or organizational structure and will ensure that no funds or personnel will be transferred from NIOSH. The NIOSH Director will continue to report directly to the Director of CDC and the NIOSH Headquarters Office will remain in Washington, D.C. In addition, the NIOSH Director will continue to have direct access to the Department of Labor, the Occupational Safety and Health Administration, and the Mine Safety and Health Administration as authorized by Congress. CDC is committed to supporting NIOSH's success and its impact on preventing work-related injuries, illnesses, and deaths.

Welfare/Community Services Block Grant

Question 18. Utah's program has been praised for its emphasis on education and training. I understand recipients can participate in such programs for up to 24 months to improve their chances of not just finding immediate work, but building a career.

As Secretary will you continue to support an emphasis on education and training in welfare reform? Will you support similar flexibility for recipients to participate in education and training programs for up to 24 months?

Answer 18. I support flexibility for States to tailor activities to the needs of individuals while continuing to maintain the emphasis on work that has been the cornerstone of the success of welfare reform. In Utah, we designed our program to constantly emphasize the importance of work as the best path toward self-sufficiency. Our TANF program, known as the Family Employment Program, was one of the first in the Nation to be integrated into the workforce development system.

The Administration's proposal for welfare reform emphasizes increased flexibility for short-term education and training while maintaining a strong emphasis on work. This approach is consistent with research findings that show that intensive activities with a focus on work produce the best result. Longer term education and training can be counted toward the work requirement when they are performed in conjunction with work.

Question 19. In addition, as you know, the Federal welfare reform law imposed harsh restrictions on public benefits for legal immigrants. Over 20 States now use State funds to replace the missing Federal benefits for such immigrants.

As Chairman of the National Governor's Association you were involved in urging the Federal Government to show more flexibility on this issue. Would you support including more flexibility for States to use Federal funds to provide social and medical services to legal immigrants?

Answer 19. As you will recall, a number of the restrictions on non-citizen eligibility have been eased over the years since the passage of the 1996 law, particularly in the area of food stamps. In 2002, President Bush proposed changes in the Food Stamp program that were incorporated in the Farm Bill of 2002 (PL 107–171). The 2002 bill expanded food stamp eligibility to legal immigrants who had resided in the United States for five years or more, bringing the eligibility provisions of the food stamp program more in line with TANF and Medicaid. It also provided that children or disabled immigrants are immediately eligible for food stamps, without a five-year waiting period.

Under current law, States have the flexibility to provide federally funded benefits for many qualified non-citizens including refugees, political asylees, and, after five

years, legal permanent residents. Others can be served with State funds, and these expenditures may count toward the TANF Maintenance of Effort requirement. I think these provisions provide considerable flexibility to States while maintaining the basic principle that regular immigrants should not enter the United States expecting to receive welfare benefits, and that the individuals who sponsor immigrants to enter the country should be held responsible for meeting their basic needs, if necessary.

Question 20. You have described the 1996 Welfare Reform as a "dramatic American success story." I agree that many Americans have left the welfare rolls successfully, and they deserve great credit for the independence and self-sufficiency they've achieved. But there remains a need to improve upon current law, particularly to address the recent increase in poverty as welfare caseloads continue to shrink. The Administration says the decline is a good sign, but it seems that welfare recipients are being dropped from the rolls, even though they can't find a job. The Administration's welfare proposal would further restrict the ability of States to address the variety of needs of welfare recipients, and lead to more recipients being forced off of welfare despite their need for work supports and other assistance.

Many of the successful aspects of Utah's welfare program that you helped implement, such as increased support for education and training, flexibility in dealing with barriers to work, and a wide variety of countable work activities, differ from the provisions supported by the Administration's welfare proposal. Will you commit to working with Congress to address these issues in the Administration's welfare proposal, ensuring that States like Utah have the flexibility they need to help welfare recipients lift out of poverty, and to address the individual needs of each family without being penalized by the Federal Government?

Answer 20. I agree that State flexibility is a key to the past and future success of welfare reform. TANF continues to be one of the best examples of the power of State innovation and flexibility. In creating the Temporary Assistance for Needy Families (TANF) program, Congress acknowledged the immense capacity of States and localities to design and conduct effective social programs, and incorporated the lessons learned from State waivers into the TANF program. Utah, and many other States, used this flexibility to design programs that respond to individual needs, providing whatever services are needed to help families put their lives back together and achieve self-sufficiency.

The Administration's welfare reauthorization plan gives States increased flexibility to count certain activities as meeting the work requirement for limited periods of time. States could receive credit for families engaged in short term substance abuse treatment, rehabilitation and work-related training designed to maximize self-sufficiency through work. Such activities could also count for longer periods when combined with work. The proposal also would allow States to spend TANF funds carried over from previous years on any benefit, service or other allowable TANF activity. This change, which would greatly increase State flexibility, is based on the recognition that cash benefits represent only one part of the services funded by TANF.

I look forward to working with the Congress to achieve the goals of flexibility while retaining the results-oriented focus of the program that is important to our success.

Question 21. I have seen the good work of the Community Services Block Grant, or CSBG, in communities throughout Massachusetts. Community Action Agencies use CSBG funds to coordinate and leverage the resources of other programs to provide comprehensive services such as Head Start, child care, energy assistance, employment and training, food and nutrition services, literacy programs, and other low-income programs. These agencies are on the front lines of service delivery for the poor.

Congress is very supportive of the Community Services Block Grant and the Community Action network. As you know, the Salt Lake Community Action Program does good work for Utah's low-income families. I have heard that the Administration's budget will not include funding for CSBG. Will you pledge to work with Congress to revisit this decision?

Answer 21. I agree that there are good examples of work done by Community Action Agencies using Community Service Block Grant funds, as well as funds from other programs. I also think that accountability for measurable results is something we must be concerned with in all programs. I look forward to the opportunity to discuss with you issues related to CSBG in the coming months as we work to improve key services to low income families.

Mental Health

Question 22. In July of 2003, the final report of the President's New Freedom Commission on Mental Health was released. It called for a fundamental restructuring of how we care for families facing mental illness, but Congress still hasn't acted. Mental illness is a crisis for millions of children and adults and families who face it everyday. It's a national crisis.

Can you commit to me to make this debate an HHS-wide priority, not just a priority for the Substance Abuse and Mental Health Services Administration within HHS, and when can we expect an Action Plan to implement the reports recommendations?

Answer 22. The President's New Freedom Commission on Mental Health's report, issued in July 2003, called for profound change and transformation of the current system, recommending new service delivery patterns and incentives to ensure that every American with mental illness has easy access to the most current treatments and best support services.

The Substance Abuse and Mental Health Services Administration (SAMHSA) was tasked by the Department to review the Commission's report and to lead the development of an Action Agenda for that transformation to create a more recovery-focused mental health services delivery system. An executive team at SAMHSA-along with senior staff from six Federal departments and the Social Security Administration-are working collaboratively to conduct a thorough review and assessment of the Report. As expected, developing the Action Agenda has proven to be a tremendous undertaking. The result, however, has been commitment for a true Federal Action Agenda that is informed by the final report of the New Freedom Commission and aligned with the President's priorities.

A hallmark of the Action Agenda is the unprecedented collaboration and partnership across the Federal Government to work together and make every effort to keep consumers and families at the center of care.

Question 23. Would you consider establishing an Inter-Agency Council much like the Inter-Agency Council on Homelessness to coordinate Federal programs that care and treat people with mental illness?

Answer 23. In response to the President's New Freedom Commission on Mental Health Report entitled "Achieving the Promise: Transforming Mental Health Care in America," the Substance Abuse and Mental Health Services Administration (SAMHSA) convened representatives from 15 different Federal agencies to develop an Action Agenda Federal plan on how to achieve mental health systems transformation. This Action Agenda is being reviewed by those agencies and should be released shortly. Contributing to the Agenda in addition to SAMHSA were the National Institutes of Health, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Administration on Aging, the Administration on Children and Families, the Centers for Medicaid and Medicare Services, the Indian Health Service, the Social Security Administration, the Department of Housing and Urban Development, the Department of Education, the Department of Justice, the Department of Transportation, The Department of Labor, and the Department of Veterans Affairs. These agencies will continue to provide continuing input and participate in our efforts to transform the mental health delivery system.

The Action Agenda, besides making recommendations for change, is itself an example at the Federal level of better coordination and cooperation among programs and agencies serving those with mental illness. It serves as an example to States and local governments on how to improve the delivery of quality services to those among us who need help in finding and living a life in the community, a life of recovery.

RESPONSE TO QUESTIONS OF SENATOR MIKULSKI

Question 1. Over six million poor senior Americans and 71,000 senior citizens in Maryland currently receive their prescription drugs though the Medicaid program. When the new Medicare program begins in 2006, Medicaid will no longer be allowed to provide any drug coverage for these Medicare beneficiaries.

Since you just referred to the new Medicare prescription drug law as the "main event of 2005," how would you ensure that no low-income Medicare beneficiary loses drug benefits next year as a result of the implementation of the Medicare law?

Answer 1. Starting on January 1, 2006, full-benefit dual eligible and other low-income individuals will be provided drug coverage at little or no cost through the new Medicare drug benefit. Approximately six million full-benefit dual eligible individuals will automatically qualify for subsidies of premiums and cost-sharing

amounts under the Medicare prescription drug benefit. I agree that it is critical that we work to ensure as smooth a transition as possible for the dual eligible population. As Secretary, this will be a priority of mine, and I hope to work with you as we move forward in these efforts.

Question 2. Right now, if someone needs long-term care they must work their way through a fragmented, patchwork array of programs to piece together their long-term care needs. Given your experience as Governor of Utah and managing many of the elements of this system, what is your vision for a comprehensive national approach for strengthening America's long-term care system?

Answer 2. Planning and paying for long-term care—and ensuring that services are high quality—are among the biggest challenges America will face as the population continues to age. Indeed, the array of Federal, State and local programs, faith based services, self-funded care, and long-term care insurance, combined with informal care by family members and friends can be difficult to maneuver. We should focus long-term care on the individual; people should be aware of the need to plan for their long-term care needs, increase their savings, purchase long-term care insurance, and take other steps to be prepared. For some people this may not be possible and Medicaid will remain a critical part of the system. Here too individuals should have more control, building on the experience of Cash and Counseling. Medicaid options that support consumer direction, such as Cash and Counseling, are promising and represent a win-win for consumers, their personal assistance workers, and States. On the awareness side, I look forward to the results of the Department's new long-term care awareness campaign and hope we can use those results to pursue additional activities to help individuals plan for their own independence as they age.

RESPONSE TO QUESTIONS OF SENATOR MURRAY

Medicare

Question 1. As you point out in your prepared statement, implementation of the Medicare prescription drug legislation will be immense and very challenging. I believe we have an obligation to assist our seniors and disabled in making very difficult and complex decisions in choosing a new MA plan or Drug Only Plan. It would be easy for those of us who opposed final passage to simply refer confused and concerned seniors, the disabled and their families to CMS. But, I do not think this is helpful for anyone and would ask for your commitment to meeting the challenges of outreach and education. I would also be interested in your plans for moving forward with implementation. What resources would be available? How can we work in a bipartisan fashion to educate and help our seniors and disabled make informed decisions?

Answer 1. CMS will work with a broad array of partners, including SSA and other federal agencies, States, employers and unions, and national and community-based organizations to educate people with Medicare, their caregivers and other who help them about the new Medicare prescription drug benefit and other new Medicare benefits and options. Importantly, CMS will conduct an integrated education campaign and will reach out at the grass roots level to help people with Medicare understand their options to access Medicare prescription drug coverage. CMS is investing more than $300 million in this integrated and multi pronged education effort including simple language fact sheets, more detailed publications including the annual "Medicare & You" handbook, direct mail, community based grassroots efforts to target the different populations with messages directed to their specific needs, e.g., low income, people with retiree drug coverage, 1-800-MEDICARE, www.medicare.gov.

In the fall of 2005, the "Medicare & You 2006" handbook will outline the specifics of Medicare prescription drug plans and list the Medicare prescription drug plans available in each beneficiary's area and people with Medicare will be able to get customized local Medicare plan information, including cost, pharmacy, and formulary information, at www.medicare.gov on the web, or by calling 1-800-MEDICARE.

Question 2. As you are aware, in the MMA legislation in 2003 we took great strides to close the inequity in Medicare reimbursement between rural and urban providers. This $25 billion investment will reduce these inequities and provide relief to many rural providers. However, Washington State remains at the bottom of per beneficiary reimbursement for Medicare which puts our providers at an economic disadvantage. Doctors and hospitals in Washington State receive far less from Medicare because they are more efficient and have significantly lower utilization rates. I believe we should provide incentives to encourage more efficient use of care and begin to base reimbursement on performance. I would be interested in knowing of

your plans for providing greater regional equity in Medicare and would like to work with you to implement real reforms that reward performance as opposed to over-utilization.

Answer 2. I certainly appreciate and understand the unique challenges faced by rural providers. This Administration has made a strong commitment to rural health issues and has implemented many significant regulatory and Departmental reforms to promote rural health care providers. Also, as you mention, the MMA included several provisions to enhance beneficiary access to quality health care services and improve payments in rural areas. As Secretary, I will ensure that rural health care issues remain a top priority and continue to receive the attention they deserve.

Encouraging improved health care quality is a top priority of mine and of the President's. The Administration has promoted accountability for quality, creating incentives to collect data from Medicare providers on quality measures. I am intrigued by the possibility of approaches to link Medicare reimbursement to provider performance. While I certainly am not versed in the variety of ways that pay-for-performance could be incorporated into the Medicare and Medicaid payment systems, I am excited to be involved in conversations regarding the issue. If I were to be confirmed, I would expect the Department would continue to review this issue and I would want us to work with the provider and beneficiary communities and the Congress in doing so.

Title X Family Planning

Question 3. As Governor of Utah you made statements and took actions to reduce access to safe and effective family planning services for all women, including minors. We know the cost of unintended pregnancy, especially for teenagers. We know the importance of comprehensive family planning that offers health care services and access to safe and effective family planning. Unintended pregnancy is a public health issue that needs to be addressed with sound, public health strategies. Title X providers offer low income women access to a whole range of reproductive health care services beyond simply contraception. As the Secretary of HHS, will you support Title X funding that provides the greater access possible to effective family planning services? Are you aware of the importance of Title X in meeting the reproductive health care needs of millions of low income women?

Answer 3. Helping women to prevent unwelcome pregnancies is indeed a public health concern, particularly when we are talking about our young people. I am aware of the role that Title X has played in providing family planning services to low-income women. As Secretary, I will ensure that all of our programs, including Title X, are sensitive and responsive to the needs of low-income Americans and that we carefully assess concerns about access to care.

HEAD START

Question 4. President Bush has included in past budgets funding for a block grant pilot program to States. However, funding of Head Start has not kept up with the rising costs in Head Start while the funding dedicated to a block grant could provide funding for services for thousands of children. In such tight budget years, how can you justify siphoning funding for a demonstration program that is unproven?

Head Start is one of the few Federal programs where funding goes directly to locals. By block granting funding at the State level, you would be adding bureaucracy to a highly successful program. What is the Administration's intention in adding in this extra level of bureaucracy to the program?

Answer 4. I share your interest in the Head Start program and the contribution it has made to American's poorest children and families for almost 40 years. Nevertheless, research continues to indicate that too many children are leaving Head Start without certain key skills needed for success in early schooling. One way to address this issue is to strengthen Head Start's coordination efforts with local schools and other pre-school programs.

However, I can assure that the President's reauthorization proposal, which would allow States the option of administering Head Start and making changes to improve child outcomes and better coordinate services, is quite different from a block grant. States will have to follow very specific procedures in applying. There will be continuing Federal oversight of the State's delivery of Head Start services. Moreover, States will be required to continue to serve at least as many Head Start eligible children as are currently served while maintaining the comprehensive nature of Head Start.

I am committed to ensuring that implementation of the President's proposal will provide an opportunity for more children to be served by local Head Start programs at the highest level of quality.

Washington State 1915(b) Waiver Services for People With Mental Illnesses

Medicaid Capitation Savings Question

Question 5. Mr. Leavitt, as I understand the situation, the department is prohibiting the State of Washington from using its Medicaid savings to finance community-based and inpatient psychiatric hospital services for adults with severe and persistent mental illnesses.

Specifically, CMS used negotiations over a 1915(b) waiver renewal to bar the State from using Medicaid capitation savings—achieved by Washington's quasi-governmental regional managed care entities—to pay for community-based and inpatient care for extremely vulnerable people. This was a disturbing development because the State for more than a decade had reasonably relied upon the agency's previous position, which permitted such payments. CMS's new stance caused the loss of $80 to $100 million in combined Federal and State spending, and threatened mental health care for 127,000 Washingtonians. CMS has allowed the State a 14-month extension in which to realign its system and funding mechanisms with the new CMS policy and, for that, the State is extremely appreciative.

However, since the prohibition does not apply to savings generated by for-profit managed care companies, I find the CMS position to be bewildering. Can you please explain the rationale behind this policy? And can you tell me how CMS's recently announced position is consistent with President Bush's public commitment to give States more flexibility over the Medicaid program?

Answer 5. Medicaid statute and regulations do not restrict a managed care organization's use of capitated payments as long as the health care of Medicaid enrollees, per the managed care contract, is met. However, CMS is working with Washington and other States to assure that rate setting data, based on previous Medicaid services, is consistent with Medicaid statute and regulations. These provisions, which apply equally to both public and private entities, require that program contract rates be developed based on Medicaid services to Medicaid eligibles only (per 42 CFR 438.6). This means that rates must be developed exclusive of non-approvable expenditures such as funds expended for persons in an Institution for Mental Disease (IMD) (per 42 CFR 435.1008). During CMS review of Washington State's waiver renewal application, the cost for non-Medicaid eligibles and non-state plan services were included in the State's calculations for determining future rates for this program, which is not permissible under Federal law.

The Balanced Budget Act of 1997 included very specific provisions concerning contract requirements to assure appropriate levels of payment to Medicaid managed care entities. In response, CMS implemented the Medicaid Managed Care Rule, which includes contract requirements that prevent the CMS from approving contracts in which Medicaid rates include non-state plan services and services to non-Medicaid beneficiaries. These provisions, which changed how States previously calculated their program's cost effectiveness, ensure the fiscal integrity of the Medicaid program. States were required to be in compliance with these regulations by August 13, 2003.

As Secretary, I assure you that the Department will work with the State of Washington to provide the most flexibility possible within the Medicaid program, while meeting all statutory and regulatory requirements.

Institution for Mental Diseases (IMD) Exclusion

Question 6. Current CMS policy prohibits Medicaid reimbursement for adults with serious mental illnesses served in inpatient psychiatric hospitals, which are known in Medicaid parlance as "Institutions for Mental Diseases" or IMDs. The prohibition specifically applies to facilities with sixteen (16) or more beds.

In Washington, the rule complicates the ability of the State to move people out of public hospitals and into community-based residential services. Apparently, the IMD rule specifically applies to non-hospital, residential facilities which are essential to the web of services necessary to sustain adults with severe and persistent mental illnesses in the community.

Upon your confirmation as Secretary of DHHS, will you look into this outdated regulation with an eye toward at least raising the sixteen (16) bed limit, or alternatively exempting residential facilities from the IMD exclusion?

Answer 6. Since the IMD exclusion is rooted in legislation, not regulation, congressional action is needed to change this provision. However, I understand that CMS has been working with States and providers to develop community-based alternatives and find ways to make the current mental health system to operate more effectively.

RESPONSE TO QUESTIONS OF SENATOR REED

Question 1. Many health experts, including infectious diseases physicians, predict that the next influenza pandemic is imminent. During the past century, pandemics of influenza occurred in 1918, 1957, and 1968, with significant morbidity and mortality in both high risk and normal children and adults. In 1918 alone, more than 500,000 people died in the United States, and 20 million to 50 million people may have died worldwide. It is estimated that the next influenza pandemic could cause an average of up to 200,000 deaths in the United States alone. The recent influenza vaccine shortage has demonstrated that our Nation is not adequately prepared to deal with the next flu pandemic. Challenges such as a limited influenza vaccine market, too few dedicated manufacturers, a lack of adequate coordination among Federal agencies, and the absence of an international influenza research agenda compound the list of inadequacies our Nation is facing. Influenza represents a global danger that cannot be underestimated, and I hope you will consider it a public health priority. If confirmed, how do you plan to address these challenges?

Answer 1. Preparation for the annual flu season has been a priority at HHS. I will ensure that it continues to be a priority. I believe that the CDC and FDA have successfully taken great strides toward responding to an unforeseeable shortage of vaccine, through the creation of tools to help States identify additional vaccine, through the identification and purchase of additional vaccine under an investigational new drug (IND) application, and through effective public communication about the prioritization of high-risk groups who should receive the available vaccine.

I will also ensure that efforts to prepare against a possible influenza pandemic continue to be a priority, including through the continued review and finalization of the national pandemic response plan, as well as through the utilization of the $100 million recently allocated to these efforts in the Omnibus appropriations bill.

Looking forward to the future, we will continue to work with vaccine manufacturers to encourage them to bring their vaccine for licensure and sale in the United States, as well as taking longer-range steps to encourage the development of a domestic vaccine supply, to ensure appropriate supplies of influenza vaccine. I look forward to working with the committee on this issue—any steps that we take should be careful to remove disincentives that may have hindered manufacturers from entering or remaining in the U.S. vaccine market.

Question 2. The National Bone Marrow Donor Registry (Registry) operated by the National Marrow Donor Program (NMDP) is a critically important national resource. As an original sponsor of the legislation authorizing the National Bone Marrow Donor Registry, the continuation of this national resource remains a top priority to me. We created this program to provide patients and their doctors with a single point of access to locate volunteer, unrelated marrow donors. However, I am extremely concerned that the authorization for this highly successful program has been allowed to expire. What additional support can the Department provide to ensure the continuation of this model Federal program?

Answer 2. Bone marrow transplants offer the possibility of a cure for many people suffering from blood and genetic diseases, such as leukemia. The National Bone Marrow Donor Registry is an important program that helps transplant candidates, who cannot locate a donor related to them, to search for a suitable unrelated donor. The Registry is the largest system connecting patients and physicians with volunteer donors. And this year, the Registry received a good assessment from OMB. Thank you for your support for this successful program. If I am confirmed as Secretary, I will stand ready to work with you to ensure the continuation of this program.

Question 3. I have recently heard from a number of my constituents who are concerned about tobacco companies marketing flavored tobacco products that could be attractive to children. More generally, tobacco companies are increasing their marketing and promotional expenditures. According to the most recent data from the Federal Trade Commission, the companies now spend $12.7 billion annually on marketing, an increase of 84 percent since 1998. At the same time, the resources to fund anti-smoking education efforts targeting children are disappearing. For example, the Legacy Foundation, which is responsible for the truth media campaign, has been funded through the tobacco industry's Master Settlement Agreement with the States since 1998. However, due to the terms of the settlement, nearly all of the industry payments to the Legacy Foundation ended in 2003—a reduction in funding of $300 million per year. If you are confirmed, what steps will you take to protect our kids from tobacco marketing and prevent them from smoking? Can you make a commitment that as Secretary of HHS you will do everything in your power to support initiatives that science tells us are essential to protect our kids?

Answer 3. Tobacco-related deaths are the leading preventable cause of death and disease in the United States. Each year, smoking causes about 440,000 premature deaths and costs the Nation $75 billion in direct health care expenses. Our first priority should be to keep tobacco products out of the hands of America's children and to encourage all Americans not to smoke, including by helping them quit smoking.

Last year, the President proposed $701 million for HHS activities related to tobacco. I intend to continue plans announced recently by Secretary Thompson to help Americans quit smoking. The initiatives include the opening of a national quitline number (1-800-QUITNOW) that puts users in touch with programs that can help them give up tobacco. In addition, a new HHS Web site (www.smokefree.gov) offers online advice and downloadable information to make cessation easier.

The Office on Smoking and Health (OSH) is the Nation's lead Federal agency for tobacco use prevention efforts and plays a critical role in the fight to reduce the health effects of tobacco use. OSH's program efforts are directed toward achieving progress in the following goal areas: preventing initiation of tobacco use among youth and young adults; eliminating exposure to secondhand smoke; identifying and eliminating tobacco-related disparities; and promoting tobacco use cessation among adults and youth to promote a comprehensive approach for tobacco use prevention and control. All OSH activities directly or indirectly support these goal areas.

Question 4. In 1995, you stated your disapproval of the Federal Government creating new areas of eligibility and benefits under Medicaid. In fact, you stated that the average Medicaid recipient in Utah had a benefit package 30 percent richer than the average working person. Unfortunately, these are often very ill or disabled individuals who require a disproportionate amount of care and are unable to pay substantial out-of-pocket expenses such as deductibles and co-pays for care. Cindy Mann, a research professor at the Health Policy Institute of Georgetown University, was quoted in the New York Times as saying that the coverage under the Utah waiver was "well below any generally accepted standard of what it means to be insured." Can you address this assessment? Can you summarize the services that the Utah program actually covered and what it excluded? As Secretary of HHS, how would you define basic Medicaid benefits?

Answer 4. First and foremost, I believe strongly that waivers provide States with the flexibility to implement innovative ways to extend health coverage to more people. This is a goal we should all support. The waiver that I implemented in Utah did not make any changes to the benefit for mandatory populations. Instead, the waiver expanded preventive and primary care coverage to an additional 25,000 uninsured adults. To do so, a $50 enrollment fee was instituted, but with exemptions for vulnerable optional populations (including the elderly, blind, disabled, children and pregnant women).

Question 5. Do you support the President's Medicaid reform proposal that would give States the option of getting a capped amount of money for "optional" populations? As a former Governor and Medicaid work group leader, you know the National Governors Association continues to oppose such a step to shift the fundamental partnership between State and Federal Governments. As Secretary of HHS, how would you work with governors to maintain our commitment to low-income and medically needy Americans who rely on Medicaid as their only option for health care? Would you favor extending further flexibility to States without capping federal matching funds? How would you justify removing Federal beneficiary protections in exchange for this flexibility?

Answer 5. Reform itself should be designed to give States the tools they need to bring Medicaid into the 21st century on a cost effective basis. Medicaid remains under rules designed specifically for the 1960s. Its mission has changed and expanded but the rules have not. People with disabilities especially want better choices than what Medicaid currently offers them for long term care services. It is clear when you talk to any governor or State legislator, regardless of political affiliation, that they believe the rate of growth in Medicaid is unsustainable.

I want to work with Congress and the Nation's Governors to examine the Medicaid program and to change it to give States the tools to provide basic health coverage to the most low-income people possible.

Question 6. As you know, there have been ongoing issues with regard to the redistribution of unused SCHIP funds. This year, $1 billion in unexpended funds actually reverted back to the Treasury. Rhode Island is one of several States that exhausts its allocation of funds each year and is deeply concerned about reallocated, unexpended funds. My State was one of the first States to expand coverage to kids prior to the creation of the SCHIP program. It is my understanding that the Administra-

tion is interested in SCHIP reauthorization in the coming years. In what ways do you think the program needs to be changed?

Answer 6. First, published in the Federal Register recently is the notice for the redistribution of fiscal year 2002 SCHIP funds which were unexpended at the end of fiscal year 2004. This has assured that no State will experience a funding shortfall this fiscal year.

The Federal Register notice details the methodology used, as well as the list of States that will receive redistributed funds. In the notice the five States which would have had shortfalls (Arizona, Minnesota, Mississippi, New Jersey and, most notably for you, Rhode Island), will first receive sufficient funds to cover their shortfalls. After these shortfall States are made whole, 28 States (including the 5 shortfall States) will receive redistributions. Rhode Island received over $23 million from this redistribution.

I look forward to working with Congress to re-authorize SCHIP, to assure stability in the program.

Question 7. As Secretary of HHS, you will be charged with overseeing the administration's abstinence-only programs, which are slated to receive an unprecedented $168 million in Federal taxpayer funding this year. A recent report by the House Committee on Government Reform revealed that many of the most common federally funded abstinence-only curricula contain errors, distortions and stereotypes while other recent reports have called into question the effectiveness of abstinence-only programs. For example, in 2001 the National Campaign to Prevent Teen Pregnancy found no credible studies of abstinence-only programs showing any significant impact on participants? initiation or frequency of sex. The National Academy of Sciences' Institute of Medicine has criticized the investment of hundreds of millions of dollars in unproven abstinence-only programs as "poor fiscal and public health policy." What steps will you take as secretary to evaluate the accuracy and effectiveness of these programs and ensure that science, not ideology, is driving administration policy?

Answer 7. I share the President view that . . ."Abstinence is the surest way and the only completely effective way to prevent unwanted pregnancies and sexually transmitted diseases." I also agree with the President that we must promote public policies that are medically accurate. I also am committed to continuing to support the rigorous evaluation efforts currently underway in the Department.

Question 8. What were EPA's considerations in accepting $2 million from the American Chemistry Council to help fund the Children's Environmental Exposure Research Study? In light of recent challenges faced by the FDA, how would you balance the collection of user fees by FDA under the Prescription Drug User Fee Act (PDUFA) and FDA's regulatory role in ensuring the safety of drugs seeking approval?

Answer 8. Because protecting the health and well-being of children is of paramount importance, EPA has decided to send the Children's Environmental Exposure Research Study (CHEERS) for another external, independent review by an expert panel made up of members of the Science Advisory Board, the Science Advisory Panel, and the Children's Health Protection Advisory Committee. It is anticipated that this review will be completed and that a report will be forwarded to the Administrator in the spring of 2005. [Based on this review, the Agency will reassess the study.]

EPA scientists need to fully understand how children are exposed to pesticides and through what media (air, water, soil, etc.) EPA is particularly concerned about childhood exposure, because children may be more vulnerable than adults to the effects of environmental contaminants due to their smaller body sizes and rapid physical development. There is insufficient research to define pathways of exposure—the routes by which pesticides may enter a child's body. Possible pathways that could be investigated are ingestion (food and drink), inhalation, residue from crops, soil and ingestion of household dust.

CHEERS was designed to fill these critical data gaps in our understanding of children's exposure to pesticides and chemicals in household environments, ultimately leading to actions that would lower children's exposures to pesticides. The study design was externally reviewed for scientific merit and ethical protections by four Institutional Review Boards (IRBs) for the Protection of Human Subjects. The IRBs and the dates they approved the study are: Battelle Memorial Institute (August 2004), University of North Carolina (September 2004), Duval County (Florida) Health Department (conditional approval) and University of Florida (May 2004).

If confirmed, I will work to ensure that FDA performs its important statutory responsibility to monitor the safety of approved drugs. The enhanced post-marketing

surveillance provisions in the Prescription Drug User Fee Act provide new tools and opportunities to accomplish this goal.

[Whereupon, at 11:56 a.m., the committee was adjourned.]

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