S. HRG. 111–938

NOMINATION OF MARGARET A. HAMBURG

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

ON

NOMINATION OF MARGARET A. HAMBURG, M.D., OF THE DISTRICT OF COLUMBIA, TO BE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION

MAY 7, 2009

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

Available via the World Wide Web: http://www.gpoaccess.gov/congress/senate

U.S. GOVERNMENT PRINTING OFFICE
49–716 PDF WASHINGTON : 2011

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C O N T E N T S

STATEMENTS

THURSDAY, MAY 7, 2009

ADDITIONAL MATERIAL

NOMINATION OF MARGARET A. HAMBURG

THURSDAY, MAY 7, 2009

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

The committee met at 2:15 p.m., in Room SD–430, Dirksen Senate Office Building, Hon. Patty Murray, presiding.

Present: Senators Dodd, Mikulski, Murray, Sanders, Brown, Casey, Hagan, Whitehouse, Enzi, Burr, and Hatch.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. We are going to begin this hearing on the Health, Education, Labor, and Pensions Committee.

I am very pleased to be chairing this committee today on the hearing on the nomination of Margaret Hamburg for Commissioner of the Food and Drug Administration.

Before I get started, I do want to extend all of our warmest wishes to Senator Kennedy who continues to be a great champion for high-quality health care for all Americans who would like to be here today. I am substituting in his absence and he is missed.

Senator Enzi, our Ranking Member, will be joining us shortly, and I will allow him to make his statement after I do this afternoon as well.

Dr. Hamburg, I know you have some family here today. So before we begin, I would like you, if you would not mind, to introduce your family to the panel today.

Dr. HAMBURG. It would be a great pleasure. This is my husband, Peter Brown, and my daughter Rachael and Evan Brown. I am also joined today by my parents, Dr. Betty Hamburg and Dr. David Hamburg, and my mother-in-law, Betsy Brown. I want to thank you all for the kindness and support you have given me throughout this process. I suspect I will need more of that kindness and support should the Senate choose to confirm me.

Senator MURRAY. Well, you are fortunate to have a wonderful family who is seated here with you, and thank you, all of you, for being there behind Dr. Hamburg as she gives her testimony today.

I am rambling for a minute while we wait for Senator Lugar to sit down and join us, and while he is doing that, I would like to ask unanimous consent to put in the record a statement from former Senator Nunn who also shares his support for you as well.

[The information referred to above may be found in additional material.]

Senator MURRAY. Senator Lugar, if you are ready—I know you are on an extremely tight timeframe. Before I make a statement, I would be happy to yield to you to introduce Dr. Hamburg.

STATEMENT OF SENATOR LUGAR

Senator LUGAR. Thank you very much, Chairman. I really appreciate that. I thank you for the opportunity to introduce Peggy Hamburg whom the President has nominated to lead the Food and Drug Administration.

I would first like to thank Chairman Kennedy, Ranking Member Enzi, and you, Senator Murray, for holding the hearing today, for moving forward on this very important nomination.

At a time of heightened awareness about the need for food safety oversight, growing demand to address the cost and assure the quality of prescription drugs and medical devices, and the critical importance of addressing pandemics and biological threats, the FDA will play an increasingly integral role in the public health matters that impact our everyday lives.

Madam Chairman, it is my privilege to recommend a signal leader to address these challenges and opportunities for reform.

My association with Dr. Hamburg began through a close personal relationship with her father who is here today. I have known David Hamburg, the former President of the Carnegie Corporation of New York, for decades. David played a critical role in the formation of the Nunn-Lugar Cooperative Threat Reduction Program in 1991. He joined Sam Nunn and me on our first trip to the former Soviet Union where we found unfathomable risks and potential threats to our country. As the Red Army dissolved, the nuclear, chemical, and biological weapons stockpiles under its control were at risk of being stolen or sold to the highest bidder. David was a crucial ally in developing the approach that led to the Nunn-Lugar program deactivating more than 7,200 nuclear warheads, eliminating thousands of missiles, missile launchers, submarines, and bombers. His leadership and his friendship have been extraordinary and his contributions to U.S. national security immeasurable.

David Hamburg's commitment to his country's security has been deeply ingrained in his daughter. In 2001, Dr. Peggy Hamburg joined the staff of the Nuclear Threat Initiative, reuniting the Hamburg family with my friend, former Senator Sam Nunn, one of the founders of NTI. In her original capacity as the founding Vice President for Biological Threats, Dr. Hamburg was instrumental in crafting the organization's global health and security initiative to address the broad range of naturally occurring and deliberate biological threats to health. She now serves the organization as senior scientist.

As a member of the NTI board of directors, I have had the pleasure of working with Dr. Hamburg in her efforts to address threats posed by biological weapons, and through this relationship, I have always been impressed with her consummate knowledge of the issues, personal integrity, and her remarkable dedication to public service.

Together we have strongly supported the growing efforts of the Nunn-Lugar program and its partner programs of the Department of State in the biological weapons field. We share a strong belief

in the vigorous need for the United States' collaboration and cooperation with governments around the world in the area of infectious diseases and pathogens. As many pathogens can now be modified and engineered to increase their lethality and potential to spread, Dr. Hamburg and I have urged the U.S. Government to utilize the Nunn-Lugar program to help secure pathogen strains to ensure they do not fall into the wrong hands.

Equally important, Dr. Hamburg was a strong supporter of U.S. projects to assist in the establishment of systems designed to detect, characterize, and respond to outbreaks of infectious diseases. I am pleased to report to date the Nunn-Lugar program's biological threat reduction efforts are underway in more than a dozen countries.

Prior to her work at NTI, Dr. Hamburg attended Harvard University where she received both her undergraduate and medical degrees. She went on to complete her internship and residency in internal medicine at the New York Hospital at Cornell University Medical Center and is certified by the American Board of Internal Medicine.

Dr. Hamburg served 6 years as the Health Commissioner for New York City where she was in charge of food safety inspection and enforcement activities, including investigations of food-borne outbreaks, food contamination, adverse outcomes from drug therapies, and restaurant concerns.

In addition to her distinguished public accolades, fellowships, honorary degrees, and awards, Dr. Hamburg has also assumed leadership roles within the Department of Health and Human Services as Director of the National Institute of Allergy and Infectious Disease at the National Institutes of Health and as Assistant Secretary for Planning and Evaluation where she led the Department of Health and Human Services' first major bioterrorism initiative and Federal pandemic flu preparedness efforts.

Dr. Hamburg's impressive career and remarkable breadth of knowledge and experience in public health would be a tremendous asset to the FDA and to our Nation. She has the ability to recognize the domestic and international health concerns facing our Nation, while balancing the interests and science that shape policy needs and directives. I have always respected her counsel and appreciated her utmost professionalism.

I thank you again, Madam Chairman, for this opportunity to present this distinguished nominee to the committee.

Senator MURRAY. Thank you very much, Senator Lugar, and we really appreciate your coming by and introducing Dr. Hamburg to all of us.

At this time, I will proceed with my opening statement and again thank you, Dr. Hamburg, for being here today.

You know, the Food and Drug Administration plays a crucial role in ensuring that drugs and medical devices are safe and that lifesaving drugs move safely from the laboratory to the patient. Over the past 8 years, American consumers have come to question the independence and effectiveness of this agency. I have always supported a strong and independent Food and Drug Administration. It is the only way in which the FDA can truly operate effectively and with the confidence of American consumers and health care pro-

viders. Americans must have faith that when they walk into their local grocery store or their pharmacy, that the products that they purchase are safe and effective and that their approval has been based on sound science, not political pressure or pandering to interest groups.

A number of issues have come up recently that have highlighted just how important the FDA is in the lives of American families. We have all seen the importance of effective drug oversight with the recent concerns over medications like Vioxx. I hear from families all the time who tell me they do not want to have to worry that the peanut butter sandwich they packed for their child's lunch has been tainted or that the drugs they need to stay healthy could end up making them even worse.

The FDA plays a critical role in protecting families across America, and we have to make sure that they have the leadership and resources to do that well.

We also need to make sure that the FDA puts science ahead of politics. The health and well-being of the American people should not blow with the political winds. Part of the goal of improving health care in this country is ensuring Americans have access to safe, effective medicines in a timely fashion, and guaranteeing that the FDA remains the gold standard, when it comes to drug approval, is key to that effort.

For all of those reasons, I believe that Dr. Hamburg is the right nominee to lead the FDA. As we heard in Senator Lugar's introduction, Dr. Hamburg is a highly qualified expert in the area of public health. Not only is she a Harvard-educated doctor, but she also has strong public health experience at both the U.S. Office of Disease Prevention and Health Promotion, as well as the National Institute of Allergy and Infectious Diseases at NIH.

Dr. Hamburg also has great leadership experience serving from 1991 to 1997 as New York City's youngest-ever Health Commissioner. In this position, she designed an aggressive tuberculosis control program that is credited with lowering the city's TB rate by 46 percent between 1992 and 1997. She also worked to put in place programs designed to slow the spread of AIDS, helped boost childhood immunization rates, and developed one of the first programs to prepare the public for a terrorist attack using anthrax or other biochemical weapons.

After serving at the Department of Health and Human Services in the Clinton administration, Dr. Hamburg became Vice President for Biological Programs at the Nuclear Threat Initiative, a foundation dedicated to reducing the threat to public safety from nuclear, chemical, and biological weapons.

Dr. Hamburg has displayed strong leadership and ability over the course of her career and comes to us now highly qualified to lead the FDA and help restore America's families' confidence in our medicine and in our food. We need a highly qualified leader like Dr. Hamburg.

I want to thank you, Dr. Hamburg, for taking the time to have a conversation with me a few weeks ago. I know that the FDA faces a number of significant challenges from concerns about available resources, to organizational challenges, to management issues. I am confident that although you have a tough job ahead of you,

your experience, your ability and leadership are just what we need at the FDA.

I hope I can encourage all of my colleagues to help us move Dr. Hamburg quickly through this process because, frankly, families across the country deserve an FDA Commissioner who is going to help protect them from unsafe food or drugs and who will always put science over politics.

With that, I am going to turn to Senator Hatch for his opening statement and to any of our other colleagues who would like to do a short opening statement before we hear from Dr. Hamburg.

Senator Hatch.

STATEMENT OF SENATOR HATCH

Senator HATCH. Thank you so much, Madam Chairman.

Dr. Hamburg, I am very pleased that you are willing to accept this job. This is a thankless job in some ways. It is a very difficult job. It is filled with politics and controversy, and it should not be. But you are coming in at a time when, with real effort, you can help produce the greatest campus for food and drugs in the history of the world. It has taken us since 1992 when we passed the FDA Revitalization Act, to get us to where we are today, and we are still not there. I hope you will drive that home because once we have the highest facilities with the best equipment, then we will be able to attract some of the best scientists in addition to those who have agreed to serve out there so far. It is about time to bring all these folks into one central campus instead of having 30–35 different places spread all over the greater Washington area, where some of them worked in less than desirable conditions.

You have a great opportunity here to really lead, but that is only part of it. We need to make the safety and efficacy process move more smoothly. We need to attract top people to be able to take some of the heavy burdens off those who have been carrying them for so long. We need to work on all kinds of projects that will help health care in this particular country. As you know, we are working on health care reform as we speak in this committee and in the Finance Committee, and we are far from getting that right now, getting that done, or getting it done in a way that will be more desirable. You can probably do more in some ways at FDA than what we are going to do in Congress.

This is a very, very important position. I take tremendous interest in it, as I think does everybody on this committee.

I want you to know that I support you and that I intend to help you not only to get through this process, but also to do your job out there. I hope that you will do everything you possibly can to upgrade that agency to even more than it currently is. I think it is one of the most important agencies in the world. I believe that it does more good for people than almost any other Federal agency. It handles so many important issues that really are absolutely crucial to the health care of our people and not just here, but around the world.

Handled properly, I think we can even augment the safety and efficacy process for companies so that we can do much more innovation than we have done in the past. We do need to move it along. We do need to make sure that people are given fair hearings, and

that they are treated properly and that we do everything we can to spur on innovation and creativity in this country, especially in all of the areas that you are going to be working in. That does not just include the drug area. It is going to include biologics. Hopefully, we will do a follow-on biologics bill that will work with the appropriate exclusivity period that you just have to have to be equivalent to Hatch-Waxman. Of course, medical devices, etc., plus all of the other foods and so forth that this agency handles.

You are going to be handling between 20 and 25 percent of all the consumer products of America. This is not some itty-bitty job. This is a big-time job that really is going to take a lot of your time and a lot of effort. We need to give you the right kind of support and help, and I think you should not be afraid to advocate for that and for money and for more facilities and to get that campus at White Oak completed.

I am sorry I took so long, but I just wanted to let you know that I feel very deeply about FDA and want to help you in every way I possibly can.

And I want to thank the chairman for allowing me these few minutes.

Senator MURRAY. Thank you, Senator Hatch.

Senator Brown.

STATEMENT OF SENATOR BROWN

Senator BROWN. Thank you, Madam Chair.

Thank you, Dr. Hamburg. It is great to see you again. Thank you for your terrific public service.

I agree with Senator Hatch that FDA is one of the most important agencies in our Government and, frankly, in the world. Your work there will be particularly important.

Several years ago, when I was with Senator Burr on the House Energy and Commerce Health Subcommittee, I remember the FDA came and did a presentation on sort of the status of the FDA. This was in the early Bush years. What was so telling is at the beginning of the hearing, the first thing they told us was thanks to the FDA and other agencies, that the U.S. drug companies' market share in Europe had increased dramatically, as if that was the major function of the Food and Drug Administration. I look to you and understand that your work in public health will not put that as the major priority, what the drug companies want.

Several years ago, the FDA used to be one of the greatest public health agencies in the entire world. I think its reputation, its integrity, its closeness to the industry has compromised that, and I look to you to restore that greatness and the agency's reputation, its integrity, its competence. I think you can do that.

I watched you from afar in the early 1990s with what you did with multidrug-resistant tuberculosis in New York and what you did at Ryker's Prison. I know that you understand that the reason that multidrug-resistant tuberculosis became such a humanitarian disaster and such a fiscal disaster for the city of New York was that we had relaxed our vigilance in public health. The government simply was not doing in public health what it should have been doing, as it has not done prior to the TB multidrug-resistant outbreak. We have seen some of the same relaxation or indifference,

if you will, to public health in the last few years, and I know that your role at FDA will help us to answer that.

Briefly, Madam Chair, I just want to recount a couple of other things. When Dr. Hamburg was in my office, I appreciated your comments on following biologics, to move on that, on the backlog of generic drug applications at FDA and the importance of that, and also protecting the food supply and the drug supply. We know that, in part, because of our trade practices, as we import products from around the world, we also import too often contaminated ingredients in prescription drugs. We import toys that are unsafe because of lead-based paint. We import other kind of contaminants in pharmaceuticals and food.

I appreciated your comments about what do we do as more drug companies outsource more of their production. The previous FDA told us in this committee, as I presided 1 day, a year or so ago, that these drug companies move to China not just to save costs in wages but also because the safety regimen is not as tough on them in China as they produce ingredients and ship them back to the United States. I hope we can continue to pursue that issue because nothing is more important than pharmaceutical and food safety for people of this country.

I am thrilled that you want to be FDA Commissioner. I look forward to voting for you in this committee and look forward to supporting you on the floor.

Thank you.

Senator MURRAY. I am not sure if any of other Senators want to do an opening statement or if we want to go to questions. I will go to Senator Burr and Senator Sanders, for a quick opening statement.

STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Madam Chairman.

I think when you have an exceptionally qualified individual that has been nominated, you should take as much time to highlight those qualifications. Margaret Hamburg has the expertise and the experience to bring to the FDA that is both impressive and, I might say, needed. As a clinician, she has the scientific background necessary to understand the complex world of drugs and medical device development, as well as the importance of a sound, science-based standard to protect our food supply.

She has run a largely and unwieldy government agency for 6 years, as the Commissioner of Health in New York City, at times when New York City's Health Department was suffering from low morale and, in fact, a serious lack of focus. And I think she brought that back on course.

The challenges of the FDA are not dissimilar today, as I shared with you in our meeting. The agency regulates 25 cents of every dollar of our economy. That is only one side of the coin. FDA must have the adequate resources and the ability to attract the best investigators, inspectors, and scientists to protect the public from food-borne illness, approve the next lifesaving drug, and/or pull harmful products off the marketplace.

Dr. Hamburg, should—no—when the Senate confirms you, I hope to work with you to ensure that the FDA is, No. 1, adequately

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funded, but I would also hope that you take this opportunity to improve the culture at the FDA. I think I could broadly apply that to just about any Federal agency. The FDA is under siege, and we can ill-afford an agency worried to make important decisions that not only affect the health and the well-being of the American people, but our economy and our competitiveness in a global marketplace that continues to get more competitive.

Clearly, there are several other issues to address and your input will be crucial. Follow-on biologics, as Senator Hatch mentioned, food safety, product liability and pandemic preparedness are just a few and FDA will play a major role in that. Medicine is on the cusp of a revolutionary shift in treating individual patients with therapies specific to their genetics and with new regenerative techniques. FDA will be the center of all these issues, and I am hopeful you will be there to guide it.

Welcome today and welcome to your family.

Senator MURRAY. Thank you very much.

Senator Sanders, you had a short opening statement?

STATEMENT OF SENATOR SANDERS

Senator SANDERS. Thank you, Madam Chair.

Welcome, and we certainly look forward to working with you in the next several years.

There is an issue that I have been working on for a number of years, when I was in the House and in the Senate, and that is the re-importation of prescription drugs. As you probably know, we in the United States pay in many instances far, far more for brand names than do our friends in Canada or in the United Kingdom. I find it very hard to believe, in a world of unfettered, free trade, which in many ways is causing us a whole lot of problems, that we cannot safely bring medicine in from Canada or the United Kingdom. I just do not believe it.

For years, we have been hearing that the FDA was unable to make sure that the medicine coming into this country is safe. I hope that you will work on that issue. I think it is absolutely doable and I think that millions of people would be very grateful to see lower-cost prescription drugs in this country.

A second area that I would hope that we could focus on is, as you well know, there are some studies out there which suggest that, if you can believe it, the younger generation will have a shorter life span than our generation because of obesity and all of the illnesses that go with that. I know you are familiar with this issue. Trying to get a handle on caloric intake of people, maybe making fast food chains publish in their menus the kinds of calories that people are absorbing, but in general, launching a significant effort to address the obesity crisis which leads to so many other illnesses.

Those are a couple of issues that are of concern to me.

Thank you very much. We look forward to working with you in the years to come.

Senator MURRAY. Thank you.

Dr. Hamburg, we will turn to your opening statement in just a minute.

Senator Mikulski, you wanted a quick moment?

STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Very quickly because we do want to hear from Dr. Hamburg.

As the Senator who has FDA in her own State, I just want to give Dr. Hamburg a very cordial and enthusiastic welcome. I look forward to working with her to rebuild and recapitalize FDA.

You have a strong civil service to work with at FDA. What they lacked was political leadership that did not put politics into FDA, and if we can restore the integrity of FDA where the people who work there can speak truth to power, I will believe that we will really be able to stand sentry over America's food and drug supply.

I know that you have a wonderful family with you. You yourself said you feel very prepared for the challenges at FDA. You are the daughter of a psychiatrist, and you will need all the mental health that you can get.

[Laughter.]

We want to hear from you today and work with you in the future.

I just want to note that the facilities at FDA have been enormously stressed, and we have worked at rebuilding them over the years on a bipartisan basis. I want to note the partnership that I have had with Senator Hatch in doing that. Now we are going to have the right buildings, but we want to make sure we have the right leadership. Thank you and I look forward to working with you.

Senator MURRAY. Thank you very much, Senator.

Dr. Hamburg, we will now turn to you for your opening statement. Again, welcome to you and to all your family who are here.

STATEMENT OF MARGARET A. HAMBURG, M.D., VICE PRESIDENT FOR BIOLOGICAL PROGRAMS, NUCLEAR THREAT INITIATIVE, WASHINGTON, DC

Dr. HAMBURG. Thank you very much, Madam Chairwoman and members of the committee. It is a privilege to be here today to discuss my nomination as Commissioner of the Food and Drug Administration. Let me also thank the members of this committee for the wise counsel that you gave me during my individual visits and for your courtesy in allowing me to appear before you today.

I also want to thank my family for joining me today.

I am deeply honored that President Obama has asked me to serve at the FDA at such a critical point in the agency's history. As a public health professional and a physician, I have devoted my entire career to improving the health and safety of Americans.

Today, the agency is facing a range of new and daunting challenges. These include the globalization of food and drug production, the emergence of new and complex medical technologies, and the risk of deliberate adulteration, as well as terror attacks, on our food and drug supplies. The emergence of the novel influenza A, H1N1, virus in the last several weeks has highlighted the critical role played by FDA even further.

If confirmed, I would look forward to working closely with this committee and with the dedicated, hard-working, and talented staff

at the FDA to improve the effectiveness of the FDA in protecting health and safety.

I want to share with you briefly my background and then discuss some of the key issues that face FDA.

My expertise spans basic and clinical biomedical research, public health practice and policy, health agency management, global health, infectious diseases, bioterrorism, and emergency preparedness. I have had direct experience helping in developing policies and treatments for infectious diseases during my tenure at the National Institutes of Health.

Then becoming Health Commissioner in New York City, I entered a department where morale was low and resources were scarce. As Commissioner, I embraced the mission of the agency and worked with the staff to implement science-based public health policies and practices. During this time, we increased the number of children who received immunizations and decreased the number of new HIV infections. Our rapid response to an epidemic of drug-resistant tuberculosis became a model worldwide. I was on the front lines overseeing food safety and a range of regulatory and enforcement activities in the Nation's largest city. Through our actions, we gave the city an energized department the public could trust again.

I later served as the Assistant Secretary for Planning and Evaluation, or ASPE, at the U.S. Department of Health and Human Services, where I led the staff in the formulation and analysis of health policies for the Federal Government. During that time, I worked closely with the FDA on food safety and security issues and on strategies to expand the availability of new drugs and vaccines, diagnostics, and medical devices.

While serving as ASPE, I also created the HHS bioterrorism initiative and led a major effort to develop an influenza pandemic preparedness plan for the Nation.

These are some of the experiences that have shaped my outlook on how to conceive and implement effective approaches to protecting health and safety. They will also help me address the priorities that will guide my work, if confirmed, as FDA Commissioner.

To me, this means operating an agency that is accessible and transparent, strengthening the FDA's science base, hiring and retaining the best and the brightest scientists that FDA can recruit, and ensuring that FDA has the resources and capacity to understand the latest advances in science and apply them to regulatory and public health issues. The FDA must carefully protect scientific integrity as the cornerstone of the regulatory process.

Let me now turn to a few specific priorities.

First, if confirmed, I will review FDA's work on the H1N1 influenza outbreak to determine if there are additional steps FDA can take to make safe and effective medical products and laboratory tests available. I look forward to being actively involved in discussions within HHS on such critical questions as to what vaccine to make, how much to make, whether to alter seasonal flu vaccine manufacturing, and ultimately, whether to recommend vaccination for the American people.

I will focus on improving food safety. Domestically, this means taking advantage of the growing consensus among experts and in-

dustry that now is the time to shift to a food safety system that puts prevention first. Important steps must be taken to better protect the Nation's food supply from farm to fork, to strengthen our food safety system so we prevent outbreaks from occurring in the first place. Globally, this means FDA's attention and energies must be given to import safety and working more closely with our international allies.

Equally important, we must continue to make advances in the safety of medical products. Using the authorities granted in 2007 legislation passed by this committee, the agency can now build safety considerations into every aspect of product development. Close monitoring after marketing will be critical to identifying early safety signals and to acting quickly to protect the public.

We must also foster innovation. There has never been a time when advances in science and technology have offered so many opportunities to bring new medical products to the marketplace and to the people who need them. As FDA Commissioner, I would strive to lead an agency that appropriately balances innovation with regulation.

A fifth priority is accountability. Responsibility to ensure the integrity of our food and drug supply is a shared responsibility throughout the life cycle of a product. The FDA has responsibility to ensure that its work is driven by the best possible science and is undertaken with integrity, openness, and credibility. Responsibility must also lie with the food and drug producers themselves.

The FDA touches every American through every stage of life. The agency regulates almost one-quarter of all the products Americans consume, including much of the food we eat, the drugs we take, biologics like vaccines, the medical devices our doctors use, veterinary medicines, pet food, cosmetics, and numerous other products.

The American people place a huge trust in the FDA. It is critical that we take steps to boost their confidence, particularly when it comes to the safety of drugs and food.

Madam Chairwoman and members of the committee, I have devoted my professional life to protecting the health of the American people. In the positions in which I have been honored to serve, I have been able to reform the machinery of government to offer this protection, serve the public, work across party lines, and provide better health and safety outcomes for the public. It is to these objectives that I will devote myself if the committee and the Senate confirm my nomination as FDA Commissioner.

I am happy to answer any questions that you may have.

[The prepared statement of Dr. Hamburg follows:]

PREPARED STATEMENT OF MARGARET A. HAMBURG, M.D.

Mr. Chairman, Ranking Member Enzi, and members of the committee, it is a privilege to be here today to discuss my nomination to be Commissioner of the Food and Drug Administration (FDA). Thank you, Senator Lugar, for that kind introduction. Let me also thank members of this committee for the wise counsel I have received from you in private, and for your courtesy in allowing me to appear before you this afternoon.

INTRODUCTION

I am deeply honored that President Obama has asked me to serve at the FDA at such a critical point in the Agency's history. As a public health professional and

physician, I've devoted my entire career to improving the health and safety of Americans.

Today, the Agency is facing a range of new and daunting challenges. These include the globalization of food and drug production, the emergence of new and complex medical technologies, and the risk of deliberate terror attacks on our food and drug supplies.

The emergence of the novel Influenza A (H1N1) virus in the last several weeks has highlighted the critical role played by FDA even further.

If confirmed, I would look forward to working closely with this committee and with the dedicated, hard-working, and talented staff at the FDA to improve the effectiveness of the FDA in protecting the health and safety of the American people.

MY BACKGROUND

I want to share with you briefly my background and then discuss some of the key issues that face the FDA.

My expertise spans basic and clinical biomedical research, public health practice and policy, health department management, global health, infectious diseases, bioterrorism and emergency preparedness.

I have direct experience helping develop policies and treatments for infectious diseases during my tenure at the National Institute of Allergy and Infectious Diseases at the National Institutes of Health.

When I became Health Commissioner in New York City, I entered a department where morale was low and resources were scarce. As Commissioner, I embraced the mission of the agency and worked with the staff to implement science-based public health policies and practices. During this time, we increased the number of children who received immunizations and decreased the number of new HIV infections. Our rapid response to an epidemic of drug-resistant tuberculosis became the model worldwide. I was on the front lines overseeing food safety and a range of regulatory and enforcement activities in the Nation's largest city. Through our actions, we gave the city an energized department the public could trust again.

I later served as the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services, where I led the staff in the formulation and analysis of health policies for the Federal Government. During that time, I worked closely with the FDA on food safety and security issues, and on strategies to expand the availability of new drugs and vaccines, diagnostics, and medical devices.

While serving as ASPE, I also created the HHS bioterrorism initiative and led a major effort to develop an influenza pandemic preparedness plan for the Nation.

APPROACH AND PRIORITIES

These are some of the experiences that shaped my outlook on how to conceive and implement the most effective approaches to protecting health and safety. They will also help me address the priorities that will guide my work, if confirmed, as Commissioner of the Food and Drug Administration.

To me, this means operating an agency that is accessible and transparent, strengthening FDA's science base, hiring and retaining the best and brightest scientists that FDA can recruit, and ensuring that FDA has the resources and capacity to understand the latest advances in science and apply them to regulatory and public health issues. The FDA must carefully protect scientific integrity as the cornerstone of the regulatory process.

Let me now turn to a few specific priorities.

First, if confirmed, I will review FDA's work on the H1N1 influenza situation to determine if there are additional steps FDA can take to make safe and effective medical products and laboratory tests available. I look forward to being actively involved in discussions within HHS on such critical questions as how much vaccine to make, whether to alter seasonal flu vaccine manufacturing, and, ultimately, whether to recommend vaccination for the American people.

Second, I will focus on improving food safety. Domestically, this means taking advantage of the growing consensus among experts and industry that now is the time to shift to a food safety system that puts prevention first. Important steps must be taken to better protect the Nation's food supply—from farm-to-fork—to strengthen our food safety system so we can prevent outbreaks from happening in the first place. Globally, this means increasing FDA's attention and energies to import safety and working more closely with our international allies.

Third, we must continue to make advances in the safety of medical products. Using the authorities granted in 2007 legislation passed by this committee, the agency can now build safety considerations into every aspect of product develop-

ment. Close monitoring after marketing will be critical to identifying early safety signals and to acting quickly to protect the public.

A fourth priority is fostering innovation. There has never been a time when advances in science and technology have offered so many opportunities to bring new medical products to the market and to the people who need them. As FDA Commissioner I would strive to lead an agency that appropriately balances innovation with regulation.

A fifth priority is accountability. Responsibility to ensure the integrity of our food and drug supply is a shared responsibility throughout the lifecycle of a product. The FDA has responsibility to ensure that its work is driven by the best possible science, and is undertaken with integrity, openness and credibility. Responsibility must also lie with the food and drug producers themselves.

CONCLUSION

The FDA touches the life of every American, through every stage of life. The agency regulates almost one-quarter of all the products Americans consume—including much of the food we eat, the drugs we take to improve our health, the medical devices our doctors use, biologics like vaccines, veterinary medicines, cosmetics, and numerous other products.

The American people place a huge amount of trust in the FDA. It is critical that we take steps to boost their confidence, particularly when it comes to the safety of drugs and foods.

Mr. Chairman and Ranking Member Enzi, members of the committee, I have devoted my professional life to protecting the public health of the American people.

In the positions in which I have been honored to serve, I have been able to reform the machinery of government to offer this protection, serve the public, work across party lines, and provide better health and safety outcomes for the public. It is to these objectives that I will devote myself if the committee and the Senate confirm my nomination as Commissioner of the FDA.

I'm happy to answer any questions the committee may have.

Senator MURRAY. Thank you very much, Dr. Hamburg. I appreciate that.

Senator Enzi is going to submit his statement for the record. So we will go straight to questions, and I appreciate your accommodation on that.

Senator MURRAY. I just have a couple of questions. You and I had the opportunity to meet in my office. I just wanted to ask you two questions.

One was that our next FDA Commissioner is going to have a very important role to play in the safety of our Nation's food supply and is going to have to restore America's confidence actually that our food supply is being effectively regulated. I think it is going to require additional resources and authority so that we will be able to respond in a time of crisis. It is going to require a strong FDA leadership, someone who can work with our farmers and our food processors, all of the executive branch, and Congress to make those improvements.

We have seen report after report saying that FDA has failed to pay proper attention to many risks consumers are facing just from the food we eat. I wanted to ask you if you can tell us if you intend to increase FDA focus on high-priority food issues.

Dr. HAMBURG. Absolutely, Senator. This is one of my highest priorities, and I think we all share the concerns you mentioned about the recent outbreaks and the illness and sometimes deaths caused by food-borne disease in our country. This is a critical time for us to really modernize our food safety systems and really to put in place the kinds of programs and approaches that will better serve our Nation in a world that is transforming rapidly where we not only have huge challenges with respect to the domestic food supply but also the challenge of the imported food. Today, almost 15 per-

cent of the food on our tables actually comes from overseas, 60 percent of our fruits and vegetables and almost 80 percent of our seafood I believe. This is quite a challenge.

Clearly, at the present time, we do not have an approach that is either adequately resourced or sufficiently modern to address the many challenges before us, and I would work very hard to move us swiftly and surely in new directions.

Clearly, inspection is an important element of what we would do, and at the present time, we are not able to inspect all of the food production facilities, either domestically or internationally, at the levels that we would like, not by any means. We need to certainly increase the numbers of inspections, but we also have to be smarter about how we do inspections.

I think the FDA at this point needs to focus on prevention. Responding to an outbreak is important, of course, and the more efficiently and effectively we can do it, the more lives will be saved. We need to have clear strategies for enforcement and the tools to achieve our goal. We also need to really take a risk-based approach to prevent these problems from occurring in the first place, and that means that we need to really target the highest risk products and look at the life cycle of a product and where are the points of vulnerability where we can target our efforts to reduce risk so that we can ensure a safer food supply. We need to leverage existing science so that we can better detect problems and address them.

We clearly need to work in greater partnership across agencies of the Federal Government, across levels of government—State and local public health departments are critical partners in our efforts to control food-borne disease—and of course, work with industry. We need to strengthen, modernize, and work in partnership with clear policies, definition of our goals and objectives, and to find a strategy to address them. And I look forward to working with you on that.

Senator MURRAY. I appreciate that.

I have a minute left, and I wanted to ask you about something that Senator Mikulski brought up as well. We are seeing a trend of politicizing public health decisions. Just this year, employees at the FDA sent letters to President Obama outlining mismanagement at the agency and asking that he ensure that professionalism is returned to the agency. Can you just tell us if you are aware of that?

Dr. HAMBURG. I am aware of that. I am very concerned by some of what I have heard. I hope that, if confirmed as Commissioner, I can, through my leadership, create an environment where scientists feel very free to raise issues and concerns without any fear of retaliation, an environment that will foster open debate. I think science is best served by robust discussion, and I think that we need to have a clearly defined process to ensure the integrity of the science-based decisionmaking at the FDA.

Senator MURRAY. I appreciate that very much.

Senator Enzi.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. Thank you, Madam Chairman.

I appreciate that I got an opportunity to meet with Dr. Hamburg before and that she has already answered a lot of questions for me. I think it is very beneficial for us and probably daunting for you to be coming on at this point in time. I appreciate the expertise that you have in the area of pandemics. We may need it, and with your expertise, hopefully we will not.

You will also be in charge of a trillion dollars' worth of products every year, and that does not even get into the food safety. I do not know how many trillion we do in food. We have had some hearings on food safety before, and while we always need improvement, one of the things that I have really been impressed with from those hearings is we have three agencies that cooperate and are able to take relatively few samples out of thousands of possible problems and isolate a problem and get that food off the market and find out where it came from. I think it is has to be one of the unusual things in Government to have three agencies doing that. You will get to participate in that. Of course, we will be interested in any suggestions for how we can do it better.

Now, one of the questions that I ask everybody that comes before this committee—this used to be one of the most contentious committees, and I think it is now one of the most productive committees. That is because we have learned to cooperate and work together to get a lot of things done. What I always ask is, in order to continue to sponsor that kind of a relationship, whether it is a Democrat or a Republican, would you be willing to promptly respond to any written or phone inquiries, sharing information whenever it becomes available, and directing your staff to do the same?

Dr. HAMBURG. Senator Enzi, I pledge to you that I am more than willing to cooperate as fully as possible and would ask the staff at the FDA to be responsive in every way possible, should I be confirmed as FDA Commissioner.

Senator ENZI. Thank you.

Dr. HAMBURG. I think that cooperation is vital and I think that really strengthening the working relationships with Congress is a very important aspect of what the FDA needs to do at the present time.

Senator ENZI. I appreciate that.

My next question kind of follows along that line. Senator Hatch and I and Senator Kennedy and last year Senator Clinton worked on some biologic drugs, biosimilars, and we came up with a bill, and we are going to be working to make sure that the evergreening in it is solid and wanting to get that back in again. We will be asking for some input from you. Again, it is kind of a simple question. I would expect that you would help. But I will ask that question anyway.

Dr. HAMBURG. I think that as you point out, there have been a number of pieces of legislation around follow-on biologics, and it is a very important topic, a very exciting area of modern science as well with opportunities to greatly improve the health of the American people. Right now, biologics represent very important medications and they are making a huge difference in the lives of many Americans. They are expensive, and there are for many of these products just one manufacturer. In the near term, as you well know, many of these products will be losing their patent protection

and so thinking about establishing a pathway for these so-called biosimilars, I think, is very important. It has the opportunity to expand the manufacturing base so more products will be available and also could yield significant savings.

There are challenges involved in it, and it will take careful deliberations on the part of Congress and serious work on the part of FDA. Clearly, we need to find a strategy that balances the continuing requirements for innovation with the desire to have more available and more affordable products. And for the FDA there is the challenge of really understanding how best to evaluate these biosimilars so that we can move them forward to the American people with a surety of their safety and efficacy. I think that it is something that is a very exciting opportunity. I would certainly support establishing such a pathway and would look forward to working with you.

Senator ENZI. It is definitely a balancing act, as you mentioned. We want to make sure it is a streamlined process. We want to make sure that we do not stifle innovation, but we want to get the products on the market as fast as possible. I think we have a bill that kind of does that. We will be checking with you and looking for some help on that. It is a very bipartisan bill and one that we have worked on for a long time. I have run out of time.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

I would like to begin by thanking Senator Murray for calling this hearing today, and by welcoming Dr. Hamburg. I would also like to thank Dr. Hamburg for her previous public service, and her willingness to once again go through the process of Senate confirmation. The vetting process for executive nominees is thorough, and not without some degree of personal and professional sacrifice. Thank you for your willingness to serve.

Dr. Hamburg is an internationally recognized leader in public health and medicine, and an authority on global health, public health systems, infectious disease, bioterrorism and emergency preparedness. This background is especially important given that the swine flu (H1N1 influenza) has been on the front pages for nearly 2 weeks, and spread across several continents during that time. Dr. Hamburg, you have a tremendous amount of experience with emergency preparedness. Given this developing story, today I would like to learn more about your priorities for FDA in the area of bio-defense and pandemic flu preparedness.

The FDA has a very broad and critical mission in protecting the public health. You will be in charge of an agency that regulates $1 trillion worth of products a year. The FDA ensures the safety and effectiveness of all drugs, biological products such as vaccines, medical devices, and animal drugs and feed. It also oversees the safety of a vast variety of food products as well as medical and consumer products, including cosmetics.

As Commissioner of the FDA, you will be responsible for advancing the public health by helping to speed innovations in its mission areas, and by helping the public get accurate, science-based information on medicines and foods.

Another core mission of FDA is approving drugs and ensuring their safety. However, the FDA can't ensure the safety of deadly products such as tobacco—it kills people, not cures them. Yet next week this committee is set to consider legislation that would require the FDA to regulate tobacco. At a time when Federal dollars are stretched and resources are limited, I have serious concerns about adding more statutory responsibilities at FDA. In addition, given the recalls of spinach, peanuts, and tomatoes over the past 2 years—FDA's resources are already stretched too thin on the food safety front. Dr. Hamburg, today I would like to hear more about your views on why the FDA should regulate tobacco.

I represent a State that has substantial agricultural interests. Food safety and food labeling are critically important to me and my constituents. I look forward to hearing from you what the agency plans to do to continue protecting the American food supply.

Dr. Hamburg, if confirmed, I look forward to working with you, Senator Kennedy and with the other members of this committee to protect and promote the public health, and to restore the FDA's status as one of the strongest regulatory agencies in the world. I have no doubt that, with the right leadership in place and with Congressional oversight, the FDA will again be the gold standard and our regulatory process the envy of the world.

I look forward to hearing your testimony today.

Senator MURRAY. Thank you very much.

Senator Dodd.

Senator DODD. Madam Chairman, I arrived a little bit late, and I see some of my colleagues who have been here a little longer than I have. So I will defer.

Senator MURRAY. Senator Mikulski.

Senator MIKULSKI. Thank you, Senator Dodd.

Dr. Hamburg, I want to pick up on the employee issue that Senator Murray raised. A group of our constituents in the CDRH wrote to me in October 2008 saying that they were forced to recommend the clearances of devices over their objection. I understand it has been referred to the IG. I will not go into that specific case, but raise the issue of two things. No. 1, whistle blowers, which in this case they said they were. We need the facts then to be investigated appropriately. Then there is the dissent channel where decisions are made but people wanted to raise a dissent or something might be going on and raise a dissent.

My question to you organizationally and as essentially the CEO of FDA, how will you handle—what organizational mechanisms will you have for whistleblower concerns to rise to the top to you? Also would you consider even having some type of mechanism for a dissent channel of communication so that you would be aware, with the 4,000 people who work for you, if they had flashing yellow lights about decisionmaking?

Dr. HAMBURG. Let me first begin, Senator Mikulski, by thanking you for all the hard work you have done to make White Oak possible, working closely with Senator Hatch and so many others, because that facility is really an extraordinary undertaking, and it represents a great opportunity to improve morale and strengthen the cooperative nature of the workforce within FDA. I think that is a contributor to the kind of positive, constructive work environ-

ment about which you are concerned and about which I would deeply commit myself, if I was confirmed as FDA Commissioner, to support and strengthen.

I think that whistle blowers serve a very important role in government in surfacing critical issues and concerns and making sure that they are addressed. As I indicated before, as leader of the FDA, I would very much want to create a culture that enabled all voices to be heard, that enabled serious discussions around important issues to involve every voice at the table. In the final analysis, I think that is the best way for decisions to be made, a lively—

Senator MIKULSKI. Dr. Hamburg, I think culture is an important thing, but organizational mechanisms are another. I know you are just looking at FDA, and perhaps this is something that we should discuss more specifically, should you be confirmed. I look forward to voting for you. I think we would like to know if someone feels they are a whistleblower, where can they go. Is there a direct channel in which they would not be muzzled, presuming you would not try to? Also, toward that end, we would like to talk with you about that. Perhaps that would be better later. I know you want to do the culture and you want to have this——

Dr. HAMBURG. Absolutely, and leadership is important. But as you say, what are the structures and policies is also key. To answer your question for that, I would need to spend some time, look closely at these issues. Certainly some of the concerns that have been raised publicly and by Members of Congress about events in the past are of great concern to me, and I would review them.

Senator MIKULSKI. I am going to jump in with one more question, not to cut you off. I think we are on the same broadband here.

I want to go to another issue. The FDA has always focused on safety, and that has to be an obsession. I am also concerned about efficacy, which I believe should be a mandate. As we take a look at the whole idea of reforming health care and more access, one of the things that we have to be able to do is get value for what we pay for, which also goes to efficacy of pharmaceuticals, biologics, and medical devices.

What role will you be playing in the health care debate to give us ideas and recommendations on efficacy, and have you had a chance to look at something like the Dartmouth Institute's idea on a drug box labeling that would comment on the efficacy of a product?

Dr. HAMBURG. You raise a very important point. I am not familiar with the Dartmouth box labeling approach but would love to learn more about it. I think that FDA clearly has an important role to play, and as you say, safety and efficacy are at the core of its mission. I would very much look forward to being involved with health care reform efforts around these important issues and making sure that drugs, vaccines, diagnostics, and devices are as appropriately used as possible to make a real and enduring difference in health in this country.

Senator MIKULSKI. My time is up. I hope you are at the table too and I hope FDA is at the table because I do not want the person who determines what drugs the American people have access to or devices determined by insurance company formulary gatekeepers. I would hope that it would be based on efficacy, as well as safety,

so that a clinician, when they prescribe, not only knows what is safe—also, that would include interactions—but also what has the greatest efficacy and therefore get the most value for health care. I do not want the determination to be made by an insurance gatekeeper. We look forward to working with you so we can have science-based, evidence-based decisionmaking.

Thank you and good luck, and I sure look forward to voting for you and working with you.

Dr. HAMBURG. Thank you.

Senator MURRAY. Thank you.

Senator Hatch.

Senator HATCH. Thank you, Madam Chairman.

During the announcement by President Obama to appoint you as FDA Commissioner, the President also appointed Dr. Josh Sharfstein as the principal FDA Deputy Commissioner. I am not sure that has ever been done before. Has that ever done before?

Dr. HAMBURG. I cannot answer that question, Senator. I just do not know.

Senator HATCH. I would like to know the answer to that. It is just interesting to me.

Do you know how you are going to divide the responsibilities out there between you and Dr. Sharfstein? Have you worked on that at all or even thought about it?

Dr. HAMBURG. I will be the Commissioner, if confirmed by the Senate, and I look forward to taking on that role. I know that Dr. Sharfstein is very broadly knowledgeable about the FDA. He, in fact, is already there serving in an acting role, and I will, I am sure, benefit from his early experience there as I make the transition in, if the Senate does choose to confirm me.

Senator HATCH. Well, he is very knowledgeable.

Dr. HAMBURG. I believe that there were reports in the press that were quite misleading—and perhaps I should take this opportunity to clarify them—that I would focus on food and tobacco, should that become part of the FDA's mandate, and he would focus on drugs. That is simply untrue. I am very eager to take on the broad range of challenges, and I, should I be so honored to serve, would be the Commissioner.

Senator HATCH. I think that is right. That is why I asked that question. It is not meant to find fault with anybody. I just wanted to know the answer to that.

As you might know, the Dietary Supplement Health and Education Act of 1994 provides FDA with the authority to oversee and regulate the supplement industry. In December 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act was also signed into law. Now, this law requires mandatory reporting of serious adverse events for dietary supplements and over-the-counter products.

Do you agree with me and all former FDA Commissioners that I have chatted with that those laws are still adequate and that they give the FDA sufficient authority to regulate the dietary supplement industry and to protect consumers?

Dr. HAMBURG. This is really a complex issue and one that I have not been deeply involved in my other professional experiences. It

is one that I want to take time to study and examine and work with you and others.

Clearly, the FDA has a very important role in assuring to the American people that these products that they take to improve their health and supplement their health will be what they claim to be and will be safe. I think the Congress has given FDA important authorities to support that role in terms of protecting the health and safety of Americans. The GAO took a recent look at some of what is being done in that area and made recommendations to the FDA about how they can do their job better and also some potential additional areas that need to be strengthened.

I think it is very, very important. We know that more than half of American adults take these products and value them and trust them, and I think we all share the desire to make sure that their trust is grounded in the safety of these products.

Senator HATCH. The GAO report has indicated that the biggest problem is that you do not have enough funds. That is the problem. Of course, Senator Harkin and I are very much interested in alternative medicine that we have put into law, and we think it is given kind of a short shrift. So I hope you look at that as well.

Let me just ask one other question. You mentioned the tobacco issue. Congress is considering legislation that would give the FDA jurisdiction over tobacco and designating the FDA as a regulatory body goes against the agency's mission to "protect the public health."

Now, how does the FDA regulate a product that is neither safe nor beneficial to public health?

And finally, if the tobacco legislation becomes law, how does the FDA intend to obtain the necessary resources in order to carry out this new responsibility, especially when it lacks the resources to conduct its current responsibilities?

Dr. HAMBURG. First, let me say, Senator, that I think that we all recognize that smoking represents a terrible burden to health in this country and that tobacco products are unlike any other products on the market, in that they are unusually lethal but yet not highly regulated. This is a critical moment for us to take a more aggressive look at how we can regulate tobacco products to reduce smoking and to reduce the risks of tobacco products to the American people.

I think that the FDA is the appropriate agency to regulate tobacco. It has the scientific expertise, the regulatory experience, and the public health mission to do so, and I think that if done successfully, we can reduce smoking and we can help to make cigarettes less harmful.

I have heard the concerns about whether or not this is a time when FDA can take on more tasks when it already has so many challenges before it, and it has for a very long time been underresourced to do all of the important tasks already on its agenda. As I understand it, the legislation being considered does build in a mechanism to support the development of regulatory activities within the FDA to create a new center for tobacco product regulation and to hire the necessary staff. I think that I am very comfortable moving forward if that is the will of Congress.

Senator HATCH. My time is up.

Senator MURRAY. Thank you very much, Senator Hatch.

Dr. Hamburg, I apologize. I am going to have to go to another meeting. We are going to do a little musical chairs here and Senator Dodd is going to take over the chairmanship of this committee for a short while and then pass it on to Senator Sanders about 3:30, is my understanding. I appreciate all of our colleagues' willingness to jump in and help as we started a little bit late. Some of us had some time commitments.

I look forward to working with you as we move your nomination forward. And with that, I will turn the gavel and the speaking arrangement over to Senator Dodd.

STATEMENT OF SENATOR DODD

Senator DODD [presiding]. Thank you very much, Madam Chairman.

Welcome, Doctor. It is a pleasure to see you again. Welcome to your family as well that are here, and congratulations on your willingness to accept this very important job, and congratulations to our President for seeking you out.

I think probably this job—I know the Secretary of Health and Human Services is obviously a critical job as is the Secretary of Education. I do not think any of us think any of those jobs are any more important than the one that you are going to take on. We have spent an awful lot of time in this committee over the years dealing with FDA issues, and so I, for one, am very excited about your nomination. You bring a wealth of talent and experience that is going to be invaluable to this committee but, more importantly, to the country. I thank you for your willingness to do that.

The questions I would like to raise with you have a lot to do with pediatrics. I chair the Subcommittee on Children and Families and have for a long time. Many members of this committee have been tremendously helpful over the years on a lot of these issues dealing with the better pharmaceuticals for children, going back to the Family Medical Leave Act that members of this committee, Senator Murray, Senator Hatch, and others were very helpful on, child care, a lot of issues focusing on children.

The recent outbreak—and your experience, by the way—and I commend you. I was reading over what you had done as New York's Health Commissioner developing a successful tuberculosis control program and increased childhood vaccines availability across the city. When I saw that, I said I think I have an ally on the issues I am about to raise because so often the assumption is that children are just smaller versions of adults, and we have seen dreadful problems with overdosing or underdosing and all sorts of other things. Studies done under the Better Pharmaceutical Act for Children have proven, just how important this area is.

I noticed with the H1N1 outbreak, again, there are some questions that have occurred to me dealing with pediatric populations and we start talking about having adequate supplies of Tamiflu and Relenza. The question is whether or not we are going to have adequate and appropriate testing of these vaccines, given the age, by the way—I was struck with the age—the average age being 15 of those who have been affected, not exclusively so, but the bulk of them in that age group, and really very little, if any, testing at

all done with these vaccines as to what the effects are in children. So I was interested in that.

There are a couple other points on this thing. Your reactions to that. The combination of the migration, the inextricable link between human and animal health is raised. I call it H1N1 because I know the sensitivities of calling it swine flu, but there clearly is an inextricable link between animal and human health. While FDA deals with human health and the Agriculture Department deals with animal health, it seems to me that we have got to start thinking about how these two agencies begin to cooperate more effectively in these areas. I do not think that has been the case.

I just heard you talk about taking on additional responsibilities in response to Senator Hatch, but I would be very interested in any thoughts you may have on that. Let me start with that question. Then I have some similar questions dealing with the follow-on biologics in children, as well as in pediatrics.

Dr. HAMBURG. With respect to the last part of your question on animal and human health, the interconnection is very important, and if you look over the last couple of decades actually, we have seen a surprising number of emerging infectious disease threats including, of course, H1N1 but also SARS, HIV, avian flu, West Nile, you know, many important diseases with huge impacts on the American people. The large majority of those cases have been what are called zoonoses or diseases that emerge in animal populations and merge over into human populations. It is a very important area of study that has huge impacts on health and society more broadly, and it is an area that I have worked on in the past. And from the perspective of FDA, I would want to continue to work on it. It is very, very important.

Obviously, the linkage that we are seeing now with H1N1 in the area of antibiotic resistance, how animal health and human health is addressed is also very, very key. There is a long list of arenas where that intersection is important, and I would be eager to pursue those issues from the role of FDA Commissioner.

With respect to your pediatric questions, your leadership on this issue has been very important and really moving toward more and more focus on addressing the needs of the pediatric population for drugs, vaccines, and devices that are really tailored to the needs of children at different stages of development and not treating them like little adults. Of course, the same holds true when we are addressing the problem that is currently before us of H1N1, making sure that children are not left out simply because some of the studies might not have been done in that population group.

You should know that the FDA has already moved to address some issues about making sure, through emergency use authorizations, that some critical antiviral medications could be made available to a somewhat younger age population, and I think we need to continue moving forward to think about pediatrics as a special population and continue to make sure that we can stimulate the investments to discover, develop, review, and make available the drugs and devices we need.

Senator DODD. That is very good, because in this particular case, you do have, as I said, that younger population. I would be very interested in that and the coordination between the Department of

Agriculture and the FDA. There has not really been much in my view, and it seems to me it is long overdue. If you are going to have that migration problem, you have to look at it.

I want to mention as well, too, the follow-on biologics. Again, as Senator Enzi pointed out, there has been a lot of work on this. I, along with others, authored that Better Pharmaceuticals Act for Children, which has been remarkable. It is actually way beyond the imaginations of any of us, who authored the bill, how much has actually been done under that bill to provide the kind of adequate testing on products used for children.

We have not required this at all under the proposed follow-on biologics legislation, and it is one of these things I would like very much for the FDA to insist that as we move forward with the follow-on biologics, if that is the case—I know it is a heated debate, but if we do so, that we are not going to have to go back through a whole legislative process again here to insist that there be adequate testing and so forth of these products to make sure that children are going to be safe.

I raise that with you but would love to see some leadership out of the FDA that, instead of bucking some of these things, they would become an ally in the process. Maybe we have to legislatively. Someone could tell me maybe I am going to have to do that for some statutory reason, but if I do not, I would like to be able to have it handled otherwise.

I have authored the legislation on pediatric medical devices as well for much of the same reason. I want to take the opportunity to thank the FDA, by the way. From the Office of Orphan Products development, they recently released the grant applications for $2 million in demonstration grants for improving pediatric device availability, which I authored and this committee supported, as part of the FDA amendments in 2007. This bill provides grants to nonprofit pediatric medical device consortia of scientists and innovators, particularly small businesses, with technical and financial resources to improve the number of medical devices available to children. I would hope that you would continue supporting that effort.

There are problems within the FDA's Center for Devices and Radiological Health. My time is expired here, but I would ask you maybe to respond in writing, if you might, what is your plan to restore confidence in the center, and how do you think the pediatric medical device development can be a part of that?

My colleagues have questions for you as well. I do not want to interrupt their time.

My focus is usually in this pediatric area and has been. I have a lot of interest, and I am excited about the fact you are going to have some colleagues joining you who come and bring particular expertise and experience in this arena, which is very exciting indeed.

Congratulations to you.

Dr. HAMBURG. Thank you.

Senator DODD. I look forward to supporting your nomination and working with you in the coming months.

Dr. HAMBURG. Thank you.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

Thank you Senator Murray. I want to welcome and congratulate Dr. Hamburg on her nomination to be Commissioner of the Food and Drug Administration (FDA).

I also want to thank Dr. Hamburg for her long-standing public service and for taking on this newest challenge, leading the FDA. I cannot remember a time when the need for strong, independent leadership at the FDA was more critical. Dr. Hamburg's distinguished qualifications will serve her well as Commissioner of the FDA and I strongly support her nomination. I am joined by a wide range of organizations and individuals including former HHS Secretary and Governor Tommy Thompson in voicing strong support for Dr. Hamburg's nomination to be FDA Commissioner.

The FDA regulates 25 percent of all products consumed by Americans. We rely on the FDA to ensure that our food is safe, and that the medicines we take won't harm us or our loved ones. Make no mistake about it—this position is as important as any that this committee we will consider.

We are currently in a public health emergency because of the H1N1 flu outbreak which has infected 896 people in 41 states and killed two people in the U.S. scandal after scandal with food and medical product safety—from tainted Heparin to contaminated spinach, peppers, and peanut butter—have rocked the Nation's confidence in the FDA's ability to keep Americans safe.

On top of all that, the FDA's own house has not been in order. The last 8 years of repression, of dissent, and political ideology trumping science-based decisionmaking have left an agency weakened as a result. At the time of this committee's last consideration of a nominee to head FDA, a study conducted by the Union of Concerned Scientists found that almost half of FDA scientists surveyed reported that they knew of cases in which the Department of Health and Human Services or FDA political appointees had inappropriately injected themselves into FDA determinations or actions. The same study also found that about 38 percent of FDA scientists surveyed disagreed or strongly disagreed that the FDA is acting effectively to protect public health.

Dr. Hamburg possesses the experience and leadership necessary to restore America's confidence in this vitally important agency. We can't afford to wait to confirm her. Thankfully, Secretary Sebelius is now in place and at the helm of the Department of Health and Human Services but it was not without unnecessary delay.

I urge my colleagues not to use partisan, political delay tactics to prevent this committee or the Senate from moving Dr. Hamburg's nomination as quickly as possible. The American people deserve a Commissioner of the FDA, an agency that is playing a critical role in the Nation's response to the H1N1 flu outbreak and countless other public health functions.

In the coming weeks, two major pieces of health care legislation will be considered in the HELP Committee. In each instance, we would be doing a great disservice to the process by not having Dr. Hamburg confirmed. One is comprehensive health reform. The FDA has a role to play in that debate, especially as it relates to the creation of a pathway to approve follow-on biologics.

The other is FDA regulation of tobacco. Tobacco use kills more than 400,000 Americans each year, making it the leading preventable cause of death. Each day 3,500 children try smoking a cigarette for the first time, with an additional 1,000 children becoming regular, daily smokers. One third of these children will die prematurely from smoking. It is time for us to act.

Next week this committee will take up and hopefully pass the Family Smoking Prevention and Tobacco Control Act. This landmark public health legislation has been championed for many years by Senator Kennedy and many others on this committee. It will give the FDA the authority to regulate the production, marketing, and sale of tobacco products—especially for children. This is not new legislation.

The Senate passed similar legislation in 2004 by unanimous consent. The HELP Committee reported out a nearly identical bill last Congress after a lengthy markup. The House of Representatives passed the bill twice by overwhelming bipartisan majorities, once in the last Congress and once earlier this year. It is endorsed by over 1,000 national, State, and regional public health and faith based organizations. With this committee and the Senate poised to pass this legislation, we finally can see the finish line and I look forward to working with you to implement this important legislation.

I have great confidence in the job Dr. Hamburg will do as commissioner of the FDA. I strongly support her nomination and urge her swift approval by this committee and the Senate.

Senator DODD. With that, Senator Sanders.

Senator SANDERS. Thank you, Mr. Chairman.

Just two brief questions. As you know, the United States pays by far the highest prices in the world for prescription drugs. The same medicine sold in the United States is often sold at a much higher price than in Canada or the United Kingdom. I personally find it hard to understand how we can import food from small farms in Mexico and in the back woods of China, and that is OK, but somehow or another we are not able to import less expensive prescription drugs from industrialized, sophisticated countries like Canada or the United Kingdom.

The drug companies have spent hundreds of millions of dollars trying to convince us that this cannot be done. Just impossible.

Dr. Hamburg, do you think it is impossible? Do you think we can safely inspect the medicines coming from the UK, Canada, other industrialized countries so that we can save the people of this country substantial amounts of money on their prescription drugs?

Dr. HAMBURG. Senator Sanders, this is clearly an issue that we will be working on together, should you choose to confirm me as FDA Commissioner, and I look forward to that opportunity. As I am sure you know, Senator Obama supports the importation of drugs so that—President Obama——

Senator SANDERS. He won the election. That is right. I do know that. Right.

[Laughter.]

Dr. HAMBURG. He has actually given FDA $5 million to begin a planning process to study how best safe importation can be done.

It does raise some serious issues for the FDA in terms of how can we assure the safety that Americans count on. Some of the issues you just discussed about contaminated products from China and other problems with counterfeit drugs, which are becoming a very serious global concern, remind us that we need to take this very seriously.

Senator SANDERS. It is an issue. It is an issue, but every day millions of people are eating vegetables that come from small farms in Mexico, and we are eating food that comes from China. I kind of think we can do it. I think what you will have to be aware of is the drug companies will spend hundreds of millions of dollars trying to prevent us from doing that, and I hope we will be able to stand up to that pressure because high cost of prescription drugs is one of the reasons that health care is so expensive in America, which we are trying to deal with.

My second issue. Let me read you a quote—well, not a quote. I am paraphrasing what I hope and expect will be—as you take his seat, David Kessler—you may know Dr. Kessler who was a former FDA Commissioner. In his new book, The End of Overeating, he says that foods high in fat, salt, and sugar alter the brain's chemistry in ways that compel people to overeat. Now, I do not know if his theory is right or not, but I think generally speaking we know that if we eat a lot of fat, salt, and sugar, it is probably not so good for our health. Yet, every Saturday morning there are television commercials telling our kids pretty much to do just that.

So my question is, as we are concerned about obesity in this country and the health of our kids, which is a growing problem, what do you see the proper role of government is in terms of regulating the food industry?

Dr. HAMBURG. These are really important concerns. As you point out, the food we eat, as well as other aspects of lifestyle, make a huge difference on health and throughout the life cycle and starting early habits that are formed make a difference in a lifelong way.

I think it is very important that the government lead the way with communicating critical information in terms of establishing guidelines and standards, and in many cases, mandating certain kinds of activities helping consumers to better understand the potential risks they are being exposed to is important and labeling of—

Senator SANDERS. What do we do about commercials, one of many examples, on TV which are encouraging kids to eat extremely unhealthy foods?

Dr. HAMBURG. I think that that is a bit beyond the scope of the FDA Commissioner, but it is a challenge. I think we know that what kids see on television, both infomercials and in the programming on television, influences behavior in ways that can be harmful to health.

Senator SANDERS. Correct me if I am wrong now. In New York State, there are fast food places obliged to indicate the calories of the food that they are serving?

Dr. HAMBURG. To be honest, I do not know the specifics. I know within New York City there have been activities undertaken—

Senator SANDERS [presiding]. I have seen that in New York City.

Dr. HAMBURG. Yes. I think it is an interesting and important model. It is one that I would like to learn more about. I think that the FDA has a very clear and important role in helping consumers to better understand the health quality of the food that they eat.

Senator SANDERS. My time has expired. Thank you very much, and I will certainly look forward to working with you in the years to come.

Senator CASEY. Dr. Hamburg, thank you very much for your willingness to serve. I want to commend you and your family for taking on this responsibility. I know this is not your first commitment to serve the public, but we are grateful that at such an important time in our country's history that you are willing to serve.

And I want to say to your extended and immediate family, thank you for helping her do this. I am speaking directly to your children. You are part of this, and your support for your mother is very important to the work that she is doing. She is serving your country and you are helping her do it, and we are grateful for that.

I wanted to focus really on one kind of broad issue. It is an issue that you addressed several times today and also, as well, in your testimony, at the bottom of page 2, onto page 3, food safety, in particular, the criticism which I do not think is isolated. I think there is a fairly substantial degree of consensus that there is at least concern about, if not a real hard and fast conclusion that many have reached—the authority to tackle or to confront the problems that arise with food presents. The authority for that and the mission for that does not reside in any one place, that it is too disparate or spread out. A, the lack of a single official who is working full-time on food safety; and B, kind of the direct line of authority but also budget authority.

This is an age-old challenge we have in any government, especially a government as large as ours at the Federal level. There are some parallels, obviously a much different challenge when it comes to homeland security, for example. A determination was made that we should put that under our roof, so to speak. It seems like almost every agency in government has these debates about who or what is in that direct line of authority.

I guess my question would be very simple. No. 1, do you believe that that needs to be corrected? Do you believe that that challenge of combating the problems with food safety needs to be in one person or one—some have recommended having a Deputy FDA Commissioner. If you either do not agree with that or have not had a chance to review—and you may not want to because you are just starting—would you make a commitment to examine it so you can report back to us?

Dr. HAMBURG. If confirmed, I would make one of my most immediate priorities looking at how FDA can further strengthen food safety and all of its component challenges. I think one piece of it, as you appropriately point out, is making sure that we have the right alignment of all the critical players both within FDA and the collaboration with all of the critical partners external to FDA. I do intend to look very closely at the organization of FDA and that we have the right team and expertise assembled to do what needs to be done.

I also really feel very strongly that the components of partnership are very key because, as you pointed out, many of the responsibilities for food safety span numerous agencies, USDA of course being the major partner, but there are other partners at the Federal level as well and then at the State and local level and then with industry. Food safety is a shared responsibility across many different players and throughout the entire life cycle of the food we eat from the farm that it is grown on through the processing and the production facilities, through the distribution and the handling, and finally, when it gets into our households and on our table.

I will be working very hard to strengthen food safety within FDA and would be delighted to discuss it further with you and other Members of Congress and welcome ideas and insights that all of you may have.

Senator CASEY. Thank you very much.

The other question I had was—and I am over time now. I will try to be brief— what you might call the magic wand question. If you had a magic wand and you could wave it to provide the resources and authority—not authority really, but just resources, budgetary resources that you would need. Where do you think the agency currently stands in terms of its resources to do the job you think it must do?

Dr. HAMBURG. I think that, unfortunately, for quite a long time now, the demands and the mission of FDA have far outstripped the available resources to enable FDA to do its job appropriately, efficiently, and with the kind of strength of scientists and personnel that we need. I know there is no magic wand, but I am eager to provide leadership to make sure that we have the best and the brightest staff and that we can not only recruit them, but that we can retain them, that we can strengthen our science base, which is so fundamental to all that we do, that we can restore the trust and confidence of the American people and of Congress in our ability to do the jobs before us. I look forward to taking on that challenge.

Senator CASEY. Thank you very much. Thanks for your public service, and good luck, as you get to the end of this process.

Dr. HAMBURG. Thank you.

Senator SANDERS. Let me conclude the hearing by wishing you the very best of luck. You are undertaking and going to be moving into a job of enormous consequence. There are very special interests out there who are prepared to spend huge sums of money and make a quick profit at the expense of the health and well-being of the American people. We look forward to working you to withstand that pressure.

Let me just say members are strongly encouraged to submit their questions for the nominee by close of business tomorrow. The record will remain open for 10 business days for additional statements.

The hearing is adjourned. Thank you very much for being with us.

ADDITIONAL MATERIAL

NATIONAL THREAT INITIATIVE (NTI),
WASHINGTON, DC 20006,
May 4, 2009.

Hon. EDWARD M. KENNEDY, *Chairman,*
Committee on Health, Education, Labor, and Pensions,
428 Senate Dirksen Office Building,
Washington, DC 20510.

Hon. MICHAEL B. ENZI, *Ranking Member,*
Committee on Health, Education, Labor, and Pensions,
428 Senate Dirksen Office Building,
Washington, DC 20510.

DEAR TED AND MIKE: I am writing to express my strong support for the nomination of Dr. Margaret A. (Peggy) Hamburg as Commissioner of the Food and Drug Administration.

Dr. Hamburg is a physician who is a nationally and internationally recognized leader in public health and medicine, and an authority on global health and safety, public health systems, infectious disease, bioterrorism and emergency preparedness. She has devoted her entire career to issues of protecting health and safety, and she did an outstanding job as New York City's Commissioner of Health and as Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services. At HHS, Peggy led the way in both sounding the alarm as to the danger of bioterrorism and laying the foundation for a governmental response. Understanding the connection between infectious disease and national security, she initiated an effort to connect health officials and security officials on a regular basis to greatly improve the government's crisis response capability. After leaving HHS, Peggy provided the leadership for the Nuclear Threat Initiative (NTI) and other NGOs to contribute to this nexus between health and security.

At NTI, which I co-chair, Peggy did an outstanding job launching and implementing our innovative biological program—now the Global Health and Security Initiative. Peggy has a rare and valuable talent for identifying emerging issues and developing creative and effective strategies to address them. She exerts firm leadership, but is a strong team player who is able to work effectively and collegially across many sectors, including government (local, State, Federal and international), industry (including the pharmaceutical and biotech industries), the non-profit sector, and academia.

Peggy has worked hard to raise awareness about naturally occurring and deliberately caused threats to public health, including food safety. She has been deeply engaged in designing a program to develop and make available new drugs, vaccines and diagnostics to strengthen our defenses against threats to public health, especially in the context of emerging biological threats. She has also helped lead the way in creating early warning surveillance and cooperation across borders.

My bottom line: Peggy has unquestioned integrity and good judgment and brings strong intellectual vigor to everything she does. She is a problem solver who has extensive public service experience, and she knows how to get things done. She is widely respected and is an excellent communicator. In addition, Peggy comes from a long line of distinguished public servants and is continuing the tradition of outstanding public service set by her parents Drs. David and Betty Hamburg.

I strongly recommend her to you, the committee and the Senate. I hope that you will give her nomination favorable consideration.

Sincerely,

SAM NUNN,
Co-Chairman and Chief Executive Officer.

[Whereupon, at 4:02 p.m., the hearing was adjourned.]

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