Opening Statement

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Commissioner-Designate of the Food and Drug Administration

Senate Committee on Health, Education, Labor, and Pensions

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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 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 development. 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.