Testimony
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A Nation Prepared: Strengthening Medical and Public Health Preparedness and Response

Statement of

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Good afternoon Chairman Harkin, Ranking Member Enzi, and distinguished Members of the Committee. I am pleased to be here today on behalf of the U.S Department of Health and Human Services (HHS) to testify on national public health preparedness and response. My name is Nicole Lurie and I serve as the HHS Assistant Secretary for Preparedness and Response. Today, I will discuss how critically important the Pandemic and All Hazards Preparedness Act (PAHPA; the Act) is to our public health preparedness and the progress we have made since its enactment in 2006.

First, I would like to recognize the Congress, and especially this Committee, for its strong leadership in advancing the public health and preparedness of our Nation by enacting this important legislation in 2006. PAHPA has supported our efforts to foster stronger, more resilient communities able to respond to and recover from public health emergencies. PAHPA established the foundation for a consolidated and thorough response to emergencies and HHS has since built on these authorities to ensure the nation has the tools necessary to save lives.

The Pandemic and All-Hazards Preparedness Act Established a Formalized Approach to Public Health Preparedness

PAHPA strengthened our country's foundation for public health preparedness by helping us fix some of the problems our nation encountered when preparing for and responding to disasters in the past. As we have seen from a variety of recent emergencies and disasters as of late – including tornados, floods, influenza pandemic,

earthquakes, damage to a nuclear facility and a large oil spill – there is always a significant impact to the public's medical care and public health.

The Pandemic and All-Hazards Preparedness Act has been instrumental to support State and local preparedness and response efforts. Since the passage of the Act, HHS has implemented a number of initiatives to strengthen preparedness and response efforts. We look forward to working with you on improvements to strengthen our public health and medical preparedness and response.

The Pandemic and All-Hazards Preparedness Act designated the HHS Secretary as the lead federal official for public health and medical response to emergencies and incidents covered by the National Response Plan and its successor plans, and created my office, the Office of the Assistant Secretary for Preparedness and Response (ASPR). Under the Act, ASPR serves as the principal advisor to the Secretary on all matters related to federal public health and medical preparedness and response and plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our federal interagency partners.

Guided by the authorities in PAHPA, HHS established organizational priorities and enhanced its operations and response capabilities. Moreover, to carry out PAHPA authorities, ASPR's mission was defined as leading the country in preparing for, responding to, and recovering from health effects of emergencies and disasters by supporting our communities' abilities to withstand adversity, strengthening our health and response systems, and enhancing national health security. The future of federal

public health and medical preparedness and response is a "whole community" approach. This approach requires that we institutionalize community resilience by building practices nationally that strengthen preparedness efforts implemented by local institutions including state and local government and private sector partners; creating a fundamental body of knowledge for preparedness, response, and recovery; and encouraging innovative efforts to build the nation's capacity to stabilize and recover from an event. We are also working to ensure that our public and private sector partners are promoting a culture of budget preparedness to quickly and efficiently get resources where they are needed before and after a disaster.

The National Health Security Strategy Established a Common Strategic Framework to Align National Preparedness Efforts

Since the enactment of PAHPA in 2006, HHS has had many significant accomplishments preparing for and responding to public health incidents. To help better align efforts internally, support and promote coordination efforts with federal, state, local, and private sector partners, and be efficient stewards of federal dollars, in December 2009 we released the *National Health Security Strategy* (NHSS*)* – a blueprint for preparedness and response. PAHPA required the completion of a NHSS as a first step in ensuring we have a fully integrated and coordinated strategy to address how various sectors of our medical and public health systems will work together to respond to emergencies and save lives.

The principle at the heart of the strategy is that our public health security is about ensuring resilient communities; health systems that coordinate and work together during disasters; and public and private sectors working together. National health security is a shared responsibility – from individuals and families, to private industry, to every level of government. It recognizes that to build community resilience we need effective public health systems working seamlessly in collaboration with a strong healthcare system. The NHSS also promotes building more resilient communities by including at-risk populations in planning and day-to-day operations. Supporting this strategy, HHS has taken steps to ensure that at-risk individuals – children, pregnant women, senior citizens, individuals with disabilities, and others who have special needs – are included in all planning scenarios, guidance documents, plans, and will be effectively treated in the event of a public health emergency.

Recognizing that we have learned a great deal about these strategic planning processes in the past four years, we are interested in efforts that enhance operational and long-term planning efforts while also streamlining requirements. In support of the principles of the NHSS, state and local jurisdictions have operational plans that describe operations during pandemic influenza incidents. These plans – required by PAHPA – include a framework that guides communications and logistics, and coordinates general response efforts during pandemic influenza incidents. At the time PAHPA was enacted, these plans were a relatively new concept – the original provision was to ensure that any plan in place was strong and relevant. To ensure the nation is prepared for threats beyond pandemic influenza, we believe these plans should include planning for all-hazards.

The Medical Countermeasure Review Established the Strategic and Operational Plan for HHS Countermeasure Preparedness

To ensure the nation has adequate countermeasures available to respond quickly and efficiently following a chemical, biological, radiological, nuclear (CBRN), or other public health emergency, HHS released the *Public Health Emergency Medical Countermeasures Enterprise Review* (MCM Review) in August 2010. The MCM Review identifies "processes, policies, and activities required to take a product concept derived from a national requirement through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling." This ground-breaking review looked across the entire spectrum of product development, from early discovery through regulatory approval, and identified the chokepoints where product development was stalling or failing. To address these chokepoints, which create technical, business, and regulatory risks for small innovator companies and form the basis of the medical countermeasure "valley of death," the MCM Review proposes:

- The establishment of a Concept Acceleration Program at the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases to work with partner agencies, academic researches, biotechnology companies, and large pharmaceutical companies to identify promising scientific discoveries and expedite their transformation into practical, usable products;
- The establishment of a nonprofit Strategic Investor firm to spur innovation and create a viable biodefense business sector by supporting companies that possess strategic technologies applicable to both commercial and government

needs, but which might otherwise lack the necessary financial capital or business acumen to develop a commercially-viable, approved product;

- The establishment of U.S.-based Centers for Innovation in Advanced Development and Manufacturing; and,
- An increased investment in regulatory sciences and review capabilities at the Food and Drug Administration (FDA) focused on pandemic influenza, chemical, biological, radiological, and nuclear (CBRN) medical countermeasures (MCMs).

The Concept Acceleration Program (CAP) will leverage existing intramural and extramural research programs as well as applied and translational resources throughout the NIH, Centers for Disease Control and Prevention (CDC), FDA, and Department of Defense (DoD) to expedite the translation of promising concepts into candidate MCMs. We are committed to applying $50M towards CAP activities in FY11. Evaluations are in progress to identify CAP biological product candidates.

With congressional authorization, the Strategic Investor initiative will spur innovation and provide the kinds of business and financial services and support that venture capital firms typically provide, while mitigating the risk that biotechnology firms face. The Strategic Investor initiative will promote the transition of MCM development and procurement from a “one bug, one drug” approach to an enterprise capable of responding to any threat at any time. It is important to note that the Strategic Investor is intended to work in concert with the BioShield program, not replace it.

In March, we published a request for proposals for the Centers for Innovation in Advanced Development, that we will create to reduce risk, increase domestic manufacturing and surge capacity for MCM, and reduce total life-cycle costs through flexible manufacturing. These U.S.-based Centers are expected primarily to provide, on a routine basis, core services to commercial partners who collaborate with HHS's Biomedical Advanced Research and Development Authority (BARDA). These services include advanced development and manufacturing capabilities and other technical services needed by the developers of medical countermeasures for MCMs to address national preparedness and response priorities and needs. In the event of a pandemic, the Centers will also be available to manufacture influenza vaccine and other biologics, as well as provide training opportunities for the pharmaceutical workforce.

Finally, expanding regulatory science and review capabilities at the FDA will strengthen and clarify the MCM regulatory process, which will expedite MCM development and availability. Regulatory uncertainty is a major barrier to engaging MCM developers in the MCM Enterprise. This initiative will provide private sector partners with greater access to regulators and greater clarity about the pathways to product approval, which will reduce uncertainty and foster greater engagement and program success.

Collectively, once implemented, these initiatives will help us establish a more nimble and diversified approach in preparing for and responding to CBRN, pandemic influenza and other public health threats.

PAHPA Helped Spur Development and Procurement of Medical Countermeasures

Prior to PAHPA, the Project BioShield Act of 2004 authorized the Project BioShield program and established the Special Reserve Fund (SRF). The Project BioShield Act provides additional and more flexible authorities and funding to support and expedite the development and procurement of CBRN medical countermeasures. The SRF is a secure funding source for the procurement of critical medical countermeasures, such as vaccines, therapeutics, and diagnostics that are close to or have achieved licensure. The SRF, as industry partners and other non-governmental stakeholders have continually asserted, is a market guarantee for medical countermeasure development and clearly demonstrates U.S. Government's commitment to the procurement of security countermeasures. Finally, the Project BioShield Act provides the Secretary with the authority to authorize the emergency use of unapproved products or the unapproved use of approved products, if certain standards are met.

Since its inception, we have drawn steadily on the use of Special Reserve Funds and have developed and procured:

- Anthrax therapeutics and vaccines;
- Heptavalent botulinum antitoxin;
- Smallpox vaccine for immunocompromised persons; and
- A number of MCM products intended for use after radiological or nuclear events.

PAHPA included authorities that strengthened Project BioShield and HHS was able to leverage these authorities to promote successful collaboration and procurement to keep

the nation safe against CBRN threats. In order to improve the federal coordination of government policy, investments, and activities related to the development and procurement of medical countermeasures for CBRN threats, in July 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). ASPR leads the PHEMCE, which includes principal representatives of CDC, FDA, and NIH. PHEMCE also includes key interagency partners from DoD, the Department of Homeland Security (DHS), the Department of Veterans Affairs (VA), and the Department of Agriculture (USDA).

The overarching mission of PHEMCE is to:

- Define and prioritize requirements for public health emergency medical countermeasures;
- Coordinate research, early and late stage product development, and procurement activities addressing these requirements; and
- Set deployment and use strategies for medical countermeasures held in the Strategic National Stockpile (SNS).

Using its Advanced Research and Development (ARD) authority, HHS bridges the "valley of death" funding a gap that exists between the early stages of product development and the procurement of medical countermeasures under Project BioShield. Congress recognized that since commercial markets do not exist for many of the products we are trying to develop, robust funding for ARD is essential if we are to build and sustain a substantial pipeline of products to diagnose and treat illness, or prevent the effects of CBRN agents. Current priority investment areas include anthrax

vaccines and treatments, broad spectrum antimicrobial drugs, and treatments and diagnostics for illnesses associated with exposure to radiation. In FY 2012, the President's Budget requests $765M from Project BioShield balances to support these priorities.

While the imminent threat of H1N1 influenza has subsided, avian influenza viruses continue to circulate, and critical work continues to prepare for the next influenza pandemic. One of the functions of the Centers for Innovation in Advanced Development and Manufacturing mentioned earlier, in addition to providing development and manufacturing of medical countermeasures to CBRN threats, will be to expand domestic pandemic influenza vaccine manufacturing surge capacity. HHS continues to develop flu antiviral drugs and vaccines and a more robust domestic vaccine manufacturing capability. We are focused on ensuring the nation has access to safe and effective vaccine as soon as possible following the start of an influenza pandemic. We continue to implement strategies that work toward producing influenza vaccine more rapidly during an influenza pandemic, including the development and implementation of more rapid testing methods for vaccine release and the establishment of domestic recombinant and cell-based vaccine manufacturing capabilities. Supporting this effort, shortening the time frame for vaccine availability with new and faster product testing and next generation influenza vaccines made in the US will achieve better products faster. I am pleased to inform you that we are already making great progress in these efforts.

HHS Has Significant Accomplishments Since The Enactment of PAHPA

We have accomplished much since the passage of PAHPA and were able to respond to a number of public health emergencies including:

- The first pandemic in 40 years;
- An earthquake in the western hemisphere's poorest country;
- The largest oil spill in history;
- The 2011 Japan earthquake, tsunami, and associated radiological contamination event; and,
- Other domestic events including hurricanes, floods, and tornadoes.

In addition, as I mentioned previously in my testimony, we were also successful in procuring and stockpiling medical countermeasures to protect against CBRN threats, as well as against pandemic influenza and other emerging infectious diseases.

Since I was sworn in as the Assistant Secretary for Preparedness and Response, one thing has been clear - the investments we've made in the last decade have had a positive effect on our ability to respond to emergencies. In each response, HHS provided support to state, local, or international partners and in return learned valuable lessons to guide future response operations. We are working internally to strengthen and incorporate the lessons learned from these and other recent responses to ensure future response efforts are enhanced.

The Japanese earthquake and subsequent nuclear reactor crisis is an example of a catastrophic scenario that would present formidable public health and healthcare challenges to the U.S. should such an event occur here. We already knew the importance of deploying medical countermeasures as quickly as possible following an incident. However, as a result of this crisis, we have expedited efforts internally to ensure adequate countermeasures are stockpiled and can be deployed as soon as possible following incidents. It is critical that we have the flexibility to use and deploy countermeasures as soon as possible following the start of a public health incident to help reduce morbidity and mortality.

Beyond medical countermeasures, many lessons learned during our 2009 H1N1 pandemic response will strengthen HHS's ability to respond to other emergency events. The 2009 H1N1 experience stressed the interdependence of the public health, pre- and post-hospital care, primary care, hospital care systems and community and business organizations. It also confirmed the need for a "whole of community" approach in planning and responding to a disaster, and confirmed that, going forward, we must address the entire healthcare community in our preparedness activities. The Department is considering proposals to strengthen the ability for medical and public health professionals to be of assistance in an emergency situation.

Lastly, after our response to the Haiti earthquake we have taken actions to: streamline internal operations to ensure providers are adequately supported; provide needed services quickly and efficiently following disasters; and, ensure we have access to information that supports surveillance of the spread of illness. I am pleased to inform

you that we have been working to strengthen the National Disaster Medical System (NDMS). NDMS is a Federally-coordinated system closely linked to the Hospital Preparedness program that augments the Nation's medical response capability. The primary purpose of the NDMS is to supplement an integrated National medical response capability for assisting State and local authorities in dealing with the medical impacts of major peacetime disasters. NDMS now uses an Electronic Medical Record (EMR) system that standardizes record keeping and promotes enhanced health surveillance during disasters. This, and other enhancements we have made, enable us to better identify population needs as we respond, including in the area of pediatrics. These developments in identifying the needs of populations, specifically pediatric and at-risk populations, will support a better and more focused response in the future.

All of the accomplishments I have just described were supported through the close collaboration of many HHS partners including CDC, NIH, FDA, ASPR as well as the Centers for Medicare and Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Indian Health Service (IHS), just to name a few.

HHS has a number of programs and tools that aid state and local response and coordinate efforts during disasters. The ASPR Hospital Preparedness Program (HPP) has advanced the preparedness of hospitals and communities in numerous ways, including through planning for all-hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners. We

recently issued a report on the Hospital Preparedness Program that describes the achievements of our state partners in building healthcare preparedness across the nation, and illustrates how states have used the capabilities developed and funded through the program in both large and small incidents. One specific accomplishment detailed in this report is that more than 76 percent of hospitals participating in the HPP met 90 percent or more of all program measures for all-hazards preparedness in 2009. This is a significant accomplishment and clearly demonstrates participants' commitment to investing in preparedness. Copies of this report were provided to each Member of the Committee in advance of this afternoon's hearing.

In addition to HPP, CDC's Public Health Emergency Preparedness (PHEP) cooperative agreements provide funding to enable state and local public health departments to have the capacities and capabilities to effectively respond to the public health consequences of not only terrorist threats, but also infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies.

To promote coordination and efficient use of resources, we are working together to determine the best path forward for alignment of the HPP and PHEP grant programs to ensure we are efficient with resources and that we eliminate duplicative or conflicting programmatic and administrative efforts for grantees. Once we complete our internal alignment process, we will engage interagency partners to examine additional opportunities for synergy with other federal preparedness grants. Consistent with Presidential Policy Directive 8, we are working toward a framework for priority-setting, review, and reporting measures; development of a common pathway to focus dollars,

measure outcomes, reduce duplication, and enhance return on investment and reporting; and enhanced data sharing for improved situational awareness during a response.

PAHPA authorized the HPP and PHEP grant programs. These programs, as I have just mentioned, are critical to ensuring state and local jurisdictions have the tools and resources to prepare for public health incidents.

Conclusion

The experiences since the passage of PAHPA have shown clearly that every part of the public health and medical community is critical to building resilience. We applaud Congress' wisdom in enacting PAHPA as the foundation for this approach, which is so critical to our preparedness.

At this time I would be happy to address any questions you may have.