Written Testimony
Senate Health, Education, Labor, and Pensions (HELP) Committee

Medical and Public Health Preparedness and Response: Are We Ready for Future Threats?

Statement of

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Good morning Senator Burr, Ranking Member Casey, and other distinguished Members of the Committee. I am Dr. Nicole Lurie and I serve as the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services (HHS).

I appreciate the opportunity to talk to you today about the Office of the Assistant Secretary for Preparedness and Response (ASPR) and its accomplishments in moving the country forward in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters. Recognizing lessons learned from disasters including the terrorist attacks on 9/11, the anthrax attacks in 2001, and Hurricane Katrina, ASPR and its predecessor agency were established to improve coordination and direction across the spectrum of HHS preparedness and response Activities. Under the Public Health Service Act, as amended by the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) and the Pandemic and All-Hazards Reauthorization Act of 2013 (PAHPRA), ASPR was established as the lead for HHS emergency preparedness and response and serves as the principal advisor to the Secretary regarding Federal public health and medical preparedness and response to public health emergencies.

INTRODUCTION

Over the past six years, ASPR has significantly advanced the Nation's preparedness, contributing to enhanced response and more resilient communities that are better prepared to recover from an emergency or natural disaster. We have found innovative ways to identify and protect vulnerable populations, including targeted approaches for children, pregnant women, and people with special medical needs, like those who need dialysis or electrically dependent durable medical equipment. We restructured the National Disaster Medical System teams so they are more flexible, are pediatrics capable, and can provide other specialized capabilities to assist

communities after disasters. We developed and now use innovative approaches to stimulate private sector interest in partnering with us to develop medical countermeasures to protect against threats to health. ASPR and the Centers for Disease Control and Prevention (CDC) aligned preparedness grants to State and Local partners to reduce their administrative burden and maximize the return on investment and are building new tools to assist hospitals and other healthcare coalition members in meeting the medical and public health needs of their communities. Today, we integrate behavioral health into our response to every disaster, recognizing that community-level recovery depends on individual ability to cope with the impacts of disasters. We are galvanizing the scientific community to be ready to conduct research quickly to answer the tough questions your constituents will have for you about their health after disasters.

These advances – vital to our Nation's health security – have been supported and made possible by the authorities provided in PAHPA and PAHPRA and an incredible team of men and women who comprise ASPR. Under these authorities, ASPR's responsibilities are broad, and include: overseeing advanced research, development, and procurement of resulting medical countermeasures, coordinating with health care systems, and providing integrated policy and strategic direction under the National Response Framework. In addition, ASPR directs medical and, with CDC, public health grants and cooperative agreements, provides leadership in international programs and policies with global impact, and has developed and submitted a 5-year budget plan for countermeasure priorities. ASPR oversees the National Disaster Medical System (NDMS), the Hospital Preparedness Cooperative Agreement Program (HPP), and the Biomedical Advanced Research and Development Authority (BARDA). And, through guidance

documents like the National Health Security Strategy (NHSS) and Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP), ASPR leads the path forward for our partners and stakeholders.

Since PAHPRA was passed in 2013, ASPR has provided to the Congress critical requested deliverables including a new National Health Security Strategy for 2015 to 2018, and a National Health Security Review for 2010 to 2014. In addition, ASPR provided a five year Medical Countermeasure budget plan, a new PHEMCE SIP, an Interagency Coordination Plan with the Department of Defense regarding medical countermeasures, established a new National Advisory Committee on Children and Disasters, and issued guidelines for temporary reassignment of state and tribal public health personnel, state pandemic influenza plans, a public health and medical situational awareness strategy, and an annual review of the Strategic National Stockpile (SNS).

IMPROVING THE MEDICAL COUNTERMEASURE ENTERPRISE

Recently, my office released the 2014 PHEMCE SIP, which guides medical countermeasure priorities for short, middle, and long term projections. The PHEMCE is one of many great examples of ASPR's whole-of-government approach. In 2006, ASPR established the PHEMCE to be the single Federal coordinating body that oversees the entire medical countermeasure lifecycle across the various Federal departments and agencies. My office manages the PHEMCE in partnership with other HHS agencies including the National Institutes of Health (NIH), the Food and Drug Administration (FDA), CDC, and BARDA, along with interagency partners such as the Department of Defense (DoD), the Department of Homeland Security (DHS), the

Department of Agriculture (USDA), and the Department of Veterans Affairs (VA). Prior to the PHEMCE, Federal efforts were fragmented, and collaboration with our industry partners was limited. With a variety of potential threats requiring substantial investment, we needed a method to make sure we were not wasting resources on duplicative ventures. The resulting governance process and decision framework provides means to coordinate across government, prioritize investments, and get results.

As you know, HHS recently provided estimated funding requirements for HHS PHEMCE agencies, including NIH, ASPR/BARDA, FDA, and CDC, in the first-ever PHEMCE multi-year budget. The multi-year budget describes a plan for funding BARDA's Advanced Research and Development programs and Project BioShield over five years; to maintain the current level of preparedness at the SNS; to continue the NIH investments in biodefense basic research and development; and to sustain FDA's Medical Countermeasure Initiative, initially recommended by the 2010 PHEMCE Enterprise Review. It is a critical companion to the PHEMCE SIP in accurately projecting the resource estimates required for end-to-end medical countermeasure life-cycle management as a product, or candidate product, moves through development, licensure, acquisition, and stockpiling.

THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Coordination made possible through the PHEMCE continues to drive progress and success in making medical countermeasures available. BARDA has made great progress, from a time when there were almost no medical countermeasures in the pipeline, to a robust pipeline with over 160 candidate medical countermeasures for chemical, biological, radiological, and nuclear (CBRN)

threats and pandemic influenza. Eight of these products have received FDA approval in the last three years including countermeasures for anthrax, botulinum and pandemic influenza. Moreover, BARDA procured twelve novel medical countermeasures for the SNS through Project BioShield, including those for smallpox, anthrax, botulinum, radiologic/nuclear emergencies and chemical events. Since 2007, BARDA has supported the development of 18 influenza medical countermeasures, including those used during the 2009 H1N1 pandemic and others stockpiled for potential avian influenza H5N1 and H7N9 outbreaks.

We are on a trajectory to make available twelve new medical countermeasures through Project BioShield procurements in the next five years. These medical countermeasures include next generation anthrax vaccines, new smallpox vaccines, biodosimetry diagnostic devices, thermal burn radiation drug and skin replacement therapies, radiation cell therapies, new antibiotics to counter the ever growing public health threat from antimicrobial resistance, and new chemical antidotes.

We have moved from a one-bug, one-drug approach in countermeasure development, to a capabilities based approach in which we are able to make novel medical countermeasures when they are most needed during an emergency. With the establishment of the three Centers for Innovation in Advanced Development and Manufacturing in 2012 and a Fill Finish Manufacturing Network comprised of four aseptic filling manufacturers in 2013, we are developing, manufacturing, and filling medical countermeasures for CBRN threats like anthrax, for emergency situations like pandemic influenza like the H7N9 vaccines in 2013, and for emerging infectious diseases. In keeping with the parameters of our public-private partnership,

these state-of-the-art facilities may also be used by our private sector partners to develop new vaccines and drugs for the open market.

We've also made huge progress in pandemic influenza preparedness. In 2004, the Nation had a single domestic influenza vaccine manufacturer. Due to planning, foresight and support across the Federal Government, and robust public-private partnerships, we now have robust and rapid domestic manufacturing capacity for pandemic influenza vaccines, capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats.

EMERGENCY PREPAREDNESS AND RESPONSE

HHS is the coordinator and primary agency for the Public Health and Medical Services Emergency Support Function of the National Response Framework. Our day-to-day work involves supporting local and state partners to build stronger, more resilient communities. Ultimately, communities should be able to respond to a wide-range of threats to public and medical health emergencies on their own, limiting the need for Federal assets to augment response. Critical to this effort is the National Hospital Preparedness Program – or HPP, which strengthens the day-to-day activities necessary to maintain readiness by providing resources to state, territorial, and local awardees.

Over the last few years, ASPR has shifted the focus of HPP from preparing one hospital at a time to preparing all of the healthcare entities in a community through Health Care Coalitions. Health Care Coalitions are formal, collaborative networks of hospitals, health care organizations, public health providers, emergency management, emergency medical services, and other public and private sector health care partners within a defined region. We saw the importance of this first

hand, during Hurricane Sandy, when nursing homes and hospitals needed to evacuate, and mobile satellite emergency units funded in part by HPP were used to relieve pressure on the remaining facilities. Further, hospitals can now communicate with other responders through interoperable communications systems; track bed and resource availability using electronic systems; protect health care workers with proper equipment; train health care workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises. There are many more examples of how HPP has demonstrated a return on investment, notably during the outbreak of fungal meningitis in Michigan; the ammonium nitrate explosion at a fertilizer facility in West, Texas; and during the bombings at the Boston Marathon.

ASPR HAS FOUCUSED ON THE NEEDS OF AT-RISK POPULATIONS

The underlying goal of my office is to make sure our Nation is secure and resilient when confronting diverse incidents with challenging health consequences. The National Health Security Strategy guides the Nation in achieving that goal. The first NHSS was submitted to the Congress in 2009. The second quadrennial report builds on the lessons of the first four years, and was submitted to the Congress, on time, in December 2014.

Central to the NHSS is the understanding that resilient communities include healthy individuals and families with access to health care, both physical and psychological, during routine and emergency situations. Enhanced resilience is critical to mitigating vulnerabilities, reducing negative health consequences, and rapidly restoring community functioning. ASPR provides subject matter expertise, education, and coordination to make sure the functional and access

needs of at-risk individuals and behavioral health issues are integrated with national public health and medical emergency preparedness, response, and recovery Activities, as required by PAHPA and PAHPRA.

ASPR works to promote strategies for building individual and community resilience that are inclusive of both behavioral health and the functional needs of at-risk individuals. Such strategies will improve communities' ability to maximize resources, meet needs, and recover from the adverse health consequences of public health emergencies and disasters at the individual and community levels. PAHPRA provided my office with the tools necessary to strengthen our capabilities and highlighted the need to address the risks and challenges faced by children during emergencies and disasters. Just this past year, we established the National Advisory Committee on Children and Disasters to further address the public health needs of children affected by disasters, a critically important component of our response efforts.

CONCLUSION

In the past six years, we have learned many things about how to become more prepared, how to respond more effectively, and how to recover faster. However, it is critical that we recognize that there is no end point in preparedness—and that maintaining a strong, steady state of preparedness is our new normal. Our objective has been to create a system of flexible and nimble capabilities which can be used in response to the range of threats we face. PAHPA and PAHPRA have given us many of the tools we need, from programs like HPP and BARDA to authorities like emergency use authority (EUA) flexibility. We have used each and every one of them, including in the Ebola crisis. We appreciate the support and partnership we have had with

this committee and with the Congress and look forward to continuing to work together to enhance our Nation's health security.