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The Public Health Emergency Medical Countermeasures Enterprise

Statement of

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Chairman Kingston, Ranking Member DeLauro, and distinguished Members of the Committee, thank you for inviting me to testify on behalf of the Department of Health and Human Services (HHS) regarding the Public Health Emergency Medical Countermeasures Enterprise, also known as the PHEMCE.

Over the past ten years, we have made significant advances in the research, development, procurement, and distribution of medical countermeasures (MCMs) to address a wide range of naturally occurring and manmade threats, ranging from accidental releases to terrorism-induced. Congressionally supported initiatives such as the establishment of Project BioShield in 2004, the development of a national strategy to respond to pandemic influenza in 2005, and passage of the Pandemic and All-Hazards Preparedness Act in 2006 and its reauthorization in 2013, have provided valuable guidance and resources to address the potentially devastating consequences of a public health emergency. As a result of our efforts, twelve new, critical MCMs have been developed and delivered to the Strategic National Stockpile (SNS) including those for anthrax, smallpox, botulism toxin, and radiological and nuclear agents. These innovative countermeasures will allow our nation to better respond to emergencies, save lives, and mitigate illness. These achievements would not have been possible without federal interagency collaboration through the PHEMCE.

Established in 2006, the PHEMCE is the federal coordinating body that oversees the whole MCM lifecycle and assures that federal departments and agencies are not only coordinated, but working well together. The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR), in partnership with other HHS agencies, the National Institutes of Health (NIH), the Centers for Disease Control

and Prevention (CDC), and the Food and Drug Administration (FDA), and our interagency partners, the Department of Defense (DoD), the Department of Homeland Security (DHS), the Department of Veterans Affairs (VA), and the Department of Agriculture (USDA). Prior to the PHEMCE, federal efforts were fragmented and collaboration with our industry partners was limited. Through implementation of the 2007 and 2012 *PHEMCE Strategy* and *Implementation Plan* and the recommendations of the 2010 Secretary's Medical Countermeasure Review, the PHEMCE has become a model for innovative governance and accountable decision-making.

PHEMCE coordination and decision-making extends to encompass all stages of the MCM pathway, from identification of requirements for particular types and quantities of MCMs, through product development, and ultimately to distribution and use. All of these efforts are collaborative; agencies coordinate activities within their mission space and ensure smooth handoffs as products move from stage to stage. PHEMCE partners meet at least monthly to provide input into each stage of the process, develop plans and assessments, and centrally track implementation to ensure accountability. This level of coordination reduces duplication of effort and fragmentation. One notable example of this is the PHEMCE Integrated Portfolio for CBRN MCMs, which aligns the DoD and HHS advanced research and development programs across the civilian and military populations. This unprecedented collaboration allows both departments to pursue their distinct mission space while harmonizing overall objectives.

The lifecycle of a new MCM typically begins with risk assessment and requirements setting. DHS conducts the threat and risk assessments that result in Material Threat Determinations, which are required for procurement of MCMs under

Project BioShield; ASPR and other PHEMCE partners then use these assessments to establish MCM requirements Based on these requirements, NIH shapes its investment strategy for new product research and discovery. Utilizing the early stage research funded by NIH and DoD, the Biomedical Advanced Development and Research Authority (BARDA, a component of ASPR) provides support to industry through advanced development programs. Once a product is ready, it moves forward for FDA approval to ensure that it is safe and effective. The culmination of this process is the stockpiling of FDA-licensed or approved products by the CDC in the SNS for use in an emergency. Once the products are delivered to the SNS, CDC develops operational plans to ship products to public health officials and clinical sites, where clinicians and responders will distribute them to individuals in need of medical care. These plans are integrated into the preparedness planning activities of all PHEMCE partners. In addition to the stockpiling and distribution through CDC, DoD and the VA procure and distribute products. Throughout, USDA works closely with HHS to address the zoonotic threats that may affect both animals and humans, such as highly pathogenic avian influenza.

The PHEMCE's ability to coordinate across the pipeline extends beyond our federal interagency to encompass public-private partnerships. As articulated in the Secretary's Review, the nation "must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat;" this is only possible through close and continuing collaboration with our industry partners. The PHEMCE has promoted a number of innovative mechanisms for information sharing. For example, working with the FDA, we have clarified regulatory pathways and improved regulatory science to provide industry with the information they need to help move their products toward FDA

approval. All of our PHEMCE partners meet regularly with the private sector in a wide-range of forums, such as the annual BARDA Industry Day.

Above all, the PHEMCE must support the federal government's mission to preserve and protect people's lives against a wide range of dangerous threats and do so as good stewards of taxpayer dollars. The PHEMCE has thus developed a governance process and decision framework to ensure accountability and maximize the return on investment. PHEMCE leadership established criteria to ensure the maximum benefit to the health of the public, these include (1) addressing the most significant threats, (2) fostering approaches with the potential to provide protection against multiple important threats, and, (3) maintaining the capability to effectively use the assets developed in the envisioned operational setting.

As we look to the future, the PHEMCE continues to explore innovative ways to enhance the MCM pipeline and better serve the American public. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) requires HHS to develop, and make available to Congress upon request, a five-year budget plan on the medical countermeasure enterprise. This multiyear plan is a tool for strategic project coordination, product transitions between agencies, communicating priorities and resources to partners stakeholders, and assisting with long-term forecasting..

The goal of the multiyear plan is to outline PHEMCE programmatic estimates on a five-year rolling basis and to identify the hand-offs in the development cycle in anticipatable budget terms. This forecast allows agencies to understand the dynamic effects of PHEMCE decisions on their own strategic planning and those of downstream partners. Forecasting can also inform the PHEMCE members of the effects of funding

on MCM availability in future years. For example, through a multiyear plan, the PHEMCE can forecast the programmatic goals of the SNS assuming various funding levels for Project BioShield. Additionally, this tool communicates the PHEMCE's commitment and priorities to our industry partners for their own planning purposes. By coordinating resources and priorities, we can ensure an active MCM industry that meets our essential needs for a nimble and flexible response capability.

The American people depend on HHS to protect against public health threats such as bioterrorism and emerging infectious diseases. A vibrant MCM enterprise, from end to end, is critical to our ultimate objective: a resilient nation prepared to respond to and recover from a wide range of potential threats. Since 2006, the PHEMCE has succeeded in establishing a strong pipeline of over 150 MCMs in all stages of development. Because of the PHEMCE's collaboration, communication, and accountability efforts, we now have a wider range of tools to address an ever-expanding list of threats but additional work remains. The PHEMCE is providing a roadmap for research, development, and procurement, to enable our federal and industry partners to prioritize resources and planning to fill those gaps. The true value of the PHEMCE to the nation may be in large-scale, public-private collaboration that enables us to evolve to meet the next treat, whatever that may be. Going forward, we will continue to refine our capacity and work towards meeting the expectations of Congress and the needs of the American people.