



**Testimony**  
**Subcommittee on Emergency Preparedness,**  
**Response and Communications**  
**Committee on Homeland Security**  
**U.S. House of Representatives**

**HHS Efforts to Prepare for and Protect Against  
CBRN Threats**

*Statement of*

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Good afternoon Chairman Bilirakis, Ranking Member Richardson, and distinguished Members of the Subcommittee. Thank you for inviting me here today to testify on the Department of Health and Human Services' (HHS) efforts to prepare for and protect against chemical, biological, radiological, and nuclear (CBRN) threats. My name is Richard Hatchett and I serve as the Chief Medical Officer and Deputy Director for Strategic Sciences and Management at the HHS Biomedical Advanced Research and Development Authority. I am pleased to join my Department of Homeland Security and Department of Defense colleagues, as well as the Government Accountability Office, to discuss these very important issues. The threats that our nation faces continue to evolve, and we know that we cannot identify and characterize them all in advance. It is critical that we have the capability, as a nation, to be resilient when disaster strikes – and to be resilient, we must be able to respond quickly and effectively to all disasters with the appropriate resources necessary to limit casualties and disruptions to communities.

## **INTRODUCTION - ASPR/BARDA MISSION**

The HHS Assistant Secretary for Preparedness and Response, Dr. Nicole Lurie, serves as the principal advisor to the Secretary on all matters related to federal public health and medical preparedness and response for public health emergencies. The Office of the ASPR (or ASPR) promotes community preparedness and resilience; builds public health partnerships with federal departments and agencies, State and local governments, non-governmental organizations, academic institutions and private sector partners; and coordinates federal public health and medical response capabilities.

Within ASPR, the Biomedical Advanced Research and Development Authority (BARDA) is responsible for developing and procuring safe and effective medical countermeasures (MCMs) against CBRN threats, pandemic influenza, and emerging infectious diseases. A principal BARDA responsibility is to help bring promising MCMs through the so-called “valley of death.” The “valley of death” describes a period of time during MCM research and development when promising innovative technologies fail to advance to a marketable product due to entrepreneurial capital shortage or other similar cause. Left to their own devices and resources, most of our small biotech partners would find that the “valley of death” poses a nearly insuperable set of financial, technical, and regulatory challenges. BARDA provides the financial and technical resources our partners need to address these challenges. BARDA supports medical countermeasure activities such as industrialization, non-clinical and clinical testing, development of manufacturing technologies and scale-up, submissions for FDA regulatory review, and procurement for the Strategic National Stockpile (SNS). BARDA works closely with its HHS partners at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), as well as at the Department of Defense (DoD) and the Department of Homeland Security (DHS) to ensure the Nation has appropriate MCMs to save lives during a CBRN event.

As the BARDA Chief Medical Officer and Deputy Director for Strategic Sciences and Management, one of my primary responsibilities is to ensure we have safe and effective medical countermeasures available for our response efforts. One of the key avenues BARDA uses to align its work with that of our HHS and interagency partners is the HHS

Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE, which encompasses the development, manufacturing, production, stockpiling, and deployment and use strategies of products deemed critical to protecting or treating our population against a variety of CBRN threats, as well as against pandemic influenza and other emerging infectious diseases. My written testimony discusses the PHEMCE MCM requirements setting process; BARDA's MCM procurement and advanced research and development efforts; our collaboration with federal partners and outreach efforts to industry; and identified gaps and challenges related to MCM development and procurement and how we are addressing these challenges.

## **THE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE**

In July 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise to improve the federal coordination of government policy, investments, and activities related to the development and procurement of medical countermeasures for CBRN threats. The overarching mission of the 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 SNS.

ASPR leads the PHEMCE, which includes the CDC, the FDA, and the NIH. The PHEMCE also includes key interagency partners from DHS, DoD, the VA, and the USDA. The PHEMCE uses a decision forum named the Enterprise Senior Council (ESC) for MCM policy and implementation development. The ESC is chaired by the ASPR and is comprised of the senior leadership of the Enterprise. Together, the PHEMCE organizations and agencies work to improve our preparedness for public health emergencies with respect to the development, stockpiling, and use of medical countermeasures.

### **PHEMCE MCM Requirement-Setting Process**

Simply stated, medical countermeasure requirements answer the questions of “**What do we need, and how much should we buy?**” For CBRN threats, these MCM requirements serve two critical functions:

- to improve the outcome of public health emergencies by focusing MCM activities across a wide range of key stakeholders, and
- to align the multibillion-dollar investments of the NIH, BARDA, and CDC in the discovery, advanced development, acquisition, deployment, and use of MCMs; and
- to coordinate programs effectively with interagency partners at USDA, VA, DoD and DHS.

The current PHEMCE MCM requirements process includes the following activities:

- **Threat Assessments.** DHS develops Material Threat Assessments (MTAs) to support use of Project BioShield Special Reserve Fund acquisitions based on

“plausible, high- consequence” scenarios. To date, CBRN medical countermeasure requirements have derived from these scenarios. The classified MTAs prepared by DHS estimate the number of people in the population exposed to specified levels of a given threat agent. Issuance by DHS of a Material Threat Determination (MTD) based on the information in the MTA and on risk assessments is a requirement for use of Project BioShield Special Reserve Funds.

- **Medical and Public Health Consequence Assessments.** ASPR modeling staff collaborate with threat-specific Requirement Working Groups (including Subject Matter Experts) to develop medical and public health consequence assessments using epidemiological modeling tools that estimate the number of people who would benefit from a particular medical countermeasure using the population exposure numbers derived from the MTA. Subject Matter Experts review and discuss the appropriate disease-related parameters that should be included in the modeling and what those values should be. They review the modeling outputs and provide feedback on the model and the results in an iterative and highly collaborative process.
- **Consultation with Subject Matter Experts.** ASPR staff consult with a wide range of federal subject matter experts (with expertise in areas including, but not limited to, microbiology, health physics, chemistry, toxicology, medical care, and diagnostics) through the PHEMCE Requirements Working Groups and Integrated Program Teams. Expertise from non-federal personnel is sought as needed and appropriate.

- **Consultation with End-Users.** Through one-on-one, small and large group settings, PHEMCE partners work with emergency planners as well as public health, first responder, and hospital-based end-users of medical countermeasures at the local, state, regional and national levels to understand the concept of operations (CONOPs) under which the medical countermeasures will actually be used. Examples of past interactions include roundtable settings, one-on-one interviews supporting interactive design methodologies, and the annual PHEMCE Stakeholders Workshop. Of note, there is an Institute of Medicine Study Committee presently looking at issues related to pre-deployment of MCMs in community settings.
- **Leadership Approval.** CBRN medical countermeasure requirements are approved through a formal governance process within the PHEMCE. Following concurrence by the appropriate PHEMCE Requirements Working Group and Integrated Program Team, the draft requirements are briefed to the interagency Enterprise Executive Committee and to interagency leadership at the Enterprise Senior Council.
- **Requirement Revision.** ASPR leads re-examination and update of requirements at the request of the PHEMCE leadership or as needed as response capabilities and CONOPs evolve or new technological or threat information is gained, or as real events present new information through lessons learned (e.g. 2009 H1N1, or the Japan nuclear crisis).

MCM requirements fall into two major classes: (1) scenario-based requirements, and (2) product-specific requirements.

**(1) Scenario-Based Requirements** establish the classes and quantities of MCMs necessary to effectively respond to plausible, high consequence scenarios for each threat agent. Medical and public health consequence assessments are used to inform these requirements.

**(2) Product-Specific Requirements** determine the acceptable (threshold) and ideal (objective) characteristics for individual MCM product types. These are set through consideration of existing research and development technologies and response capabilities, and are communicated in the form of a Target Product Profile that calls out minimal qualities acceptable and goal characteristics for medical countermeasures HHS will pursue. Product-Specific Requirements also specify the quantity of a product with ideal characteristics that might be acquired to meet the specified needs, along with an indication of how variations in product characteristics might affect the quantity sought. Final acquisition quantities are determined based on product-specific characteristics and other considerations in the acquisition strategy and plans developed by program staff.

## **MCM PROCUREMENTS, ADVANCED RESEARCH AND DEVELOPMENT, AND OUTREACH TO INDUSTRY**

Once the requirements setting process is complete, and the PHEMCE determines that advanced development or acquisition of unlicensed medical countermeasures is appropriate to meet these requirements, BARDA funds these activities to protect the American civilian population against CBRN and naturally occurring threats to public health. Further, BARDA collaborates with intra- and inter-agency partners in MCM

research that may be a precursor need for meeting these requirements and has a robust process for screening new technologies and interacting with the private sector on novel MCM technologies and products.

### **Project BioShield MCM Procurements**

Project BioShield, authorized by the Project BioShield Act of 2004 (P.L. 108-276), established the Special Reserve Fund, a market signal, a guarantee, and a secure funding source for the procurement of critical medical countermeasures, such as vaccines, therapeutics, and diagnostics that are close to licensure. It provides a tangible guarantee to industry that a market will exist for these products. The Project BioShield Act also provides additional and more flexible authorities and funding to support and expedite the development and procurement of CBRN MCMs. Finally, the Project BioShield Act provides the Secretary with the authority to authorize the use of unapproved products or the unapproved use of approved products during emergencies.

In 2003, Congress appropriated \$5.593B to support Project BioShield over a ten-year period. Since its inception, ASPR has used Project BioShield funds to procure

- anthrax therapeutics and vaccines;
- heptavalent botulinum antitoxin;
- smallpox vaccine; and
- a number of MCM products intended for use after radiological and/or nuclear events.

Of the \$5.593 billion originally appropriated, \$2.348 billion remains available. The difference includes \$2.130 billion directed towards the procurement of MCMs and \$1.114 billion transferred, rescinded, or spent on ARD contracts.

### **Advanced Research and Development**

Using its Advanced Research and Development (ARD) authority, BARDA bridges the “valley of death” funding gap that exists between the early stages of product development and the procurement of approved or approvable medical countermeasures under Project BioShield. Given that 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 a substantial pipeline of products to diagnose and treat illness with, or prevent the effects of CBRN agents. The FY 2011 Budget includes a request that \$476M be made available from Project BioShield balances to support such ARD projects. 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 Budget requests another \$765M from Project BioShield balances to support these priorities.

### **Integrated Portfolio for CBRN Medical Countermeasures**

The DoD and HHS each identify medical countermeasure requirements to address their different missions and focus. Historically, DoD has prioritized the development of MCMs to protect our military prior to exposure to CBRN agents, whereas HHS’s focus has been on responding to threats to the civilian population once exposure has occurred. However, there are areas of common requirements or interest where medical

countermeasure candidates, resources and information can be appropriately shared to maximize opportunities for success in the development of medical countermeasures for the highest priority threats. BARDA, in partnership with other HHS and DoD partners, is leading an Integrated Portfolio for CBRN Medical Countermeasures to leverage resources and programs across the agencies that develop and acquire CBRN medical countermeasures to more effectively address the broad range of common threats and requirements. Members of the *Integrated Portfolio* working to integrate HHS and DoD efforts include BARDA, biodefense programs at NIH, and multiple elements of the DoD Chemical and Biological Defense Program.

### **BARDA TechWatch Program**

BARDA has developed an active *TechWatch* program, which provides an opportunity for external organizations to meet with the federal government to discuss their new and innovative medical countermeasure technologies. Companies may request meetings with government subject matter experts to discuss their products and plans for submitting proposals in response to BARDA's Broad Agency Announcements (BAAs) through the PHEMCE portal website [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov). These meetings provide the federal government with the latest information about emerging technology and inform strategic and programmatic planning for effective public health emergency response. The *TechWatch* program has been highly successful in improving communication with potential partners. Those companies who utilize *TechWatch* prior to submitting a white paper in response to a BAA are three times more

likely to be invited to submit a full proposal than companies that proceed directly to the white paper without the benefit of a *TechWatch* meeting.

## **MEDICAL COUNTERMEASURE ENTERPRISE REVIEW**

Recently, our department undertook an effort to address gaps and challenges in MCM development and procurement by improving the efficiency of our translational efforts, enhancing the advanced development and manufacturing services we provide our partners, clarifying regulatory pathways, and building a strong base for MCM regulatory science at the FDA. These initiatives, once implemented, will provide the capability to speed MCM development and respond faster and more effectively to rapidly evolving public health threats. In December 2009, on the heels of the 2009-H1N1 pandemic, HHS Secretary Kathleen Sebelius requested a complete review of the MCM enterprise and assigned this responsibility to ASPR. The goal of the review was the end-to-end transformation of the enterprise: to improve its performance, enhance collaborations with the private sector, and prepare the nation for the threats of the 21<sup>st</sup> century – those we can predict as well as those we cannot. The MCM Enterprise Review, released in August 2010, identifies “processes, policies, and infrastructure required to take a product concept derived from a national requirement through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling.” Specifically, this review looked across the entire arc 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 MCM “valley of death,” the Review proposes a series of initiatives:

- The establishment of a Concept Acceleration Program at the NIH National Institute of Allergy and Infectious Diseases to work with partner agencies, academic researches, biotech companies, and large pharmaceutical companies to identify promising scientific discoveries and expedite their transformation into practical, usable products.
- The establishment of a nonprofit [501(c)3 or equivalent] Strategic Investor firm to spur innovation by supporting companies that possess strategic technologies that 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.
- A major investment in regulatory sciences and review capabilities at the FDA focused on CBRN MCMs.

The Concept Acceleration Program will leverage existing intramural and extramural research programs as well as applied and translational resources throughout NIH, CDC, FDA, and DOD to speed the translation of promising concepts into candidate MCMs.

The Strategic Investor initiative would spur innovation and provide the kinds of business and financial services and support that venture capital firms typically provide, mitigating the risk that funded pharmaceutical manufacturing firms will fail because of poor

management, an inadequate business model, or lack of financial expertise. The Strategic Investor initiative is critical to transitioning MCM development and procurement from a “one bug, one drug” approach to an enterprise capable of responding to any threat at any time.

The Centers for Innovation will be created to reduce risk, increase product yields, 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 that include advanced development and manufacturing capabilities of USG-supported developers of medical countermeasures for chemical, biological, radiological, and nuclear MCMs to address national preparedness and response priorities and needs. In the event of a pandemic, the Centers will also be available to assist in the manufacture of influenza vaccine and other biologics. The Request for Proposals for this latter initiative was published on March 30, 2011, and we have been working closely with our colleagues at DoD, who are preparing a complementary initiative for release in the near future.

Finally, expanding regulatory science and review capabilities at the FDA will strengthen and clarify the MCM regulatory process, which will expedite MCM development.

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

## **MCM DISTRIBUTION - EXECUTIVE ORDER 13527**

Finally, Mr. Chairman and Members of the Subcommittee, I must address the importance of the entire MCM continuum--from research and development to procurement to distribution and dispensing. The MCM enterprise is one component of a broader response strategy to mitigate the effects of a CBRN event. To be resilient in the face of CBRN disasters, we need a fully integrated and coordinated strategy to address how the various sectors of our healthcare system will work together to respond and save lives. We need an integrated healthcare system that can address patients' needs when and where necessary. After we work to procure valuable CBRN medical countermeasures, we need adaptable distribution and dispensing plans in place capable of quickly delivering these countermeasures to every American who needs them.

On December 30, 2009, the President issued *Executive Order 13527* establishing the federal government policy, in the event of a biological attack, to plan and prepare for the timely provision of medical countermeasures to the American people through a rapid federal response in coordination with state, local, territorial, and tribal governments. Section 2 of the Executive Order tasks HHS and DHS, in coordination with the USPS to develop a national USPS medical countermeasures dispensing model for U.S. cities to respond to a large-scale biological attack, with anthrax as the primary threat consideration. This dispensing model was delivered to the President on June 30, 2010 and was included in a recent grant announcement issued through ASPR. The President's FY 2011 budget requested \$10 million to fund this initiative. However, these funds were eliminated in the previous, current, and proposed continuing resolutions to

fund government operations in FY 2011. The President's FY 2012 budget requests \$5 million for this initiative.

## **CONCLUSION**

In closing, I want to reiterate that as the threats we face evolve, we will continue to work closely with our colleagues at DHS, DoD, and across government to ensure that our investments are rational and sustainable. We understand the importance of thorough surveillance and early detection to limit the impact of a CBRN event and will continue to work closely with our partners to build upon existing infrastructure and align supporting investments and capabilities. We continue to face significant challenges in the realm of MCM research and development and hope that through implementation of the priorities established in the MCM Enterprise Review, we can transform the way we collaborate with our industry partners while demonstrating our sustained commitment to developing new and promising MCMs. Medical countermeasures are a bulwark against the deliberate and natural threats we face, a critical link in the chain of preparedness.

I speak for all my colleagues throughout HHS in saying that we look forward to working with you on the matters I have raised this afternoon. With the leadership and support of Congress, and in collaboration with our agency partners, we have made substantial progress in MCM development and procurements. We have accumulated a great deal of practical experience over the last decade and have a deep understanding of the challenges our private sector and academic partners face. To meet these challenges, we have made changes in our governance – continual improvements in our processes

and institutions, our standard operating procedures, and our collaborations with our DHS and DoD partners. We are in the process of transforming the MCM Enterprise to ensure its sustainability while meeting the threats of the future.

Let me assure you that we take our mission of preparing the nation against these threats with the utmost seriousness and that we know how much we still have left to do.

Thank you again for inviting me to testify. At this time I would be happy to address any questions you may have.