



**Written Testimony
House Committee on Energy and
Commerce, Subcommittee on Health**

“Public Health Emergency Response”

Statement of

Richard J. Hatchett, MD

Acting Deputy Assistant Secretary and Acting BARDA Director
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services



**For Release on Delivery
Expected at 10:00 a.m.
May 19, 2016**

Chairman Pitts, Ranking Member Green, and distinguished Members of the House Energy and Commerce Committee, thank you for the opportunity to testify today regarding biosecurity issues and H.R.3299, the Strengthening Public Health Response Act. I am Dr. Richard Hatchett and I serve as the Acting Director of the Biomedical Advanced Research & Development Authority (BARDA) and as an Acting Deputy Assistant Secretary for Preparedness and Response. BARDA is a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR). The ASPR, Dr. Nicole Lurie, serves as the principal advisor to the Secretary of Health and Human Services (HHS) on all matters related to federal medical preparedness and response for public health emergencies.

Securing our nation against biological threats is a challenging endeavor. The array of threats for which we must be prepared is vast. Such threats include bioterrorist agents such as anthrax, smallpox, and botulism; evolving and emerging threats causing substantial regional disruption such as Ebola and Zika; and highly communicable diseases with pandemic potential such as influenza. In the last fifteen years, the world has experienced the first influenza pandemic in 40 years, devastating outbreaks of foot-and-mouth disease, anthrax attacks, the re-emergence of cholera in the Western Hemisphere, the largest Ebola epidemic ever recorded, and the global dissemination of vector-borne viral diseases such as chikungunya and Zika.

Thanks to lessons learned from previous responses, biomedical breakthroughs, and sound strategic investments, we have improved our preparedness for and capability to respond to a wide-range of threats regardless of their origin and properties. We have read with interest the report and recommendations of the Blue Ribbon Study Panel on Biodefense, which I know to be

of interest to this Committee. With that in mind, I would like to update you on some of the areas in which ASPR and BARDA have progressed in recent years.

ASPR has made numerous improvements to ensure national health security and to protect the American people. One such improvement is the development and continued refinement of the National Health Security Strategy (NHSS), which unified a patchwork of public health and medical preparedness, response, and recovery strategies. The NHSS works to ensure that the nation is prepared for, protected from, and resilient in the face of public health threats. The NHSS is the first strategy specifically focused on protecting public health during an emergency. It envisions resilient and strong communities with sustainable health and emergency response systems. The NHSS, with its accompanying implementation plan, lays out actionable goals and objectives to achieve these ends.

Among her many responsibilities, the ASPR serves as the chair of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE is a standing virtual enterprise that coordinates the entire life cycle associated with the development and procurement of medical countermeasures. It was created explicitly to improve coordination and collaboration within the Department and with our external stakeholders, including nonprofits, other federal departments, the private sector, and the international community.

The PHEMCE is comprised of ASPR, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), as well as the Departments of Homeland Security (DHS), Defense (DoD), Veterans Affairs, and

Agriculture. It has been uniquely successful in promoting the development and acquisition of medical countermeasures for chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, and emerging infectious disease threats. PHEMCE activities are governed by the PHEMCE Strategy and Implementation Plan (SIP). The PHEMCE SIP is updated annually and describes the PHEMCE's governance and decision-making structure. One of the most important functions of the SIP is to provide clarity and guidance about PHEMCE objectives to our external partners and stakeholders.

PHEMCE coordination and decision-making encompass all stages of the medical countermeasure life cycle from identifying requirements and developing target product profiles through product development to distribution and dispensing. Agencies take responsibility and are held accountable for activities within their mission space and PHEMCE coordination establishes common priorities, facilitates joint decision making and information sharing, and ensures the smooth transition of products through development. The PHEMCE has an outstanding record of success and is now being studied as a model for global preparedness against emerging infectious diseases. It was established in 2007 and its processes have been iteratively refined and improved over the last 9 years.

Operationally, the PHEMCE establishes product-specific requirements for CBRN medical countermeasures based on Material Threat Assessments developed by DHS. NIH and DoD support discovery and early stage development of product candidates, often in collaboration with academic and industry partners, and prepare them for the transition to BARDA. In turn, BARDA supports and assists product candidates through advanced research and development,

including preparation for FDA review, until they are ready for acquisition under Project BioShield. After procurement, medical countermeasures are maintained at CDC's Strategic National Stockpile (SNS) locations or within virtual stockpiles maintained by commercial vendors (in so-called vendor-managed inventory). If advanced development data lead to FDA approval of a marketing application, the financial responsibility of purchasing medical countermeasures for stockpile and delivery transfers from BARDA under Project BioShield to SNS. Items that have not yet received FDA licensure can also be procured for the stockpile if they are eligible for use during an emergency under an Emergency Use Authorization.

During evolving public health emergencies, NIH, BARDA, and DoD may shift into response mode, interfacing with other federal agencies and manufacturers to develop, produce, and test products for FDA review and approval and (where necessary) distribution by CDC to state and local health departments. Our investments in preparedness have already paid dividends in this regard. Because of the workforce and capabilities we have developed over the last nine years, we are much better prepared to respond quickly to emerging threats. The PHEMCE, for example, advanced multiple vaccines and therapeutics and an innovative lateral flow diagnostic into clinical trials during the response to the Ebola epidemic and more recently has mobilized to support the development of vaccines, diagnostics, blood donor screening tests, and pathogen reduction technologies for Zika virus.

Within the overarching framework provided by the PHEMCE, BARDA supports the advanced research, development and procurement of medical countermeasures—vaccines, therapeutics,

antiviral and antimicrobial drugs, diagnostics, and medical devices. Advanced development includes critical steps needed to transform a candidate to a product that is ready to use. These steps include optimizing and validating commercial scale manufacturing processes; optimizing product formulations, storage, product longevity, and effectiveness; creating, optimizing, and validating assays to assure product integrity; conducting late-stage clinical safety and efficacy studies; and carrying out pivotal animal efficacy studies.

BARDA's considerable success with making available CBRN medical countermeasures derives from a business model that depends on a set of supporting incentives that can be likened to a three-legged stool. Each leg of the stool has proved critical to BARDA's success, and it was only after all three legs were firmly established that BARDA truly began to deliver on its promise.

The first leg is provided by Project BioShield funding, which serves as a market guarantee (or advanced market commitment) for products that otherwise might have no or very limited commercial prospects. Maintaining the integrity of this market guarantee has been critical to maintaining the confidence of our private sector partners as they undertake high-risk development programs. Project BioShield funding represents the government's bipartisan commitment to support private sector innovators who are willing to address unmet public health preparedness needs. With our private sector partners, we are building capacities to maximize a flexible, nimble response. We are also working across the government to ensure threats are identified, requirements are established, and the medical counter measures are in place to protect the nation's health. The need for medical countermeasures against threats is regularly assessed

and informed by DHS's Material Threat Determinations, to which threat information provided by the Intelligence Community contributes.

The second leg is provided by the classic push incentive of BARDA's advanced research and development contracts, grants, cooperative agreements, and other transactions. These funding vehicles provide firms with access to the substantial amounts of funding required to navigate the "valley of death" represented by late-stage clinical development. Small to mid-size biotechnology firms have found it virtually impossible to obtain funding from traditional capital markets for inherently non-commercial biodefense projects. Absent the push incentives that BARDA provides, these firms would not be able to advance their products to regulatory end points; they would simply die on the vine, victims of the market failure that underlies biodefense.

The third leg of the stool is the direct product development support that BARDA provides. Since most of BARDA's partners have been small to mid-size biotechnology firms that have gaps in their product development expertise and capabilities, BARDA has established an array of core services that it can bring to bear in support of its partners' product development efforts. These core services facilitate access to subject matter experts in a variety of disciplines germane to product development (such as clinical trial design, regulatory affairs, process engineering, etc.) as well as access to animal models and preclinical laboratories, a clinical studies network, a fill-finish manufacturing network, and BARDA's Centers for Innovation in Advanced Development and Manufacturing. These latter assets, which support BARDA's core mission of promoting biodefense product development, also enhance BARDA's response capability and collectively constitute BARDA's National Medical Countermeasures Response Infrastructure, which was

mobilized for the first time during the Ebola epidemic to accelerate the development of Ebola vaccines and therapeutics and is being engaged now to expedite the development of vaccines against Zika.

Since its creation, BARDA has built a comprehensive and formidable advanced development product pipeline that has supported close to 200 medical countermeasure development projects. To date, at least 23 medical countermeasures that BARDA has supported have been approved, licensed or cleared by FDA. Of these, 15 have been approved since 2011 and five have been approved in the last 14 months. Seventeen products, ranging from anthrax antitoxins and smallpox vaccines to anti-neutropenia cytokine therapeutics for radiation illness and an array of products for the management of thermal burns, have been procured under Project BioShield with another seven anticipated between now and the end of FY 2018. To better serve the needs of special populations, BARDA has funded the development of a smallpox vaccine (Modified Vaccinia Ankara) suitable for use in immunocompromised individuals as well as pediatric formulations of drugs like Prussian Blue (a treatment for internal radiation contamination) and solithromycin (an antibiotic candidate under investigation). BARDA has also supported the development and manufacturing of 18 influenza vaccines, antiviral drugs, and diagnostics that were either used in the 2009 H1N1 pandemic or stockpiled to enhance preparedness for H5N1 and H7N9 influenza viruses with pandemic potential.

To provide contracting support to BARDA's activities, ASPR has established a separate and specialized Office of Acquisitions Management, Contracts and Grants (AMCG) whose contracting authority is delegated from the HHS Senior Procurement Executive (SPE). This

independent line of reporting to the ASPR and the SPE mitigates potential conflicts of interest and maintains the highest standards of program integrity. AMCG is an award winning and innovative contracting office, having received the HHS Secretary's 2015 Hubert H. Humphrey Award for Service to America, the 2012 HHS Small Business Award, and the 2010 HHS Project Team Award for its contribution to the H1N1 Influenza Virus response. It introduced competitive solicitation procedures known as Broad Agency Announcements which streamline the acquisition process for basic and applied research, and initiated the use of Other Transaction Agreements to further engage industry.

AMCG has led the department in meeting contracting time lines. While the federal government and Department standard time line for awarding contracts is 180 days, AMCG awarded the majority of its Ebola contract actions within 60 days. In the same time frame (FY2014-FY2015), Project BioShield contracts were awarded within an average of 128 days from the publication of a Request for Proposals. In summary, ASPR awarded 91 grants totaling \$212,649,385.67 in FY 2015. During that fiscal year, 90 percent of ASPR's contract actions were competed, thereby ensuring that there is opportunity for businesses capable of meeting the needs of HHS to compete on a level playing field. Exceeding targets under the President's Small Business Initiative, ASPR awarded 51 percent of eligible contract dollars to small businesses. This also exceeded our own 35 percent small business goal.

The Federal Acquisition Regulation (FAR) provides flexibility in the event of an emergency to expedite contract award by the contracting officer. This emergency authority was recently put to use by AMCG in what U.S. News and World Report on March 18, 2016 called "an

unprecedented relief effort, [by] the federal government and blood banks in the United States... to provide the entire territory of Puerto Rico with safe blood to protect recipients from the Zika virus.” AMCG was notified on February 24, 2016 that FDA guidance recommended that— among other things—whole blood and blood components for transfusion be obtained from areas of the United States without active transmission and that blood collection in affected areas such as Puerto Rico would have to stop no later than March 1 until donor screening measures could be put in place to prevent transfusion transmission of Zika virus. Working closely with BARDA to define the actual requirement, conduct market research, obtain legal advice, and draft the contract document, the contracting officer awarded a \$4.6 million contract on March 3, 2016 to transport blood products from the U.S. mainland to Puerto Rico, six business days after being notified of the impending shortage. On March 5, 2016, Chris Hrouda, Executive Vice President of Biomedical Services for the American Red Cross, announced that nearly 5,000 units of blood and other products per week had commenced, enough to meet the whole territory's needs. These efforts by AMCG and BARDA prevented a public health crisis from becoming a medical crisis by demonstrating the flexibility, speed, and coordination with which the two offices can operate. As a result, a solution was eventually reached with the Roche blood screening.

ASPR strives to preserve health, mitigate suffering due to illness and injury, and expedite recovery through the development of resilient communities before, during, and after events ranging from bioterrorism attacks to natural disasters that impact public health and well-being. To achieve this goal, ASPR supports building preparedness capabilities and resiliency at the community level before disasters or public health incidents occur. ASPR’s flagship program in this regard, the Hospital Preparedness Program (HPP), has provided approximately \$5.6 billion

to state, local, and territorial health departments since 2002 to better prepare the nation's health care systems and hospitals for man-made or natural disasters.

While hospitals remain at the center of a prepared health care system, events of the last decade, including the 2009 pandemic, the Joplin, Missouri tornado, and Superstorm Sandy, have highlighted how important it is for hospitals to work with one another and with other community health care entities, such as EMS and skilled nursing facilities, to prepare and execute a health care system response. Consequently, since 2012, HPP has emphasized the importance of regional health care coalitions to save lives during emergencies that exceed the day-to-day capacity of the health and emergency response systems. Health care coalitions (HCCs) incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together. They ensure that each HCC member has the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to an emergency, so that each patient impacted by a disaster receives the right care at the right place at the right time. The health of communities is deeply intertwined with the ability of its institutions to provide care to all populations and investments in HPP are critical to limiting the cascade of negative health effects that disasters can have on a community.

HCCs have already proven beneficial. For example, even as emergency crews were still onsite searching for survivors and victims of the 2015 Amtrak train derailment in Philadelphia, local health care facilities, emergency medical services, and emergency management agencies, all members of HPP-supported HCCs, were already in action, working together to facilitate a swift, coordinated response. Systems funded by HPP were able to send out notifications of emergency

room capacity to HCC members a full 30 minutes prior to the official city alerts. This enhanced communication provided responders real-time information on resources and capacity throughout the region. HCC members immediately activated another HPP-funded response platform to track and triage patients, facilitate the proper distribution of patients, and prevent any single hospital from being overburdened. The operational response of HCC members, along with their systems and training, allowed for an effective response within an organized incident command structure, thus saving lives, improving care, and increasing accountability.

ASPR has supported a number of recent initiatives to enhance the HPP program. In 2010, ASPR led an effort to ensure that HPP funding and its health care preparedness mission was better aligned with CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement and its public health preparedness focus. This alignment reduced bureaucracy and administrative workload for both programs' awardees, and ensured the programs could leverage one another's work and avoid duplication. Alignment of the exercise requirements for both cooperative agreements and the integration of annual awardee meetings are just two examples of efficiencies that have been achieved through this process. Further, ASPR's and CDC's alignment efforts for HPP and PHEP also serve to ensure the programs are complementary.

Over the last several years, HPP has evolved from an individual health care facility capacity-building program to a health care system capability-development program. In 2012, ASPR identified eight national health care preparedness capabilities that awardees, health care coalitions, and health care facilities and organizations strive to achieve. These capabilities are sufficiently flexible to enable all-hazard planning for natural disasters, terrorist events, infectious

disease outbreaks, and industrial accidents. The capabilities are designed to facilitate and guide preparedness planning and to serve the needs of communities in every-day local emergencies as well as disasters eliciting state and federal disaster declarations. HPP awardees use the health care preparedness capabilities to identify gaps in their preparedness efforts and target investments to ensure that their communities are safer, more resilient, and better prepared. In a recent survey, HPP awardees indicated overwhelmingly that the Program’s support—including funding, guidance, and technical assistance—is critical to developing, implementing, and maintaining health care preparedness capabilities. For example, 100 percent of awardees agreed or strongly agreed that HPP was critical to health care system preparedness, and 92 percent agreed or strongly agreed that HPP was critical to health care worker safety.

The HPP appropriation funds a health care preparedness, response, and recovery *ecosystem* that extends from day-to-day emergency department improvements to recovery from major disasters. Funding supports HPP cooperative agreements as well as a set of supporting federal efforts that help HPP awardees, coalitions, and health care facilities and providers prepare for and respond to emergencies. These include:

- The Technical Resources, Assistance Center, and Information Exchange (TRACIE), which ASPR launched in September 2015 to serve as a one-stop interchange for HPP awardees, health care coalitions, and other health system partners to gain access to best practices, guidance documents, and technical assistance as well as to share ideas and to collaborate with stakeholders on matters pertaining to healthcare emergency preparedness, response, recovery, and mitigation. TRACIE has responded to nearly 500 training and technical assistance requests in the eight months since the program launched;

the vast majority of those requests came from HPP awardees and coalition members. TRACIE has received more than 35,000 visitors to the website, its listserv has nearly 5000 recipients, and more than 1300 individuals have registered as members of the program's Information Exchange.

- The Emergency Care Coordination Center within ASPR strengthens the day-to-day emergency care system so that the nation's emergency departments are better prepared in times of crisis.
- ASPR's Critical Infrastructure Protection for the Health Care and Public Health Sectors leads a public-private sector partnership focused on protecting the essential goods, services, and functions of health care and public health that, if destroyed or compromised, would negatively affect the nation. This program served a coordinating function during the Ebola outbreak to ensure that hospitals that served as Ebola Treatment Centers had the personal protective equipment they needed despite a national shortage. The program also leads the Department's health care cybersecurity work.
- ASPR's Division of Recovery advances the nation's ability to recover from the health and social services impacts of emergencies and disasters. ASPR's Recovery experts not only assist HPP awardees during and after emergencies, but they also promote pre-disaster health and social services recovery planning. Currently, ASPR's Recovery team is leading efforts to respond to the health and human services crisis in Flint, Michigan.

Infectious disease threats manifest in myriad forms and present unique challenges for preparedness and response. Fortunately, many of the lessons learned in responding to emerging infectious disease threats can inform our preparedness for acts of bioterrorism, while many of the

capabilities we have developed to promote preparedness for bioterrorism simultaneously enhance our preparedness for and ability to respond to natural threats.

What is required to respond effectively may differ substantially from agent to agent and over time within a given event, as recent crises demonstrate. To meet such threats, our nation requires an array of response capabilities, the ability to adapt in real time to changing circumstances, and robust mechanisms for coordination and communication. In the less than ten years that it has existed, ASPR and its component programs have made signal contributions in each of these areas and today play a critical role in preparing for public health and medical emergencies, whether natural or deliberate in origin. Through concerted effort over many years, ASPR has brought closer to realization the aspiration articulated in the NHSS of “National health security [as] a state in which the nation and its people are prepared for, protected from, and resilient in the face of incidents with health consequences.”