Written Testimony
Committee on Homeland Security and Governmental Affairs

"ASPR's Role in Biodefense"

Statement of

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ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

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Chairman Johnson, Ranking Member Carper, and distinguished Members of the Senate Committee on Homeland Security and Governmental Affairs – thank you for the opportunity to testify on behalf of the Office of the Assistant Secretary for Preparedness and Response in support of our recent progress enhancing coordination, building community resilience, and responding to threats against the health and well-being of our nation. 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 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. However, 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 we 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.

In the wake of the 2001 anthrax attacks and subsequent disasters such as Hurricane Katrina, Congress and the Executive Branch reevaluated the preparedness and response strategy of our nation. In 2006, Congress passed and President Bush signed the Pandemic and All-Hazards Preparedness Act (PAHPA), which established both ASPR and BARDA. ASPR will celebrate its tenth anniversary on December 19 of this year. Within ten years, ASPR has significantly enhanced the preparedness of our nation.

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. Originally released in 2009 and updated in 2014, 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.

ASPR has the authority to deploy federal public health and medical personnel; oversees the advanced research, development, and procurement of medical countermeasures; coordinates the integration of federal preparedness and response activities for public health emergencies; and provides logistical support for the federal component of medical and public health responses. In light of these responsibilities, the ASPR has provided leadership over the last seven years in response to a number of public health and medical emergencies including the 2009 H1N1 pandemic, the Deepwater Horizon oil spill, Superstorm Sandy, and the recent Ebola and Zika epidemics. Most recently, in January, Dr. Lurie was designated the lead federal official in response to the Flint, Michigan water crisis.

In executing her responsibilities, the ASPR serves as the chair of two interagency coordinating bodies, the Disaster Leadership Group (DLG) and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The DLG is convened on an as-needed basis to respond to emergencies while the PHEMCE is a standing virtual enterprise that coordinates the entire life cycle associated with the development and procurement of medical countermeasures. Both were 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 DLG, comprised of decision makers from across HHS, including representatives from the Office of the Secretary, NIH, the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and other HHS operating and staff divisions with incident-specific responsibilities, serves as the Department's main policy-making body during emergency responses. Under the scope of its policy-making responsibilities, the DLG advises the Secretary on critical preparedness matters, addresses

ongoing response activities, and mitigates the lasting effects of disasters. The PHEMCE is comprised of ASPR, NIH, CDC, and FDA as well as the Departments of Homeland Security (DHS), Defense (DoD), Veterans Affairs, and Agriculture.

The PHEMCE 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 smooth transitions as products move from stage to stage of 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. At least 23 medical countermeasures developed under its purview have been approved, licensed, or cleared by the FDA by the FDA. Of these, 15 have been approved since 2011 and five have been approved in the last 12 months.

The PHEMCE facilitated the rapid development of vaccines, therapeutics, and diagnostics during the Ebola epidemic and is fully engaged in the current response to Zika.

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 by academic and industry partners, preparing them for transition to BARDA. In turn, BARDA supports and assists product candidates through advanced research and development until they are ready for acquisition under Project BioShield. After procurement, medical countermeasures are maintained within CDC's Strategic National Stockpile (SNS) or within virtual stockpiles maintained by commercial vendors (in so-called vendor-managed inventory). If advanced development data leads 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. During evolving public health emergencies such as the 2009 H1N1 pandemic, the Ebola outbreak, and the current Zika crisis, 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.

The ongoing response to the Zika epidemic illustrates how these coordinating bodies function and interact in a crisis. As was also the case with Ebola, the PHEMCE response was initiated well before we had a recognized problem with either virus in the US. In the case of Ebola, PHEMCE processes began to gear up in the spring of 2014, and for Zika, it was early December

2015. A subcommittee of the PHEMCE, the medical countermeasures Senior Steering Group, has met almost weekly throughout both crises. The Zika DLG convened for the first time on January 5, 2016 and meets at least twice weekly to coordinate and guide the policy approach to Zika and to coordinate the major strategic workstreams. These workstreams focus on maintaining situational awareness, communications and stakeholder outreach, international engagement, enhancing laboratory tests and diagnostics capacity, vector control, improving availability and access to contraceptive and other health services, addressing the particular needs of territories with ongoing transmission (especially Puerto Rico), promoting domestic preparedness in states at high risk of autochthonous transmission, ensuring blood/tissue/organ safety, and accelerating the development of effective medical countermeasures such as vaccines, therapeutics, and pathogen reduction technology for blood. The PHEMCE Senior Steering Group meets once weekly and has focused on the three major areas of emphasis within countermeasures development based on the special characteristics of the Zika epidemic (diagnostics, vaccine, and pathogen reduction technologies). Interagency participation facilitates coordination of effort and rapid problem solving. This is exemplified by the rapid generation of vaccine and diagnostics landscapes, efforts to ensure the integrity of the blood supply, and prospective monitoring of contraceptive and insecticide supply chains.

A well-coordinated PHEMCE response is a critical enabler of a rapid science and industry response. Last month, ASPR hosted the General Assembly of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), which consists of 23 globally recognized research funding institutions. This meeting focused largely on lessons learned from the Ebola response and planning for research on and development of medical countermeasures against

Zika. A couple of weeks ago, HHS sponsored another major international meeting, "Zika Virus in the Americas: An HHS Expert Consultation to Accelerate the Development of Countermeasures" that was attended by nearly 700 people and included representatives from academia, industry, and major international partners. These meetings and associated outreach activities have allowed the PHEMCE to better understand the needs of our partners and to identify and address major barriers and rate-limiters for countermeasure development.

To best support information flow within the PHEMCE and DLG, as well as across the interagency response components, ASPR supports operational coordination through staff in the Secretary's Operation Center (SOC). ASPR supports the surveillance of emerging threats and critical incidents, nationally and internationally, 24 hours a day, seven days a week using staff and technologies in the SOC. Staff monitors information from federal, state, local, territorial, tribal, private-sector, non-profit, and international partners to identify potential or emerging threats to public health and facilitate the rapid implementation of response activities when necessary.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) requires HHS to develop a five-year budget plan for the medical countermeasure enterprise. This multiyear plan is a tool for strategic project coordination, product transitions between agencies, communication of priorities and resources to partner stakeholders, and assistance 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. Additionally, this tool communicates PHEMCE commitments and priorities to our industry partners. By coordinating resources and priorities, we can ensure an active medical countermeasure industry that meets our essential needs for a nimble and flexible response capability.

Created in 2006 by PAHPA, BARDA supports advanced research, development and procurement of countermeasures—vaccines, therapeutics, antiviral and antimicrobial drugs, diagnostics, and medical devices—that mitigate the medical consequences of man-made CBRN agents of terrorism and naturally-occurring and emerging threats like the 2009 H1N1 pandemic, the 2013 H7N9 influenza outbreak, and the recent Ebola epidemic. BARDA is the only federal agency that is exclusively focused on promoting the advanced development of medical countermeasures. 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, and 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.

PAHPA directed BARDA to promote countermeasure and product advanced research and development. Since its creation, BARDA has built a comprehensive and formidable advanced development product pipeline that has supported close to 200 medical countermeasure development projects. 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. BARDA has 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. 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).

To address its core mission of developing medical countermeasures against CBRN threats and pandemic influenza, BARDA has honed its processes and procedures, supported the development of critical product development support services and infrastructure, and assembled a world-class workforce expert in all aspects of product development. These product development capabilities have allowed BARDA to pivot to address emerging threats when a rapid response is required. For example, BARDA 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, and pathogen reduction technologies for Zika virus.

BARDA has vigorously pursued innovations to reduce the time and cost of countermeasure development. Investments have yielded a next generation anthrax vaccine candidate by coupling an expression system with rational genetic design technology using a novel bacterial expression system; the objective of which is an anthrax vaccine with increased stability and production

yields, and thus a lower overall product cost. BARDA partnered with industry to use synthetic biology technology to generate influenza vaccine seed strains. In 2013, this technology was pivotal in making pre-pandemic H7N9 bulk vaccine for stockpiling in record time. In 2014, BARDA began working with industry partners to develop new Ebola monoclonal antibodies rapidly using the latest innovations in monoclonal antibody development. These new Ebola antibody candidates have now been tested in non-human primate challenge studies and could move into clinical trials later this year. BARDA has kept a keen eye on and supported innovative technologies that may enhance existing medical countermeasures or generate new transformative medical countermeasures at lower costs and with longer shelf lives.

BARDA has established its medical countermeasure development pipeline by collaborating closely with federal partners, primarily NIH, CDC, FDA, and DoD, and by establishing public-private partnerships with industry and academia. BARDA has established partnerships with almost 100 pharmaceutical and biotechnology companies and more than 25 academic and other institutions since 2006. BARDA established the first and largest pre-pandemic influenza vaccine stockpile in the world, one that could, if necessary, vaccinate tens of millions of Americans in the event of H5N1 or H7N9 pandemics. Using the Other Transaction Authority granted by PAHPA, BARDA has established novel portfolio partnerships with GSK and AstraZeneca to support the development of new antimicrobial drugs. Finally, because many 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.

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 eliminates undue influence from program offices, maintains the highest standards of program integrity, and mitigates potential conflicts of interest. 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 is contribution to the H1N1 Influenza Virus response. It introduced the use of Broad Agency Announcements to ASPR which streamlined the acquisition process 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. All Project BioShield contract actions were awarded within 128 days starting at the end of FY 2014 and with the bulk of these actions in FY 2015. In FY 2015, 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, exceeding our own 35 percent small business goal. Additionally in FY2015, ASPR awarded 91 grants totaling $212,649,385.67.

AMCG follows the acquisition processes required by the Federal Acquisition Regulation (FAR). The FAR allows for some flexibility to streamline the acquisition process, in the event of any 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 there was an urgent and immediate need to restock the blood supply in the Commonwealth of Puerto Rico following FDA-issued guidance effective March 1 that led to cessation of the blood collection on the island due to the need to prevent transfusion transmission of Zika virus. Working closely with BARDA to define the actual requirement, conducting market research, and seeking legal advice, and drafting the contract document; the contracting officer awarded a $4.6 million contract within six business days on March 3, 2016. On March 5, 2016, delivery of "nearly 5,000 units of blood and other products per week, enough to meet the whole territory's needs" commenced. Chris

Hrouda, Executive Vice President of Biomedical Services for the American Red Cross, commented, "I don't think this has ever been done, and I've been in this business 30 years." This herculean effort by AMCG and BARDA prevented a public health crisis from becoming a medical crisis and demonstrates the flexibility, speed, and coordination with which the two offices can operate.

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 more than $5.1 billion to state and local health departments since 2002 to better prepare the nation's health care infrastructure for man-made or natural disasters.

While hospitals remain at the center of a prepared health care system, events of the last decade, including H1N1, 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 to prepare and execute a health care system response. Consequently, since 2012, HPP has emphasized the importance of regional coalitions of health care entities, promoting a bottom-up approach to national resiliency that has already proven beneficial in recent responses. These Health Care Coalitions (HCCs) incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together. They ensure that each

member has the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to an emergency. The health of communities is deeply intertwined with the ability of its institutions to provide care to all populations and we believe investments in HPP are critical to mitigating the cascade of negative health effects that disasters can have on a community.

ASPR has supported a number of recent initiatives to enhance the HPP program. In 2010, ASPR took the initiative to ensure that HPP funding was better aligned with CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement. This alignment reduced bureaucracy and administrative workload for grantees, 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 the annual grantee meetings are just two examples of efficiencies that have been achieved through this process.

Another example of program improvement was in 2012 when HPP identified eight national health care preparedness capabilities that grantees were required to support. 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 are scalable to maintain effectiveness during every day 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 better target investments to ultimately assure that their communities are safer, more resilient, and better prepared.

Lastly, to ensure that stakeholders have access to critical and up-to-date information to better support emerging needs during disaster, ASPR launched the Technical Resources Assistance Center and Information Exchange (TRACIE) in September 2015. TRACIE provides one-stop shopping for partners and stakeholders 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. TRACIE ensures that stakeholders at all levels of government and the private sector have access to information and resources to improve preparedness, response, recovery, and mitigation efforts. TRACIE's listserv has nearly 4000 recipients, has received over 30,000 visitors to the website, responded to more than 300 training and technical assistance requests, and signed up nearly 1200 members to the Information Exchange.

During the Zika response, ASPR has used HPP mechanisms to share information with state and local health care partners. For example, HPP's weekly update to awardees includes all of CDC's Health Alert Network advisories as well as links to other CDC-produced guidance documents. HPP encourages HCC coalition leaders and awardees to share information about Zika virus with their member facilities and organizations. HPP also encourages the HCCs to identify specialized resources, such as neurology services and maternal-fetal medicine units, and share information with member facilities and organizations about how to access and utilize them as resources for preparedness, communications/messaging, and consultative purposes.

While ASPR's ultimate goal is to empower communities to respond effectively without federal assistance, ASPR is organized to deploy subject matter experts, medical personnel, and supporting medical caches of lifesaving equipment to disaster areas when called upon. The National Disaster Medical System (NDMS) within ASPR is able to assist communities with medical services after a disaster or public health emergency and to support the DoD when there is a surge of military casualties that could overwhelm the military medical system. Since its establishment, NDMS has responded to over 300 incidents to support communities both domestically and internationally. NDMS provides assistance to communities impacted by public health and medical emergencies ranging from severe weather incidents to terrorist acts by deploying deeply experienced and specially trained medical teams. In cooperation with FEMA at the Center for Domestic Preparedness in Anniston Alabama, NDMS routinely trains for mass casualty events involving terrorist attack or natural disasters. NDMS is a unique national asset positioned and authorized to deliver essential medical services when requested by a community or partner federal agency.

During the Zika crisis, ASPR operations staff worked with key partners to share information and provide detailed situational awareness reports to senior leaders within the Department as well as across the interagency. Utilizing technologies in the SOC and various Fusion tools to collect information from internal and external data sources such as GeoHEALTH and social media analytics, staff monitor media reports, various official information systems, and other data streams to ensure that leaders and decision-makers are provided up-to-the-minute situation reports.

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 less than ten years, ASPR and its component programs have made 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 a concerted effort over many years, ASPR has brought us closer to realizing the goals articulated in the NHSS: "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." Thank you again and I look forward to your questions.