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"Examining the U.S. Public Health Response to the Ebola Outbreak"

Statement of

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ASPR
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Good afternoon. Chairman Murphy, Ranking Member DeGette, and other distinguished Members of the Subcommittee, thank you for the opportunity to speak with you today about our Government's Ebola epidemic response efforts. I am Dr. Robin Robinson, Director of the Biomedical Advanced Research and Development Authority (BARDA) and Deputy Assistant Secretary to the Assistant Secretary for Preparedness and Response (ASPR) of the Department of Health and Human Services (HHS).

Ebola is a potential biological threat agent as determined by the Department of Homeland Security through the issuance of a Material Threat Determination in 2006 , as well as an emerging infectious disease. The current Ebola epidemic is the worst on record. As the Centers for Disease Control and Prevention (CDC) has stated, we do not view Ebola as a significant public health threat in the United States; however, the best way to continue to protect our country from any domestic threat posed by Ebola is to take action to address the epidemic in West Africa.

ASPR is supporting the Federal Government's Ebola response effort through policy development, advancements in medical countermeasures, logistical support for deployed personnel, and broader community and healthcare preparedness and resilience through grant funding, dissemination of information to state and local partners, and communication with international partners concerning health security issues. Originally authorized by the Pandemic and

All-Hazards Preparedness Act (PAHPA) of 2006, ASPR leads the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security.

BARDA is the Government agency mandated to support advanced research and development and procurement of novel and innovative medical countermeasures such as vaccines, antimicrobial drugs, therapeutics, and medical devices, including diagnostics, to support the Nation in addressing the medical consequences of chemical, biological, radiological, and nuclear (CBRN) agents that might be used in terrorism-related activities. It also addresses naturally-occurring, emerging, and reemerging threats like the H1N1 influenza pandemic, last year's H7N9 influenza outbreak, and the current Ebola epidemic.

BARDA exists to address the medical consequences of these threats and to bridge the gap between early research and development and eventual Food and Drug Administration (FDA) clearance and procurement of medical countermeasures for novel threats by supporting advance development of medical countermeasures.

BARDA works with Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) partners to transition medical countermeasures from early

research and development into advanced development and ultimately to FDA for regulatory review and clearance. Advanced development includes critical steps needed to transform a candidate to a product that is ready for use in humans. These include: optimizing and validating manufacturing processes such that products can be made at commercial scale; optimizing product formulation for optimum field usage, storage, and product longevity and effectiveness; creating and optimizing assays to assure product integrity; conducting late-stage clinical safety and efficacy studies; and carrying out pivotal animal efficacy studies that are often required for approval. Since 2006, BARDA has funded and successfully managed the advanced development of more than 150 medical countermeasures for CBRN threats and pandemic influenza. Seven of these products have received FDA approval in the last two years alone, and twelve of these products have been procured under Project BioShield for potential use in a public health emergency.

Over the last decade, the PHEMCE has supported funding basic research and early stage development of numerous Ebola and Marburg Viral Hemorrhagic Fever medical countermeasure candidates. Now, as a result of this work, several promising Ebola vaccine and therapeutic candidates have matured enough for BARDA to transition them rapidly from early development into advanced development. BARDA aims to develop medical countermeasures that can be clinically evaluated for safety and efficacy, and once safety and efficacy are established, to manufacture these products on a commercial scale in large

enough quantities for use in a meaningful public health response. Ultimately, we strive to have these medical countermeasures cleared by the FDA as soon as it is feasible. Specifically, BARDA is now providing funding and providing technical assistance for the development and scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic and several Ebola vaccine candidates that the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) and the Department of Defense (DoD) Defense Threat Reduction Agency (DTRA) supported through early development. Given the manufacturing processes involved and the state of the development of the product, scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic may produce sufficient doses for clinical safety and initial efficacy studies, but it cannot be produced on commercial scale in large quantities at this point.

BARDA, along with its PHEMCE partners, uses public-private partnerships with industry to ensure that we have the medical countermeasures to protect the national health security of the United States in emergencies. Over the past five years, BARDA—with NIH, CDC, FDA, and industry partners—has built a flexible and rapidly-responsive infrastructure to develop and manufacture medical countermeasures. Last year, for example, in response to the H7N9 influenza outbreaks in China, ASPR mobilized these partnerships to design, develop, manufacture, clinically evaluate, and stockpile several vaccine candidates in record time. In the current Ebola response, the PHEMCE is working with a wide array of partners in addition to its Federal partners. They include other countries,

specifically the affected and at-risk African countries; the World Health Organization (WHO); the Bill and Melinda Gates Foundation; and others. These expanded partnerships are critical to our efforts to address the current Ebola epidemic.

BARDA has established a medical countermeasure infrastructure to assist product developers on a daily basis and enable rapid response in a public health emergency. BARDA is employing this infrastructure to respond to the current Ebola epidemic by helping the development and manufacturing of several investigational Ebola therapeutics and vaccines. BARDA's Nonclinical Development Network is conducting critical animal challenge studies for promising investigational Ebola therapeutic candidates. Established in 2012, BARDA's Centers for Innovation in Advanced Development and Manufacturing are positioned to expand the production of Ebola monoclonal antibodies like those in ZMapp, in tobacco plants and mammalian cells. Last year, as part of its pandemic preparedness efforts, BARDA established the Fill Finish Manufacturing Network, which will be used to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses. The investments BARDA has made to create this infrastructure over the past four years are helping the Nation respond to the current epidemic.

BARDA also supports large-scale production of medical countermeasures as an essential part of the response to public health emergencies. BARDA led the

manufacturing of vaccine and antiviral drugs in response to the H1N1 influenza pandemic in 2009 and of vaccines as a preparedness measure for H7N9 influenza in 2013. In the current Ebola epidemic, BARDA is providing assistance to vaccine and therapeutic manufacturers to scale up production from pilot scale, in which a handful of doses can be made, to commercial scale. For ZMapp, BARDA is currently supporting the manufacture of sufficient doses for clinical safety and initial efficacy studies. Furthermore, with funds from the Fiscal Year (FY) 2015 Continuing Resolution (CR), BARDA is expanding production capacity to other domestic manufacturers who can produce monoclonal antibodies targeted against Ebola antibodies using tobacco plants. Additionally, BARDA is working on an alternative manufacturing process for these monoclonal antibodies using mammalian cells. These mammalian cells are commonly used in the production of other monoclonal antibodies for other diseases, and may serve as a means of further expanding production capacity for this product.

With respect to vaccines, BARDA is working with industry partners to scale up the manufacturing of one of several promising investigational Ebola vaccine candidates to commercial scale with funds provided by the FY2015 CR.

In the coming months, BARDA and our industry partners face challenges to manufacture these Ebola medical countermeasure candidates. The major challenge is being able to provide sufficient quantities quickly to support clinical studies. BARDA is prepared to meet those challenges and provide resources,

expertise, and technical assistance for these and other promising investigational Ebola vaccine and therapeutic candidates. BARDA is working with our Federal Government partners, new and existing industry partners, and international partners including the WHO, non-governmental organizations, West African countries, and other allied donor nations to meet these challenges.

In addition to supporting and facilitating the manufacturing of Ebola medical countermeasures, the BARDA Analytic Decision Support team leads the interagency discussion of models of the epidemiology of the West Africa Ebola epidemic, as well as forecasts of the impact of mitigation measures that are in the process of development and/or deployment. This interagency forum facilitates the exchange of the latest available information and discussion among subject matter experts to provide informational products to support decision making by senior leadership.

Related to support for the Ebola outbreak in West Africa and in addition to medical countermeasure development, ASPR is supporting a number of activities including: supporting healthcare system preparedness; developing a number of policies and guidance documents on patient-movement issues and repatriation issues, and standards of care and clinical guidance; supporting the logistical aspect of deploying U.S. Public Health Service (USPHS) officers to West Africa; and, ongoing critical coordination and communication within the national and international communities responding to the threat.

Through the Hospital Preparedness Program (HPP) staff in ASPR, both the Office of Emergency Management and the Office of Policy and Planning (OPP) are supporting domestic preparedness by producing and disseminating educational materials on awareness and response regarding potential Ebola patients. ASPR is working to ensure state and local partners have relevant information at their fingertips to understand the emerging situation and have the right protocols and procedures in place to mitigate the threat. Specifically, ASPR HPP staff, along with other ASPR and HHS partners including CDC, assisted with the development and dissemination of a suite of checklists to prepare healthcare providers, hospitals, emergency medical services, and community healthcare coalitions. The checklists provide practical and specific suggestions to ensure healthcare workers, facilities, and coalitions are able to detect possible Ebola cases, protect their employees, and respond appropriately.

In addition, the HPP staff have collected and disseminated various "promising practices" from healthcare facilities and jurisdictions to advance the healthcare system's preparedness for Ebola. Specifically, HPP staff have disseminated various examples of Ebola-related tabletop exercises for hospitals and jurisdictions, as well as examples of hospital infectious control plans, so their facilities and jurisdictions can quickly adapt and use them. More broadly, ASPR, in coordination with CDC, the Federal Emergency Management Agency, the Association of State and Territorial Health Officers and the National Emergency Management Association coordinated conference calls with State Health

Officials, State Directors of Public Health Preparedness, State Emergency Management Officials, and State Homeland Security Advisors to share information regarding Ebola preparedness and response. This call offered an opportunity to provide up-to-date information as well as address and respond to questions real-time. HPP staff are assisting CDC with the recruitment of U.S. hospitals that are willing and able to volunteer to care for confirmed cases of Ebola among U.S. citizens that are medically evacuated to the United States from the affected countries in West Africa. Lastly, HPP awardees may use their current HPP funds to prepare for suspected or known Ebola patients, including the development of action plans, purchase of supplies for health care facilities, and training for all personnel. In emergency circumstances, HPP awardees may request approval to use grant funds for activities outside the currently approved scope of work. Some awardees have already initiated these requests.

ASPR is also working closely with other HHS and Federal partners to support the development of policies to address a number of emerging issues related to Ebola response. Specifically, ASPR co-leads a group to identify and resolve clinical issues that arise, ranging from clinical guidelines for standards of care to the requirements for the 25-bed hospital that will be staffed by the Commissioned Corps officers in Liberia. ASPR is also addressing and collaborating with other Federal partners on protocols for contingency evacuation and repatriation, including issues related to patient movement when infected patients return to the continental United States.

Regarding the international response, OPP, through its international health security efforts, continues to receive and share information with the WHO and countries around the world about Ebola through the International Health Regulations National Focal Point. In addition, ASPR maintains regular communications and coordination with G7 countries, Mexico and the European Commission on public health measures, development and deployment of medical countermeasures, and support for African countries.

In conclusion, ASPR has established a solid track record in developing and manufacturing medical countermeasures and coordinating successful emergency responses. ASPR, in coordination with the rest of the PHEMCE partners, is using all of its capabilities to address the Ebola epidemic in West Africa, and has identified crucial additional steps that can be supported through the end of FY 2015. These investments in Ebola medical countermeasures and response will help to address the current epidemic and any future Ebola outbreaks, and will also help the United States to become better prepared for a potential bioterrorism event. Again, I would like to thank the Subcommittee for your continued support and for the opportunity to testify. I look forward to your questions.