Written Testimony
Committee on Health, Education, Labor and Pensions and the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
United States Senate

"Ebola in West Africa: A Global Challenge and Public Health Threat"

Statement of

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Good afternoon. Chairman Harkin, Ranking Members Alexander and Moran, and other distinguished Members of the Committees, 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).

In 2006, the Pandemic and All-Hazards Preparedness Act (PAHPA) created BARDA and its parent organization, ASPR. Two years ago, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). 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, diagnostics, and medical devices for the entire nation to address the medical consequences of chemical, biological, radiological, and nuclear agents of terrorism ("biothreats") and naturally-occurring and emerging threats like the H1N1 pandemic, the H7N9 influenza outbreak last year, and the current Ebola epidemic.

BARDA exists to address the medical consequences of these threats and to bridge the gap between early development and procurement of medical countermeasures for novel threats. Ebola is simultaneously a biothreat (with a

Material Threat Determination issued in 2006 by the Department of Homeland Security) and an emerging infectious disease. The current Ebola epidemic is the worst on record. As CDC has said, we do not view Ebola as a significant public health threat to the United States. 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 Africa.

BARDA works with our PHEMCE partners in HHS and other Federal agencies to transition medical countermeasures from early development into advanced development and ultimately to Food and Drug Administration (FDA) regulatory review and approval. Advanced development includes critical steps needed for a product to be ready to use, such as optimizing manufacturing processes so products can be made in quantity to scale, 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 managed the advanced development of more than 150 medical countermeasures for chemical, biological, radiological, and nuclear threats and pandemic influenza. Seven of these products have received FDA approval in the last two years alone.

Over the last decade, the PHEMCE has supported basic research and early stage development of numerous Ebola and Marburg virus 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 to advanced development. Our aim is to have products we can use in time to make a difference in the current Ebola epidemic. We seek to have FDA-approved medical countermeasures as soon as it is feasible. Specifically, BARDA is now providing assistance for the development and scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic and two Ebola vaccine candidates, early development of which has been supported by the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) and the Department of Defense's (DoD) Defense Threat Reduction Agency (DTRA).

Working in conjunction with PHEMCE partners, BARDA uses public-private partnerships with industry to ensure that we have the medical countermeasures to protect the emergency health security of the United States. 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, the PHEMCE 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 wider array of partners in addition to our 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. The medical countermeasure infrastructure also allows for BARDA to respond immediately in a public health emergency. Today, BARDA is using this infrastructure to respond to the current Ebola epidemic by helping to develop and manufacture several investigational Ebola therapeutics and vaccines. BARDA's Animal Studies Network is conducting critical animal challenge studies for promising investigational Ebola therapeutic candidates. BARDA's Centers for Innovation in Advanced Development and Manufacturing, established in 2012, are positioned to accelerate production of Ebola monoclonal antibodies, like those in ZMapp, in tobacco plants and mammalian cells if clinical trials demonstrate that ZMapp is safe and effective. BARDA will monitor ZMapp throughout the development cycle, and, if necessary, can shift funds to test other candidate therapeutics. Our Fill-Finish Manufacturing Network, established last year for pandemic preparedness, stands ready to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses. The investments we have made to create this infrastructure over the past four years are helping us respond to the current epidemic.

BARDA also supports large-scale production of medical countermeasures as a response measure for public health emergencies. BARDA led the manufacturing of vaccine and antiviral drugs in response to the H1N1 pandemic in 2009 and of vaccines as a preparedness measure for H7N9 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, we are currently supporting the manufacture of enough doses for clinical safety studies, but we need to start now to expand the number of domestic manufacturers who can produce Ebola monoclonal antibodies using tobacco plants. Therefore, the Administration is requesting funding for this purpose through an anomaly to the Fiscal Year 2015 Continuing Resolution. Additionally, we are looking at alternative Ebola monoclonal antibody production systems, including those used for similar families of products in the commercial market, as a means of further expanding production capacity for this product. With respect to vaccines, BARDA is working with NIH/NIAID, DoD/DTRA, and industry partners to scale up the manufacturing of the two promising investigational Ebola vaccine candidates. To enable the conduct of clinical efficacy studies for investigational Ebola therapeutics and vaccines in Africa throughout the next year, we need appropriations to fund investments in these medical countermeasure candidates now as proposed through the Continuing Resoltion anomaly.

BARDA faces significant challenges in the coming weeks and months with the manufacturing of these medical countermeasures. The major challenge is being able to provide sufficient quantities soon enough to support clinical studies. BARDA is prepared to meet those challenges and provide resources, expertise, and technical assistance for other promising investigational Ebola vaccine and therapeutic candidates. We are working with our United States Government partners, new and existing industry partners, the WHO, non-governmental organizations, African countries, and others to meet these challenges.

In conclusion, BARDA has established a solid track record in developing medical countermeasures. With the rest of the PHEMCE, we are using all of our capabilities to address the Ebola epidemic in Africa, and have identified crucial additional steps that can be supported through the Fiscal Year 2015 Continuing Resolution. BARDA's investments today into Ebola medical countermeasures will address not only the current epidemic and any future Ebola outbreaks, but they will also help the United States to become better prepared for bioterrorism. Again, I would like to thank the Committee and Subcommittee for your generous and continued support, and for the opportunity to testify. I look forward to your questions.