



**Written Testimony  
Committee on Health,  
Education, Labor, and Pensions  
United States Senate**

**“ASPR’s Role in the Zika Response”**

*Statement of*

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Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to testify before you again. As you may recall, within the Department of Health and Human Services (HHS), I serve as the Director of the Biomedical Advanced Research and Development Authority (BARDA) and as a Deputy Assistant Secretary for Preparedness and Response (ASPR). Through ASPR and the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), BARDA leads the advanced development of medical countermeasures to prepare for and respond to emerging infectious diseases, man-made national security threats, and other public health emergencies. In ASPR we have been working to advance a mission delineated by the Pandemic and All-Hazards Preparedness Act (PAHPA) and realize our full leadership capabilities. ASPR and BARDA have matured and flourished in many diverse ways over the past nine years. We operate efficiently and from a position of strength with the ability to manage numerous lines of effort including the water situation in Flint Michigan, the recent Ebola epidemic, and the current Zika outbreaks. With this testimony I intend to provide a progress report on our current efforts and hope to clarify our capabilities in the context of Zika.

The Administration is taking appropriate action to protect the American people and, as you know, on February 8, it announced a request to Congress for approximately \$1.9 billion in emergency funding to enhance ongoing efforts to prepare for and respond to outbreaks of the Zika virus, both domestically and internationally. This includes funding for work on the development of vaccines and diagnostics and to improve scientific understanding of the disease. While I will briefly describe some of ASPR's activities overall, as the BARDA director, I will focus my remarks on the development of vaccines and diagnostics.

The Zika virus is primarily a mosquito vector-borne viral disease threatening the United States and our neighbors in Latin America and other parts of the world. Zika is a flavivirus in the same family as dengue, West Nile virus, and Yellow Fever, diseases we have been monitoring and combating for years. On February 1, the World Health Organization (WHO) declared clusters of microcephaly and other neurological disorders, and their possible association with Zika virus, a public health emergency of international concern. Named after the Zika Forest in Uganda, Zika includes common symptoms such as fever, skin rash, joint pain, or conjunctivitis. However, eighty-percent of people with Zika do not appear to have symptoms at all. Considering recent outbreaks in the Pacific Islands, Central America, South America, and the Caribbean, we anticipate that the number of Zika cases among travelers visiting or returning to the United States is likely to increase. We have already seen cases of travelers returning to the United States with confirmed Zika virus disease and are particularly concerned about the virus becoming endemic in the Commonwealth of Puerto Rico, the U.S. Virgin Islands, the American Samoa, with potential for local outbreaks in parts of the southern United States. Moreover, the Brazilian Ministry of Health estimates that between 440,000 and 1.3 million suspected cases of Zika occurred in Brazil in 2015.

There is still much that we do not know about Zika and its adverse health effects on a population. Evidence associating Zika with birth defects like microcephaly and other adverse health conditions such as Guillain-Barré Syndrome is growing; however, there is still much to learn including whether additional factors are involved. HHS is actively monitoring the Zika virus, investigating outbreaks, and working with domestic and international partners to update health

care providers and the general public. In addition, HHS is providing laboratory and diagnostic tests both domestically and internationally.

As we learned with Ebola and pandemic influenza, one of our key responsibilities in addressing an infectious disease is effective communication. This involves delineating a leadership structure and updating information as soon as possible using principles of risk communication and using multiple including translated materials for non-English speaking communities and enhanced outreach to vulnerable populations. Clear, concise, and accurate information can reduce the level of concern among the general population and support appropriate action by health care providers. With that in mind, HHS and our federal partners are stressing a coordinated response to this emerging threat.

ASPR is fulfilling its leadership roles both through the Disaster Leadership Group (DLG) through the PHEMCE to develop and provide medical countermeasures. Both were created to effectively improve coordination within the Department and with our external stakeholders, including nonprofits, other federal departments, the private sector, and the international community. Specifically, the DLG is comprised of leadership from across HHS to advise and coordinate policy on critical issues related to preparedness and response. Additionally, the the Secretary's Operations Center serves as the focal point for International Health Regulation, and for communication across government. The PHEMCE, chaired by the ASPR, serves as the focal point for coordinating medical countermeasure development.

I will focus the remainder of my testimony on BARDA's role. BARDA has a mandate from PAHPA to transition medical countermeasure candidates from early development across the "Valley of Death" into advanced research and development towards FDA approval. BARDA has established four strategic goals to address medical countermeasure needs for the Zika response domestically and globally. These are prevention of Zika virus infection through new vaccines; detection of acute and previous Zika virus infections through new rapid diagnostics; ensuring a safe blood supply from Zika virus through screening and virus inactivation; and activation of our National Medical Countermeasure Response Infrastructure to aid medical countermeasure developers.

Building on existing and new partnerships and lessons learned from the H1N1 and Ebola responses, we are implementing our Zika medical countermeasure strategy through the advanced development and manufacturing of new Zika-specific vaccine candidates. In collaboration with NIH, FDA, and the Walter Reed Army Institute of Research, we are working on vaccine development, pre-clinical and clinical testing, and commercial scale production, including vaccine manufacturing through our Centers for Innovation in Advanced Development and Manufacturing. We are also providing technical assistance to our global partners in Brazil for Zika vaccine development and commercial scale manufacturing. We are supporting industry partners to develop and utilize new and innovative vaccine platform technologies to address public health emergencies for multiple emerging infectious diseases including new Zika vaccine candidates. We are collaborating with CDC, FDA, and NIH to facilitate the development of rapid point-of-care and laboratory-based serological assays for Zika to determine who has been infected previously, especially pregnant women. With regard to the blood supply, we are

collaborating with FDA to support the development and implementation of rapid high-throughput molecular diagnostic screening and pathogen reduction technologies. We're particularly concerned about blood supplies at risk due to recent Zika virus outbreaks in the Commonwealth of Puerto Rico and potentially other parts of the United States. As we did for the Ebola response, we are assisting medical countermeasure developers through our National Medical Countermeasure Response Infrastructure, which is comprised of six core service assistance programs that provide animal and human clinical testing, product development and manufacturing, and regulatory and modeling needs. This infrastructure could potentially be used to develop vector protection countermeasures such as mosquito repellants.

We are also encouraging and receiving numerous inquiries from academic and industrial stakeholders for potential medical countermeasures through our Tech Watch program. Moreover, contracting for ASPR's medical countermeasure programs has been designed to be transparent and responsive to industry but also ensure that we have appropriate internal controls for the contracting process overall. We're able to efficiently move from the idea and proposal stage to acquisition. Considering a government-wide benchmark of 180 days to award a contract, ASPR is consistently awarding major acquisition contracts within 128 days. During the height of the Ebola response we were awarding contracts within 60 days. This success is a demonstration of the mature contracting function that ASPR has implemented and one that is fulfilling its requirements to support our industry partners and the medical countermeasure enterprise.

Recognizing the domestic impact of global public health emergencies, we have strengthened our international partnerships as cited above for vaccine development with Brazil. Whether it is pandemic influenza, Ebola, or a vector-borne disease like Zika, public health emergencies have no borders. We have forged trusted networks and relationships with key international partners and continue to receive and share information with the WHO, the United Nations, the United States Agency for International Development, the U.S. Department of State, and countries around the world about best emergency preparedness practices and surveillance data on infectious diseases. We maintain regular communications and coordination with the G7 countries, Mexico, and the European Commission on public health measures, including the development and deployment of medical countermeasures. These collaborations range from discussing domestic preparedness activities of other countries to the medical evaluation and coordination of medical countermeasure development. Our weekly Americas' Call teleconference involves eighteen countries from North America, Central America, South America and the Caribbean. Thanks to this mode of outreach and coordination, we learned that Panama had Zika samples they were willing to share for research, which was a big step forward in helping to identify the strain for diagnostic comparisons. The Global Health Security Initiative (GHSI) is another success story for international coordination. Established shortly after the September 11, 2001, terrorist attacks, GHSI is an assembly of Ministers, Secretaries, Health Commissioners and other senior health officials from the European Commission, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, and the WHO to address global health security issues. GHSI played a crucial role in bringing countries together for the Ebola response and is already turning its focus to Zika. An early focus has been on sample sharing, which is critical to the development of vaccines and diagnostics. The next ministers

meeting is taking place this week in the United States, and Zika will be one of the main topics of discussion.

In closing, our foremost concern is protecting public health from known or emerging threats. Zika is our newest threat, but not our last. Congressional approval of the Administration's approximately \$1.9 billion funding request will ensure an effective and rapid response to outbreaks that threaten the health of the American people and can accelerate our ability to prevent, detect, and respond to Zika and other emerging infectious diseases. Thanks to our combined efforts and with lessons learned from previous challenges, we are a better prepared and more resilient nation with the flexibility to successfully address a variety of public health threats. Thank you again and I look forward to your questions.