



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

**“Examining the U.S. Public Health
Response to the Zika Virus”**

Statement of

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Good morning Chairman Murphy, Ranking Member DeGette, and distinguished Members of the Subcommittee. I am Dr. Nicole Lurie and I am the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS).

Thank you for the opportunity to testify before you again. ASPR was established by the Pandemic and All-Hazards Preparedness Act (PAHPA) to lead the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters. Over the past nine years, with the support of Congress and this committee, ASPR has built a comprehensive array of capabilities that enable us to ably and expeditiously fulfill this mission. ASPR works within HHS and with its Federal, state, tribal, and local partners to advance the public health preparedness of our nation by helping build communities that are more resilient to events that threaten the public's health, whether they are naturally occurring disasters, infectious disease outbreaks, or acts of terrorism. Our structure enables us to operate efficiently and simultaneously manage multiple responses including the recent Ebola epidemic, and the current Zika virus (Zika) outbreaks in the Americas.

The Administration is taking proactive and aggressive action to protect the American people and address the threat posed by Zika virus. As you know, the President recently announced a request to Congress for \$1.9 billion in emergency funding, including \$295 million for urgent and emerging threats to enhance ongoing efforts to prepare for and respond to outbreaks of the Zika virus or other vector borne or infectious diseases, both domestically and internationally. Within the \$1.9 billion funding request, there is support for the development and emerging manufacturing of new Zika-specific vaccines; development of vaccine platform technologies for multiple emerging infectious diseases; development of rapid serological diagnostics to determine whether someone has

been infected previously with the Zika virus such as pregnant women; and pathogen reduction technologies for blood supplies related to the recent Zika virus outbreak in the Western Hemisphere.

An important lesson learned from the Ebola epidemic is the need for a flexible funding stream that can adapt to whatever crisis comes our way. We learned how important it is to get ahead of a crisis, before it becomes an emergency. Ebola was not the first such crisis, and Zika will certainly not be the last. However, to be prepared for new or emerging, threatening diseases, we must maintain a readiness posture, and right now that means being prepared for and doing everything we can do to stop Zika and other potentially dangerous vector-borne diseases. The funds for Zika will support our efforts to direct the right resources at the right time as the Zika epidemic unfolds and we learn more about its impact and how it is transmitted. An effective, coordinated response, to this significant public health threat requires a comprehensive, immediate response with the ability to adapt to unanticipated needs. Regardless of the shape this crisis takes, it is clear that funding for work on the development of vaccines and diagnostics, including blood and tissue donor screening tests, and to rapidly improve scientific understanding of the disease is required. Furthermore, aggressive education and outreach is needed to ensure health care providers are prepared to counsel and treat patients with Zika virus or its complications.

The Zika virus is primarily a mosquito vector-borne viral disease currently threatening the United States and many other countries in the Americas, Pacific, and Africa. Named after the Zika Forest in Uganda, acute Zika infection can cause common symptoms such as skin rash, fever, joint pain, or conjunctivitis. Most Zika infections are associated with no symptoms at all; however, there has been a concerning association between women who become infected with

Zika during pregnancy and babies born with microcephaly and other complications. Zika infection has also been associated with Guillain-Barré Syndrome, in which the body's immune system attacks the nervous system and causes muscle weakness or paralysis. On February 1, the World Health Organization (WHO) declared the clusters of microcephaly and other neurological disorders that are possibly associated with Zika virus a public health emergency of international concern. The Brazilian Ministry of Health estimates that between 440,000 and 1.3 million suspected cases of Zika occurred in Brazil in 2015. As of February 25, 34 countries and three U.S. territories, including the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and American Samoa have reported cases of local mosquito-borne transmission. Considering these recent outbreaks in the Pacific Islands, Mexico, 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 limiting transmission of the virus in the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, and the Marshall Islands. Last week, CDC published the first information on pregnancy outcomes for women in the United States known to be infected with Zika virus. That information continues to add to the evidence base about the association between Zika virus and adverse pregnancy outcomes.

ASPR took some early steps to address Zika virus. On December 2, 2015, one of the first steps we took to address Zika virus was to call on the infrastructure of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) to assess what medical countermeasures were in the development pipeline. In addition, on January 3, 2016, we convened the HHS Disaster

Leadership Group (DLG) to coordinate Zika-related issues across HHS's Operational and Staff Divisions. Both of these structures were created to improve coordination within the Department and in the case of the PHEMCE, across U.S. Government stakeholders. Specifically, the DLG is comprised of leadership from several HHS components, such as the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA), to facilitate coordinated policy decision making on critical preparedness matters, ongoing response activities, and mitigation efforts to limit the lasting effects of disasters. We also elevated the activation level of the Secretary's Operations Center (SOC), which, in coordination with the DLG, serves as the focal point to collect and share operational information on this new threat across other federal departments, state, local, and tribal governments and our external stakeholders, including nonprofits, the private sector, and the international community. In this way, the SOC leverages our combined capabilities to effectively prepare our nation and execute an organized response.

As was the case for H1N1 and for Ebola, ASPR is coordinating medical countermeasure activities in the Zika response by activating the PHEMCE infrastructure, which, on a daily basis, supports the development and acquisition of medical countermeasures to prepare for biological threats. ASPR convenes a weekly Senior Steering Group composed of senior leaders across the PHEMCE to discuss Zika-related medical countermeasure policy and operational issues and to coordinate activities. In addition, through guidance documents such as the PHEMCE Strategy and Implementation Plan and the National Health Security Strategy, ASPR leads the path forward for our partners and stakeholders.

The Biomedical Advanced Research Development Authority (BARDA), within ASPR, has a mandate from PAHPA to transition medical countermeasure candidates from early development into advanced research and development towards FDA approval. BARDA has established 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 blood supply safe from Zika virus through donor screening and virus inactivation in blood products, and activation of our National Medical Countermeasure Response Infrastructure to aid medical countermeasure developers. As we did for the Ebola response, we are assisting medical countermeasure developers through our National Medical Countermeasure Response Infrastructure 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 TechWatch program.

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 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 innovative vaccine platform technologies for public health emergencies for multiple emerging infectious diseases to produce new Zika vaccine candidates.

In regards to diagnostics, we are working with CDC to expand the number of health departments that have the ability to perform testing, but will need to increase the existing capacity to meet the projected demand for Zika testing. 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. ASPR/BARDA is collaborating with CDC, FDA, and NIH to facilitate the development and availability of commercial assays to identify Zika virus and diagnose infection. Interagency efforts are underway to acquire and distribute virus and clinical samples needed for test development and evaluation. BARDA has released a solicitation to advance the development of assays that would expand capability to provide reliable, accurate testing beyond public health laboratories to doctors' and other health care providers' offices, hospitals, and commercial laboratories.

We are collaborating with FDA to support the development and implementation of rapid high-throughput molecular diagnostic screening and pathogen reduction technologies to ensure a safe blood supply. CDC is providing technical assistance to FDA to help prevent transfusion-related Zika transmission. ASPR is working with partners across HHS to ensure that the Commonwealth of Puerto Rico has adequate blood supply.

Realizing the lessons we learned from Ebola, informative, consistent, and widely distributed messaging to the U.S. population from HHS components is a primary focus. We have delineated a leadership structure, and identified primary spokespeople for the response. Adhering to the principles of risk communication, we are updating information as soon as possible through multiple sources 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.

ASPR has facilitated opportunities for coordination among state and local health systems through Hospital Preparedness Program (HPP) grants and Health Care Coalitions. HPP enhances the capability of health care coalitions in communities across the country to build resiliency by strengthening systems, improving surge capacity, and advancing science-based decision-making before, during, and after emergencies. In response to Zika, HPP is including Health Alert Network (HAN) advisories and links to other CDC-produced guidance in its weekly update and continues to remind coalition leaders and awardees of their key role in sharing information about Zika virus with their member facilities and organizations. Further, HPP is prompting coalitions with limited specialized resources (e.g., neurology, maternal-fetal medicine, etc.) to pre-identify these resources and share information with member facilities and organizations about how to access and utilize them as coalition resources for preparedness, communications, messaging, and consultative purposes.

Whether it is pandemic influenza, Ebola, or a vector-borne disease like Zika, viral epidemics do not respect borders. Recognizing the domestic impact of global public health emergencies, we have strengthened our international partnerships as cited above for vaccine development with Brazil. Through our standing ASPR capacity building programs in the region, we have obtained viral isolates and serum samples from Panama that are being distributed to CDC, NIH, FDA and others in the government to conduct research and expedite development of serological diagnostics and blood safety screening tests. In collaboration with the Department of State and the U.S. Agency for International Development, we are currently leveraging trusted networks and relationships with key international partners that we have forged over the years. We are closely collaborating with the World Health Organization (WHO); WHO's regional arm, the Pan American Health Organization; the United Nations; and countries around the world about best emergency preparedness practices and surveillance data on infectious diseases. We maintain regular communications and coordination with partners of the Global Health Security Initiative or GHSI, which includes the G7 countries, Mexico, the European Commission, and WHO as an advisor.

On behalf of the HHS Secretary, ASPR hosted the 16th GHSI Ministerial meeting in Washington, D.C. on February 26. Within GHSI, we are collaborating to mount coordinated responses to the Zika virus to enhance information sharing about a) public health practices and policies in our countries, and b) a list of scientific and public health studies done in our institutions, and in collaboration with Latin American and Caribbean countries, to unify our efforts to expedite knowledge about potential linkages between Zika and microcephaly and

between Zika and Guillain-Barré Syndrome, as well as on the development of medical countermeasures.

ASPR, in collaboration with the HHS Office of Global Affairs, is hosting teleconference calls with U.S. Government partners to coordinate activities in the Latin American and Caribbean region. Together with the Department of State, we have implemented a tracking system to receive and respond to international requests for information and assistance in a coordinated manner for the U.S. Government. These are just examples of the myriad of coordination efforts to outreach to our international partners to collaborate in the response to Zika.

In closing, our foremost concern is protecting public health from known or emerging threats. Zika is our newest threat, but not our last. Congressional funding for 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 vector-borne and 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.