Written Testimony
House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

The U.S. government's response to the Ebola outbreak in West Africa and domestic cases of Ebola.

Statement of

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ASPR
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Good morning Chairman Cole, Ranking Member DeLauro, and distinguished Members of the Committee. My name is Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services. ASPR leads the nation in preparing for, responding to, and recovering from public health and medical disasters and emergencies.

I appreciate the opportunity to talk to you today specifically about ASPR's actions to address Ebola and how the emergency funding you provided helped us respond to Ebola and position us to address important gaps in infectious disease preparedness. As we have seen recently, with the increased number of cases in Guinea and the stuttering caseload in Liberia and Sierra Leone in the past few weeks, we cannot let down our guard. We must continue our focus on eliminating Ebola from West Africa. But we have another critical responsibility-- protecting our country from this, and other serious infectious diseases such as MERS-CoV, SARS, antimicrobial resistant pathogens, pandemic influenza, and the next unknown threat. We may not know when, where, or how, but we do know that in our increasingly global society that the next threat is inevitable. We are no longer immunized via long borders and vast oceans. ASPR is suited to address this problem. We are working daily to ensure that we have the right medical countermeasures and that we are pushing manufacturing to produce more, better, and faster. We are working with our health care system partners to ensure that hospitals can identify, isolate, and treat Ebola patients, and we are making sure that these investments today will be beneficial to our response to future outbreaks later. Finally, we are working with those providers who stepped up to treat Ebola patients, by making sure they do not have to bear a financial burden for their leadership.

Now let me focus on our primary activities with regard to the emergency appropriation. Early on in this outbreak I convened the departments and agencies that make up the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). Together we identified opportunities to rapidly accelerate the development of diagnostics, vaccines, and therapeutics for Ebola. I am proud to say the PHEMCE process has worked superbly. It is a fine example of the strong day-to-day, whole of government system that ASPR leads in order to meet our mission. This collaboration has allowed the Biomedical Advanced Research and Development Authority (BARDA) to position themselves to accelerate candidates through the medical countermeasure development pipeline.

Together with industry and U.S. government partners, including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Department of Defense (DoD), BARDA has quickly built and implemented a strategy to combat Ebola by developing, manufacturing, and testing multiple promising Ebola vaccine and therapeutic drug candidates. Those agencies are also working to ensure these countermeasures are safe, work effectively, and can be manufactured to scale if the epidemic worsens. Also key to the response was our National Medical Countermeasure Response Infrastructure, including our Centers for Innovation in Advanced Development and Manufacturing, the Fill-Finish Network and the Clinical Studies Network. These tools were established as a result of lessons learned from the H1N1 epidemic. Each of these components has been vital to our countermeasure response. Last year, BARDA successfully transitioned several Ebola monoclonal antibody candidates (like ZMapp) that were in early development at the National Institute of Allergy and Infectious Diseases (NIAID), the DoD, and industry, into accelerated development and manufacturing. Using funds included in the $215 million provided

by Congress for the development of Ebola medical countermeasures, BARDA supported manufacturing of clinical investigational lots of ZMapp, which are currently in clinical trials in West Africa and the U.S. to verify safety and efficacy. Other newly developed Ebola monoclonal antibody candidates have shown protection similar to ZMapp in nonhuman primate challenge studies and may soon enter clinical trials. BARDA is also supporting the advanced development of an Ebola antiviral drug candidate transitioned from NIH's NIAID, called BCX 001. That drug is currently undergoing safety trials. Should the epidemic get worse in West Africa, it would likely be ready for efficacy testing. Similarly, BARDA is supporting the advanced development and scaled-up manufacturing of three Ebola vaccine candidates, two of which are presently in clinical trials for safety and efficacy in West Africa. BARDA's support of these two Ebola vaccine candidates could help ensure that millions of vaccine doses can be available later this year if needed for a mass vaccination campaign. Equally important is our partnership with FDA. Their impressive speed and flexibility in making products available for emergency use and in assessing and approving designs for clinical trials has been key to moving products forward. Dr. Robinson's testimony will provide additional details both about the progress being made to develop medical countermeasures for Ebola and about how we have used our newly built infrastructure in this response.

Complementing our successes in medical countermeasure development, ASPR has made great strides in U.S. health care system preparedness. Since the beginning of the program's inception in 2002, our Hospital Preparedness Program (HPP) has been fundamental in preparing hospitals and their community health partners for all hazards that impact the public's health, including infectious diseases. In fact, in a recent survey to understand the impact of HPP, 98 percent of the program's awardees say that HPP has been critical to health care system

preparedness. In the last several years, HPP awardees have demonstrated their ability to respond to and quickly recover from disasters—from natural disasters like tornados, floods and hurricanes to the Boston Marathon bombing and diseases like fungal meningitis caused by contaminated steroids. Specifically for Ebola, HPP's efforts focused on enhancing the health care system's capabilities to identify potential patients with Ebola; isolate and evaluate them safely; and treat confirmed patients.

In order to make sure that the U.S. health care system could safely and successfully confront Ebola, HPP provided guidance and updated information to communities about how best to be prepared for Ebola. With input from the public health and hospital communities, as well as our partners at CDC, we developed a framework for a tiered approach for the U.S. health care system, which outlines the different roles facilities can play in preparing to identify, isolate, and evaluate patients with possible Ebola and / or treat patients with confirmed Ebola. Building upon that framework and in response to input from experts and public health and health care stakeholder groups, as well as meeting the Congress'—specifically this Committee's—regional directive, HPP established a nationwide, regional treatment network for Ebola and other infectious diseases. This network will balance geographic need, differences in institutional capabilities, and account for the potential risk of needing to care for an Ebola patient. It will consist of:

- Up to ten regional Ebola and other special pathogen treatment centers (one in each of the ten HHS regions) that can be ready within a few hours to receive a confirmed Ebola patient from their region, across the U.S., or medically-evacuated from outside of the U.S., as necessary. These hospitals will also have enhanced capacity to care for other highly infectious diseases.

- State or jurisdiction Ebola treatment centers that can safely care for patients with Ebola if necessary.
- Assessment hospitals that can safely receive and isolate a person under investigation for Ebola and care for the person until an Ebola diagnosis can be confirmed or ruled out and until discharge or transfer are completed.
- Frontline health care facilities that can rapidly identify and triage patients with relevant exposure history and signs or symptoms compatible with Ebola and coordinate patient transfer to an Ebola assessment hospital.

The "Hospital Preparedness Program Ebola Preparedness and Response Activities" Funding Opportunity Announcement (FOA), released on February 20, 2015, will provide awardees with a total of $194.5 million to support this regional approach. In addition, it will support future preparedness efforts for Ebola and other special pathogens, as well support facilities and health care coalitions' preparedness activities undertaken since July 2014. In developing the HPP Ebola FOA, we incorporated input from a number of data sources, including: modelling results, information about where travelers from affected countries ultimately went within the U.S., diaspora population centers within the U.S., and input from state and local health departments, hospitals, and health care professional organizations. Applications are due on April 22 and we expect to make awards by May 20.

A key lesson learned from the early health care system response to Ebola is the critical importance of protecting the safety of health care workers -from clinicians and laboratory workers to ancillary staff. Protecting these workers is essential to health care system preparedness and response activities. Other lessons involve understanding that care for Ebola

patients is clinically complex and demanding, and that early case recognition is critical for preventing spread and improving outcomes. Recognizing these important lessons, on March 19, 2015 ASPR and CDC announced a $12 million funding opportunity, from supplemental funds, to support a National Ebola Training and Education Center (NETEC). The NETEC will offer expertise, training, technical assistance, peer review, monitoring, recognition, and if feasible, certification to regional Ebola and special pathogen treatment centers, state- and jurisdiction-based Ebola treatment centers, assessment hospitals, and state health departments. This approach leverages the expertise we have seen in the United States in addressing Ebola to further support our domestic health care system to be better prepared for future patients, and expand our nation's health security. Applications are due May 20, and an award is expected by June 22.

Whether from Ebola or the next infectious disease threat, our Hospital Preparedness Program is committed to ensuring that patients receive safe and effective care. Moreover, HPP ensures that frontline providers – including emergency medical services personnel - are trained to recognize and isolate a person with suspected Ebola or other emerging infectious diseases.

While making sure that Ebola patients are safely and well treated, we also recognize that the level of constant care required for Ebola patients creates a substantial financial burden for treatment hospitals. For costs not covered by insurance, reimbursing hospitals and other providers that have taken the initiative to take care of these patients is crucial. They should not have to bear financial burden because they stepped up to treat patients. As I mentioned earlier, we have set up a mechanism to do this, and are now able to accept claims from health care providers.

Let me now turn to where we are today. We recently needed to test some of the nuts and bolts of the system we have been building. As you may know, NIH is treating an Ebola patient who was repatriated to the U.S. Other individuals who were in contact with this individual were also repatriated to the U.S. for observation. We tested our medevac system and procedures with the Department of State and they worked. I want to be sure hospitals are truly ready and willing to take care of each and every one if they had developed Ebola. When I called hospitals and state health departments to check, I heard that they were confident, felt ready, and in fact wanted to help by taking care of someone with Ebola. This was a far cry from the situation last fall when I mostly heard they were not comfortable or ready to accept an Ebola patient. We have come a long way and are incorporating lessons learned from this Ebola outbreak. While the partnership with Congress leading to the emergency funding request was excellent, we know we need to continue to be looking ahead to future potential threats and be prepared. Time is of the essence when it comes to biothreats or public health emergencies. To that end, the President's FY 2016 Budget request includes $110 million to be held in reserve as a response fund, to enable rapid response when it is needed. Second, it is very important to accelerate the development, manufacture, and testing of medical countermeasures. As a result of the Ebola epidemic in 2014, BARDA transformed its core service assistance programs that help MCM developers routinely into its National Medical Countermeasure Response Infrastructure to make these programs capable of providing a full suite of MCM activities for emergency response. The Infrastructure is comprised of BARDA's Nonclinical Studies Network, the Centers for Innovation in Advanced Development and Manufacturing (CIADM), Fill-Finish Manufacturing Network, and the Clinical Studies Network in addition to technical and regulatory assistance provided directly by BARDA including in Sierra Leone for Ebola. Together, these mechanisms

accelerate the nation's response to an outbreak. Based on successful rapid monoclonal antibody development during the Ebola response, BARDA is expanding its new Infrastructure's capabilities to include MCM research and development in an emergency to known and unknown threats. In addition, we need flexible and nimble contracting options that allow us to expedite the procurement of goods and services that are needed during a high priority public health crisis or during a response to a public health emergency. Furthermore, planning and consideration for transporting waste will continue to improve our national preparedness. ASPR and our partners are looking at ways to expedite review and approval for permits to transport biocontainment materials. While we would have preferred that this Ebola crisis had never happened, it has truly enhanced our preparedness for Ebola and for other infectious diseases. In fact, as we have seen in both measles and MERS-CoV over the past few weeks, the improvements we helped make in hospital preparedness and infection control will serve us well going forward.

At the same time, we are not done and our mission continues. The regional HPP system must be built and the preparedness of each hospital, each healthcare coalition, and the entire health care system, needs to be exercised and tested regularly. It needs to be ready for when we need it. Preparedness must be continuous; it never stops. HHS is prepared, as needed, to handle unexpected changes in this epidemic by maintaining a healthy reserve of emergency funding to address any unanticipated future needs. This could include anything from medical evacuation of the Department's health care workers abroad, additional reimbursement for uncompensated care for Ebola patients, additional international response efforts, or any other activities necessary to respond appropriately to unforeseen changes in the epidemic.

In closing, I want to reiterate that none of what has been achieved would have been possible without the strong collaboration we have built with the PHEMCE, industry, State and

local health departments, and the healthcare system as part of our preparedness efforts. Chairman Cole, the support of your committee has been critical to this success. I look forward to working with you and your staff in the future as we work together to protect our country and its people from all hazards, whether naturally occurring or manmade. There is still a lot of work to do. I thank you again for this opportunity to address these issues and welcome your questions.

Thank you.