



**Written Testimony
Senate Committee on Homeland Security
and Governmental Affairs**

**Preparedness and Response to
Public Health Threats: How Ready
Are We?**

Statement of

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Good morning Chairman Carper, Ranking Member Coburn, and other distinguished Members of the Committee. I am Dr. Nicole Lurie and I serve as the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS).

I appreciate the opportunity to talk to you today about the actions ASPR has taken to lead the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting our communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security. ASPR works within HHS and with its Federal, state, tribal, and local partners to advance the public health preparedness of our Nation, by helping to build communities that are more resilient when faced with events that have an adverse effect on the public's health, whether they are naturally occurring disasters, infectious disease outbreaks, or acts of terrorism. ASPR has led the public health response and recovery from natural disasters, such as Hurricane Sandy, the devastating earthquake in Haiti, and the Deepwater Horizon oil spill. We have responded to disease outbreaks including the H1N1 pandemic influenza and the current Ebola outbreak. In addition, ASPR provides public health and medical response capabilities for National Special Security Events, including Presidential inaugurations, the State of the Union Address, and other national events requiring high security. Over the past six years, we have improved our preparedness network with new and stronger partnerships with state, tribal, and local governments, health care systems and workers, industry, international entities, and many more. Across our mission space, I have placed a priority on working in partnership with industry and the private sector; building resilient communities; addressing the needs of the at-risk community; and instilling an enterprise

approach among our Federal partners. Collectively, we are moving aggressively forward to prepare for any contingency, ranging from natural to manmade threats.

ASPR has been uniquely successful in advancing the nation's preparedness through its coordination and collaboration with a broad array of partners. These day-to-day activities, and the infrastructure we have put in place, are key to responding to Ebola. In my testimony, I would like to highlight three areas of ASPR's work: the Biomedical Advance Research and Development Authority (BARDA), the Hospital Preparedness Program (HPP), and our emergency operations function. I will also review how ASPR's authorities provided through the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) and reauthorized by the Pandemic All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) have been critical to our response efforts. BARDA, a core component of ASPR, is dedicated to building our domestic capability to develop effective medical countermeasures (MCM).

In 2010, HHS established a plan to modernize the medical countermeasure enterprise with the release of the Public Health Emergency Medical Countermeasure Review. Key to the success of this effort was the establishment of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which oversees the entire MCM lifecycle to ensure that Federal Departments and Agencies are working well together to ensure the coordination and decision-making at all stages of the MCM research and development pathway, from identification of requirements for particular types and quantities of drugs, through product development, and ultimately to distribution, stockpiling, and use. ASPR leads the PHEMCE, working in close partnership with other HHS agencies – including the National Institutes of Health (NIH), the

Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) – and our interagency partners, the Departments of Defense (DoD), Homeland Security (DHS), Veterans Affairs, and Agriculture. This well-functioning, day-to-day system, is serving us well to help develop MCMs for public health threats, including Ebola, and to ensure that our health care system is prepared, and to make decisions with the best available science. In fact, not long after the outbreak began last spring, I convened a meeting of the PHEMCE partners to review whether there might be candidate products in the pipeline whose development could be accelerated. This led us to prioritize the development and testing of both vaccine and therapeutics candidates for Ebola. ASPR uses modeling projections to enhance preparedness and response capabilities for a broad range of threats. Its support for and coordination of mathematical and computational modeling studies across the Government and academia help to assess the current and future progression of the Ebola outbreak and assist in response planning. CDC, NIH, DOD, DHS, National Laboratories, international health partners including the U.S. Agency for International Development (USAID) and the World Health Organization (WHO), and academic organizations are all working together to ensure that biosurveillance and other data sources are being used to coordinate response decisions and to base them on the best available data and science.

Recognizing that substantial resources are essential to advance the development of new and improved MCMs, the Congress has provided critical authorities and has appropriated billions of dollars for the development and procurement of MCMS for use against chemical, biological, radiological, and nuclear (CBRN) threats. These investments, and the collective efforts of BARDA, NIH, FDA, CDC, and our private industry partners, have resulted in products that

protect the American public, and will ensure that we have the MCMs to protect and ensure the national health security of the United States in emergencies. BARDA has procured 12 products since the inception of Project BioShield a decade ago and has built a national stockpile of pandemic influenza vaccines. The FDA has approved seven products supported by BARDA, including antitoxin treatments for botulinum toxin and anthrax, which have moved through all phases of the medical countermeasure pipeline, from discovery to procurement.

These investments have also strengthened our MCM enterprise to respond to CBRN threats in the future. We have gone from having very few products in the MCM pipeline to funding over 80 candidate products. If products in this group are successfully transitioned from development to procurement contracts, we anticipate having the following new MCMs available in the Strategic National Stockpile over the next five years: (1) an entirely new class of antibiotics; (2) anthrax vaccine and antitoxins; (3) smallpox vaccine and antivirals; (4) radiological and nuclear countermeasures, including candidates to address the hematopoietic, pulmonary, cutaneous, and gastrointestinal effects of acute radiation syndrome; (5) pandemic influenza MCMs; and (6) the first set of antidotes to chemical threats, as well as diagnostics to speed the identification of patients with conditions specific to this threat.

With each experience, HHS examines lessons learned and opportunities for improvement. Following the H1N1 epidemic, we identified the need for more flexibility to develop and produce innovative, safe and effective MCMs. In 2012, HHS established the Centers for Innovation in Advanced Development and Manufacturing (CIADM), public-private partnerships that provide a significant domestic infrastructure in the United States to produce MCMs to

protect Americans. Last year, as part of its pandemic preparedness efforts, BARDA established the Fill Finish Manufacturing Network, which is now being used to formulate and fill multiple Ebola antibody and vaccine candidates into vials for potential clinical efficacy studies in West Africa. Last year, 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.

HHS is using this infrastructure right now to develop MCMs against the Ebola virus. The CIADMs are positioned to expand the production of Ebola monoclonal antibodies into tobacco plants and mammalian cells. In addition, the Fill Finish Manufacturing Network will be used to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses.

With respect to vaccines, HHS is working to scale-up to commercial scale the manufacturing of promising investigational Ebola vaccine candidates using funds provided by the Congress in the FY 2015 Continuing Resolution.

Moving to issues of response to domestic emergencies, under the National Response Framework, my office is responsible for coordinating the Emergency Support Function #8 response – Public Health and Medical Services – and coordinating Federal assistance to supplement state, local, territorial and tribal resources in response to public health and medical care needs during emergencies. My office manages the National Disaster Medical System (NDMS), and other critical medical and public health resources that can be activated during catastrophic events when requested by states and localities. ASPR supports state, tribal, and local preparedness, response and recovery efforts through coordination of the Medical Reserve Corps (MRC), the Emergency

System for Advance Registration of Volunteer Health Professionals and the Hospital Preparedness Program (HPP). HPP defines the capabilities required for effective health care system response, and focuses on strengthening the day-to-day activities required to effectively respond to emergencies.

Since 2002, as a result of funding from HPP, we have made great strides in the ability of the predominantly private-sector health care system to provide medical care during an emergency surge of a large number of patients. In order to prepare the U.S. health care system to respond to events in a coordinated and collaborative manner, rather than facility-by-facility, ASPR provides resources to 62 state, territorial, and local awardees through the HPP. HPP investments have fostered an increased level of preparedness throughout communities and contributed to a decrease in state, tribal, and local governments' reliance on Federal aid following disasters. In the last several years, HPP awardees have transitioned from providing most of their HPP funding to individual hospitals within their jurisdictions to supporting coalitions of health care facilities. This transition to supporting and building regional health care coalitions has provided dramatic examples of a community's ability to recover after a disaster. For example, in the aftermath of tornados in Joplin, Missouri; Tuscaloosa, Alabama; and Moore, Oklahoma, HPP members immediately responded, administered care to the injured, and evacuated patients to other regional facilities that were part of the health care coalitions in those jurisdictions.

The cornerstone of this regional health system preparedness is the Health Care Coalition (HCC) – a formal collaborative network of hospitals, health care organizations, public health providers, emergency management, emergency medical services, and other public and private sector health

care partners within a defined region. By fostering preparedness and collaboration at the regional level to strengthen the overall health care system, HCCs allow for the sharing of resources, leveraging of expertise, and increased capacity to respond during an emergency. Through the efforts of HPP and its state, territorial, and local awardees, there are over 16,000 members in HPP supported coalitions throughout the Nation to include 4,778 hospitals. As a result, hospitals can now communicate with other responders through interoperable communication systems; track bed and resource availability using electronic systems; protect health care workers with proper equipment; train health care workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises.

To prepare for and respond domestically to Ebola, HPP is actively engaged in a number of activities, including: providing key information, guidance, helpful checklist documents and lessons learned to state, tribal, and local public health officials, hospital executives, health care workers, and others across the United States through webinars and national calls; actively recruiting (along with CDC) hospitals willing to provide definitive care to patients with Ebola in the United States; working with personal protective equipment (PPE) manufacturers to identify and coordinate supply distribution; and serving as the clearinghouse for Ebola-related tabletop exercises for hospitals and jurisdictions, as well as hospital infectious disease plans, so facilities and jurisdictions can quickly access them and adapt them for use in their own facilities.

Recognizing that state, tribal, and local response needs to be nimble to support their health care systems, the ASPR office informed HPP awardees that funds may be used 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 originally approved scope of work. Some awardees have already initiated these requests for Ebola.

ASPR supports a coordinated medical response capability to assist states, tribes, and localities in responding to disasters. NDMS and MRC bring health care and other personnel together to support preparedness and response missions. The NDMS is a unique program which deploys federalized responders to support communities with medical, veterinary, and mass fatality assistance after a disaster or public health emergency. Most of the 5,000 NDMS employees are active locally in a civilian job, but support the Federal Government through service as intermittent employees on one of the many NDMS teams located across the Nation. By comparison, MRC is a volunteer program, with over 1,000 MRC units and 200,000 volunteers, and is primarily managed and organized at the local level to support public health and response missions through local health department initiatives. Both programs are poised to backfill staff caring for Ebola patients in the Nation's hospitals, in the unlikely event that such support would be needed.

ASPR is deploying medical response capabilities where they are needed most to keep America safe. HHS has developed focused teams of U.S. Public Health Service (USPHS) Commissioned Corps officers who have deployed and will continue to deploy to West Africa to provide care for health care providers who require Ebola treatment. ASPR is supporting this mission through the development of recommended safety guidelines and by providing operational, logistical, personnel accountability, and pre-deployment training of USPHS officers at DHS's Federal

Emergency Management Agency's Center for Domestic Preparedness in Anniston, Alabama. USPHS officers are trained on PPE, medical screening, and safety and clinical treatment recommendations. MRC is also supporting domestic readiness; some jurisdictions are using local MRC units to support call centers, assist health departments with epidemiology and surveillance activities, disseminate guidance and information to their community partners (*e.g.*, health care coalitions, emergency management, health care workers, etc.), conduct volunteer training and community educational activities, and provide partner level updates to enhance situational awareness. ASPR is leading the effort to ensure that deployed personnel have access to and receive training in the use of PPE. This training is critical to domestic preparedness and readiness. Training personnel on the use of current PPE is an absolute requirement to ensure the safety of personnel engaged in the medical care of Ebola patients. Any deployment activities for the purpose of patient screening or care will include the necessary PPE training that meets the CDC standard. Additionally, ASPR is working with other Federal Departments and Agencies to help coordinate the U.S. Government's response to the high demand for PPE nationwide. It is actively engaged with PPE manufacturers and distributors to assess the availability of products and to develop strategies to address supply chain challenges so that there are no shortages of PPE either domestically or abroad.

Recognizing the global impact of public health emergencies, HHS has strengthened international partnerships that make America safer at home. Whether it is an H1N1 pandemic, a natural disaster, or an Ebola outbreak, public health emergencies know no borders – the health of the American people is inseparable from the health of people around the world. Moreover, the same

global capacity that is needed to combat the spread of Ebola will reduce the deadly impact of future infectious disease outbreaks.

ASPR has forged trusted networks and relationships with key international partners and continues to receive and share information with the WHO and countries around the world about Ebola. In its coordination role for the medical portion of the U.S. response effort, HHS interacts regularly with physicians in developed countries who treat patients with Ebola to facilitate information-sharing and best practices. In addition, ASPR maintains regular communications and coordination with G7 countries, Mexico, and the European Commission on public health measures, development and deployment of MCMs, and support for African countries. These collaborations range from discussing countries' domestic preparedness activities and policies including board protocols, mutual notifications of imported cases, support for medical evacuation and coordination of activities to develop and manufacture medical countermeasures. The USAID Disaster Assistance Response Team incorporates specialists from DoD and HHS (including CDC) and draws upon the resources and innovation of many different departments, agencies, and ministries of health to support Ebola treatment units that help isolate and treat those affected by the disease.

In order to ensure that appropriate Federal resources are brought to bear in our international and domestic fight against Ebola, on November 5, the Administration proposed emergency funding totaling \$6.18 billion, including \$2.43 billion for the Department of Health and Human Services. I want to highlight how this request is central to some of our key response activities. First, \$157 million of the emergency will be critical to supporting Ebola vaccine and therapeutic candidates, clinical trials, and commercial scale manufacturing. Funding through HPP will both

improve our ongoing Ebola preparedness, and also strengthen our nation's general preparedness by providing for at least one infectious disease containment center in every state, and supporting the PPE purchases, training, renovation, construction, and retrofitting facilities to create isolation units and separate laboratories. Because every hospital needs to be able to recognize and isolate a potential Ebola patient, additional money would be provided through health care coalitions to efficiently support the purchase of PPE and training for the broader network of hospitals, emergency medical services providers, and ambulatory care facilities that need to be ready to recognize, isolate, and care for a suspected Ebola patient until they can be transferred to a treatment facility.

PAHPA authorities have been critical in responding to Ebola, whether related to BARDA or HPP. In addition, flexibilities provided by PAHPRA to FDA's existing Emergency Use Authorization authority have helped to facilitate the issuance of critical Emergency Use Authorizations for multiple uncleared Ebola diagnostic tests that are in use now in the United States and West Africa. PAHPA also established the office of the ASPR, which is playing a vital role in this response. As part of the HHS leadership team responding to Ebola, I lead coordination activities supporting the HHS policy team including international engagement; establishing technical assistance for state, tribal, and local health departments and private-sector health care providers; the advanced development of vaccines and therapeutic MCM for Ebola, as well as testing and manufacturing; and preparation of Federal personnel for deployments to assist the U.S. response. I engage regularly and on an ongoing basis with the Secretary, other key HHS leadership, and Departments across the Federal Government, including the Ebola Response Coordinator, Mr. Ron Klain.

Together, we are mounting an aggressive whole-of-government response strategy to the Ebola crisis. We are focusing on controlling the epidemic; mitigating the secondary impact, including economic, social, and political tensions; coordinating the U.S. and broader global response; and reinforcing global health security infrastructure in the region and beyond.

These measures demonstrate our country's commitment to building the public health resilience needed to better prepare for disasters before they occur. Moreover, these investments require our continuing attention and commitment over the long-term and should not depend solely on the occurrence of a public health emergency. Building resilience makes us more secure from a range of public health emergencies – from an H1N1 pandemic, Ebola or other emerging infectious disease outbreak, to CBRN threats, and natural disasters.

Mr. Chairman and Members of the Committee, my team, our HHS colleagues, and our interagency partners have worked long hours to prepare our Nation for public health threats and ASPR is focusing all efforts on protecting America's health security. The best way to protect America from Ebola is to support the response to the epidemic in West Africa and to get infection and spread under control as quickly as possible. We are making efficient use of investments and leveraging the infrastructure and tools we have developed, and we are far better off than we were ten years ago following the anthrax attacks and the Hurricane Katrina response.

With that in mind, our continued success in containing the current Ebola outbreak and being prepared here at home depends on receiving the emergency resources recently requested by the President. These resources are vital for ASPR to continue supporting the advanced development

and manufacturing of promising therapeutics and vaccines. In addition, the request provides funding for health care coalitions around the Nation to purchase PPE and train staff on how to use it properly and safely and for states to establish Infectious Disease Treatment Facilities. I urge you to pass the President's request.

HHS stands ready to provide health and medical support to help our states and communities to respond and recover from public health emergencies. I thank you again for this opportunity to address these issues and welcome your questions.