Written Testimony
House Committee on Oversight and Government Reform

"The Ebola Crisis: Coordination of a Multi-Agency Response"

Statement of

Nicole Lurie, MD, MSPH

Assistant Secretary For Preparedness and Response

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

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Good morning, Chairman Issa, Ranking Member Cummings, 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 U.S. Department of Health and Human Services (HHS).

I appreciate the opportunity to talk to you today about the aggressive steps that HHS and other Federal Agencies have taken since the first cases of Ebola were identified in West Africa. By all accounts, the spread of this deadly disease in West Africa is unprecedented and we continue to work diligently, as part of the global community, to support the response and make necessary preparations in this country. The likelihood of a significant Ebola outbreak in the United States is remote, but ASPR, other HHS components, and other agencies are moving forward with preparedness planning to be ready for any contingency.

As the ASPR, I serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. Since my confirmation as the ASPR in 2009, I have created cross-Department policy group, the Disaster Leadership Group, which is comprised of leadership from my HHS counterparts at the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA), to advise on critical preparedness matters, address ongoing response activities, and mitigate lasting effects of disasters. I also led the modernization of the medical countermeasure enterprise; created opportunities for new coordination among state and local health care systems; strengthened our systems for response; and advanced a science base to strengthen decision-making processes before, during, and after emergencies. Our all-hazards approach, a shift from individual planning efforts to a more comprehensive approach to all

public health and medical emergencies, allows us to be flexible and nimble to both known and unknown threats, including the current Ebola crisis in West Africa that has challenged the entire global response capacity.

As part of the HHS leadership team responding to Ebola, I lead coordination activities supporting the HHS policy team managing critical issues including: international engagement for HHS; establishing technical assistance for state and local health care providers; the development of medical countermeasures, vaccines, and treatments for Ebola as well as testing and possible use; and preparation of Federal personnel. I coordinate daily with the Secretary and other key HHS leadership to address Ebola. I engage on an ongoing basis with the Departments of Transportation (DOT), State, Defense (DOD), and Homeland Security (DHS), as well as the Department of Labor's Occupational Safety and Health Administration (OSHA), the U.S. Agency for International Development, and others, to share information and align activities. I also communicate regularly with the Assistant to the President for National Security Affairs and other White House leadership. My staff and I work aggressively to keep leadership well-informed of ASPR's engagement, needs, and priorities related to the ongoing Ebola epidemic in West Africa and our Nation's domestic preparedness. For HHS to be successful, each element of the Agency must be fully engaged in its mission space.

Recognizing the potential impact of the many threats we face, ASPR has sought to build relationships within and outside the Federal Government and internationally to enhance coordination; make improvements in planning, logistics, and personnel management for responses to emergencies within the United States; maximize coalition building under the

Hospital Preparedness Program; and coordinate efforts within the Public Health Emergency Medical Countermeasures Enterprise. Over the past five years, we have worked to create an infrastructure capable of developing, testing, producing, and deploying medical countermeasures for the range of threats we face. Even as we continue to learn from the outbreak in West Africa and the current situation in the United States and to make adjustments, that infrastructure serves us well as we develop Ebola countermeasures, ensure that our health care system is prepared, and make decisions based on the best available science.

As you know, three cases of Ebola have been detected in the United States—an individual who was infected in Liberia and two nurses who attended to him. Our hearts go out to them and their families. Mr. Duncan's death is a tragic loss. We wish the health care workers a speedy recovery as they fight this terrible illness. I understand why you and your constituents are concerned. We are extremely serious in our focus on protecting America's health security. The best way to do that is to support the response to the Ebola epidemic in West Africa to get infection and spread under control as quickly as possible. At the same time, thanks to the preparedness work and planning that has taken place over the past several years, we are speeding the development of medical countermeasures and preparing our public health and health care systems to deal with any further cases in the United States.

Let me pause here and provide an assessment of where we are today thanks to past investments. Thanks to the support of the Congress and feedback from critical stakeholders at all levels of government, we have made significant improvements in preparedness, response, and recovery at the Federal, state, and local levels. We have strengthened our medical countermeasures

enterprise to respond to chemical, biological, radiological, or nuclear (CBRN) threats. State and local partners are more prepared than ever before due to enhanced response capabilities, improved coordination, and enhanced awareness among the public health and medical communities.

HHS has made progress in preparing the Nation for the range of CBRN threats we face by creating a flexible capacity capable of developing and producing novel safe and effective medical countermeasures faster than ever before. Elements of this infrastructure are being used right now to develop countermeasures against the Ebola virus. In 2012, HHS established the Centers for Innovation in Advanced Development and Manufacturing, public-private partnerships that provide a significant domestic infrastructure in the United States to produce medical countermeasures to protect Americans. These Centers are now positioned to expand the production of Ebola monoclonal antibodies, like those in ZMapp, into tobacco plants and mammalian cells. The Fill Finish Manufacturing Network established last year 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 with funds provided by the FY 2015 continuing resolution.

The Congress provided critical authorities and appropriated billions of dollars for development and procurement of CBRN medical countermeasures that have been turned into real products by the combined efforts of ASPR's Biomedical Advanced Research and Development Authority, NIH, FDA, and CDC. Despite some of the challenges that dealing with a serious illness such as

Ebola can have on even the most advanced health care system, I can say with certainty that we are now more prepared for the range of CBRN threats and other emerging infectious diseases, such as pandemic influenza, than at any point in our Nation's history. We have gone from having very few products in the medical countermeasure pipeline to funding over 80 candidate products. If successfully transitioned to procurement contracts and inclusion in the Strategic National Stockpile, we anticipate having the following new medical countermeasures available in the next five years: an entirely new class of antibiotics; anthrax vaccine and antitoxins; smallpox vaccine and antivirals; radiological and nuclear countermeasures, including candidates to address the hematopoietic, pulmonary, cutaneous, and gastrointestinal effects of acute radiation syndrome; pandemic influenza countermeasures; and the first set of chemical antidotes to chemical threats. Furthermore, in demonstration of our end-to-end approach to development, we have successfully moved a product through all phases of the medical countermeasure pipeline—from discovery to procurement—and have begun manufacturing a new smallpox vaccine (Modified Vaccinia Ankara).

Related to state and local preparedness, HHS has also utilized and strengthened two critical tools to support community preparedness and resilience. Both the ASPR-led Hospital Preparedness Program (HPP) and the CDC-led Public Health Emergency Preparedness (PHEP) cooperative agreement grant programs have advanced our preparedness agenda within the health care and public health infrastructure as well as throughout a number of communities. HPP and PHEP support efforts at state and local public health departments and medical facilities to ensure that communities are prepared to respond to public health emergencies. With HPP grants, we made great strides in the ability of the predominantly private-sector health care system to surge to

provide medical care to a large number of patients. PHEP funding has fostered an increased level of preparedness throughout communities and contributed to state and local governments' decreased reliance on Federal aid following disasters. Specifically, since 2002, state and local health departments have used HPP grants to allow hospitals and health care coalitions to purchase equipment and supplies; exercise and train for a number of different emergency scenarios, including highly infectious diseases; and develop partnerships and coalitions across regional health care systems to address situations like Ebola. More recently, HPP has moved towards a community-based preparedness approach to build resiliency and encourage the creation of health care coalitions. Health care coalitions are collaborative networks of hospitals, health care organizations, public health providers, emergency management, emergency medical services, and other public and private sector health care partners within defined regions. The HPP program seeks to build capabilities for hospitals and health care coalitions, such as the ability to surge and manage infectious diseases.

Building on past successes, these programs are proving critical in preparedness activities for Ebola. HHS has a number of specific activities underway to support national health security and preparedness. These efforts benefit and support broader preparedness initiatives and will strengthen the national health care infrastructure going forward. CDC, in coordination with OSHA, has issued updated infection-control guidance for health care workers caring for patients with Ebola in the United States to ensure there is no ambiguity with respect to the use of personal protective equipment (PPE). In addition, HPP began informing awardees on October 1, 2014, that funds may be used to prepare for suspected or known Ebola patients. This includes developing action plans, purchasing supplies for health care facilities, including PPE, and

training personnel. Also, in emergency circumstances, HPP awardees may request, and in some cases already have requested, approval to use grant funds for activities outside the currently approved scope of work. HHS is also using these networks to disseminate educational materials on awareness and response regarding potential Ebola patients, such as checklists to prepare health care providers, hospitals, emergency medical services, and community health care coalitions. The checklists provide practical and specific suggestions to ensure health care workers, facilities, and coalitions are able to detect possible Ebola cases, protect their employees, and respond appropriately.

HHS has also organized a number of training opportunities, in coordination with other Federal partners, to ensure quick and accurate identification of persons with Ebola, including training to support ongoing screening activities at domestic airports. HHS is also supporting efforts to develop protocols for waste management, something that has been a key concern for health care providers, hospitals, and political leadership at state and local levels. For example, HHS developed Ebola Medical Waste Management guidelines with input from DOT, the Environmental Protection Agency, and OSHA. These guidelines provide hospitals and health care providers with key information about the safe handling, transport, and disposal of waste generated from the care of persons diagnosed with or suspected of having Ebola. CDC also will be coordinating with OSHA and other Federal Agencies to develop guidance that is relevant to other occupations—such as employees of the transportation industries—to address potential exposure to persons with Ebola.

Thanks to a number of new authorities provided by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), ASPR stands ready to support a response to such events as the current Ebola incidents. One specific provision of that Act allows the Secretary to authorize a state or Indian Tribe to temporarily reassign health personnel funded through HHS programs under the Public Health Service Act to augment resources for a declared public health emergency. In addition, PAHPRA gave the Secretary the authority to declare that circumstances exist to justify the authorization of emergency use of certain medical products, which, under certain circumstances, enables FDA to issue an Emergency Use Authorization (EUA) when appropriate. The Secretary issued a declaration for in vitro diagnostic devices for detection of Ebola virus on August 5, 2014, which was based on an existing Ebola virus Material Threat Determination issued by DHS. The HHS EUA declaration was then used to support FDA issuance of an EUA for an Ebola diagnostic test developed by DOD and two EUAs to permit distribution and use of Ebola diagnostic tests developed by CDC.

Understanding today's global community, HHS has strengthened international partnerships. HHS now has a number of international relationships designed to better support information sharing, leverage critical assets, and help one another in times of need. Through a variety of initiatives, plans, and strategic capacity building programs, in response to the current Ebola outbreak, HHS—in coordination with other Federal Departments and Agencies—has been able to rapidly engage with international partners in communications and collaborations, including the Ministers of Health of the G7 countries, Mexico, the European Commission, the World Health Organization (WHO), the Institute Pasteur and its affiliates in West Africa, to discuss countries' domestic preparedness activities and policies. These activities include border protocols, mutual

notifications of imported cases, support for medevac capabilities, and coordination of activities to develop and manufacture medical countermeasures among developed countries (mainly Canada, UK, and France) and the WHO, and overall support for West African countries. In its coordination role for the medical portion of the U.S. response effort, HHS convenes weekly U.S. Government and WHO clinical conference calls with physicians in developed countries who treat patients with Ebola to facilitate information-sharing and diffusion of best practices. In addition to coordinating with international partners, HHS is working to support the deployment of U.S. Public Health Service (PHS) officers to West Africa.

Throughout the Federal Government, we are all working together to ensure we are safer going forward and protecting against the growing number of threats to public and medical health. Mr. Chairman and Members of the Committee, I understand why you and your constituents are anxious and concerned. There is good reason for concern. Ebola is a dangerous disease, but there is hardly a reason for panic. There is an epidemic of fear, but not of Ebola, in the United States. We always can, and do, learn from experience, and we are making adjustments moving forward based on the first U.S. cases. I can assure you that my team, HHS, and our interagency partners have worked long hours to prepare our Nation for threats like Ebola. We are making efficient use of the investments provided and we are far better off than we were ten years ago following the anthrax attacks and the Hurricane Katrina response. As a result, HHS stands ready to provide health and medical support to our states and communities. I thank you again for this opportunity to address these issues and welcome your questions.