



**Written Testimony
Senate Appropriations
Subcommittee on Labor, Health and Human
Services, Education, and Related Agencies**

Ebola and Other Emerging Health Threats

Statement of

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**For Release on Delivery
Expected at
10am
Thursday, March 14, 2019**

Good morning Chairman Blunt, Ranking Member Murray, and other distinguished Members of the Committee. I am Dr. Bob Kadlec, 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 today on our efforts to support a coordinated response to the Ebola outbreak in the Democratic Republic of the Congo (DRC) as well as general preparedness for other emerging infectious diseases.

This morning, I will share with you how ASPR is supporting the response to the Ebola outbreak in the DRC. I will also take a few minutes to highlight existing public health and medical preparedness and response capabilities and how we monitor, consider, and incorporate global health threats into the programs and initiatives of ASPR.

Assistant Secretary for Preparedness and Response: Mission & Duties

ASPR's mission is to save lives and protect Americans from 21st century health security threats. On behalf of the Secretary of HHS, ASPR leads public health and medical preparedness for, response to, and recovery from disasters and public health emergencies in support of State, local, tribal, and territorial (SLTT) authorities, in accordance with the National Response Framework (NRF) (Emergency Support Function (ESF) # 8, Public Health and Medical Services), as well as the National Disaster Recovery Framework (Health and Social Services Recovery Support Function). ASPR also supports HHS's role in the delivery of mass care and human services in emergencies (NRF ESF # 6).

ASPR coordinates across HHS and the federal interagency to support SLTT health partners in preparing for and responding to emergencies and disasters. In partnership with HHS agencies, ASPR works to enhance medical surge capacity by organizing, training, equipping, and deploying federal public health and medical personnel, such as National Disaster Medical System (NDMS) teams, and providing logistical support for federal responses to public health emergencies. ASPR supports readiness at the state and local level for all threats – chemical, biological, radiological, and nuclear (CBRN) – by coordinating federal grants such as the Hospital Preparedness Program (HPP), leading programs like the Medical Reserve Corps, and carrying out drills and operational exercises to test capabilities. ASPR also oversees advanced research, development, and procurement of medical countermeasures (MCM) (e.g., vaccines, medicines, diagnostics, and other necessary medical supplies), and coordinates the stockpiling of such countermeasures. As such, ASPR manages the Biomedical Advanced Research and Development Authority (BARDA), Project BioShield, the Strategic National Stockpile (SNS), and the Public Health Emergency Medical Countermeasures Enterprise.

In addition to these programs, ASPR supports the development and implementation of national-level strategies and policies to frame and guide federal preparedness, response, and recovery efforts. In September 2018, the White House released the National Biodefense Strategy (Strategy). This Strategy focuses on naturally occurring, deliberate and accidental biological threats. Importantly, this Strategy is the first to identify a lead coordinating official – the HHS Secretary – for the biodefense enterprise. In addition, this Strategy establishes an organizational structure to assess and improve biodefense efforts across the federal interagency. A second critical strategy, the National Health Security Strategy (NHSS), released in January 2019,

provides a vision for strengthening our nation's ability to prevent, detect, assess, prepare for, mitigate, respond to, and recover from 21st century health security threats. Specifically, the NHSS is aligned under three objectives that are flexible and adaptable to existing or emerging threats and have an operational focus to aid implementation. The first objective is to prepare, mobilize, and coordinate the whole-of-government to bring the full spectrum of federal medical and public health capabilities to support SLTT authorities in the event of a public health emergency, disaster, or attack. The second objective is to protect the nation from the health effects of emerging and pandemic infectious diseases and CBRN threats. Lastly, the third objective is to leverage the capabilities of the private sector. Working within these three objectives, the NHSS creates a more resilient medical product supply chain and builds private sector health care surge capacity. This quadrennial strategy supports the National Security Strategy, the National Defense Strategy, and the National Biodefense Strategy. Lastly, ASPR leads and participates in a number of international initiatives to build partnerships, enhance situational awareness, and work toward better collaboration between international partners.

ASPR's Support of the Current Ebola Outbreak in the Democratic Republic of the Congo

As you are all aware, 2018 brought about a reemergence of Ebola, specifically within the DRC. This highly infectious virus is of global concern and international efforts are underway to limit its spread within the DRC and surrounding countries. ASPR is working with the Centers for Disease Control and Prevention (CDC), United States Agency for International Development (USAID), and Department of State (DOS) to monitor the events within the DRC and is working to support domestic efforts, should a highly infectious disease outbreak occur within our borders. For this, as with other health security events, ASPR is the designated lead for the HHS and is

responsible for bringing together officials from across HHS to discuss the domestic preparedness related activities relevant to the emerging event. ASPR convened the Disaster Leadership Group on January 9, 2019, to discuss the current situation in the DRC. Participants included representatives from CDC, the National Institutes of Health (NIH), Food and Drug Administration (FDA), and BARDA, along with other relevant agencies and offices. Staff provided updates on vaccination of persons within the DRC, containment efforts, engagement with DOS and other HHS officials, and general domestic preparedness efforts.

To support the development of MCMs, beginning during the 2014-2016 Ebola outbreak in West Africa, BARDA worked closely with partners in industry as well as partners at the National Institute for Allergy and Infectious Diseases (NIAID), the FDA, and the Department of Defense (DoD) to advance the development of vaccines, therapeutics, and diagnostics. Last year, BARDA transitioned two vaccine candidates (Merck and Janssen/Bavarian Nordic) and two therapeutic candidates (Regeneron and Mapp Bio) to Project BioShield. BARDA continues to support late-stage development of these candidates and several are currently being evaluated in the ongoing outbreak in the DRC. BARDA is working with NIAID to make these therapeutics available for a randomized clinical trial and continues to work with vaccine developers to support potential licensure of the vaccines. The MCM development was supported initially from supplemental funding that has been fully obligated. Through Project BioShield funding, BARDA will continue to complete activities in support of FDA licensure/approval of these products.

In addition to the development of vaccines, therapeutics, and diagnostics to treat a potential outbreak, ASPR is also supporting efforts to augment capabilities across the nation's healthcare

infrastructure to ensure that healthcare providers have the knowledge and capabilities to support a response to Ebola, or other highly infectious diseases should one arise in our country. ASPR is doing this primarily in two ways. First, ASPR has supported a patient transport exercise, to test planning assumptions, supporting infrastructure, and general knowledge and guidance about how to handle, transport, and treat an infected patient or someone suspected of infection. Second, ASPR continues to refine regional treatment centers to handle an influx of patients, should an infectious disease outbreak occur within our borders.

Immediately after the Ebola outbreak in 2014, ASPR collaborated with DOS and other federal Departments and agencies to develop protocols and capabilities, to include transport systems and a network of domestic receiving hospitals that could activate biocontainment units on short notice. Since 2014, ASPR has participated in four exercises testing the movement of patients from overseas locations to these receiving hospitals. Three of the four exercises were led by DOS and examined a number of international transport issues. The goal of the fourth ASPR-led exercise, Tranquil Terminus, April 9-12, 2018, was to focus on domestic cases and care.

Tranquil Terminus was a full-scale exercise that included officials from DOS, state, local, and health care officials. The goal of Tranquil Terminus was to review notification processes, coordination decisions, and resources needed to move highly infectious disease patients utilizing both air and ground transportation resources. Within the scenario, seven patients were presented to healthcare facilities with Ebola-like symptoms. Each patient received a positive laboratory diagnosis for Ebola which triggered a series of notification and coordination processes among local, state, federal, private sector, and nongovernmental partners to facilitate the movement of these patients to Regional Ebola Treatment Centers. The exercises revealed strengths, as well as

areas for improvement, in current planning and existing capabilities. Specific gaps included: planning discrepancies; understanding of DOS vendors' roles; and coordination of inter-regional patient movement activities. HHS is working to address these gaps and is in the initial planning phase of designing a follow-on exercise to test an even larger number of patients requiring transport and care.

To strengthen regional capabilities to support a response to a highly infectious disease outbreak, during the 2014-2016 Ebola outbreak in West Africa, ASPR, in collaboration with CDC, developed a tiered approach to prepare U.S. health care facilities to safely and rapidly identify, isolate, evaluate, and manage travelers or patients with possible or confirmed Ebola, like the Quarantine Unit at the University of Nebraska Medical Center. ASPR provided awardees with approximately \$214 million of Ebola emergency supplemental funding to establish a nationwide, regional treatment network for Ebola and other highly infectious diseases. The funding provided through HPP Ebola Preparedness and Response activities has established the foundation required for the nation's health care system to safely and successfully identify, isolate, assess, transport, and treat patients with the Ebola virus disease or under investigation for Ebola (or other highly infectious diseases). To prepare for and provide safe and successful care of patients with Ebola, ASPR also awarded \$14 million (and CDC provided \$10 million) from the same supplemental appropriation to establish a National Ebola Training and Education Center (NETEC). NETEC is a consortium of three non-governmental U.S. health facilities – Emory University in Atlanta, Georgia; University of Nebraska Medical Center/Nebraska Medicine (UNMC) in Omaha, Nebraska; and the New York City Health and Hospitals Corporation/HHC Bellevue Hospital Center in New York, New York. These are in addition to the clinical facility associated with

NIH. The NETEC provides expertise, training, technical assistance, peer review, and mentoring to state health departments, regional Ebola and other special pathogen treatment centers, state- and jurisdiction-based Ebola treatment centers, and assessment hospitals. HHS funded these activities through the Ebola emergency supplemental bill. The period of availability for these funds ceases at the end of fiscal year (FY) 2019.

Leveraging the best practices from investments made with the Ebola supplemental appropriations, ASPR is piloting innovative, tiered, regional demonstration projects that can serve as models to test a Regional Disaster Health Response System (RDHRS) that could leverage and enhance existing programs such as HPP, NDMS, and CDC's Public Health Emergency Preparedness Program. Using HPP funding provided in the FY 2018 appropriation, ASPR awarded two \$3 million grants on September 27, 2018, to the University of Nebraska Medical Center in Omaha, Nebraska, and Massachusetts General Hospital in Boston, Massachusetts. Using this funding, these centers will conduct pilot projects to test the effectiveness and viability of a RDHRS. Such a system could help integrate existing specialized capabilities, such as the tiered Ebola treatment center network to make specialized care easily accessible to all Americans. The proposed RDHRS could help expand existing training to address other modern health security threats including the medical trauma caused by CBRN weapons. The proposed RDHRS model could also expand upon health care coalitions (also funded by ASPR's HPP), adding trauma centers, burn centers, pediatric hospitals, public health laboratories, outpatient services, and federal facilities like Veterans Affairs clinics to better meet the healthcare needs in a disaster.

Lastly, to ensure that our responders are able to support future infectious disease outbreaks, ASPR is utilizing Ebola supplemental funding to provide enhanced training to NDMS personnel. NDMS has partnered with the University of Nebraska Medical Center to support two specific trainings for personnel. The first, Isolation, Simulation and Quarantine Training, provides situational awareness, preparedness and planning, infection prevention and control, and crisis and risk communications. The second, Highly Infectious Disease Patient Transport Training, trains personnel in transportation of highly infectious patients to appropriate facilities, use of personal protective equipment, and infection control practices while avoiding excessive delays in care. Both of these trainings will ensure that NDMS personnel have appropriate skills and general awareness to treat highly infectious disease patients without becoming infected or spreading infection within the impacted area.

ASPR's Capabilities to Prepare and Respond to Future Public Health and Medical Threats

Ebola is a significant threat to public and medical health and ASPR is working diligently to respond to this threat. I would also like highlight ASPR's efforts to ensure that the nation is protected against all threats. The FY 2019 appropriations bill included \$1.9 billion for ASPR's programs and activities, and I would like to thank this Subcommittee for its support of ASPR's programs. With this funding, ASPR is able to support innovative and effective programs to further the nation's preparedness against all types of threats.

Building and Supporting International Partnerships

Recognizing that effective response to 21st century health threats requires both domestic and international coordination, ASPR has and continues to participate and support a number of global

initiatives to address health security issues. First, ASPR has developed policy frameworks on the distribution of MCMs as well as the sharing of biological samples among countries within the activities of the Global Health Security Initiative (GHSI). The GHSI, created after September 11, 2001, is an informal network of G7 countries, Mexico, the European Commission, and the World Health Organization (WHO) with the goal of addressing CBRN threats to global health security and infectious diseases with pandemic potential. ASPR has also supported close coordination with Canadian and Mexican officials to prevent and prepare regionally for a potential influenza pandemic under the North American Plan for Animal and Pandemic Influenza (NAPAPI). Specifically, the three nations are working jointly to analyze key challenges, develop policy and operational instruments, and test regional capabilities to ensure that we are all able to work collaboratively in the event of a potential or actual flu influenza pandemic. Third, ASPR serves as the U.S. International Health Regulations (IHR) (2005) National Focal Point, communicating regularly with WHO and other global partners to monitor potential health security threats. Lastly, ASPR serves as the lead coordinator of U.S. activities related to the Joint External Evaluation (JEE). The JEE was released in 2016 and is an evaluation and monitoring mechanism to strengthen basic national health security capabilities. Engagement in the JEE process allows ASPR to contribute to global health security while ensuring that our national preparedness is able to address any health security threats, whether it is domestic or originates abroad. In follow-up to the U.S. JEE assessment, ASPR led the development, and is leading implementation, of the U.S. Health Security National Action Plan, released in October 2018. The Plan contains hundreds of cross-sectoral activities that the government will carry out to address capacity gaps found by national and international subject-matter experts during the JEE. Implementation of the Plan will further the multi-sectoral and multi-disciplinary approach

promoted by the IHR to adequately prevent, detect, and respond to public health security threats. Through participation in these various international organizations and policy conversations, ASPR is able to maintain awareness of emerging threats and has relationships in place to communicate evolutions in threats as well as preparedness efforts in place to mitigate such threats.

Medical Countermeasures Enterprise

To ensure that the nation has MCMs available to meet existing as well as emerging CBRN threats, \$735 million was included in FY 2019 for Project BioShield, an increase of \$25 million over FY 2018 funding levels, and \$562 million was included for BARDA advanced research and development efforts. This funding enables BARDA to continue to fill remaining gaps in our nation's preparedness for CBRN threats by transitioning products from advanced development to initial procurement and stockpiling. By using flexible, nimble authorities, multiyear funding, strong public-private partnerships, and cutting edge expertise, BARDA has successfully pushed innovative MCMs, such as vaccines, drugs, and diagnostics, through advanced development to stockpiling and FDA approval or licensure. In the last decade, BARDA's strong partnerships with biotechnology and pharmaceutical companies, the National Institutes of Health, and other HHS components have led to 43 FDA approvals for 38 unique MCMs addressing CBRN threats, pandemic influenza, and emerging and re-emerging infectious diseases.

To support preparedness for pandemic influenza, the FY 2019 appropriations bill includes \$260 million, of which \$256 million is allocated to ASPR. To date, BARDA has supported the development of 23 influenza related products: vaccines, antiviral drugs, devices, respirators,

personal protective equipment, and diagnostics to address the risk of pandemic influenza. BARDA has a unique responsibility in supporting advanced research, development, and procurement of pandemic influenza MCMs. While the promise and advantages of universal influenza vaccines may take years to achieve, with early stages led by our colleagues at NIH, the near-term threat and risk of influenza demand that we work right now to make influenza vaccines better and faster, and we must ensure that diagnostic tools and antiviral treatments are also available to save lives. Influenza virus is a formidable global threat to human and animal health because it evolves quickly and is constantly jumping between host species. We must maintain our focus and monitor the rapid changes of influenza viruses through effective international surveillance and control networks. BARDA co-chairs an active interagency group, the “Flu Risk Management Meeting (FRMM),” that is comprised of partners from HHS agencies, DoD, VA, and United States Department of Agriculture, as well as public health leaders and influenza technical experts. The FRMM meets monthly and conducts in-depth reviews of all pandemic risk assessment data, including global surveys of emerging influenza viruses. Using this information, FRMM participants review existing diagnostics, antivirals, and vaccines to frame decisions and make recommendations to senior leaders to support strategic preparedness investments. Although transmission of H7N9 to humans has been reportedly lower in the 2018 season, history indicates that avian influenza eradication is elusive because the virus evolves quickly to escape protection by any vaccine. Consequently, it is critically important for the US to continue receiving, in a timely manner, pre-pandemic viruses from China and other countries where these viruses emerge, to evaluate the efficacy of diagnostics, antiviral drugs, and vaccines. HHS has made great progress in developing new vaccines and drugs to respond rapidly to newly emerging viruses. However, there is still work to be done to ensure that we are

fully prepared for this threat. Going forward, ASPR will support continued domestic influenza vaccine manufacturing and stockpiling capacity and will maintain hard won gains in vaccine manufacturing capabilities, advanced development of novel influenza vaccines and therapeutics, and international pandemic preparedness activities.

As BARDA develops, MCMs and as products are being manufactured, long-term procurement and stockpiling needs are regularly considered, to ensure that products are available and are on hand to dispense to impacted populations. The SNS is the Nation's largest repository of life-saving MCM and medical supplies intended to support state and local emergency needs. In FY 2019, the oversight and operational control of the SNS transferred from CDC to ASPR. This move aims to more fully assimilate the SNS with other public health and medical preparedness and response capabilities under ASPR, improve the efficiency of emergency responses, strengthen and streamline the MCM enterprise, and leverage synergies in supply chain logistics. I look forward to working closely with this committee as the SNS continues to be fully integrated into the ASPR organization.

Domestic Response Capabilities

The FY 2019 appropriations bill includes \$57 million for NDMS and \$265 million for HPP. This funding will enable ASPR to rebuild NDMS teams and train them to respond to 21st century threats and invest in innovative approaches to build regional health system readiness for complex mass casualty events. In addition, the funding will enhance the efforts of HPP to prepare the nation's healthcare infrastructure.

The 2018 hurricane season highlighted the importance of regional healthcare readiness and medical surge capacity. ASPR led the public health and medical responses to Hurricanes Florence, Isaac, and Michael; Typhoons Mangkhut and Yutu; and the California wildfires under the NRF ESF # 8 mission. The Secretary's Operations Center (SOC) provided 24 hour, 7 day a week monitoring of each incident. The SOC served as the focal point for synthesis of critical public health and medical information. During these events, the SOC maintained real-time situational awareness and provided analytical reports on the incidents to senior leadership. In addition, ASPR worked to identify, organize, and visualize critical information related to the communities and people impacted by these events which informed decision makers on what and where to provide assets. During these responses, ASPR worked closely with such officials to augment care, when needed, utilizing NDMS teams, U.S. Public Health Service Commissioned Corps Officers, Department of Veterans Affairs personnel and facility support, and DoD transportation, facilities, and clinicians. Today, HHS continues to support recovery efforts in impacted communities.

Earlier in my statement, I discussed how ASPR is strengthening NDMS to support a future response to a domestic infectious disease outbreak. Going forward, ASPR is working to modernize and strengthen NDMS capabilities to ensure that NDMS continues to provide critical support during and immediately after public health and medical emergencies. ASPR has made tremendous progress in hiring NDMS personnel – increasing NDMS overall size from 2500 to approximately 4000 – utilizing the direct hire authority included in the 2017 Hurricane Supplemental appropriation. Despite this success, the direct hire authority expired in November 2018, and a gap of approximately 2000 personnel remains. ASPR will continue to hire personnel

under traditional hiring practices but encourages Congress to consider reauthorizing the direct hire authority for NDMS, if possible. In addition to direct hire authority, ASPR continues to seek Public Safety Officer Benefit (PSOB) Act coverage for NDMS personnel. The PSOB Act provides death benefits and educational assistance to survivors of fallen public safety officers killed in the line of duty, as well as disability benefits to officers catastrophically injured. This coverage is currently offered to emergency response personnel deployed by FEMA; extending coverage to NDMS personnel could ensure consistent coverage for all first responders. Lastly, ASPR will continue to utilize annual appropriations to ensure that NDMS teams are trained and ready to respond to 21st century health security threats.

Understanding that strengthening the federal response capability is critical to augment care within an impacted community, it is also critical to provide communities tools and resources so they are able to respond immediately and mitigating the overall impact of a public health and/or medical incident. HPP was established after the September 11, 2001, terrorist attacks, with the goal of improving the capacity of local hospitals across the country to deal with disasters and a large influx of patients in an emergency. Using HPP funding, state grantees initially purchased equipment and supplies needed for emergency medical surge capacity. Over time, the program successfully evolved to support local coordinated healthcare coalitions, including hospitals, public health facilities, emergency management agencies, and emergency medical services providers. Fifteen years after it was established, HPP can be further strengthened to better utilize existing resources and enhance healthcare preparedness and response capabilities at the local level.

Conclusion

Emerging disease outbreaks, particularly those with pandemic potential, are an international flight away, and are significant global health threats that require domestic preparedness investments and programs. ASPR looks forward to working with this committee in FY 2019 and beyond to protect the nation from 21st century health security threats. Thank you, again, for your bipartisan commitment to this national security imperative, and I look forward to continuing to work together to enhance our nation's health security. I am happy to answer any questions you may have.