

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

“FY 2019 Budget Health and Human Services: Biodefense Activities”

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

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Good morning Chairman Cole, Ranking Member DeLauro and Members of the Subcommittee. I am Dr. Robert 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 to discuss the state of our nation's preparedness for 21st century health security threats, including biological incidents, and HHS's plans for FY 2018 and beyond.

Before assuming this role, I served as the Deputy Staff Director for the Senate Select Committee on Intelligence, where I was immersed in understanding 21st century threats. For decades before that, I worked in various government capacities focused on biodefense and national security, including more than twenty years in the United States Air Force as an officer and physician, and as Special Advisor for Counter Proliferation Policy within the Office of the Secretary of Defense during 9/11 and the 2001 anthrax attacks. I also served two tours of duty at the White House Homeland Security Council, including as Special Assistant to President Bush for Biodefense Policy from 2007 to 2009. I am proud to have played a part in drafting the original legislation that established ASPR when, during the 109th Congress, I was Staff Director of the Senate HELP Committee's Subcommittee on Bioterrorism and Public Health Preparedness.

Readiness for 21st Century Health Security Threats: A National Security Imperative

The Constitution states that one of the federal government's fundamental responsibilities is to provide for the common defense—to protect the American people, our homeland, and our way of life. The strength of our nation's public health and medical infrastructure, and the capabilities necessary to quickly mobilize a coordinated national response to emergencies and disasters, are foundational for the quality of life of our citizens and vital to our national security. Threats facing the United States during the 21st century are increasingly complex and dangerous. Therefore, improving national readiness and response capabilities for 21st century health security threats is a national security imperative.

Additionally, we have witnessed the impacts of naturally occurring outbreaks such as influenza, Ebola, and SARS. We are currently monitoring potential emerging infectious diseases that could cause a pandemic, such as the H7N9 influenza strain circulating in China. This year marks the 100-year anniversary of the 1918 influenza pandemic, which killed more people than World War I. During that pandemic, more than 25 percent of the U.S. population became sick and 675,000 Americans, many of them young, healthy adults, died from the highly virulent influenza virus. Finally, we face extreme weather events, such as the recent 2017 hurricane season in which Hurricanes Harvey, Irma, and Maria caused an unprecedented amount of damage and destruction, reminding us of the awesome destructive power of nature.

These are threats that most people would rather not think about. However, when natural disasters, disease outbreaks, or attacks occur, the people expect our government to be ready to respond to save lives. Since September 11, 2001, the nation has made great progress in building our defenses to protect America from health security threats; however, we still have much to do.

Assistant Secretary for Preparedness and Response (ASPR)

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 accordance with the National Response Framework (NRF) (Emergency Support Function (ESF) No. 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 No. 6).

When ASPR was established by Congress a decade ago in the Pandemic and All-Hazards Preparedness Act (PAHPA), the law's objective was to create "unity of command" by consolidating Federal civilian public health and medical preparedness and response functions under the ASPR. This approach was modeled on the Goldwater-Nichols Act that created the Department of Defense combatant commands; the impetus was the disorganized and fragmented response to Hurricane Katrina in 2005.

ASPR coordinates across HHS and the Federal interagency to support state, local, territorial, and tribal 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 by coordinating Federal grants and cooperative agreements, such as the Hospital Preparedness Program (HPP) and the Medical Reserve Corps (MRC), and carrying out drills and operational exercises. ASPR also oversees advanced research, development, and procurement of medical countermeasures (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, and the Public Health Emergency Medical Countermeasures Enterprise.

Currently, ASPR has four key priorities for building readiness and response capabilities for 21st century health security threats:

- First, provide strong leadership, including clear policy direction, improved threat awareness, and secure adequate resources.
- Second, seek the creation of a "regional disaster health response system" by better leveraging and enhancing existing programs—such as HPP and NDMS—to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery.
- Third, advocate for the sustainment of robust and reliable public health security capabilities. For ASPR to accomplish its mission, CDC, and other partners need support to quickly detect and diagnose infectious diseases and other threats. This is critical to rapidly and effectively dispensing medical countermeasures in an emergency.

- Fourth, advance an innovative medical countermeasures enterprise by capitalizing on additional authorities provided in the 21st Century Cures Act, as well as advances in biotechnology and science to develop and maintain a robust stockpile of safe and efficacious vaccines, medicines, and supplies to respond to emerging disease outbreaks, pandemics, and chemical, biological, radiological and nuclear incidents and attacks.

Two areas of progress and opportunities ASPR would like to highlight are our medical countermeasures enterprise and our healthcare readiness capacity.

Medical Countermeasures Enterprise

Congress established BARDA to speed up the availability of medical countermeasures by bridging the so called “valley of death” in late-stage development where many countermeasures for health security threats historically languished or failed. By using flexible, nimble authorities, multiyear advanced funding, strong public-private partnerships, and cutting-edge expertise, BARDA has successfully pushed innovative medical countermeasures, such as vaccines, drugs, and diagnostics, through advanced development, to stockpiling and FDA approval or licensing.

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 35 FDA approvals for 31 unique medical countermeasures addressing chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, and emerging and re-emerging infectious diseases. This is a staggering accomplishment in just 12 years. BARDA has supported the development of 27 medical countermeasures against Department of Homeland Security- (DHS) identified national security threats through Project BioShield, including products for smallpox, anthrax, botulinum, radiologic/nuclear emergencies, and chemical events. Fourteen of these products have been placed in the Strategic National Stockpile and are ready to be used in an emergency, and seven have achieved FDA approval. BARDA also has supported the development of 23 influenza vaccines, antiviral drugs, devices, and diagnostics to address the risk of pandemic influenza. Because of this progress, more medical countermeasures than ever before are eligible to be acquired for the SNS, thereby creating new challenges in terms of acquiring and maintaining sufficient quantities of medical countermeasures to address the requirements for identified threats.

ASPR would like to thank this committee for its support for BARDA, Project BioShield, and pandemic influenza medical countermeasures. The Consolidated Appropriations Act of 2018 includes \$710 million for Project BioShield, an increase of more than \$200 million over FY 2017, for the initial procurement of medical countermeasures against DHS-identified national security threats, including CBRN agents. This funding will enable 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. The Administration supports a 10-year advance appropriation for Project BioShield, an approach which will help incentivize private industry to dedicate resources to developing medical countermeasures to meet the

government's national security requirements. Without this "guaranteed market", companies can be reluctant to incur the opportunity costs required to focus on a limited government market that may not materialize when product development is complete.

The committee also included \$537 million, an increase of \$26 million, to support BARDA's advanced research and development of medical countermeasures. This additional funding will enable BARDA to implement new authorities provided in the 21st Century Cures Act, without detracting from continued investments in CBRN medical countermeasures. The Medical Countermeasure Innovation Partner authority focuses on driving public and private investment in medical countermeasure innovation by investing in disruptive technologies with the potential to make far-reaching impacts in both national security and commercial medical products.

This committee also included \$610 million, an increase of \$35 million, for the Strategic National Stockpile (SNS) currently managed by the CDC. The SNS is the Nation's largest repository of life-saving medical countermeasures and medical supplies intended to support state and local emergency needs. The FY 2019 President's Budget reflects the Administration's decision to shift oversight and operational control of the SNS from CDC to ASPR. This move will more fully integrate the SNS with other public health and medical preparedness and response capabilities under ASPR, improve the efficiency of emergency responses, strengthen and streamline the medical countermeasures enterprise, and leverage synergies in supply chain logistics. The Department is committed to ensuring a smooth transition of this important national security asset, including no loss in operational capability or degradation of connection with state and local health officials. We look forward to working closely with this committee during this deliberative transition process.

The Consolidated Appropriations Act of 2018 also includes \$250 million, an increase of \$193 million, for Pandemic Influenza preparedness, which has previously been funded through emergency supplemental appropriations bills. This additional funding will support the sustainment of domestic influenza vaccine manufacturing and stockpiling capacity, advanced development of novel influenza vaccines and therapeutics, and international pandemic preparedness activities. It is urgent that the United States continue the development of modern, large-scale, domestic vaccine production. These activities are essential to responding to pandemic threats and are carried out by ASPR, as well as the HHS Office of Global Affairs. As newly evolved strains of drug-resistant influenza viruses emerge that pose a significant threat to public health, as seen with the 2017 H7N9 avian influenza outbreak in China, the Department will put these additional resources to work to ensure we do not lose ground.

Healthcare Readiness to Respond

The 2017 hurricane season highlighted the importance of regional healthcare readiness and medical surge capacity. ASPR led the public health and medical responses to Hurricanes Harvey, Irma, and Maria under the NRF Emergency Support Function No. 8 mission. ASPR worked closely with state and territory health officials in affected areas to augment care with

NDMS teams, Public Health Service Commissioned Corps Officers, VA personnel and facility support, and DoD transportation, facilities, and clinicians. Personnel under the supervision of HHS treated over 36,000 patients, and HHS deployed over 4,500 personnel, evacuated nearly 800 patients, awarded over 200 contracts, and provided nearly 950 tons of equipment. Today, HHS continues to support recovery efforts in impacted communities.

During the response, due to the combined efforts of ASPR and the Centers for Medicare & Medicaid Services (CMS), we utilized the innovative HHS emPOWER program to pre-identify at-risk individuals requiring electricity-dependent medical and assistive equipment (e.g., ventilators, oxygen concentrators, feeding machines, intravenous infusion pumps, suction pumps, dialysis machines, wheelchairs). In one instance, ASPR teams, deployed with Urban Search and Rescue teams, used this data to identify every dialysis patients in the U.S. Virgin Islands and evacuate those patients for treatment since the local dialysis centers were destroyed.

Despite our successes, we also learned that HHS and ASPR need to improve our internal capabilities as well as enhance our support for the healthcare infrastructure across the country. As with medical countermeasures, the nation's healthcare delivery infrastructure is mostly a private sector enterprise. We must better leverage and enhance existing Federal programs—such as HPP and NDMS—to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery. I call this the foundation of a “regional disaster health response system.”

ASPR would like to thank this committee for its support for HPP and NDMS. The Consolidated Appropriations Act of 2018 includes \$265 million, an increase of \$10 million over FY 2017, for HPP, and more than \$57 million, an increase of almost \$8 million, for NDMS. This funding will enable ASPR to invest in innovative approaches to building regional health system readiness for complex mass casualty events, and to rebuild NDMS teams and train them to respond to 21st century threats.

ASPR looks forward to working with this committee in fiscal year 2018 and beyond to protect the nation from 21st century health security threats. I am committing the entire ASPR team's grit, ingenuity, expertise, and perseverance to this mission. 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.