Written Testimony
House Committee on Energy and Commerce

Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act

Statement of
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Good morning Mr. Chairman, Ranking Member Pallone, 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 to discuss the state of our nation's preparedness for 21st century health security threats, including biological incidents, as you prepare to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). Building upon years of incremental legislative changes in the prior decade, this seminal legislation transformed the federal government's medical and public health preparedness for health security threats to our national security. This Committee championed the bipartisan oversight and analysis that led to the drafting and passage of this groundbreaking legislation, led by Representatives Mike Rogers and Anna Eshoo. I want to thank you for continuing that commitment here today.

I am proud to have played a part in that original legislative process, when during the 109th Congress, I was Staff Director of the Senate HELP Committee's Subcommittee on Bioterrorism and Public Health Preparedness, led by Senators Burr and Kennedy. In the decades before and after PAHPA was passed, I worked in various government capacities focused on biodefense and national security. I spent more than twenty years in the United States Air Force as an officer and physician, and served as Special Advisor for Counter Proliferation Policy within the Office of the Secretary of Defense during 9/11 and the 2001 anthrax attacks. I served two tours of duty at the White House Homeland Security Council, first as the Director for Biodefense, then as Special Assistant to President Bush for Biodefense Policy from 2007 to 2009. Most recently before taking my current position, I served as the Deputy Staff Director for the Senate Select Committee on Intelligence.

This morning, I will share with you my perspective on the national security imperative of PAHPA, the mission and duties of ASPR, the status of our Department, and our nation's public health and medical preparedness and response capabilities, and my vision for areas of improvement. I welcome the opportunity to engage with you and your staff in the weeks ahead as you continue your oversight and legislative drafting.

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

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. Health security hreats 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.

Terrorist organizations such as ISIS and al-Qaida remain determined to attack; further, ISIS has demonstrated no compunction about using chemical and other unconventional weapons in attacks overseas. State actors have already threatened our homeland with nuclear weapons and have shown the means to employ both chemical and biological weapons.

Additionally, we have witnessed the impacts of naturally occurring outbreaks such as influenza, Ebola andSARS. We are currently monitoring other 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. Cyber-attacks like the 2017 WannaCry incident that affected approximately 150 countries remind us that technological advancements have trade-offs in the form of new vulnerabilities and risks, as our healthcare delivery systems become more networked. 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 and our vulnerability.

These are threats that most people would rather not think about. However, when natural disasters, disease outbreaks, or attacks occur, the people expect our federal government to be ready to quickly respond to save lives and decrease morbidity. 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: 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 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' role in the delivery of mass

care and human services in emergencies (NRF ESF # 6, Mass Care, Emergency Assistance, Temporary Housing, and Human Services).

When ASPR was established by Congress a decade ago in PAHPA, the law's objective was to create "unity of command" by consolidating Federal nonmilitary 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 (DoD) 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, responding to, and recovering from emergencies and disasters. In partnership with HHS agencies, ASPR works to enhance U.S. medical surge capacity by organizing, training, equipping, and deploying HHS public health and medical personnel, such as National Disaster Medical System (NDMS) teams, and providing logistical support for HHS personnel responding 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), by programs like 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.

HHS and ASPR have made significant progress since PAHPA was enacted in 2006 and was reauthorized in 2013. However, we still have work to do to ensure we are ready to save lives and protect Americans. ASPR has four key priorities for building the necessary readiness and response capabilities for 21st century health security threats:

- First, provide strong leadership, including clear policy direction, improved health security 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 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, the Centers for Disease Control and Prevention (CDC) and other partners need support to quickly detect and diagnose infectious diseases and other health security threats. This is critical to rapidly and effectively dispensing medical countermeasures in an emergency.
- Fourth, advance an innovative medical countermeasures enterprise by capitalizing on new authorities provided in the 21st Century Cures Act and advances in biotechnology and science to develop and maintain a robust stockpile of safe and efficacious vaccines, medicines, equipment, and supplies to respond to 21st century health security threats, as well as the flexible response capabilities needed to handle the unexpected.

PAHPA Reauthorization Proposals

As you consider the reauthorization of PAHPA, the Administration has shared with you and your staff a list of proposals. I will highlight a few here today.

Strong Leadership

In the area of strong leadership, ASPR should continually evaluate and incorporate national health security threats by regularly coordinating with the Director of National Intelligence, the Department of Justice, and the Department of Homeland Security to assess current and future national health security threats.

Regional Disaster Health Response System

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 # 8 mission. ASPR worked closely with state and territory health officials in affected areas to augment care with NDMS teams, U.S. Public Health Service Commissioned Corps Officers, Department of Veterans Affairs personnel and facility support, and DoD transportation, facilities, naval vessels with medical and surgical capability, clinicians and support personnel. Federal personnel under the supervision of HHS treated over 36,000 patients, and evacuated nearly 800 patients. HHS deployed over 4,500 personnel, , awarded over 200 contracts, and provided nearly 950 tons of equipment. Today, HHS continues to support recovery efforts in impacted communities.

Despite our successes, we learned that ASPR needs to improve its internal capabilities as well as enhance our support for the healthcare infrastructure across the country. As with medical countermeasure development, 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."

NDMS was created during the Cold War jointly by the Departments of Health and Human Services, Defense, and Veterans Affairs, along with the Federal Emergency Management Agency, to take care of military casualties from overseas conflicts in U.S. civilian hospitals. To modernize NDMS, strengthen capabilities, and ensure NDMS continues to provide critical support during and immediately after national public health and medical emergencies, ASPR is implementing administrative modifications to the program. However, several improvements to the NDMS statute will aid in ASPR's efforts to modernize this critical asset, including:

- Direct hire authority for NDMS intermittent personnel for one to two years. Currently, NDMS is staffed at half capacity. Limited direct hire authority was included in the Hurricane Supplemental for 270 days. HHS is using this authority to its full extent but anticipates staffing shortfalls will remain after the expiration of this authority in November.
- Provide NDMS personnel with Public Safety Officer Benefit (PSOB) Act coverage. 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 FEMA employees who perform hazardous duties while deployed to declared major disaster and emergency areas; extending coverage to NDMS personnel would ensure consistent coverage for all first responders.

- An increase in the authorization of appropriations for NDMS consistent with the FY2019 President's Budget of $57 million. This funding will enable ASPR to rebuild and train NDMS teams to respond to 21st century health security threats.

The Hospital Preparedness Program (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. Congress should consider the following enhancements:

- Include healthcare coalitions and other entities as eligible entities for HPP "partnership" awards (separate from the formula awards) to acknowledge the value these coalitions provide and grant flexibility in making awards to carry out program goals.
- Expand the use of HPP awards from preparedness alone to preparedness, response, and medical surge activities. HPP's mission is to enhance community and regional health care system capabilities for emergency preparedness and response. Clarifying that HPP's mission includes strengthening both regional health care system preparedness as well as response capabilities will minimize confusion and balance investments between both preparedness and response activities.
- Expand the withholding period for failure to reach benchmarks from one year to two years to allow time to repurpose funds. Such modification will give the program time to

provide technical assistance to awardees so they are able to make corrective actions to achieve performance benchmarks.

Medical Countermeasures Enterprise

Congress established BARDA to speed up the availability and use 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 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 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 procured for the Strategic National Stockpile, thereby creating new challenges in terms of acquiring and maintaining sufficient quantities of medical countermeasures to address the requirements for identified health security threats.

As this Committee considers reauthorization of PAHPA, please consider the following proposals, which primarily relate to increasing authorization of appropriations levels for the medical countermeasures enterprise:

- Authorization for 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 may be reluctant to incur the opportunity costs required to focus on a limited government market that may not materialize when product development is complete.
- Increase the authorization of appropriations for BARDA's advanced research and development of medical countermeasures to $512 million. This increase will enable BARDA to implement new innovation authorities provided in the 21st Century Cures Act and build rapid response capabilities for unknown health security threats, without detracting from continued investments in CBRN medical countermeasures.
- Authorize a $245.9 million direct funding line for BARDA's pandemic influenza preparedness activities. This authorization of appropriations will help sustain domestic

influenza vaccine manufacturing capacity, as well as support better, faster influenza vaccine technologies and antivirals now.

- Increase the authorization of appropriations for the Strategic National Stockpile (SNS) to $575 million. The increase in the authorization of appropriations will strengthen SNS operations and procurements to meet requirements and best protect the public against public health and medical threats.
- Modifying existing annual reporting requirements to ease administrative burden and ensure staff time is dedicated to medical countermeasure development. Specifically, we propose merging reporting requirements for Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan with requirements for an SNS annual review and a multi-year budget report.

Conclusion

Through this second reauthorization of PAHPA, we have the opportunity to build on the great progress made and further improve our national readiness and response capabilities for 21st century health security threats. The Department looks forward to working with you in the weeks ahead to consider any legislative changes needed to achieve this objective. 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.