



**Written Testimony
Senate Health, Education, Labor, and
Pensions (HELP) Committee**

**Facing 21st Century Public Health Treats:
Our Nation's Preparedness and Response
Capabilities, Part 1**

Statement of

Robert Kadlec, MD, MTM&H, MS

Assistant Secretary for Preparedness and Response



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Good morning Mr. Chairman, Senator 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). I assumed this role five months ago, a week before Hurricane Harvey struck Texas. I appreciate the opportunity to appear before you today as you prepare to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), which expires at the end of this fiscal year.

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 threats to our national security. This Committee championed the bipartisan oversight and analysis that led to the drafting and passage of this groundbreaking legislation. 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 this 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 months ahead as you continue your oversight and legislative drafting.

The 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. Therefore, improving national readiness and response capabilities for 21st century health security threats is a national security imperative and is my singular focus as the ASPR.

The 21st century health security environment is increasingly complex and dangerous; it demands that we act with urgency and singular effort: to save lives and protect Americans. Terrorist organizations such as ISIS and al-Qaida remain determined to attack the United States as we experienced first-hand in 2001. ISIS has demonstrated no compunction about using chemical and other unconventional weapons in attacks overseas. State actors, such as North Korea, have

already threatened our homeland with nuclear weapons, and have the means to employ both chemical and biological weapons; the Syrian regime has already used chemical weapons against its own citizens.

Furthermore, we have witnessed the impacts of naturally occurring outbreaks such as influenza, Ebola, and SARS, and we are monitoring other potential emerging infectious diseases that could cause a pandemic, such as the H7N9 influenza strain circulating in China. 2018 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 WannaCry incident remind us that technological advancements have trade-offs in the form of new vulnerabilities and risks, as our health 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, reminding us of the awesome destructive power of nature.

These are threats that most of us 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 and protect Americans.

The ASPR Mission & Duties

When ASPR was originally established by PAHPA a decade ago, the objective was to create “unity of command” by consolidating all 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’s mission is to save lives and protect Americans from 21st century health security threats. ASPR is, in effect, the national security mission manager for HHS. As such, on behalf of the Secretary of HHS, ASPR leads the public health and medical, preparedness, response and recovery to disasters and public health emergencies, in accordance with the National Response Framework (NRF) and Emergency Support Function No. 8 (Public Health and Medical Services). It is my responsibility to coordinate the nation’s medical and public health capabilities to help Americans during such events, whatever their cause. ASPR also coordinates with other components of HHS with respect to HHS’s role in ESF No. 6 (Mass Care, Housing, and Human Services) and HHS’s lead role as the coordinating agency with respect to the Health and Social Services Recovery Support Function.

ASPR coordinates across HHS, the Federal interagency, and supports state, local, territorial, and tribal health partners in preparing for and responding to emergencies and disasters. ASPR, in partnership with HHS agencies, works to enhance medical surge capacity by organizing, training, equipping, and deploying Federal public health and medical personnel 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 and carrying out drills and operational exercises. ASPR 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. 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, which I will discuss shortly. The ASPR organization is filled with very capable, committed, and mission-driven staff; I am proud to lead them. It is my goal to further improve national public health and medical readiness and response capabilities, which have been developed by my predecessors who worked long hours to establish ASPR and build the capabilities that exist today. I aim to do that through four key priority areas:

- First, provide strong leadership, including clear policy direction, improved threat awareness, and secure adequate resources.
- Second, seek the creation of a “national disaster healthcare system” by better leveraging and enhancing existing programs – such as the Hospital Preparedness Program (HPP) and the National Disaster Medical System (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, primarily through the Centers for Disease Control and Prevention (CDC), but also through other components of HHS, including an improved ability to detect and

diagnose infectious diseases and other threats, as well as the capability to rapidly dispense 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, in order 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.

The State of Public Health and Medical Preparedness and Response Capabilities

In 2006, when then-Secretary of Health and Human Services Michael Leavitt testified before this Committee in advance of PAHPA's passage, he told Senators that we had the ability to "become the first generation in history to be prepared for a possible pandemic." At that time, HHS was closely watching the H5N1 influenza virus, and was concerned about the potential for another human influenza pandemic. Congress invested heavily by passing emergency supplemental appropriations bills, which were used to greatly expand our domestic vaccine manufacturing infrastructure, invest in new vaccine development, and provide funding to state and local governments to enhance medical and public health readiness.

Today, our capabilities are far greater than they were then; for example, we have sufficient domestic vaccine manufacturing capacity to produce bulk vaccine for every American within six months. However, we have exhausted the emergency supplemental funding balances at a time when we are now closely watching the H7N9 influenza virus circulating in China, and we are

concerned with the ominous trends that we are seeing. While building domestic manufacturing capacity may be a one-time expenditure, maintaining that capacity as well as sustaining, testing, and strengthening the readiness of our medical and public health infrastructure at the state and local level requires continuous support and an enduring commitment to the Public Health Emergency Medical Countermeasures Enterprise.

Last month, a report by the public health organization Trust for America's Health found that half of states scored five or lower out of 10 on health emergency preparedness. Earlier in 2016, the National Health Security Preparedness Index from the Robert Wood Johnson Foundation found that health security metrics showed modest 1.5 percent improvement overall during 2016, reaching the highest level of 6.8 out of 10 total; however, levels of readiness varied significantly across the country. So, while we have made progress in the last decade, we still have work to do.

Two areas of progress and opportunities I would like to highlight are our medical countermeasures enterprise, specifically BARDA, and our healthcare readiness capacity.

Medical Countermeasures Enterprise - BARDA

PAHPA established BARDA to bridge the so-called "valley of death" in late stage development of medical countermeasures where many products historically languished or failed. By using flexible, nimble authorities, multi-year 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 the National Institutes of Health, other HHS components, and biotechnology and pharmaceutical companies have led to 34 medical countermeasures approved or licensed by the FDA, which is a staggering accomplishment. 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. BARDA also has supported the development of 23 influenza vaccines, antiviral drugs, devices, and diagnostics to address the risk of pandemic influenza. As a result 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 for identified threats.

We are supporting the development and stockpiling of many more novel medical countermeasures within the next few years, such as H7N9 influenza vaccines, next generation anthrax vaccines, enhanced smallpox vaccines, biodosimetry diagnostic devices, thermal burn radiation drug and skin replacement therapies, radiation cell therapies, new antibiotics, and new chemical antidotes.

We also have opportunities to further improve our national security medical countermeasures enterprise by streamlining our internal decision-making processes, finding new ways to support innovation, promoting flexible, fast response capabilities, and increasing our collaboration with

Federal interagency partners, such as DoD and Department of Veterans Affairs (VA). We also must work closely with our state, local, territorial, and tribal partners, as well as the private sector to enhance the capability to quickly distribute and dispense medical countermeasures in an emergency – if we can't get these products to the right place, at the right time, then the enterprise has failed.

Healthcare Readiness to Respond

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

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 identify and treat 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 used this data and worked with Urban Search and Rescue teams to identify all of the 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 ASPR needs to improve its 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 the Hospital Preparedness Program and NDMS – to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery I call this the foundation of a “national disaster healthcare system.”

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 months 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.