



Written Testimony
House Committee on Energy and Commerce,
Subcommittee on Oversight and Investigations

**The State of U.S. Public Biopreparedness:
Responding to Biological Attacks, Pandemics, and
Emerging Infectious Disease Outbreaks**

Statement of

Rick Bright, Ph.D

Director, Biomedical Advanced Research and Development Authority
Deputy Assistant Secretary For Preparedness and Response



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Good morning Chairman Harper, Ranking Member DeGette, and other distinguished Members of the Subcommittee. I am Dr. Rick Bright, the Director of the Biomedical Advanced Research and Development Authority (BARDA) and the Deputy 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 behalf of ASPR to discuss the state of our nation's preparedness for 21st century health security threats, including biological incidents, as the Energy and Commerce Committee prepares to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

My expertise is in developing drugs, vaccines, diagnostics and other medical countermeasures (MCMs) for health security threats. In this testimony, I will cover a broader range of ASPR programs and activities, including some background on the nature of the health security threats facing the United States, the mission and duties of ASPR and BARDA, and our vision for where these areas can be strengthened.

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. The health 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 pandemic influenza, outbreaks of Ebola and SARS, and the emergence of antibiotic resistant bacteria. ASPR is currently engaged in coordinating HHS's response to the Ebola outbreak in the Democratic Republic of Congo and 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. As our healthcare delivery systems become more networked, 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. 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 response capabilities 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) 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, 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 BARDA, Project BioShield, and the Public Health Emergency Medical Countermeasures Enterprise.

ASPR Priorities for Improving Preparedness, Response, and Recovery

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 as HPP and NDMS – to create a more coherent, comprehensive, and capable regional medical emergency response 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. We must develop and maintain a robust supply of safe and efficacious vaccines, medicines, equipment, and other materiel to respond to 21st century health security threats, as well as the flexible response capabilities needed to handle the unexpected.

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.

Medical Countermeasures Enterprise

Congress established BARDA to speed up the availability and use of medical countermeasures (MCMs) 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 MCMs, such as vaccines, drugs, and diagnostics, through advanced development to stockpiling and commercial availability with 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 MCMs 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 these successes and 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.

Just last week, we announced an exciting new public-private engagement model – called DRIVE – which is designed to accelerate innovation, address some of the nation’s most pressing health security challenges, and potentially affect major healthcare markets.

At a time when synthetic biology and personalized medicine are not just conceivable but attainable, the time is right to apply an innovative approach to some of the most daunting, far-reaching health security problems, such as sepsis and early diagnosis of infectious diseases.

By implementing the authorities you provided to us in the 21st Century Cures Act, we are opening our doors to more innovators, and most importantly investors, to catalyze advances in science and technology.

ASPR has recommended important changes to BARDA's authorization of appropriations to meet these challenges, including, most notably, additional advanced appropriations for Project BioShield, which would help incentivize private industry to dedicate resources to developing medical countermeasures to meet the government's national security requirements. Without this "guaranteed market," companies are reluctant to incur the costs required to focus development on MCMs for CBRN agents that would rely upon a limited government market that may not materialize when product development is complete. ASPR has also recommended adding a 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 and rapid response platform technologies.

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 No. 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 progress, each event teaches us that ASPR needs to improve its internal capabilities as well as enhance our support for the healthcare infrastructure across the country. As with MCM 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 medical emergency response system integrated into daily care delivery. We call this the foundation of a “regional disaster health response system.”

NDMS was created during the Cold War 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 and national security special events, ASPR is implementing administrative changes and has recommended improvements to the NDMS statute to aid in ASPR's efforts to modernize this critical asset.

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, and ASPR has recommended modifications to the HPP statute toward this end.

Conclusion

As Congress moves forward on the 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. On behalf of the HHS Assistant Secretary for Preparedness and Response, Dr. Bob Kadlec, I want to thank you, again, for your bipartisan commitment to this national security imperative, and we look forward to continuing to work together to enhance our nation's health security. I am happy to answer any questions you may have.