



PAHPA

Pandemic and All Hazards Preparedness Act



PAHPA Overview

The events of 9/11 and the anthrax attacks led the nation to examine and address its vulnerabilities in preparedness for all hazards. In an effort to advance national health security, Congress passed and President George W. Bush signed the Pandemic and All Hazards Preparedness Act (PAHPA), Public Law No. 109-417, in December 2006.

The Act authorizes appropriations to improve bioterrorism and other public health emergency preparedness and response activities. Among other things, it established a new Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS); provided new authorities for a number of programs, including the creation of the Biomedical Advanced Research Development Authority (BARDA) within HHS for the advanced research and development of medical countermeasures (MCMs); and called for the establishment of a quadrennial National Health Security Strategy.

In 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) reauthorized funding throughout Fiscal Year 2018 for public health and medical preparedness programs, such as the Hospital Preparedness Program, the Public Health Emergency Preparedness Cooperative Agreement, Project BioShield, and BARDA. Congress must pass legislation this year to keep PAHPA programs funded past September 30, 2018.

Biomedical Advanced Research & Development Authority (BARDA)

BARDA was created through PAHPA to provide industry partners with funding and technical assistance in the advanced research and development of MCMs for chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza and other emerging infectious diseases (EID). In addition, the agency manages the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and oversees all of HHS' Project BioShield procurements. BARDA creates an ecosystem of financial incentives for developers of MCMs to help them overcome market challenges. As of August 2017, BARDA had supported the research and development of 34 products that have been approved and/or cleared by the FDA for use against bio-threats and pandemic influenza. 14 of those products have been stockpiled in the Strategic National Stockpile (SNS) for use in the event of a declared emergency. BARDA has partnered with more than 190 academic and company partners and currently has a development pipeline of more than 200 candidate MCMs.

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Project Bioshield

The Project Bioshield Act of 2004 was created to accelerate the research, development, purchase, and availability of effective medical countermeasures against CBRN agents. It supports the nation's biodefense through three approaches: (1) to secure funding of critical MCMs, Project BioShield created the Special Reserve Fund (SRF) which authorized \$5.6 billion to incentivize biopharmaceutical companies to develop and produce civilian MCMs with little or no commercial market. The SRF has supported 27 products and transitioned 14 products to the Strategic National Stockpile; (2) To facilitate research and development, Project BioShield granted the National Institutes of Health (NIH) the authority to expedite and simplify the solicitation, review, and award of grants and contracts for the development of critical MCMs; (3) To facilitate the use of MCMs in an emergency, the legislation established the Emergency Use Authorization (EUA) to provide access to the best available MCMs following the declaration of emergency by the Secretary of HHS.



PAHPA Accomplishments

34 medical countermeasures approved or licensed by the FDA

14 products placed in the Strategic National Stockpile and ready to be used in an emergency

23 vaccines, antiviral drugs, devices, and diagnostics to address the risk of pandemic influenza supported by BARDA

27 medical countermeasures supported by Project BioShield, including products for smallpox, anthrax, botulinum, radiologic/nuclear emergencies, and chemical events

>190
academic institutions and companies partnered with BARDA

>200
medical countermeasures candidates in the development pipeline

Key Policy Priorities

Congress must continue to prioritize and demonstrate their commitment to national health security by:

- Reauthorizing funding for the Project BioShield Special Reserve Fund (SRF) at a level sufficient to cover the priorities outlined in the FY16-20 PHEMCE Multiyear Budget;
- Reauthorizing funding for advanced research and development (ARD) at BARDA at \$700 million;
- Authorizing funding for the Strategic National Stockpile (SNS) at \$815 million annually;
- Authorizing pandemic influenza product development at a minimum of \$630 million annually;
- Authorizing \$300 million annually for the development of MCMs for emerging infectious diseases within BARDA.
- Extending or eliminating the sunset of the MCM Priority Review Voucher (PRV) program.