

BIODEFENSE

Issue Background

After 9/11 and the 2001 anthrax attacks, the U.S. government began a dedicated effort to develop and stockpile drugs and vaccines needed to protect the American people from chemical, biological, radiological, and nuclear (CBRN) threats. In 2004, Congress passed the Project BioShield Act which created the Special Reserve Fund (SRF). Two years later the Pandemic and All-Hazards Preparedness Act (PAHPA) was passed, authorizing the creation of many critical functions, such as the Biomedical Advanced Research and Development Authority (BARDA) and the Assistant Secretary for Preparedness and Response (ASPR). These key federal programs are reauthorized and funded every five years through the PAHPA legislation; with the last reauthorization in 2013, the legislation is due for reauthorization in 2018.

The U.S. Department of Homeland Security has identified 13 CBRN agents as material threats to our nation. In addition, given the importance and frequency of pandemic influenza outbreaks, ASPR and BARDA are charged with the prioritization and development, through partnerships with industry, of vaccines, treatments, and diagnostics for both CBRN and pandemic influenza threats for use during a man-made, natural, or accidental medical emergency.

Over the past decade and a half, the government has strategically invested in a diverse set of products to treat, diagnose or prevent a range of pathogens and toxins identified as significant threats, including anthrax, botulism, and smallpox. The funding for these vital national security products comes, in large part, from the Project BioShield SRF. The SRF successfully created a “guaranteed market” to incentivize biopharmaceutical companies to develop and produce civilian medical countermeasures (MCMs) for which there is no commercial market. The SRF was originally funded through a multi-year appropriation of \$5.6 billion over 10 years, which expired at the end of Fiscal Year (FY) 2013. Since FY 2014, the \$2.8 billion over five years appropriated to the SRF through the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013 has been funded through annual appropriations, resulting in a total of just \$1.4 billion appropriated between FY14-17. BARDA, which oversees advanced development efforts, also requires an annual appropriation to support its advanced development pipeline, which currently includes more than 200 candidate MCMs.

Past appropriations for multi-agency pandemic influenza response have been previously funded through supplemental measures. With these funds having been depleted, some companies may not have sufficient time to respond to pandemic influenza threats without continued reliable funding, worsening our nation’s capacity to respond to another pandemic influenza outbreak such as the 2009 swine flu.

BARDA and the SRF have also been called upon to assist in product development for international biological emergencies for emerging infectious diseases (EIDs) such as Ebola and Zika. Like pandemic influenza, these efforts have been funded through supplemental appropriations – usually in the midst of a crisis. While government and industry both have stepped up in these instances to accelerate development of critical MCMs, the funding has come too late to effectively intervene in the crisis with proven vaccines or treatments.

Policy Position

During the 2018 PAHPA reauthorization process, Congress must continue to send a strong signal that they are committed to prioritizing health security by providing the resources needed to allow the nation to fully prepare for and defend against biological threats. Investments in preparedness and medical countermeasure research and development will enhance our response efforts, save lives, and be more cost-effective in a biological emergency. Pandemic influenza and EID activities must be authorized and robustly funded. BARDA advanced research and development and the SRF should be funded in a sustainable way consistent with the levels in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) FY16-20 Multiyear Budget to demonstrate the government’s commitment to partnering with industry on these important national security countermeasures.

Key Points

- ✓ The U.S. has become a global leader in civilian biodefense; **continued investment is critical** to this national security mission.
- ✓ Through the investments to date, the **SRF has supported 27 products and 14 products have transitioned** into the Strategic National Stockpile (SNS).
- ✓ **More than 200** candidates are in BARDA’s advanced development pipeline, including broad-spectrum antimicrobials, rapid diagnostics, and next-generation vaccines and therapeutics.
- ✓ Project BioShield has led to significant investments in physical capital and scientific jobs around the country; BARDA has partnered with more than **190 academic and company partners**.
- ✓ The transition to annual appropriations for SRF has led to a shortfall of more than **\$1 billion under the \$2.8 billion** authorized.
- ✓ Supplemental balances for pandemic influenza have been expended; an **authorization** of the program and **new, sustained funding is needed to protect Americans** from one of the most predictable biological threats we face.
- ✓ Without adequate funding for these programs, **companies will face tremendous uncertainty** related to the timing, size, and/or speed of funding, making it even more difficult to attract private investor funding and sustain operations.