Issue Background

Since the passage of the Project BioShield Act in 2004 and the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006, our national preparedness and response capabilities against chemical, biological, radiological, and nuclear (CBRN), pandemic influenza, and emerging infectious disease threats have been enhanced by the federal programs authorized and funded under this legislation.

As there are limited markets for CBRN medical countermeasures (MCMs), pandemic influenza products, and emerging infectious disease (EID) products, the federal government plays an important role to partner with industry on the research, development, and procurement of these products. The PAHPA legislation is an important signal to industry on the research, development, and procurement of these products. The PAHPA legislation is an important signal to industry on the research, development, and procurement of these products.

Policy Position

In the 2018 PAHPA reauthorization, BIO urges Congress to:

- Reauthorize an advanced appropriation for the Project BioShield Special Reserve Fund (SRF) of $8 billion over ten years ($800 million annually) to ensure that there is sufficient funding to cover the priorities outlined in the FY16-20 PHEMCE Multiyear Budget.
- Reauthorize funding for advanced research and development (ARD) at BARDA at $700 million, a level sufficient to cover the specific areas of MCM development under BARDA authority according to the PHEMCE Multiyear Budget.
- Authorize pandemic influenza product development and sustainment at levels sufficient to meet ASPR’s projections in the PHEMCE Multiyear Budget, a minimum of $630 million annually.
- Establish a separate authorization and budget line within BARDA for the development of capabilities and medical countermeasures for emerging infectious diseases. The program should be authorized at $300 million annually.
- Allow the ASPR to manage the full life cycle of all MCMs developed under BARDA. Ensure clarity of authority, funding and accountability within HHS for the procurement of FDA-approved or licensed MCMs developed by BARDA. The Strategic National Stockpile (SNS) should be authorized at an annual level of at least $600 million.
- Extend or eliminate the sunset of the MCM Priority Review Voucher (PRV) program.
- Establish a sustainable pull incentive program to spur the development of products to combat antimicrobial resistance.
- Facilitate interagency coordination through the development of a One Health framework.

During the 2018 PAHPA reauthorization process, Congress must continue to send a strong signal that it is 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 development will enhance our response efforts, save lives, and be more cost-effective in a biological emergency.