

## BIODEFENSE AT-A-GLANCE

**After 9/11 and the 2001 anthrax attacks**, Congress mandated a dedicated effort to develop and stockpile drugs and vaccines needed to protect the American people from chemical, biological, radiological, nuclear (CBRN) and pandemic threats. Because medical countermeasures to protect against threats like anthrax, Ebola, and plague have little or no commercial market, in 2004, Congress passed the Project BioShield Act which created the Special Reserve Fund (SRF) to help fund the development of these products. The 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) created the Biomedical Advanced Research and Development Authority (BARDA) to provide industry partners with funding and technical assistance in the advanced research and development of medical countermeasures. Key federal programs are reauthorized and funded every five years through the PAHPA legislation.

### 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.



## Taking Action

The federal government plays a key role in maintaining the medical countermeasure development enterprise. **The role of the government is to:**

-  Assess the biological threat and clearly define the requirements necessary to prepare against and mitigate the risks
-  Establish health security as a policy and legislative priority
-  Promote and invest in medical countermeasure research and development
-  Stockpile medical countermeasures for emergency response

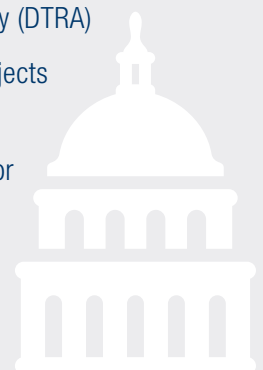
## Key Agencies and Offices Include:

### Department of Health and Human Services (HHS)

- Assistant Secretary of Preparedness and Response (ASPR)
- Biomedical Advanced Research and Development Authority (BARDA)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)

### Department of Defense (DoD)

- Defense Threat Reduction Agency (DTRA)
- Defense Advanced Research Projects Agency (DARPA)
- Joint Program Executive Office for Chemical and Biological Defense (JPEO)



## Addressing Biosecurity Threats: Gaps in Preparedness

Biotech companies are willing and active partners in the national security endeavor. Our industry plays a central role in ensuring the effective development of medical countermeasures to protect our nation's citizens against chemical, biological, radiological and nuclear threats, whether naturally occurring or man-made. Strengthening the pipeline of medical products, drugs and devices that will safeguard the nation during an emergency or pandemic is vital to our national security.

### HIGH-PRIORITY THREATS

#### Biological threats

- *Bacillus anthracis* (anthrax) and multi-drug resistant *B. anthracis* (MDR anthrax)
- *Burkholderia mallei* (glanders) and *Burkholderia pseudomallei* (melioidosis)
- *Clostridium botulinum* toxin (botulism)
- Ebola virus (Ebola hemorrhagic fever)
- Emerging infectious diseases
- *Francisella tularensis* (tularemia)
- Marburg virus (Marburg hemorrhagic fever)
- Pandemic influenza
- *Rickettsia prowazekii* (typhus)
- Variola virus (smallpox)
- *Yersinia pestis* (plague)

#### Chemical threats

- Acetylcholinesterase inhibitor nerve agents
- Chlorine
- Cyanide salts (potassium and sodium cyanide)
- Hydrogen cyanide
- Phosgene
- Vesicants

#### Radiological and nuclear threats

Source: U.S. Department of Health and Human Services, 2017–2018 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan, page 8 (<https://www.phe.gov/Preparedness/mcm/phecme/Documents/2017-phecme-sip.pdf>)

## SUCSESSES, 2004–2017



- **27 products**<sup>1</sup> supported by Project BioShield
- **14 products**<sup>2</sup> added to the Strategic National Stockpile (SNS)
- **6 products**<sup>3</sup> achieved FDA approval/clearance
- **23 candidates**<sup>4</sup> including 8 new classes of antibiotics and 5 non-traditional approaches
- A suite of capabilities-based **core services** have been developed, including a Nonclinical Studies Network, Centers for Innovation in Advanced Development and Manufacturing, a Fill Finish Manufacturing Network, and Clinical Studies Network
- **>190 academic and company partners**<sup>5</sup> have worked with BARDA on product development

## NEXT STEPS

- **By 2020**,<sup>6</sup> an estimated additional 12 medical countermeasures candidates will transition from BARDA to the SNS
- **By 2023**,<sup>7</sup> BARDA aims to reach at least one stockpiled medical countermeasure for 80% of CBRN agents with a material threat determination



<sup>1</sup> Joe Larsen PhD, "BARDA's Division of Chemical, Biological, Radiological and Nuclear Countermeasures", BARDA Industry Day 2017

<sup>2</sup> PHEMCE Multiyear Budget FY16–20

<sup>3</sup> PHEMCE Multiyear Budget FY16–20

<sup>4</sup> Joe Larsen PhD, "BARDA's Division of Chemical, Biological, Radiological and Nuclear Countermeasures", BARDA Industry Day 2017

<sup>5</sup> Rick Bright PhD, BARDA Industry Day 2017

<sup>6</sup> PHEMCE Multiyear Budget FY16–20

<sup>7</sup> Joe Larsen PhD, "BARDA's Division of Chemical, Biological, Radiological and Nuclear Countermeasures", BARDA Industry Day 2017