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* (meliodosis)
- *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

Sucesses, 2004–2017

- **27 products**¹ supported by Project BioShield
- **14 products**² added to the Strategic National Stockpile (SNS)
- **6 products**³ achieved FDA approval/clearance
- **23 candidates**⁴ 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**⁵ have worked with BARDA on product development

Next steps

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

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¹ Joe Larsen PhD, “BARDA’s Division of Chemical, Biological, Radiological and Nuclear Countermeasures”, BARDA Industry Day 2017
² PHEMCE Multiyear Budget FY16–20
³ PHEMCE Multiyear Budget FY16–20
⁴ Joe Larsen PhD, “BARDA’s Division of Chemical, Biological, Radiological and Nuclear Countermeasures”, BARDA Industry Day 2017
⁵ Rick Bright PhD, BARDA Industry Day 2017
⁶ PHEMCE Multiyear Budget FY16–20
⁷ Joe Larsen PhD, “BARDA’s Division of Chemical, Biological, Radiological and Nuclear Countermeasures”, BARDA Industry Day 2017