BARDA CBRN Medical Countermeasures Portfolio

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HIGH PRIORITY THREATS

- Radiological agents and Nuclear devices
- Cyanide and Nerve agents
- Emerging infectious diseases
  - Pandemic influenza
  - Multi-drug resistant pathogens
- Viral Hemorrhagic Fevers
  - Marburg
  - Ebola
- Gram negative organisms
  - Francisella tularensis (tularemia)
  - Yersinia pestis (plague)
  - Burkholderia mallei (glanders)
    and B. pseudomallei (melioidosis)
  - Rickettsia prowazekii (typhus)

The Enterprise will continue to address medical countermeasure needs to protect against high priority threats which have been determined by the Secretary of Homeland Security to pose a material threat sufficient to affect national security and/or which have the potential to seriously threaten national health security.

- Bacillus anthracis (anthrax)
- Clostridium botulinum toxins (botulism)
- Variola virus (smallpox)
Stockpiled CBRN Countermeasures

- Smallpox
- Anthrax
- Radiation
- Botulism

Pentetate calcium trisodium injection
1000 mg
For intravenous or inhalation use only.
See package insert for use information.
Rx only.

Pentetate zinc trisodium injection
1000 mg
For intravenous or inhalation use only.
See package insert for use information.
Rx only.

BioThrax®
ANTHRAX VACCINE ADSORBED
Contains 5 mL (0.5 ml per dose)
Rx Only.
MCMs THAT WE STILL NEED

• Anthrax vaccines
  — Faster-acting, stable, cheap
• Broad-spectrum antimicrobials
  — Novel drugs
• Radiation countermeasures
  — Acute radiation countermeasures
  — Oral decorporation agents
  — Biodosimetry/bioassays
  — Skin/lung countermeasures
• Viral hemorrhagic fever MCMs
• Diagnostics
• Volatile nerve agent countermeasures
• Thermal burn therapies
• Blood products
PRODUCT DEVELOPMENT MODEL

• Early Development
  — Emphasis on Proof of Concept
  — Integration of platforms, CROs, CMOs
  — Relies on tech-transfers, data and model sharing
  — Rapid Go/No Go Decisions

• Advanced Development
  — Emphasis on licensure and stockpiling
  — Scale-up, validation of manufacturing
  — Phase II/III, pivotal animal studies
  — Life cycle and sustainment important
SUSTAINING THE ENTERPRISE

- **Innovation**
  - Protein Expression
  - New platforms, delivery systems

- **Product Improvements**
  - Adjuvant technologies

- **Stockpile Manufacturing Intermediates**
  - Frozen stockpiles of immune sera and vaccines

- **Multi-Purpose Products**
  - Broad spectrum antibiotics
  - Anti-neutropenia/oncology drugs

- **Integrate Stockpiling with Existing Drug Inventories**
  - Anti-neutropenia/oncology drugs

- **Government furnished Core Services**
  - Manufacturing, Fill/Finish
  - Animal Model development
  - Product Testing
  - Qualified reagents
CHALLENGES

• PAHPA reauthorization and continued funding
• Sustaining successful medical countermeasures and their developers
• Technology transfers from pipeline to Centers for Advanced Development and Manufacturing
• Developing readiness and ConOps plans for all MCMs
• Establishing a rapid response infrastructure for unknown threats
• Building and maintaining strong Public-Private Partnerships