



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



BARDA CBRN Medical Countermeasures Portfolio

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BARDA Industry Day
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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)

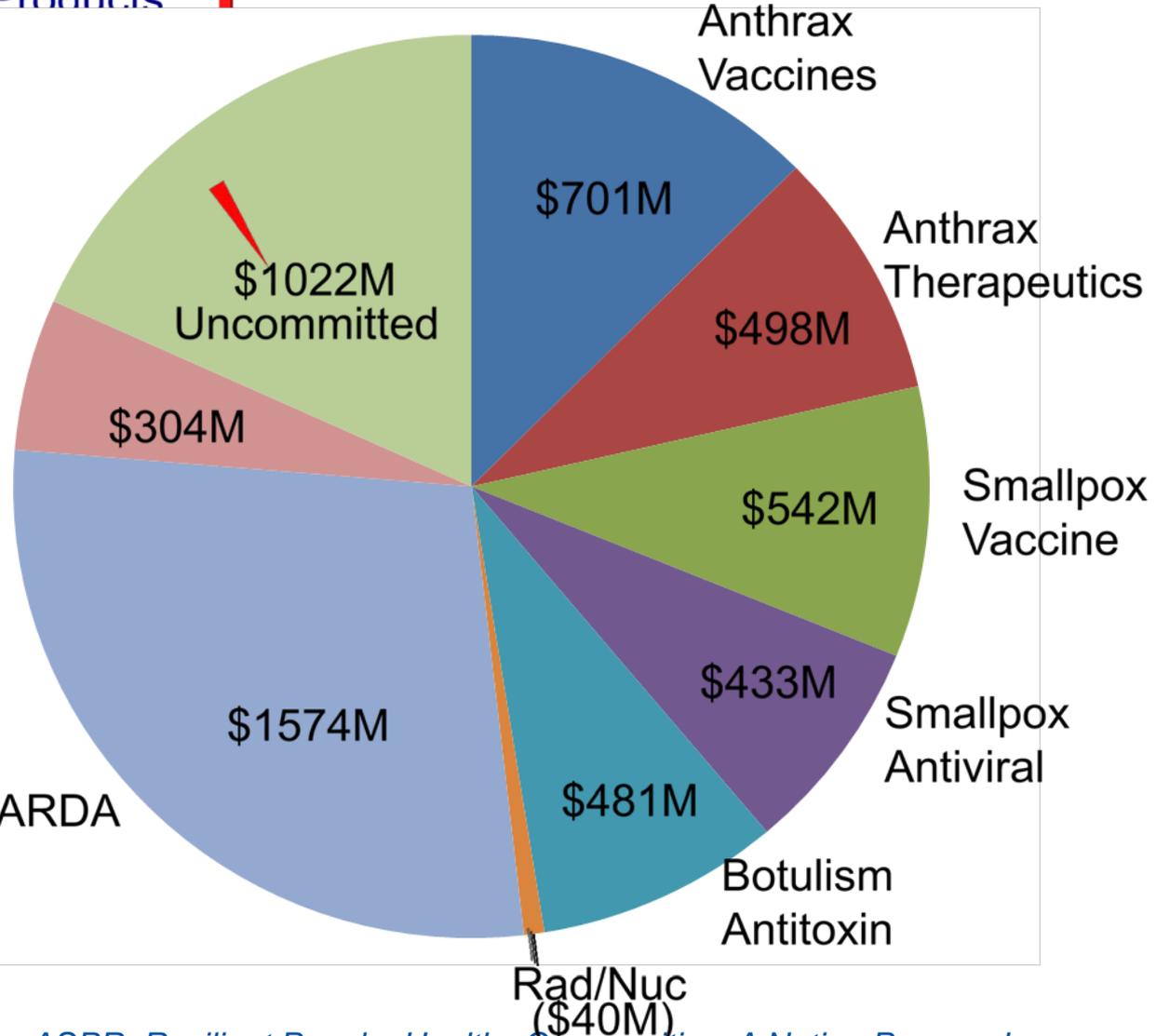
The Enterprise will continue to address medical countermeasure needs to protect against high priority threats which have been determined by the Secretary of Homeland Security to pose a material threat sufficient to affect national security and/or which have the potential to seriously threaten national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

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



Project BioShield Clock is Ticking

Replenishment of Products
ARS Anti-Neu
Chem/Anti-co
FY13 Transfer



Revised Sept 2012

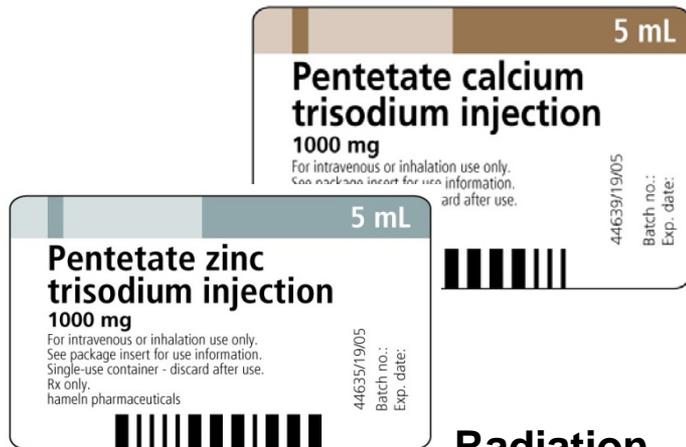
Stockpiled CBRN Countermeasures



Smallpox



Anthrax



Radiation



ASPR: Resilient Per...

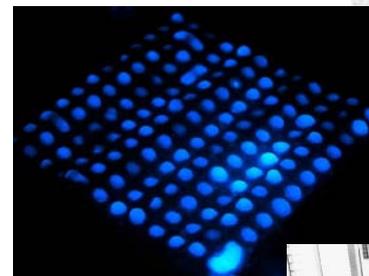
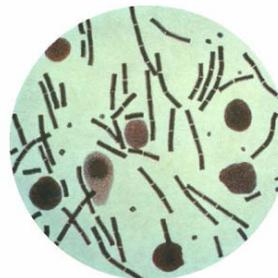


...ation Prepared.

Botulism

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



- 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



BARDA CORE SERVICES

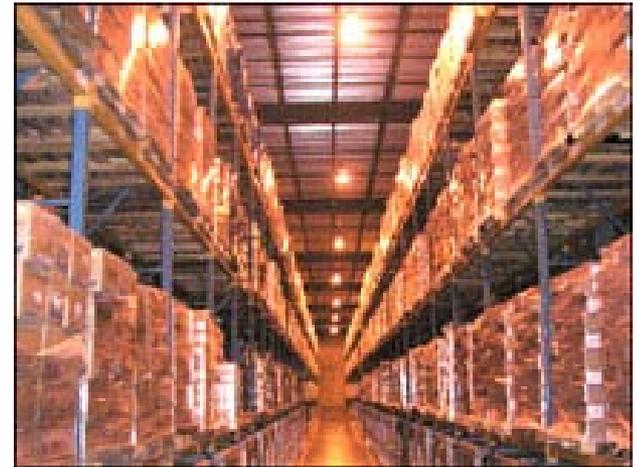




SUSTAINING THE ENTERPRISE



- 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

