

United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness & Response (ASPR)
Biomedical Advanced Research & Development Authority (BARDA)



Biomedical Advanced Research and Development Authority (BARDA)

Chemical, Biological, Radiological and Nuclear (CBRN) Division of Countermeasures

Gary L. Disbrow, Ph.D.
Deputy Director

*BARDA Industry Day
Boston, MA*



Overview



- BARDA Mission
- Budget Update
- Advanced Research and Development Priorities
- Core Services
- Programs
 - Rad/Nuc/Chem
 - Anthrax Vaccines
 - Antitoxins
 - Broad Spectrum Program
 - Biodosimetry and Diagnostics
 - Smallpox
 - Animal Models Network



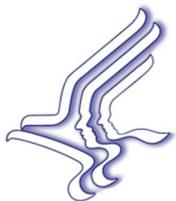
BARDA Mission



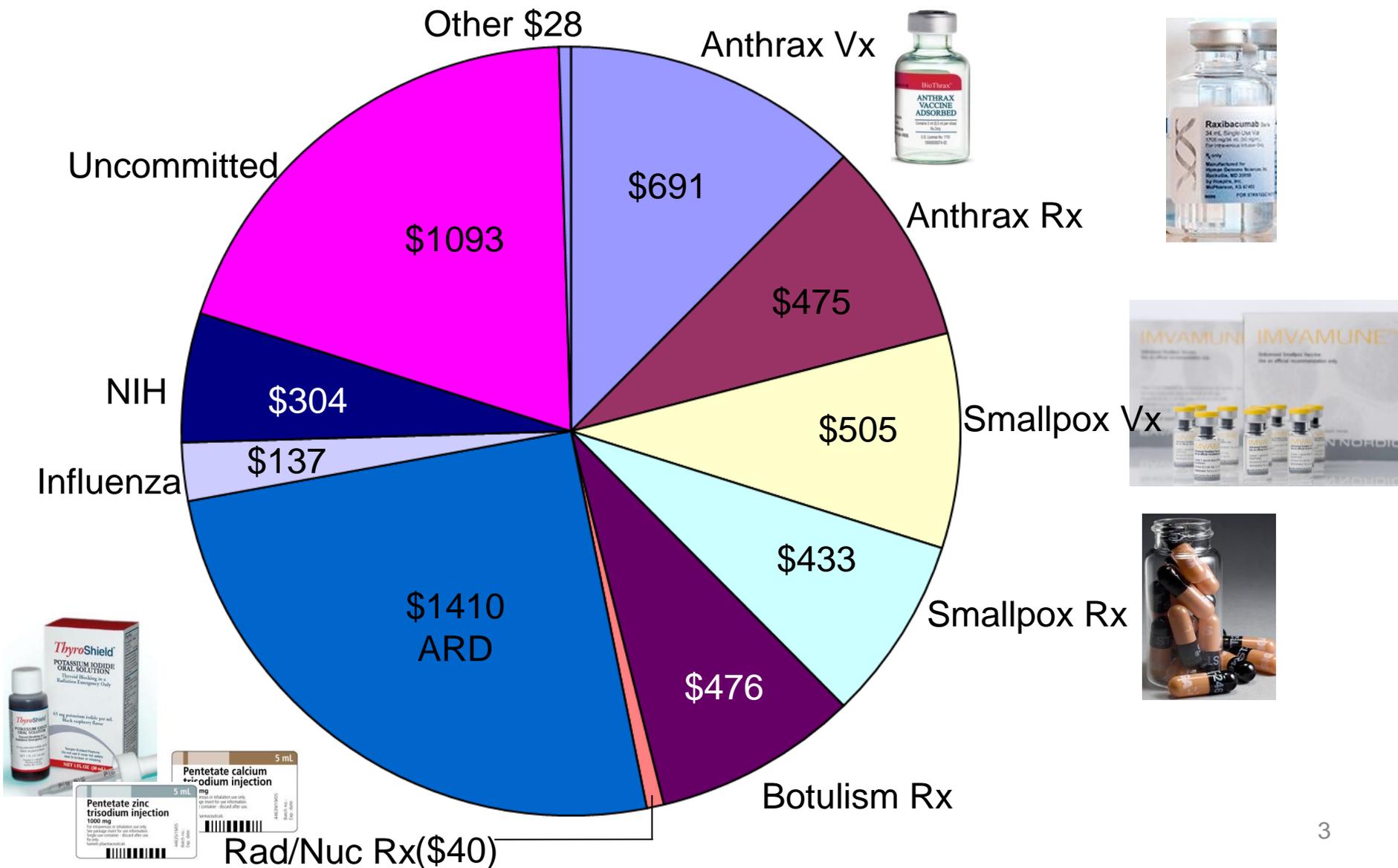
Ensuring the availability of countermeasures to address public health emergencies

- Three threat areas: Chem/Bio/Rad/Nuc, Pandemic Influenza, Emerging Infectious Diseases
- Comprehensive portfolio approach to development and acquisition of products
- Unique niche in USG biomedical R&D
 - Bridge the “Valley of Death”
 - Mid- to late-stage product development
 - Staff with experience in product development and manufacturing
 - Work with industry to progress product candidates through the pipeline





PBS Commitments To-Date





Future for Project BioShield

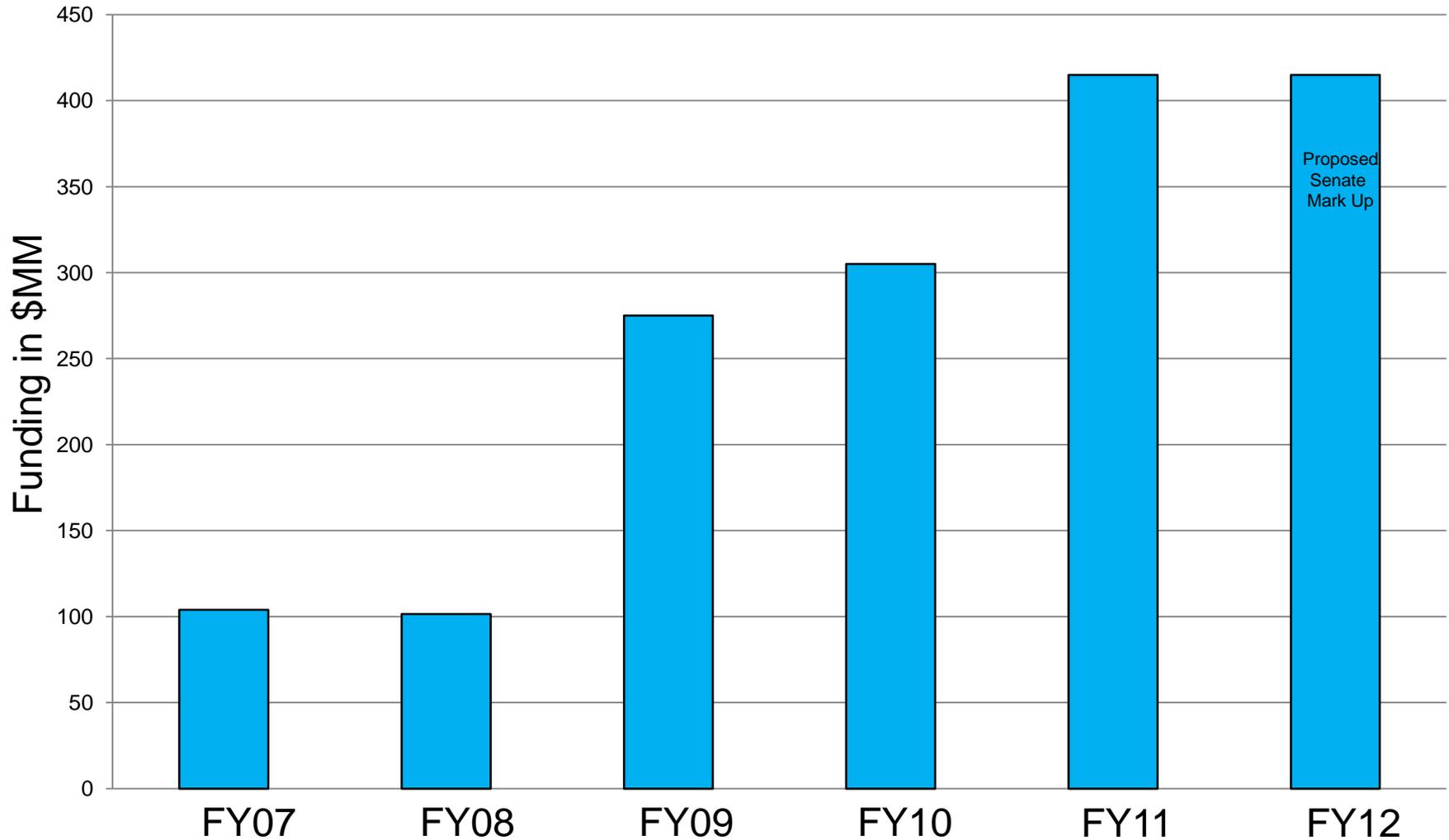


- Project BioShield sunsets at the end of FY 2013
 - Approximately \$1.1 B left after FY 2012 ARD is transferred
 - New MCMs under consideration for radiation and burns
 - Replacement product for Chem Paks
 - Replenishment of expiring product
 - Stockpiling bulk
 - Phase III requirements
 - Post-licensure commitments
- PAHPA Reauthorization discussions are currently ongoing in Congress
 - Congressional funding
 - Potential for \$2.8B for procurement FY 2014 – 2018
 - Yearly appropriations for ARD \$415M FY 2014 – 2018





ARD Funding by Fiscal Year





CBRN Priorities For ARD



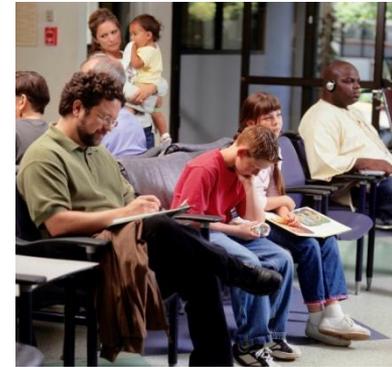
- **Smallpox**
 - Acam2000
 - VIG
 - MVA
 - ARD for vaccine enhancement
 - ST-246 under contract
 - One antiviral in development
- **Anthrax**
 - Antibiotics
 - BioThrax®
 - Raxibacumab
 - AIG
 - Two rPA products in development
 - Two alternate expression vectors in dev.
 - One enhanced monoclonal in development
- **Botulinum**
 - Heptavalent Bot antitoxin

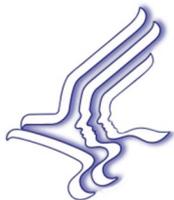


- **Broad Spectrum**
 - Two novel drugs in development
- **Chemical**
 - Three products in development
- **Radiological and Nuclear**
 - Numerous products in development
 - Very early stage of development
- **BioDosimetry and BioDiagnostics**
 - Numerous devices/assays for biodosimetry
 - No devices/assays for biodiagnostics
- **Core Services**
 - Animal models
 - Assay development
- **Product improvements**
 - Repurposing approved drugs
 - Life-cycle enhancements



BARDA Core Services





CBRN Programs



- Rad/Nuc/Chem – Dr. Ronald Manning
- Anthrax Vaccines – Dr. Thomas Dreier
- Antitoxins – Dr. Steve Morris
- Broad Spectrum Program – Dr. Joseph Larsen
- Biodosimetry and Diagnostics – Mr. Rodney Wallace
- Smallpox – Dr. Michael Merchlinsky
- Core Services – Dr. Thomas Dreier

