Biomedical Advanced Research and Development Authority (BARDA)

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

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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

- **ARD**: $1410
- **Uncommitted**: $1093
- **Influenza**: $304
- **Smallpox Vx**: $137
- **Other**: $28
- **Botulism Rx**: $476
- **Rad/Nuc Rx ($40)**
- **Smallpox Rx**: $433
- **Anthrax Vx**: $691
- **Anthrax Rx**: $475
- **NIH**: $505

Note: Total commitments as of the 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

- FY07: 100
- FY08: 50
- FY09: 250
- FY10: 300
- FY11: 400
- FY12: 450

Funding in $MM

Proposed Senate Mark Up
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
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