

United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response (ASPR)



BARDA Industry Day: East Coast 2011

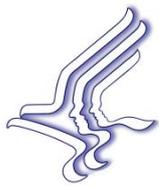
Sheraton Boston

Robin Robinson, Ph.D.

Director, BARDA

Deputy Assistant Secretary, ASPR

October 17, 2011

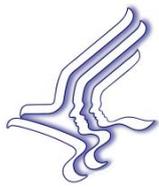


BARDA Mission

Develop and provide countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by product development, stockpile acquisition, manufacturing infrastructure building, and product innovation.

- **Unique niche in USG biomedical R&D**
 - Bridge the **“Valley of Death”**
 - Mid- to late-stage product development
 - Experienced TEAM in product development, regulatory, clinical, and manufacturing
 - Work with industry to facilitate candidates through development pipeline
 - Response capability for product manufacturing



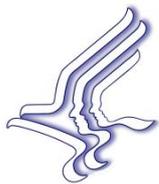


Medical Countermeasure Development is Expensive, Lengthy and High Risk

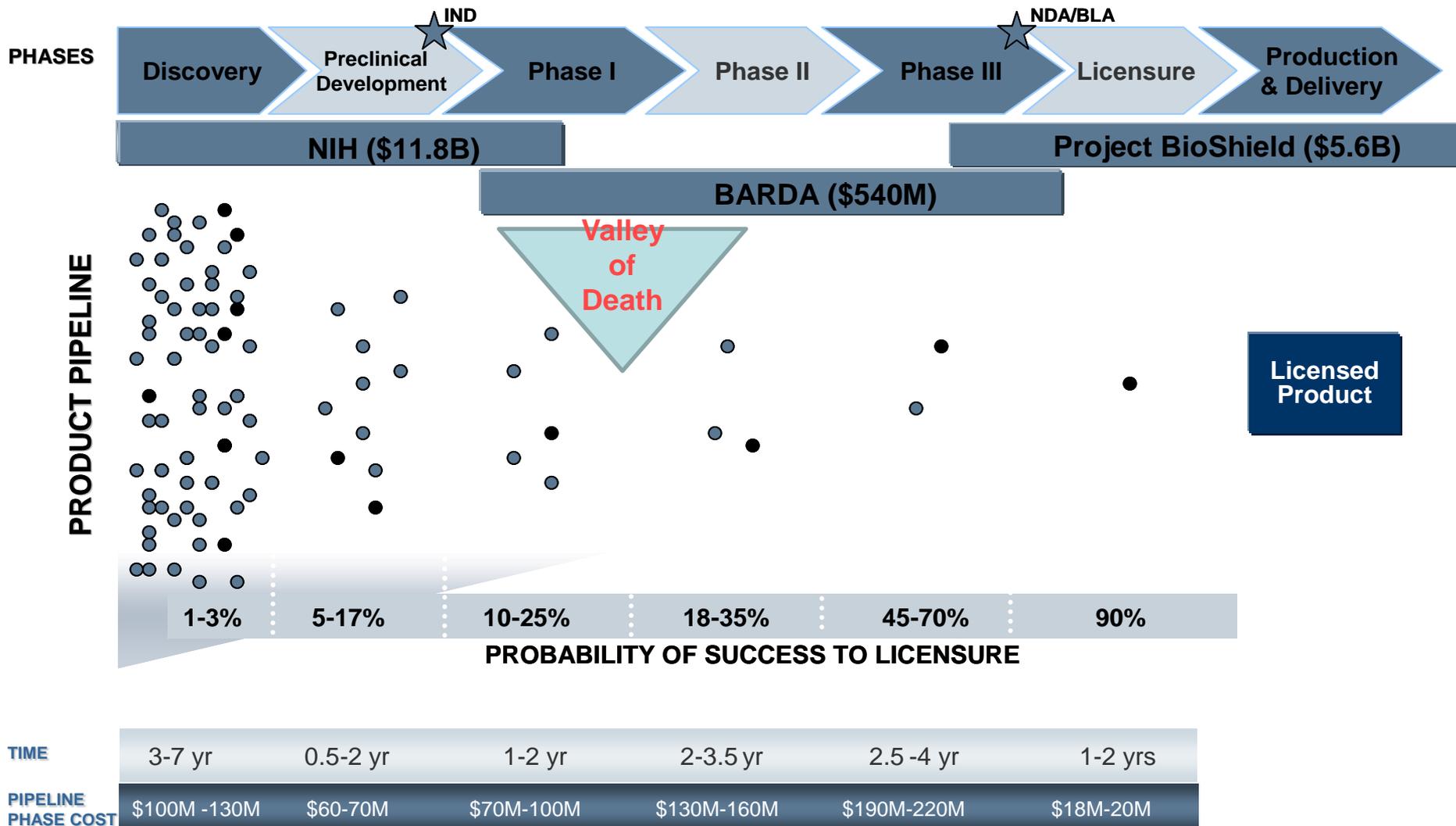


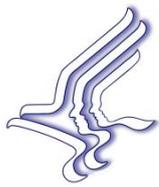
- Industry benchmarks for typical drug
 - 10-15 yrs from bench to pharmacy
 - Phase 2 to licensure 6-8 yrs
 - \$800M to \$1B investment
 - Very low probability of success
- MCM development characterized by market failure
- USG provides numerous incentives to attract private sector partners to medical countermeasure development
 - Grants and contracts provided by NIH, BARDA, and DoD
 - Drug screening, preclinical, clinical, and regulatory services
 - Project BioShield Special Reserve Fund for procurement of needed MCMs (market guarantee)





CBRN Countermeasure Development Is Risky & Expensive

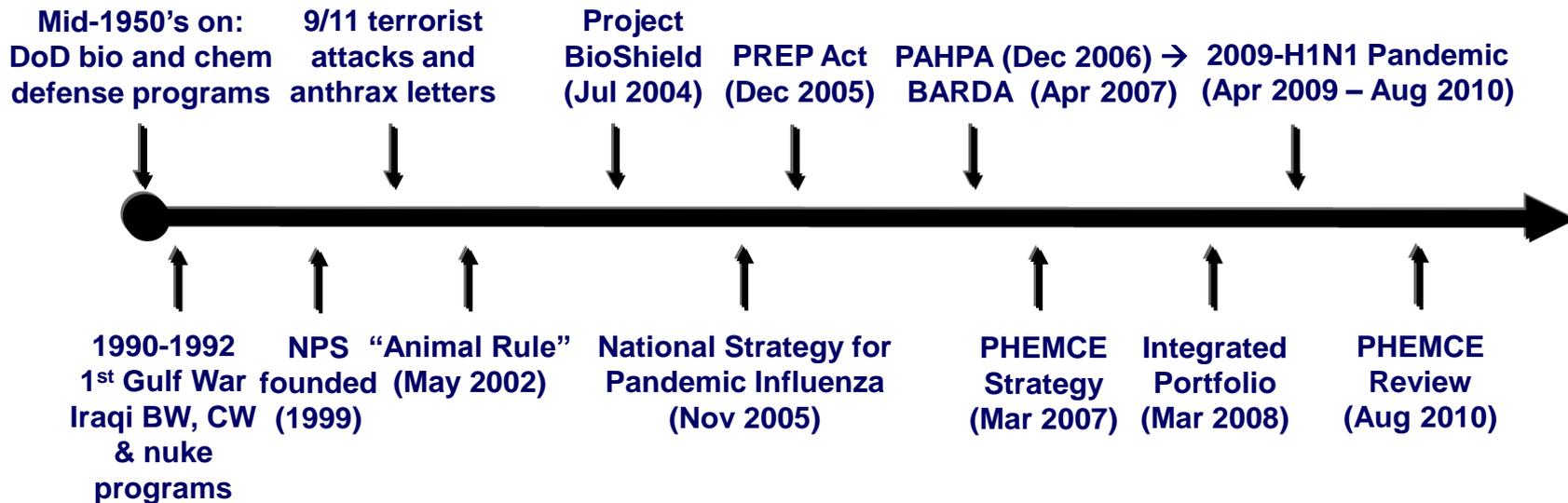


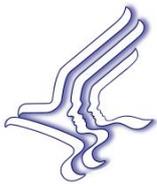


History of Biodefense & BARDA

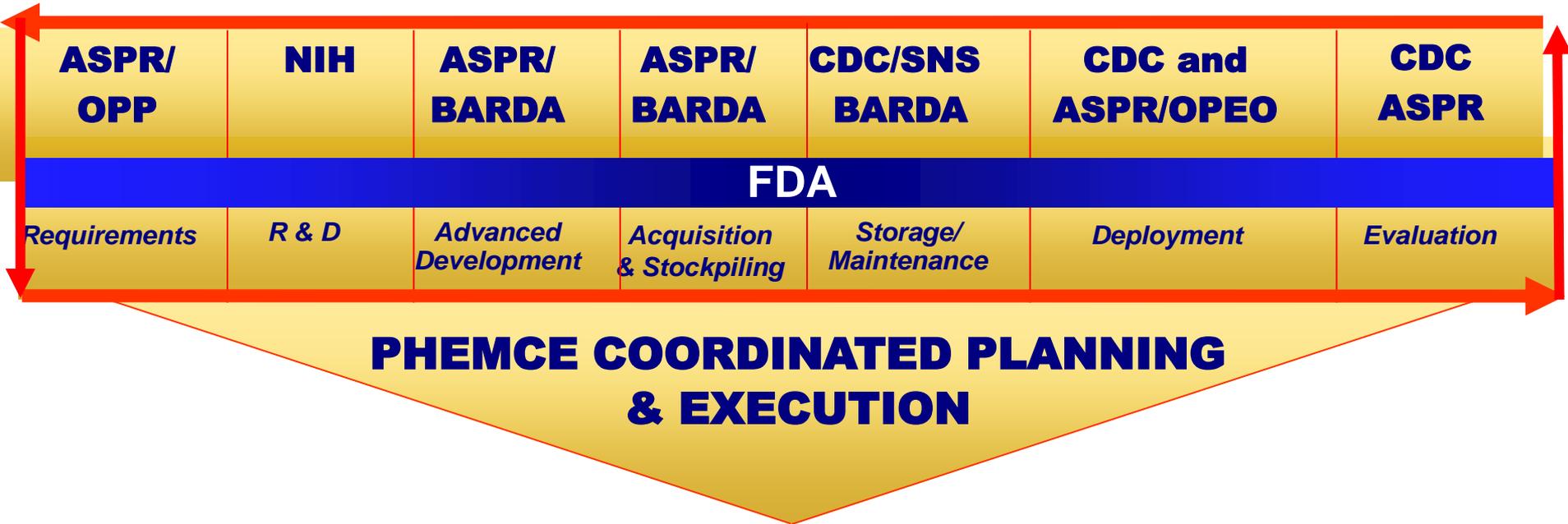


- pre-9/11, 1950s – 2001
- post-9/11 to Project BioShield, 2001 – 2004
- Project BioShield and PAHPA, 2004 – 2006
- ASPR, BARDA & H1N1, 2007 – 2009
- Enterprise Transformation, 2010 →



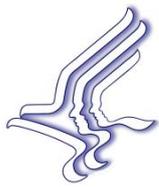


Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)



Other Members:





PHEMCE Process For Developing Medical Countermeasure Requirements and Acquisition Strategies



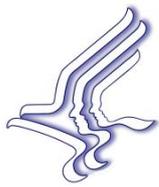
Pillar 1
Identify
and Assess
Threats

Pillar 2
Evaluate
Medical and
Public Health
Consequences

Pillar 3
Establish
and Prioritize
Medical
Countermeasure
Requirements

Pillar 4
Determine
Near-, Mid-,
and Long-Term
Development &
Acquisition
Strategies

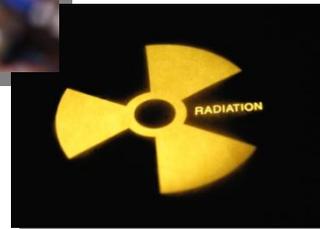


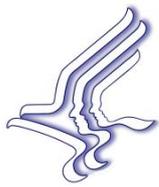


Material Threat Determinations and Population Threat Assessments Issued by the Department of Homeland Security

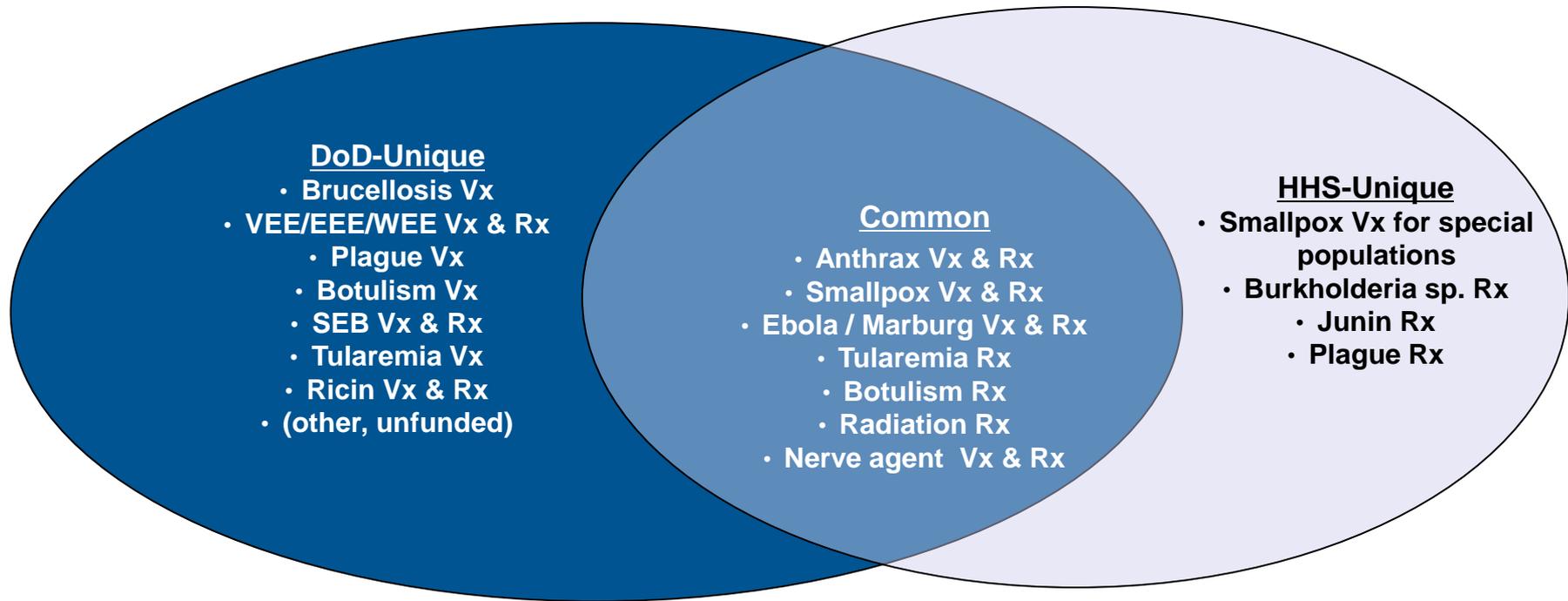


- Radiological and Nuclear agents
- *Bacillus anthracis* (anthrax)
- *Bacillus anthracis* – Multi-drug resistant (MDR anthrax)
- Botulinum toxins (botulism)
- Variola virus (smallpox)
- *Yersinia pestis* (plague)
- *Franciscella tularensis* (tularemia)
- Hemorrhagic Fever Viruses - Ebola, Marburg
- *Burkholderia mallei* (glanders)
- *Burkholderia pseudomallei* (melioidosis)
- *Rickettsia prowazekii* (typhus)
- Low volatility and volatile nerve agents
- Hydrogen, potassium, and sodium cyanide



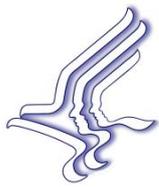


Integrated Portfolio for CBRN MCM Requirements – Unique and Convergent



DoD focus is on protecting forces prior to exposure. HHS focus is on response to threats to general civilian population after exposure

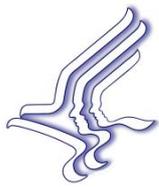
V_x = Prophylaxis R_x = Therapeutic



BARDA Threats & Projects: Facts & Figures



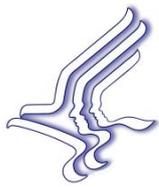
- **BARDA portfolios address serious threats**
 - Anthrax, smallpox, plague, tularemia, botulism, melioidosis, glanders, typhus, viral hemorrhagic fever
 - Acute radiation syndrome & thermal burns
 - Volatile chemical agents
 - Pandemic & seasonal influenza
 - Emerging infectious pathogens *incl. antimicrobial resistance*
- **BARDA portfolios include multiple countermeasure types**
 - Vaccines
 - Small molecule therapeutics
 - Biological therapeutics
 - Diagnostics & medical devices
- **BARDA supports 90+ candidates for advanced development of pandemic influenza and CBRN medical countermeasures**
- **BARDA is # 5 investor globally in pharmaceutical product R&D (>\$3 B since 2005)**



Public – Private Partnership Framework



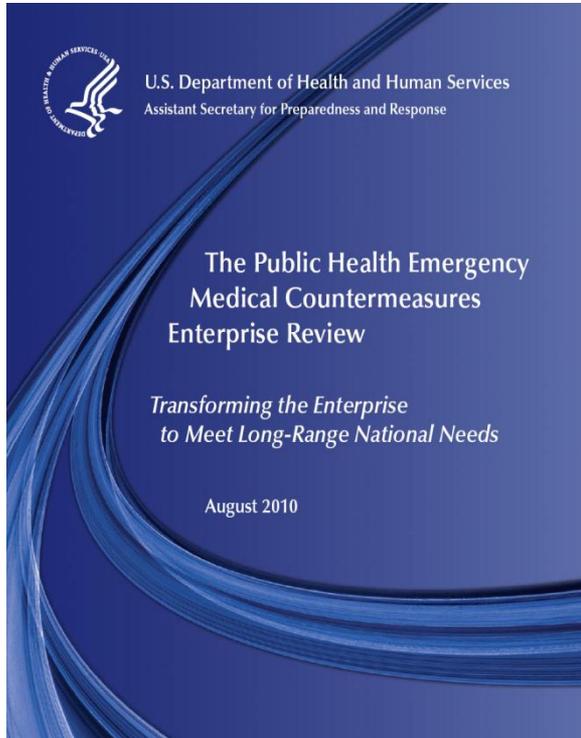
- **BARDA & Industry Areas of Interest**
 - Product advanced development
 - Stockpiling
 - Manufacturing infrastructure – *Vaccine Mfg Facilities*
- **Cost-sharing**
- **Long-term contractual relationships**
- **Address government & commercial needs**
 - Domestic & global emergency preparedness & response
 - Commercial markets
 - Public health needs – *Broad Spectrum Antimicrobials*



MCM Enterprise Review: New Strategy



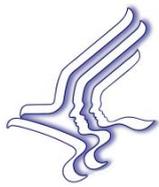
Key Initiatives



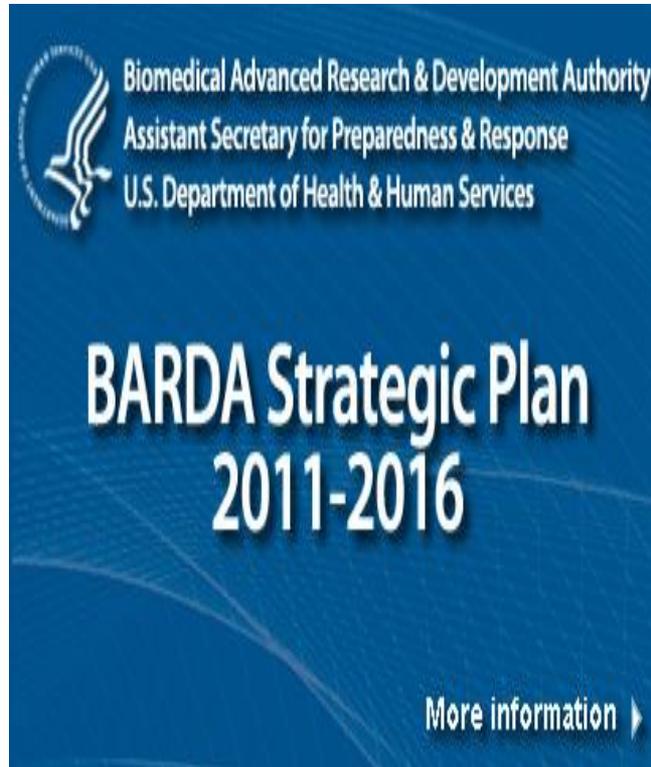
- 1. Expand Product Pipeline through Concept Acceleration Program (CAP) at NIAID**
- 2. Establish a Strategic Investment (SI) Fund to increase investments in commercial ventures with multi-use potential (BARDA)**
- 3. Establish Centers for Innovation in Advanced Development and Manufacturing (BARDA)**
- 4. Investment in upgrading science capacity at FDA**
- 5. Optimize influenza vaccine development and manufacturing (BARDA. NIAID. FDA. CDC)**

Enhancements:

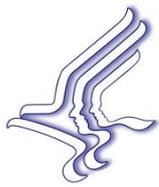
- **Business Practices**



BARDA Strategic Plan 2011-2016



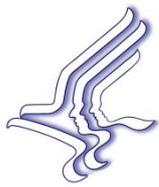
- **Five (5) major goals**
- **Strategic approaches**
- **Cascades from NHSS, ASPR, MCM Review, and other national plans**
- **View Plan on *medicalcountermeasures.gov***



BARDA Strategic Goal 1



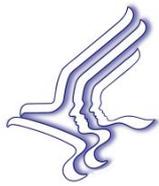
- **An advanced development pipeline replete with medical countermeasures and platforms to address unmet public health needs, emphasizing innovation, flexibility, multi-purpose and broad spectrum application, and long-term sustainability**



BARDA Strategic Goal 2



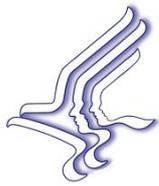
- **A capability base to provide enabling core services to medical countermeasure innovators**



BARDA Strategic Goal 3



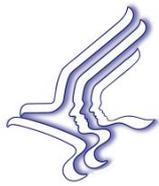
- **Agile, robust and sustainable U.S. manufacturing infrastructure capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats**



BARDA Strategic Goal 4



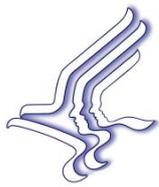
- **Responsive and nimble programs and capabilities to address novel and emerging threats**



BARDA Strategic Goal 5



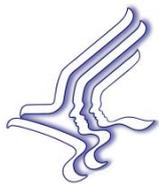
- **A ready capability to develop, manufacture and facilitate distribution of medical countermeasures during public health emergencies**



BARDA FY 2011 Major Accomplishments



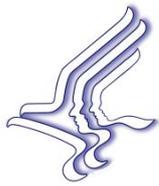
- **Expanded BARDA CBRN & Flu AD programs to 90+ product candidates**
- **Awarded 1st PBS & ARD contracts for antiviral drugs - smallpox**
- **Awarded 1st CBRN contract to major pharmaceutical company - BSA**
- **Awarded 1st contract to develop chemical antidotes**
- **Developing formulations for Rad/Nuc chelators for children**
- **Preserved botulinum antitoxin stockpile through 2026**
- **With CDC, two (2) influenza diagnostics were FDA-approved**
- **Faster sterility assay accepted by FDA for influenza vaccine mfg.**
- **New cell-based influenza vaccine facility became operational for pandemics & intl. vaccine capacity in 10+ developing countries**
- **Awarded contracts for recombinant-based influenza vaccine and longer, lasting NAI development**
- **Began CIADM program with contract solicitation**
- **Established animal studies network**



Changed U.S. Vaccine Industry



New cell-based influenza vaccine mfg. facilities (Novartis): Operational Nov. 2011

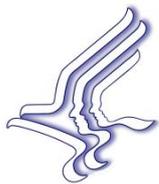


BARDA

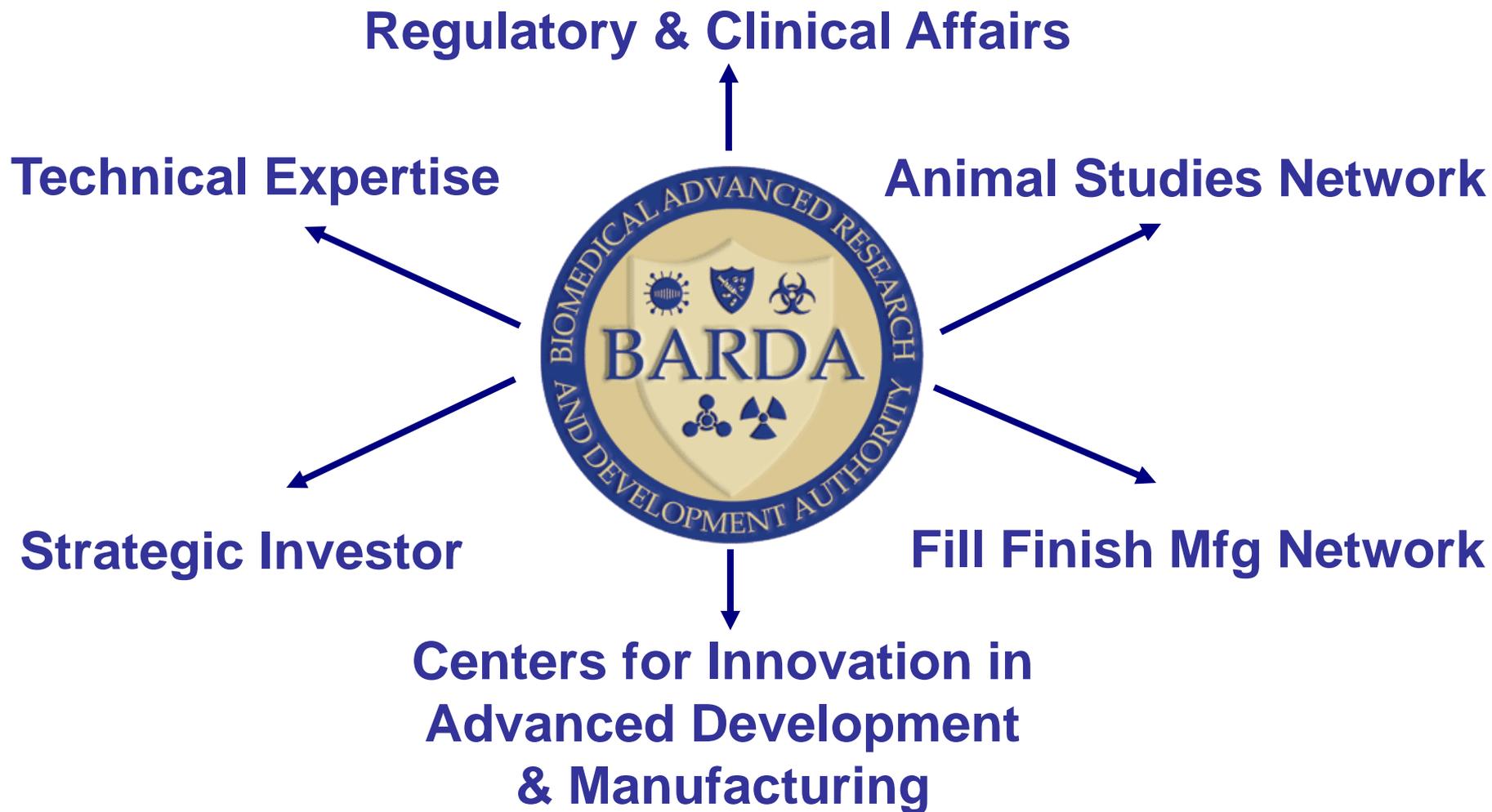
Milestones & Challenges

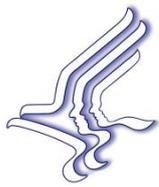


- **PAHPA Reauthorization**
- **Economic Woes & Budget Austerity**
- **Pharmaceutical & Biotech Industry Reinvention**
- **Special Populations**
- **Re-purposing Products**
- **Stockpile Replenishment**
- **Core Service Assistance**
- **Program Transitioning**



BARDA Core Services

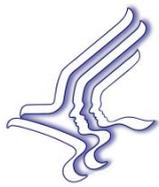




BARDA Program Transitioning



- **Completion of mature programs**
 - Cell-based influenza vaccines
 - Botulinum antitoxins
 - Smallpox Vaccines
- **Moving programs from mid-stage to maturity**
 - Next Generation Anthrax Vaccines & Antitoxins
 - Smallpox Antivirals
 - Antigen-sparing Influenza Vaccines
 - NAI Influenza Antivirals, Diagnostics, & Ventilators
- **Kicking off infant programs into growth phase**
 - Broad Spectrum Antimicrobials
 - Rad/Nuc Therapeutics
 - Biodosimetry Devices
 - Chemical Antidotes
 - Recombinant Influenza Vaccines
- **Starting new programs**
 - Biothreat Diagnostics
 - Non-NAI Antivirals & Small Molecule Immune Modulators
 - “Universal “ Influenza Vaccines ???



Contact Us

BARDA:

URL: <http://www.phe.gov/about/barda>

E-Mail: BARDA@hhs.gov

- Upcoming Events
- PHEMCE Strategy and Implementation Plan
- CBRN and Pan Flu Programs



MedicalCountermeasures.gov

- Tech Watch program
- Federally-sponsored conferences
- Funding opportunities
- Resources 7 core service programs
- Regulatory guidance
- Federal strategies and reports

