



United States Department of
Health & Human Services

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

BARDA MCM Progress

HHS PHEMCE Stakeholders Workshop

Arlington, VA

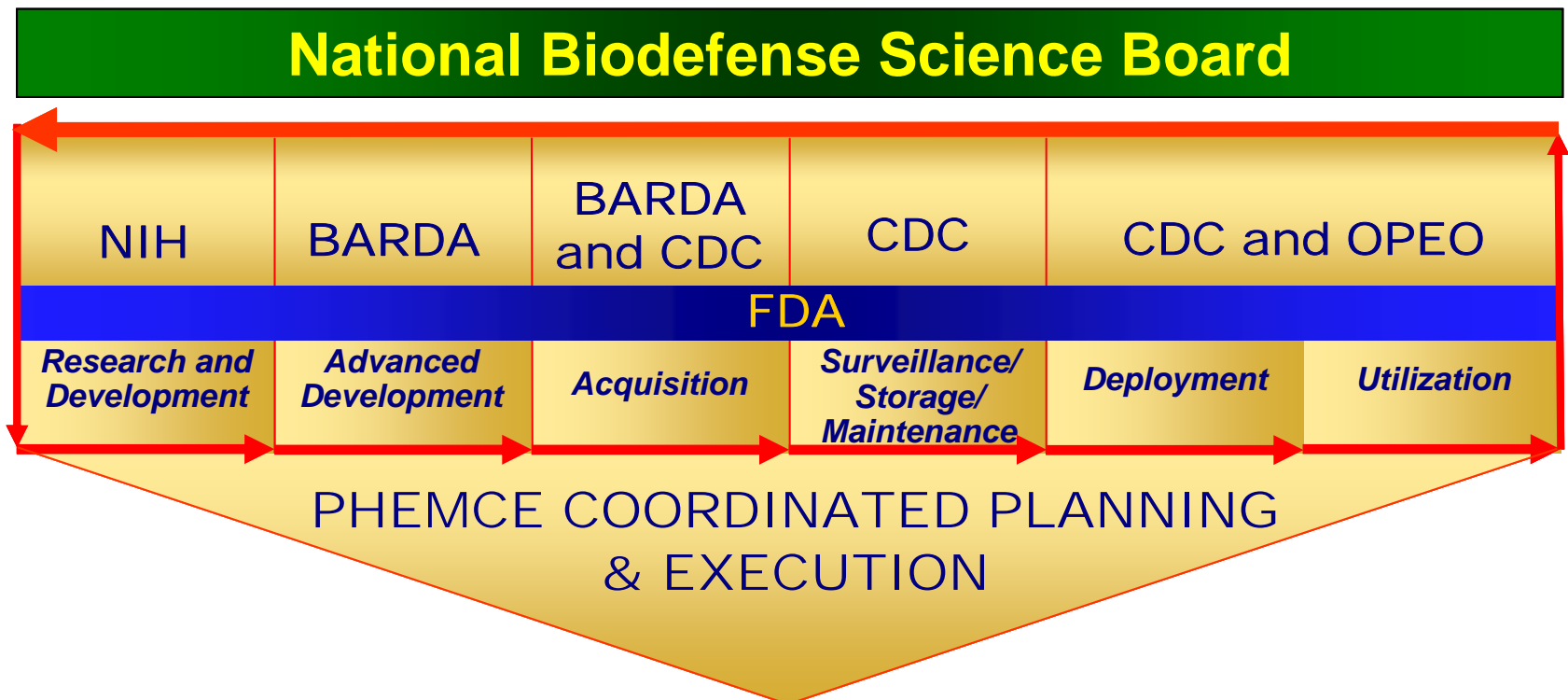
September 24, 2008

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Director

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HHS Public Health Emergency Medical Countermeasures Enterprise



Federal Planning and Funding Initiatives

BARDA



CBRN

National Strategy to Combat WMD (HSPD-4)
 Dec. 2002

Biodefense for the 21st Century (HSPD-10)
 April 28, 2004

Project BioShield Act
 July 21, 2004

Medical Countermeasures Against WMD (HSPD-18)
 January 31, 2007

HHS PHEMCE Strategy & Implementation Plan
 March/April, 2007



PANDEMIC FLU

National Strategy for Pandemic Influenza
 Nov. 1, 2005

HHS Pandemic Influenza Plan
 Nov. 2, 2005

Emergency Supplemental Appropriations (P.L. 109-148)
 Dec. 30, 2005

Emergency Supplemental Appropriations (P.L. 109-234)
 June 15, 2006

ALL HAZARDS

Pandemic and All-Hazards Preparedness Act
 Dec. 19, 2006

Draft BARDA Strategic Plan
 July 5, 2007

Public Health & Medical Preparedness (HSPD-21)
 October 18, 2007

BARDA 2008 Accomplishments

- **PAHPA**

- Establish BARDA & appoint Director
- Implemented integrated product portfolio with heavy emphasis on **advanced development** followed by acquisition of near-licensure products
- Developed amendment for **PREP Act declaration** for H5N1 vaccine to include H7 & H9 vaccines
- Utilized BARDA **antitrust exemption** for Mix-N-Match studies with multiple manufacturers and HHS agencies

- **INTRAMURAL STUDIES**

- Began program to determine feasibility of pre-pandemic flu vaccine with different adjuvants under EUA

- **REGULATORY**

- Submitted **EUAs** (2) for anthrax antibiotic MedKits for USPS and 1st responders
- Worked with NIAID on **IND** filing for H5N1 vaccine with adjuvants for Mix-N-Match Phase 1 clinical studies

PHEMCE Implementation Plan: Top Priority Medical Countermeasure Acquisitions

Near-Term FY 2007-08

- Broad-Spectrum Antibiotics
- Anthrax Vaccine(s)
- Smallpox Vaccine
- MCMs for Rad/Nuc Threats

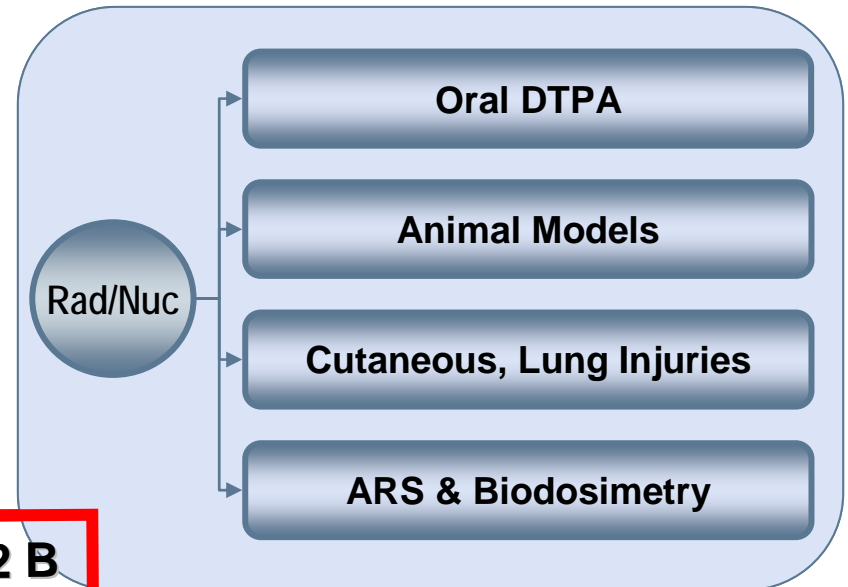
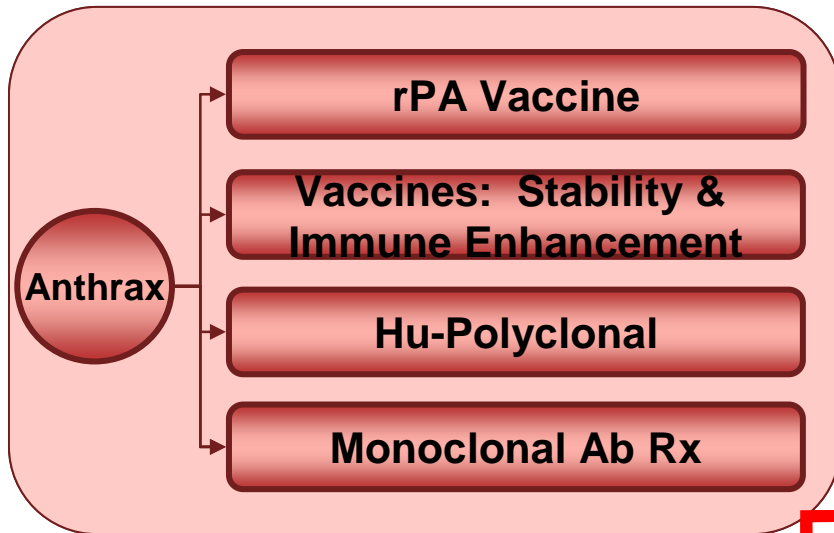
Mid-Term FY 2009-13

- Broad-Spectrum Antibiotics
- Diagnostics
- Anthrax Antitoxin(s)
- Filovirus MCMs
- Smallpox Antiviral(s)
- MCMs for ARS and DEARE
- Radionuclide-Specific MCMs
- Rad/Nuc: Biodosimetry/Bioassay(s)
- Enterprise CHEMPACKS

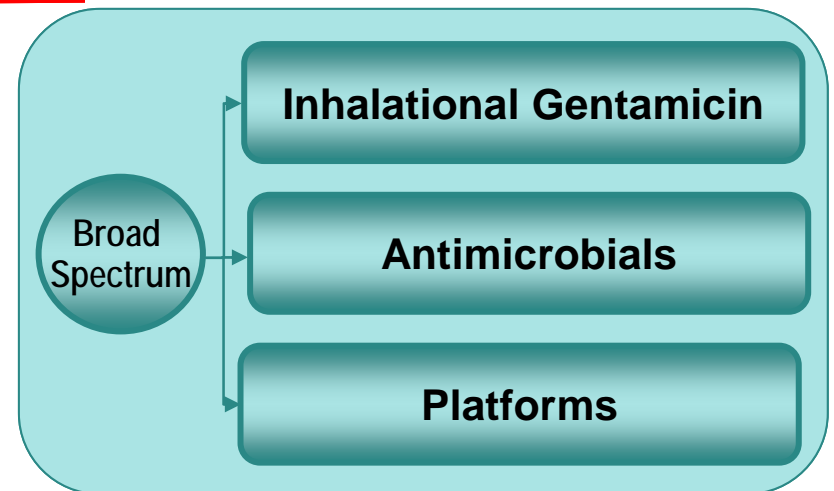
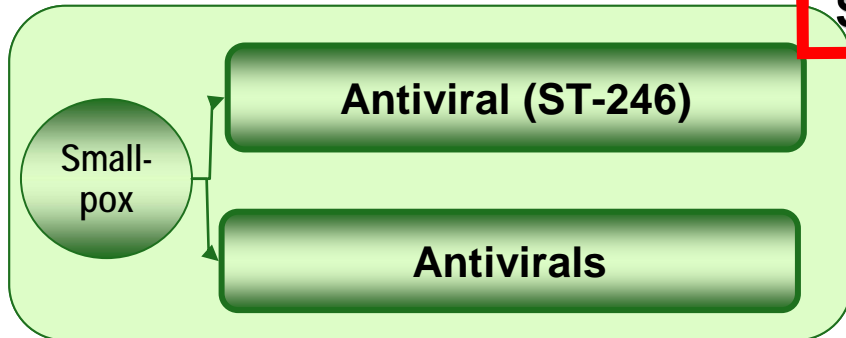
Long-Term Beyond FY 2013

- Broad-Spectrum Antivirals
- Volatile Nerve Agent Antidote(s)

Expanded CBRN Preparedness Toolkit



\$2.2 B



- **PHEMCE ENTERPRISE**

- Completed successful transition of MCM development (MVA vaccine, bot antitoxin, anthrax antitoxins) from NIAID, CDC, and DoD to BARDA and of stockpile acquisition from BARDA to CDC/SNS
- Implemented PHEMCE implementation plan
- Provided stewardship of PHEMCE Enterprise governance bodies (EGB & EEC)

- **SMALLPOX**

- Prototype for BARDA model for advanced development & PBS stockpile acquisition
- Continued development of smallpox MVA vaccine under contract with Bavarian Nordic from NIAID for expected delivery of 20 M doses in 2009
- WMD WG requirement setting for special populations
- Animal model development (3) & regulatory acceptance
- EUA guidance

- **ANTHRAX**

- Continued acquisition of AVA vaccine from Emergent for joint U.S. civilian-military anthrax vaccine stockpile to 18 M doses (BARDA → CDC/SNS) & development of post-exposure prophylaxis indication, extended product stability, **adjuvant formulations (CpG)**, & potency assays
- **Issued new solicitation (Feb. 08) for development/acquisition of rPA vaccine with contract awarding by expected end of 2008**
- Continued development & acquisition of anthrax antitoxins - polyclonal Abs (Cangene, HGS, **Emergent**) and mAbs (Emergent, Elusys, Pharmathene)
- **Began development of Medkit (doxycycline) for 1st responders & general population (palatability & label comprehension studies) & acquisition for 1st responders (EUA)**

- **BOTULISM**

- Established horse farm for production of equine-derived botulinum antitoxin, developed plasmaphoresis, & implemented GLPs (CDC → BARDA)
- Continued production & acquisition with Cangene of heptavalent botulinum antitoxin for delivery of 200 K t.c. thru 2011

- **ACUTE RADIATION SYNDROME**

- Acquired ARS chelating agents (DTPA, KI, Prussian Blue) using PBS for SNS
- Awarded contracts (7) for development of broad array (small molecule, cytokines, stem cells) of ARS therapeutics for multiple indications (Sept. 08)
- Issued new solicitation (Mar. 08) for development/acquisition of ARD therapeutics for neutropenia indication with contract awarding by expected end of 2008

CBRN: Acquisition

- RFP-BARDA-08-15: Recombinant Protective Antigen (rPA) Anthrax Vaccine for the Strategic National Stockpile
- HHS-BARDA-08-10 (RFP): Advanced Therapeutics for Treating Neutropenia Resulting from Acute Exposure to Ionizing Radiation
- RFP-BARDA-08-12: Medkits
- CBRN: Advanced Development
- BAA-NIH-BARDA-NIAID-DMID-AI2007007: Biodefense Vaccine Enhancement
- BAA-DMID-NIAID-BARDA-NIHAI20080022: Application of Platform Technologies for the Development of Therapeutics for Biodefense
- CBRN: Request for Information/Sources Sought:
- RFI-BARDA-08-21A: Physical and Biological Dosimetry Techniques and Devices Useful in Initial Triage after Radiologic and Nuclear Events
- SS-HHS-BARDA-08-99: Emergency Responder Anthrax Antimicrobial Kits

- **Vaccines**

- Develop filovirus vaccines
- Develop 3rd generation anthrax vaccines

- **Therapeutics**

- Develop ARS biologicals for multiple indications
- Develop new chemical antidotes

- **Antivirals/Antibiotics**

- Develop smallpox antivirals
- Develop broad spectrum antibiotics
- Support anthrax antibiotic MedKit studies

- **Diagnostics**

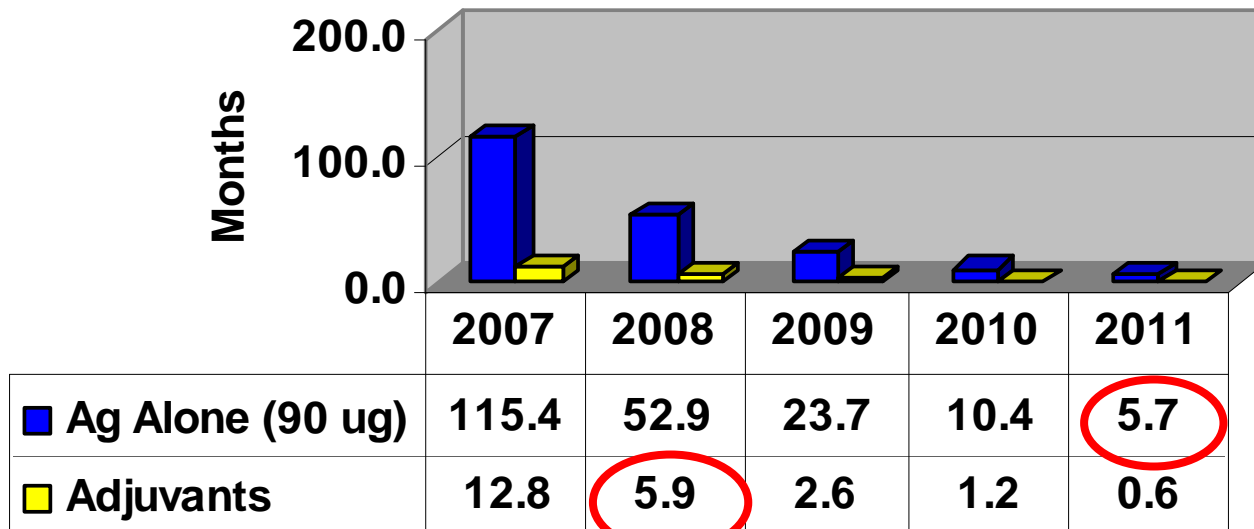
- Develop biodosimetry devices
- Develop multiantigen detection devices

BARDA Pan Flu Integrated Program Portfolio Approach

34 contracts & 3 grants totaling \$4.2 B	Vaccines	Antivirals	Diagnostics/ Respiratory Devices
Advanced Development	Cell-based Antigen-sparing Next Generation Recombinant	Peramivir More to Come	<u>Diagnostics</u> Point of Care Clinical Lab <u>Ventilators</u> Next Generation
Stockpile Acquisitions	H5N1 Pre-Pandemic Vaccine Stockpiles	<u>Tamiflu & Relenza</u> Federal Stockpiles State Stockpiles AV MedKits	Masks & Respirators
Infrastructure Building	Retrofit Mfg Facilities Build New Cell-based Mfg Facilities Egg-based Supply Intl. Vaccine Mfg. Cap.		

U.S. Pandemic Influenza Vaccine Capacity Forecast

**U.S. PANDEMIC VACCINE GOAL TIMELINES
 (300 M Vaccine Courses)**



U.S. H5N1 Vaccine Stockpile Inventory: 2008

H5N1							
Vaccine Strain	Clade	2004	2005	2006	2007	2008	Totals
A/VTN/1203/04	1	0.22	4.33	0.78		1.08	6.39
A/Indo/05/05	2.1			6.25	2.25	0.04	8.54
A/BHG/QL/1A/05	2.2				6.41		6.41
A/Anhui/1/05	2.3				2.56		2.56
Totals (90 ug/dose)		0.22 M	4.33 M	7.03 M	11.22 M	1.12 M	23.92 M
Totals w/adjuvants 7.5 ug/dose		2.64 M	51.96 M	84.36 M	134.64 M	13.4 M	287.04 M

! Adjusted for usage and potency (as of 09/22/08)

- Stockpile manufacturing requirements:
 - Produce U.S.-licensed seasonal influenza vaccines
 - Store, test, formulate & fill in U.S.
 - Able to manufacture H5N1 bulk vaccine at commercial scale

Vaccines: Infrastructure Building

- **Novartis – new cell-based flu vaccine manufacturing facility started 2007**



Influenza Vaccine Production Capacity: HHS Accomplishments

- Supported the development and licensure of the first H5N1 vaccine named the number one technological advance in 2007
- Established the first and largest pre-pandemic vaccine stockpile in the world that represents multiple H5N1 virus strains
- Supported advanced development of new cell-based influenza vaccines towards U.S. licensure accompanied by concomitant expansion of domestic vaccine manufacturing surge capacity 3-4 fold by 2012
- Supported advanced development of H5N1 influenza vaccines using antigen-sparing techniques towards U.S. licensure expected by 2009 leading to the technological breakthrough of new vaccine adjuvants that expand pandemic vaccine manufacturing capacity by 10-20 fold and that may provide cross-protection against influenza genetic variants
- Supported retrofitting of existing U.S. manufacturing facilities that increases egg-based pandemic influenza vaccine production capacity by 150 million doses by 2011 & provides production of live, attenuated influenza vaccine completely within the U.S.
- Secured year-round egg supply and other materials needed for uninterrupted domestic manufacturing of seasonal and pandemic influenza vaccines

Influenza: Advanced Development

- RFP-BARDA-07-06 Advanced Development of Recombinant Influenza Virus Vaccines
- HHS-BARDA-08-20: Advanced Development of Next Generation Portable Ventilators

MedKits

- Stockpiling of MCM for businesses, healthcare organizations, & individuals to address dispensing timing issues
- Personal preparedness measure: home stockpiling
- CDC-sponsored MedKit concept for anthrax antibiotics (2004): St. Louis compliance study
- BARDA projects developing MedKits for influenza antivirals & anthrax antibiotics
- Home antimicrobials stockpiling guidances
- USPS & 1st responders (EUA)



- **Vaccines**

- Continue advanced development of vaccines
- Continue expansion of pre-pandemic vaccine stockpile
- Continue expansion of domestic manufacturing surge capacity
- Stockpile syringes/needles for pre-pandemic vaccines

- **Antivirals**

- Complete State AV stockpiles for treatment
- Procure federal share of outbreak antivirals for prophylactic usage
- Continue & expand advanced development of antivirals
- Support antiviral MedKit studies

- **Diagnostics**

- Facilitate development of simple influenza virus detection devices

- **Other Countermeasures**

- Issue guidance for masks & respirators
- Develop next generation ventilators

New Perspectives

- Turning the page → Integrated BARDA programs
- USG One Portfolio MCM approach
- Advanced development
- PAHPA-modified BioShield for stockpile acquisitions
- MCM product market sustainability
- Innovation
- Extramural/Intramural activities
- New public-private bioproduction/development MCM facility approaches

Challenges

- Funding CBRN MCM advanced development
- Funding remaining pan flu MCM projects
- BARDA organizational growing pains
- Staffing with public health, scientific, & technical experts
- Coordination with CONOPS & end-users
- Establishment of intramural programs
- Building the BARDA bridges over the “Valley of Death”



BARDA Contact Info

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- Upcoming Events
- Acquisitions
- BioShield
- Influenza Programs



MedicalCountermeasures.gov

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- Regulatory guidance
- Federal strategies and reports

