



United States Department of
Health & Human Services
Office of the Secretary
Office of the Assistant Secretary for
Preparedness and Response (ASPR)

BARDA: Old & New Perspectives

**NBSB Meeting
Arlington, VA
June 18, 2008**

Dr. Robin Robinson
Director
HHS/ASPR/BARDA



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Health & Human Services
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Office of the Assistant Secretary for
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HHS Public Health Emergency Medical Countermeasures Enterprise

National Biodefense Science Board

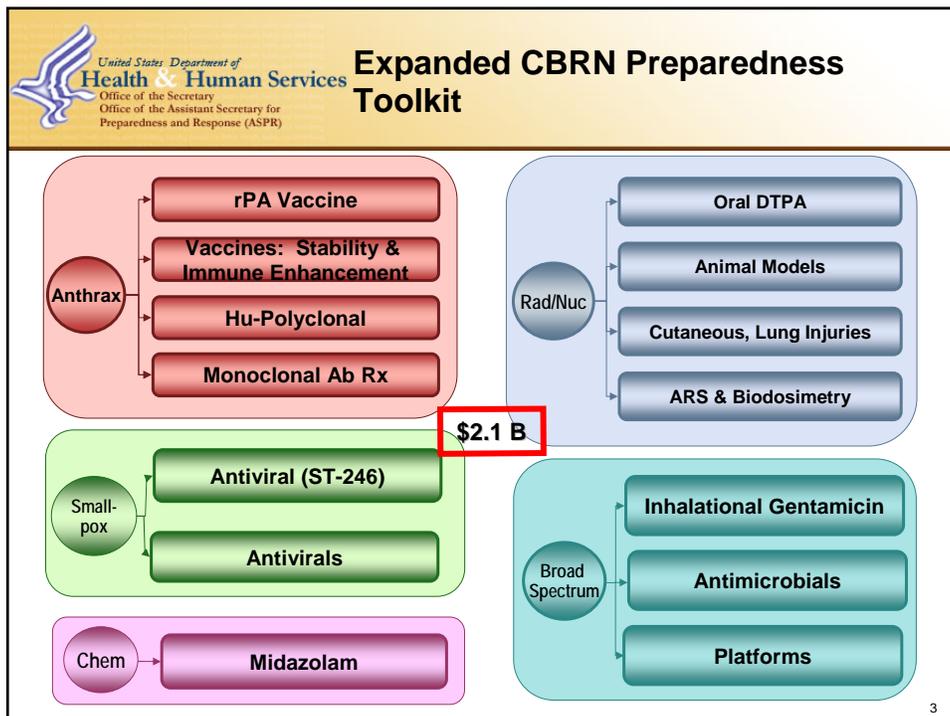
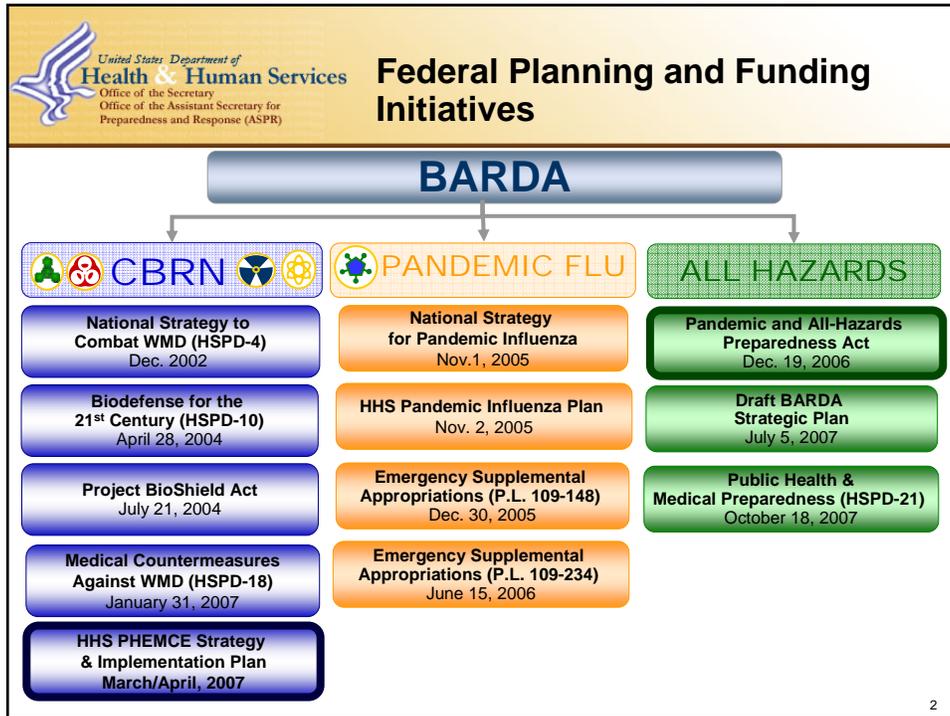
NIH	BARDA	BARDA and CDC	CDC	CDC and OPEO	
Research and Development	Advanced Development	Acquisit	Surveillance/ storage/ intenance	Deployment	Utilization

FDA

**PHEMCE COORDINATED PLANNING
& EXECUTION**



1



 BARDA Pan Flu Integrated Program Portfolio Approach			
29 contracts & 2 grants totaling \$4.1 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 Existing Mfg Facilities Build New Cell-based Mfg Facilities Egg-based Supply		



Federal
Business
Opportunities




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
- BAA-BARDA-08-08: Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss and Vascular Injury Resulting from Acute Exposure to Ionizing Radiation

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

Influenza: Advanced Development

- RFP-BARDA-07-06 Advanced Development of Recombinant Influenza Virus Vaccines
- RFQ-BARDA-08-17: Contract Research Organization for Toxicology Studies
- RFQ-BARDA-08-19: Contract Research Organization for Immunogenicity Studies
- HHS-BARDA-08-20: Advanced Development of Next Generation Portable Ventilators (Sources Sought)

5



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MedKits

- **Stockpiling of MCM for businesses, healthcare organizations, & individuals to address inequities & delivery timing issues**
- **Personal preparedness home stockpiling measure**
- **CDC-sponsored MedKit concept for anthrax antibiotics (2004)**
- **BARDA projects developing MedKits for influenza antivirals & anthrax antibiotics (2007)**
- **Home antimicrobials stockpiling guidances (2008)**



6

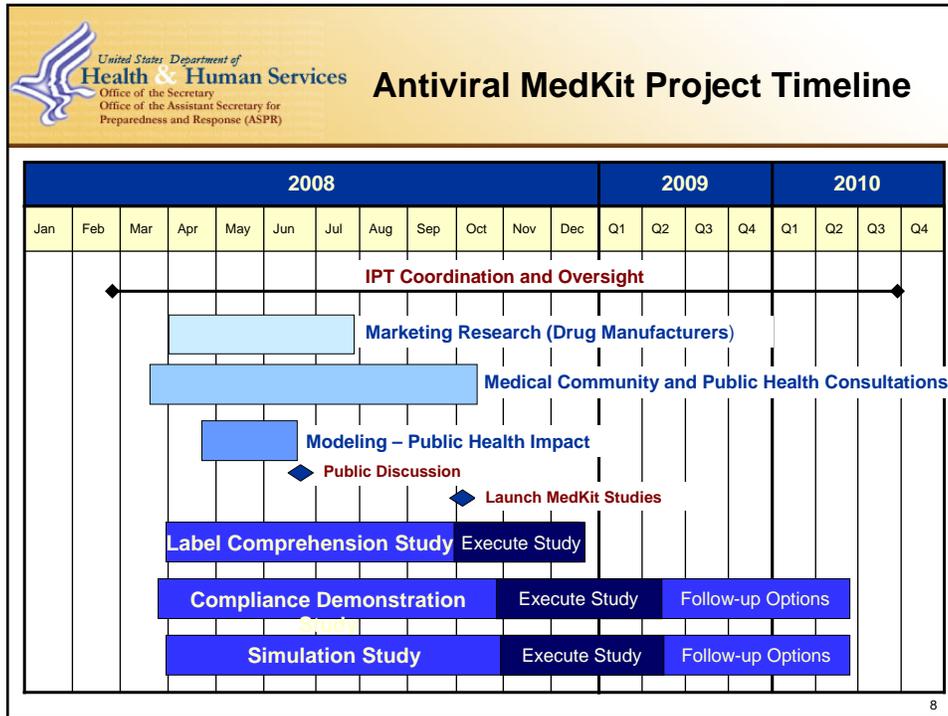


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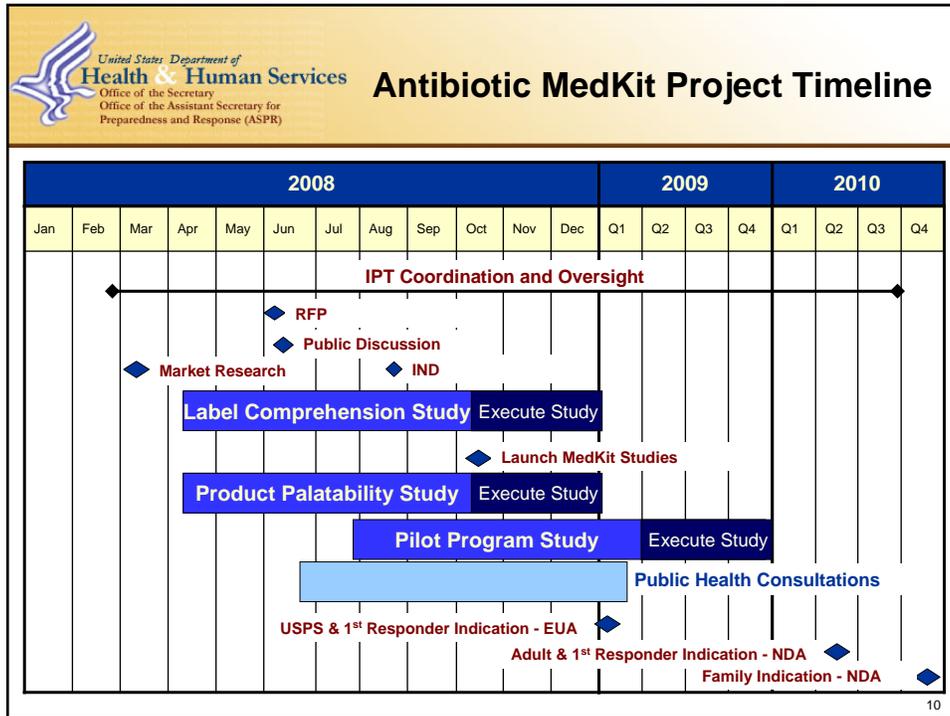
Influenza Antiviral MedKits

- **Pharmaceutical adjuncts to community mitigation for pandemic influenza**
- **Draft guidance on pandemic AV usage for preparedness (2008)**
- **Roche- & GSK-sponsored studies for Tamiflu & Relenza on label comprehension, compliance, & simulation + marketing research**
- **MedKit target groups: prophylaxis**
 - General public: adults (licensed – 2Q10) → all populations
- **Regulatory pathway: Currently licensed products (now) → MedKits (IND) → MedKits (EUA) → MedKits (licensed)**
- **Computer modeling to analyze impact**
- **BARDA-sponsored public discussion (Jun. 17, 2008)**

7



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- **Antimicrobial drug anthrax Medkit**
 - Compliance study (St. Louis, 2006-07)
 - Palatability study (2008)
 - HHS-sponsored doxycycline on label comprehension (RFP)
 - Generic antibiotics drug manufacturers (Sources Sought Notice, Mar. 08) → Market research (Apr. 08)
 - CDC draft advisory document guidance to physicians and patients for doxycycline-only usage (2008)
 - MedKit target groups: pre-exposure prophylaxis
 - USPS workers: EUA (Dec. 2008)
 - First responders & emergency care workers: (HHS & DHS) EUA (Dec. 2008) → State/local govts. & MCOs (licensed)
 - General public: adults (licensed – 3Q09) → all populations
 - Regulatory pathway: Currently licensed products (now) → MedKits (IND) → MedKits (EUA) → MedKits (licensed)
- 9



What's BARDA

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BARDA = (CBRN + PI + ED)^{MCM}

- Coordination PHEMCE Enterprise
- Advanced development
- Stockpile procurement & establishment
- Manufacturing infrastructure building
- Innovation

11

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Old Perspectives

- Stockpile! Stockpile! Stockpile!
- CBRN & PI independent programs in same organization
- BioShield used for high risk “acquisition” of CBRN MCMs

12

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New Perspectives

- Turning the page → Integrated BARDA programs
- USG One Portfolio MCM approach
- Advanced development at work
- PAHPA-modified BioShield for stockpile acquisitions
- MCM product market sustainability
- Innovation
- Extramural/Intramural activities
- Combined MCM manufacturing base building approaches

13

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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

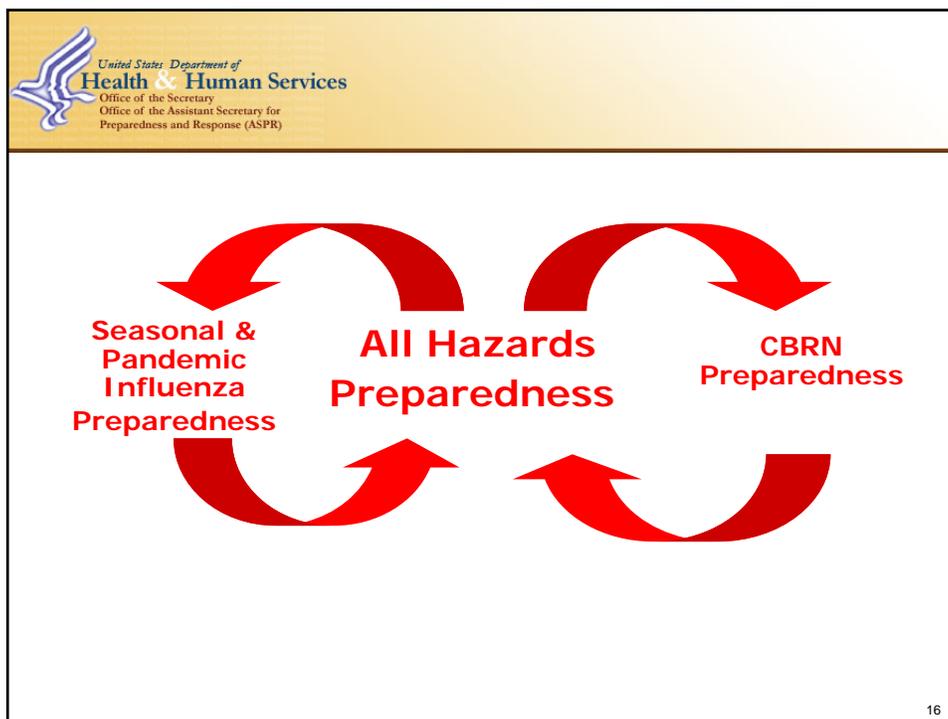
14

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NBSB Questions

- Should pre-pandemic influenza vaccination be expanded?
- Should pan flu MCM portfolio include pneumococcal & streptococcal vaccines? Develop staphylococcal vaccines?
- What is the right mix of shared responsibility for influenza antivirals for pandemic prophylaxis?
- Should prime-boost vaccination strategies for BARDA MCMs be pre-event? Commercial market?
- Are there better ways to prepare other than stockpiling?
- What are the emerging infectious diseases on the horizon?
- Is home stockpiling of MCMs a safe & effective preparedness measure?

15



DEPARTMENT OF HEALTH & HUMAN SERVICES - USA

HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE
STAKEHOLDERS WORKSHOP 2008

September 24–26, 2008
Crystal Gateway Marriott, Arlington, VA

This event will bring together public and private stakeholders for a dynamic dialogue on

- BARDA Strategic Plan unveiling
- Countermeasure Preparedness and PHEMCE Initiatives
- Cutting Edge Medical Countermeasure Research and Development
- Distribution and Utilization of Medical Countermeasures at the Point of Care
- **NEW!** BARDA Industry Afternoons and Evening Poster Sessions

Registration and Call for Abstracts Now Available:
<http://www.hhs.gov/aspr/barda/>



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Contact Us



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 URL: www.hhs.gov/aspr/barda/
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- Upcoming Events
- Acquisitions
- BioShield
- Influenza Programs



MedicalCountermeasures.gov

- Federally-sponsored conferences
- Funding opportunities
- Resource programs
- Regulatory guidance
- Federal strategies and reports



18