United States Department of Health Human Services



U.S. Department of Health and Human Services

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

August 23, 2007



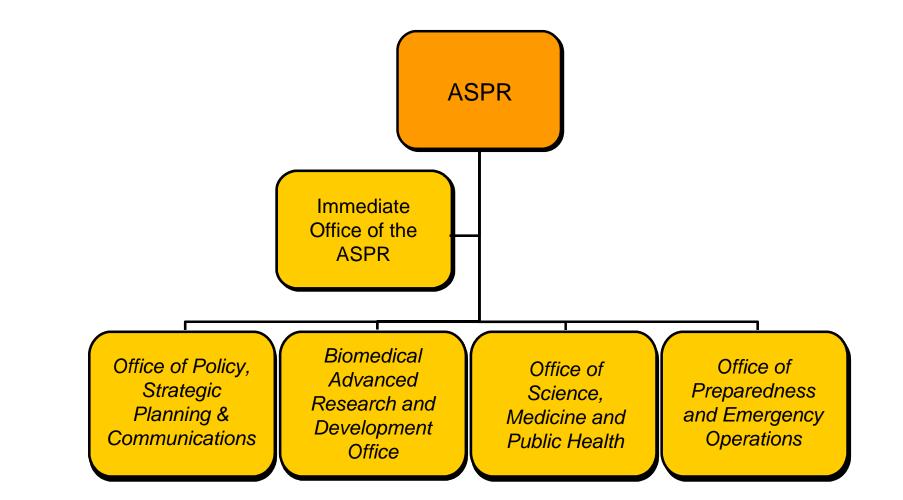
Briefing Overview

- ASPR Overview
- ASPR Organization
- Pandemic and All-Hazards Preparedness Act
- Planning and Emergency Operations
- Biomedical Advanced Research and Development (BARDA)
- Questions



- **Mission:** Lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters.
- Vision: A Nation prepared to prevent, respond to, and reduce the adverse health effects of public health emergencies and disasters.







- Enhancement of state and local preparedness
- Development and implementation of National and Departmental plans/policies for responding to public health/medical threats and emergencies
- Departmental and interagency planning and response coordination
- Rapid public health and medical support for Federal, State, local and Tribal governments
- Leadership in international programs, initiatives, and policies
- Coordination, support, and participation in Medical Research, Development, and Acquisition of medical countermeasures



Pandemic and All-Hazards Preparedness Act (PAHPA)

- Codifies HHS as lead of Federal public health and medical response to public health emergencies and National Response Plan (NRP) incidents.
- Directs HHS to enter into an interagency agreement with DHS, VA, DoT to assume operational control of Federal public health and medical personnel and assets during incidents.
- Creates a new Assistant Secretary for Preparedness and Response (ASPR):
 - Senate confirmed position
 - Principal advisor to the Secretary on public health and medical preparedness and response
 - Deployment authority for Federal personnel (including National Disaster Medical System)
 - Oversee advanced research, development, and procurement of qualified countermeasures
 - Coordinate public health and medical response systems with Federal, State, local, Tribal and EMAC
 - Transfers all prior functions of ASPHEP



- ASPR has "authority over and responsibility for":
 - NDMS (transferred to HHS as of January 1, 2007)
 - Hospital Preparedness Cooperative Agreement Program (transfers from HRSA)
- Creates the Biomedical Advanced Research and Development Authority (BARDA)
- ASPR shall "exercise the responsibilities and authorities of the Secretary with respect to the coordination of":
 - Medical Reserve Corps
 - ESAR-VHP
 - Strategic National Stockpile
 - Cities Readiness Initiative
- ASPR leads in international preparedness and response initiatives and activities
- Starting in 2009 and every four years, the Secretary shall submit the National Health Security Strategy and implementation plan for public health emergency preparedness and response, to include an evaluation of progress of Federal, State, local, and Tribal entities based on the evidence-based benchmarks and objective performance standards.



Primary Response Assets within HHS:

- Secretary's Operations Center
- National Disaster Medical System teams (e.g., Disaster Medical Assistance Teams)
- U.S. Public Health Service Commissioned Corps Teams (coordinated with the Assistant Secretary for Health and Surgeon General)

Emergency Support Function (ESF) #8 Partners:

- Department of Veterans Affairs teams and assets
- Department of Defense personnel and materiel support

State and local:

Medical Reserve Corps Teams



National Bioterrorism Hospital Preparedness Program Focus

- Mission To ready hospitals and supporting health care systems, in collaboration with other partners, to deliver coordinated and effective care to victims of terrorism and other public health emergencies
- Emphasis on Hazard Vulnerability Assessment process
- Focus on the development of tiered response capabilities
- Supports integration of preparedness efforts across disciplines and level of government



Biomedical Advanced Research and Development Authority (BARDA)

Title IV: Pandemic and Biodefense Vaccine and Drug Development

- Establishes BARDA to:
 - Facilitate collaboration among USG, industry, and academia
 - Support the advanced research and development of MCMs
 - Promote innovation to reduce time and cost of MCM
- Establishes the Biodefense MCM Development Fund (Advanced Development)
 - Fund development of products across so-called "Valley of Death"
 - Separate from the preexisting BioShield Special Reserve Fund
- Makes reforms to BioShield procurement program
 - Allows for milestone-based performance payments
- Establishes the National Biodefense Science Board





BARDA – Roles & Responsibilities

- Coordinate an integrated, systematic approach to planning for and executing research, development and acquisition of medical countermeasures for public health emergencies
- Support the ASPR in leading the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)
- Drive medical countermeasure analysis and prioritization
 - HHS PHEMCE Strategy for CBRN Threats
 - HHS PHEMCE Implementation Plan for CBRN Threats
- Execute advanced development and procurement of medical countermeasures for CBRN threats and pandemic influenza
 - Advanced development under BARDA
 - Acquisition under Project BioShield (CBRN material threats)
 - Acquisition with direct appropriations for pandemic influenza



Public Health Emergency Medical Countermeasures Enterprise

- Enterprise Governance Board: ASPR, CDC, FDA, NIH
- The Enterprise is a coordinated interagency effort responsible for
 - Defining and prioritizing requirements for public health emergency medical countermeasures
 - Focusing and aligning research, development, and procurement activities on prioritized requirements
 - Setting deployment and use strategies for medical countermeasures held in the Strategic National Stockpile
- Advises HHS Secretary:
 - Address naturally-occurring and deliberately-induced public health events
 - More fully integrate the Project BioShield, DSNS, and Pandemic Influenza missions
 - Encompass medical countermeasure issues along the full spectrum of the Enterprise



Regulatory Functions

Research

Development Acquisition

Storage/ Maintenance

Deployment

Utilization



Public Health Emergency Medical Countermeasures Enterprise

- Serves as the mechanism for implementation of the medical countermeasures mission
- Addresses both naturally occurring and deliberately induced public health events
- More fully integrates the Strategic National Stockpile (SNS), BioShield, and Pandemic Influenza missions
- Expands beyond the scope and range (\$5.6B; FY04-13) of the Project BioShield Act of 2004
- Encompasses medical countermeasure issues along the full spectrum of the Enterprise













BARDA - Milestones in Strategic Planning and Policy

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Sept 2006: HHS releases the Draft *Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear Threats* and first BioShield Stakeholders Workshop convened

19 Dec 2006: Enactment of the *Pandemic and All-Hazards Preparedness Act*

31 Jan 2007: President Bush Signs HSPD-18 *Medical Countermeasures against Weapons of Mass Destruction*

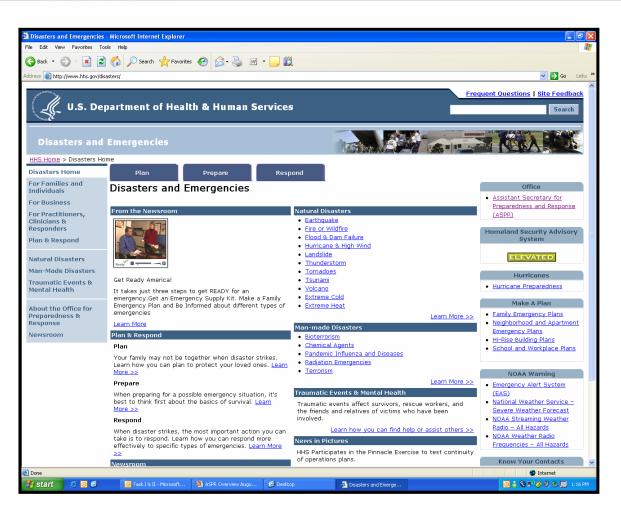
20 Mar 2007: HHS releases the *PHEMCE* Strategy for *Chemical, Biological, Radiological and Nuclear Threats*

23 Apr 2007: HHS releases the *PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear (CBRN) Threats*

6 July 2007: HHS releases the Draft BARDA Strategic Plan for Medical Countermeasure Research, Development and Procurement



Questions



www.HHS.gov/disasters/