



The Public Health Emergency Medical Countermeasures Enterprise

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The Challenge



- The response to biological threats, either from nature or man-made ultimately become public health events
- The commercial market is not attracted to development of drugs, vaccines and diagnostics for these problems
- The U.S. government identified a need to incentivize the market and developed a series of financial, technical and regulatory tools
- Ultimately, an inter-agency governance system was needed to oversee and course-correct these investments

The Answer = the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)



Broad Outline



- The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is:
 - A U.S. federal government interagency coordinating and oversight structure that aids in the full life cycle management of medical countermeasures which prevent or respond to high consequence threats
 - Organized under the office of the Assistant Secretary for Preparedness and Response, HHS
 - Addresses the needs to produce and have drugs, vaccines, diagnostic materials and medical supplies available during a public health emergency

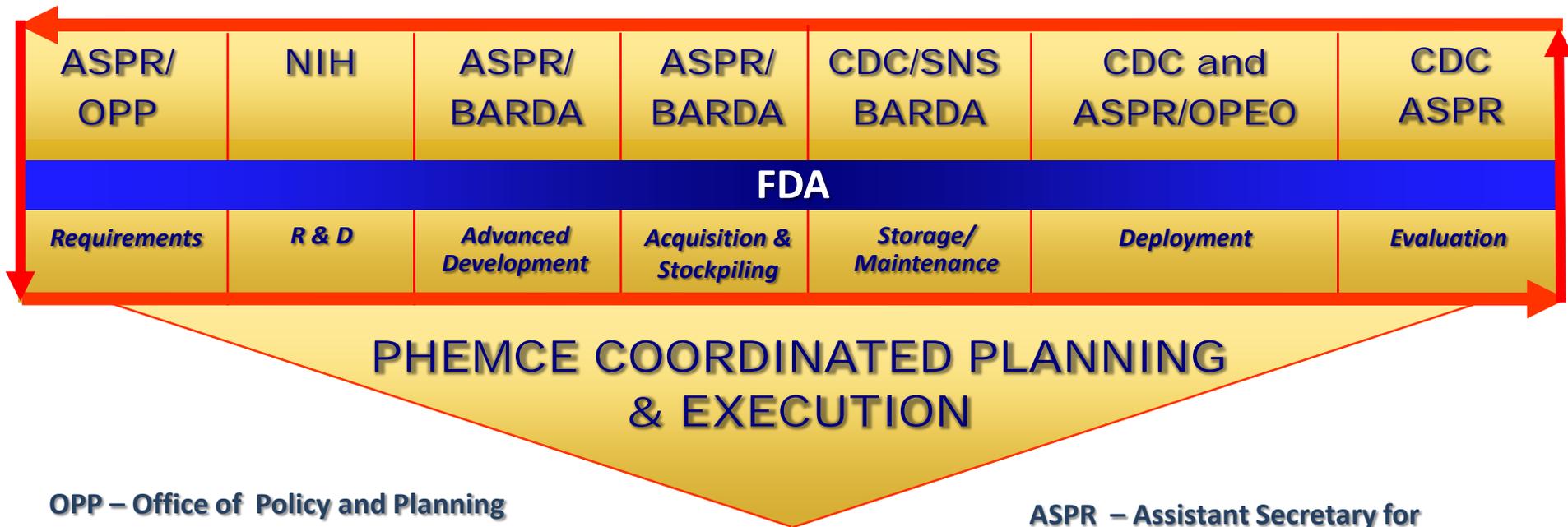


Principal Focus of the Enterprise



- Covers
 - Well-recognized Biological, Chemical and Radiological threats
 - Pandemic (acute) diseases
 - Emerging Threats
- Does not cover
 - Major endemic public health issues (e.g. malaria)
 - Rare or low impact public health threats
- May partially cover
 - Approaches for emerging antimicrobial resistant

Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

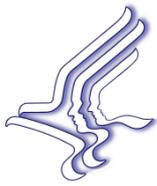


OPP – Office of Policy and Planning
FDA - Food and Drug Administration
NIH – National Institutes of Health
BARDA – Biomedical Advanced Research and
 Development Authority

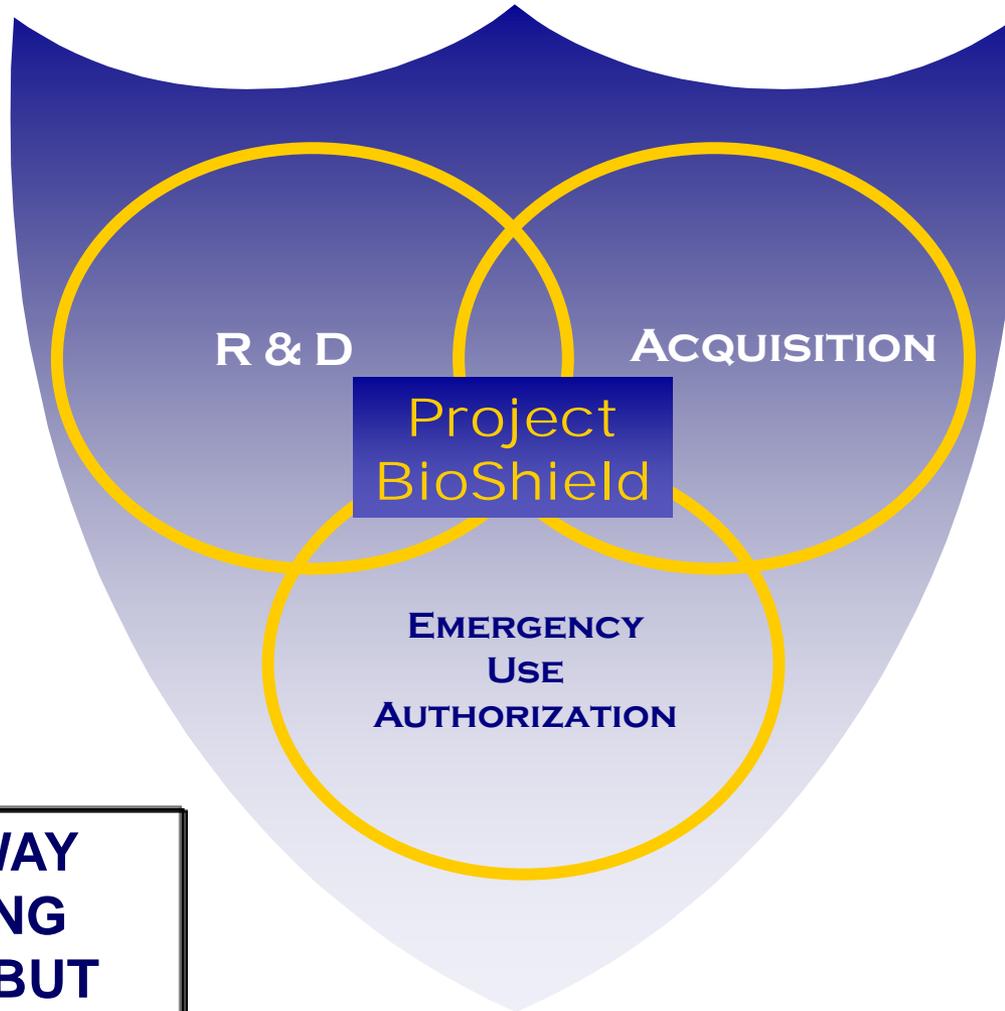
ASPR – Assistant Secretary for
 Preparedness and Response
CDC – Centers for Disease Control and
 Prevention

Interagency Partners:

- Department of Veteran Affairs
- Department of Homeland Security
- Department of Defense
- U.S. Department of Agriculture



Project BioShield Act of 2004



**PAVED THE WAY
FOR ENGAGING
INDUSTRY....BUT
WAS NOT
ENOUGH....**



Pandemic and All-Hazards Preparedness Act (Dec 2006)



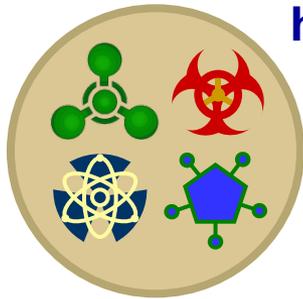
Pandemic and Biodefense Vaccine and Drug Development

- Establishes the Biomedical Advanced Research and Development Authority (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)
- Reforms to BioShield procurement program / New Authorities
 - Advanced payments to businesses
 - Milestone payments for work performed over time
 - Anti-trust exemption



Scoping the Challenge

**Define, Design, Develop, Deliver and Dispense
Medical Countermeasures to reduce the adverse
health consequences of public health emergencies**



**Complex array of
Threats**



Diverse population

A Nation Prepared



**Lengthy, risky and
expensive product
development**



**Prioritize medical
countermeasure programs
to effectively address
mission goals**



**Strategies &
dependencies for
effective use**



The PHEMCE Identifies Medical Requirements



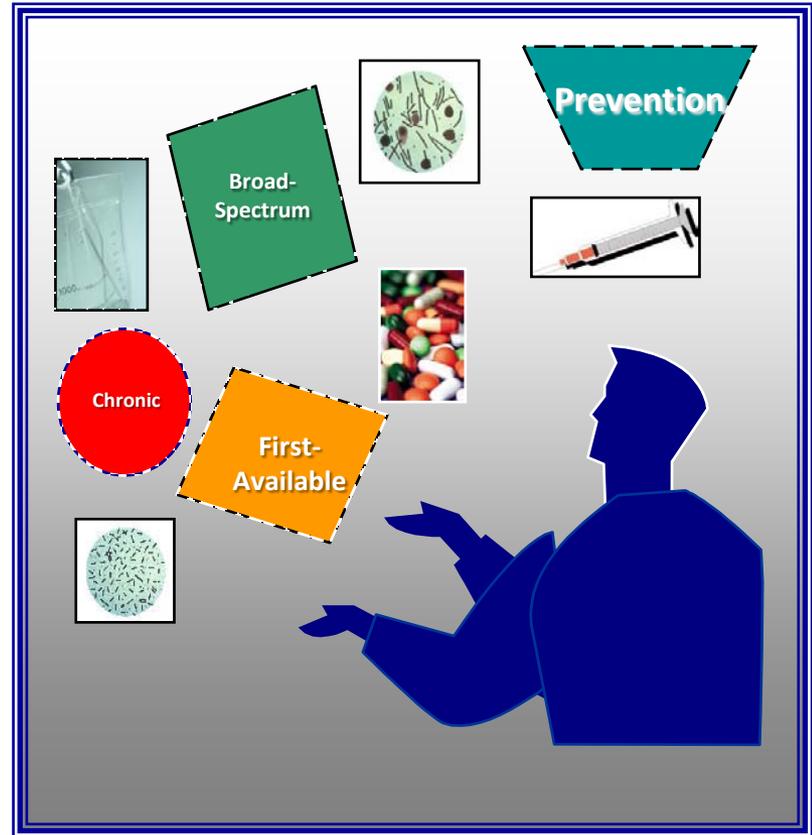
- Type of Threat posing risk is based on Material Threat Determinations
 - PHEMCE works issue on medical assessments
- PHEMCE assesses the level of impact on public health
 - Scenario based and employs advance modeling
 - Identifies extent of population impact
 - Determines best medical countermeasure approach
 - Develops **Scenario-based Analysis** (SBA) in a formal approval process
 - Develops **Product-specific Requirement** (PSR) to define the desired characteristics of the product
 - Used by the Advanced Development & Research Program to build a strategy to acquire the product.



Strategic Issues to Consider

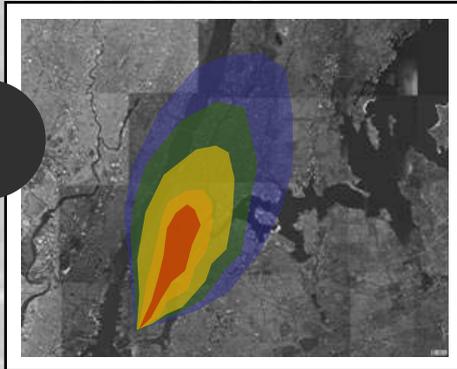


- Number of Threats
- Traditional/Known vs. Emerging/Engineered Threat
- Fixed vs. Flexible Defense
- Specific vs. Broad-Spectrum Drugs
- Prevention vs. Treatment
- Acute vs. Chronic
- First-Available vs. Next-Generation
- General vs. Special Populations
- Domestic vs. International
- Sustainability

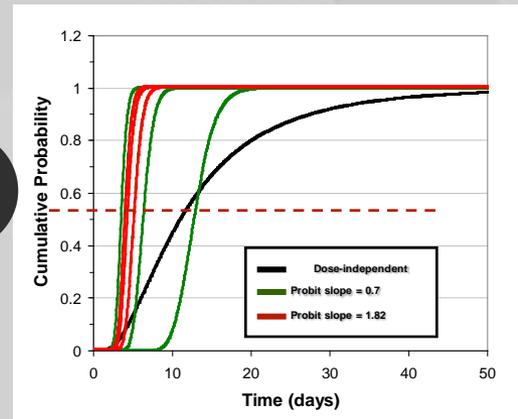


Step-wise Assembly of a Medical Consequence Model

Exposure and Infection

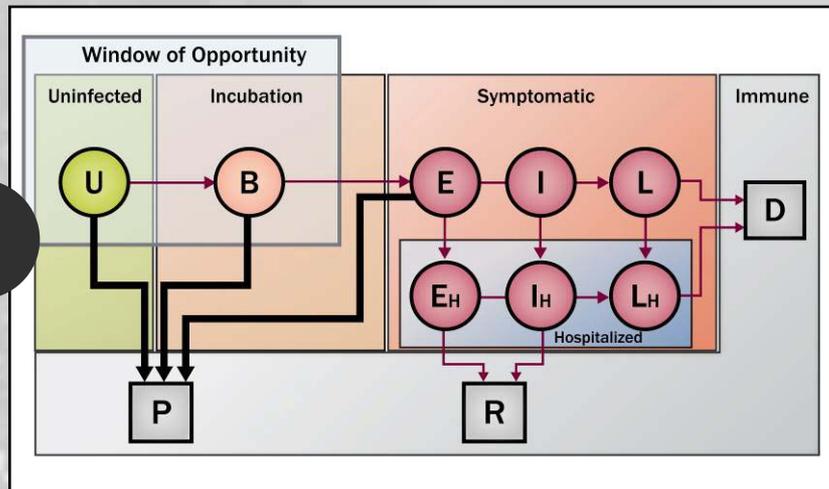


Incubation

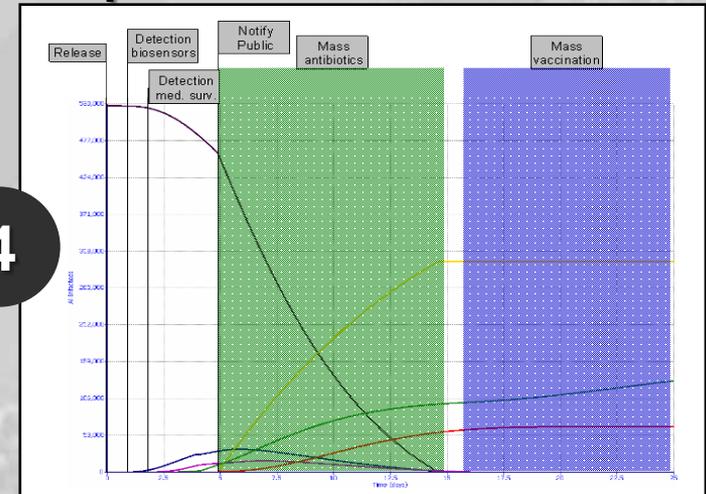


What kind of medical response do we need ?

Disease Progression



Response / Countermeasures





PHEMCE Implementation Plan: Priority Medical Countermeasure Acquisitions



Mid-Term

Near-Term

- Broad-Spectrum Antibiotics
- Anthrax Vaccines
- Smallpox Vaccines
- Therapeutic Drugs for Acute Radiation Injury

- Broad-Spectrum Antibiotics
- Diagnostics
- Anthrax Antitoxins
- Filovirus MCMs
- Smallpox Antivirals
- MCMs for ARS and DEARE
- Radionuclide-Specific MCMs
- Rad/Nuc: Biodosimetry/Bioassays
- Enterprise CHEMPACKS

Long-Term

- Broad-Spectrum Antivirals
- Volatile Nerve Agent Antidotes



Glimpse at the Future: BARDA Early Development Pipeline

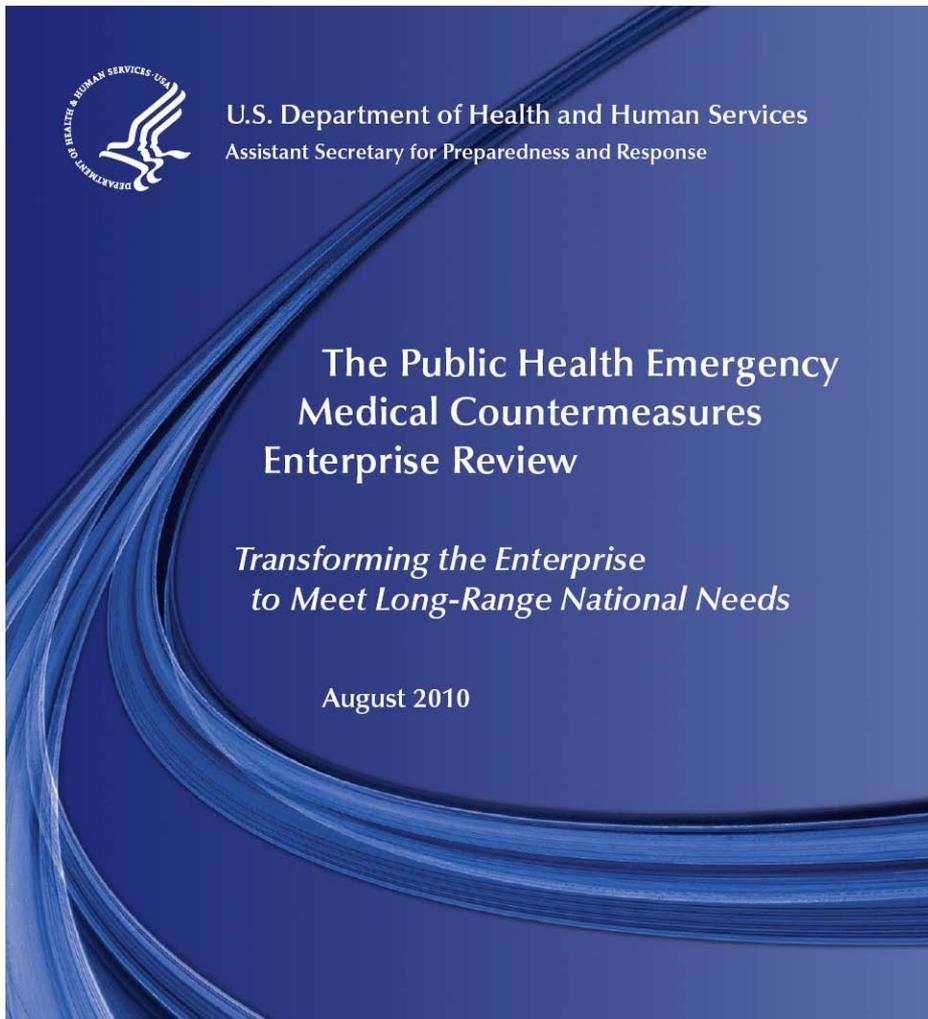


- Anthrax
 - Vaccines – novel adjuvants and formulations
 - Antitoxins – enhanced affinity
- Smallpox
 - Antivirals
 - Vaccine enhancement
- Hemorrhagic fever viruses
 - siRNA-based antivirals
 - Post-exposure prophylactic vaccines
- Broad-spectrum antimicrobials
 - Inhalational delivery systems
- Radiation/Nuclear
 - Therapeutics: acute radiation syndrome & thermal burns
 - Decorporation agents
- Biodosimetry
 - Devices and assays

**Moving toward
broad-spectrum
approaches that have
greater public health
potential**



2010 MCM Enterprise Review: Bolster Project BioShield



- **Expand Product Pipeline through Concept Acceleration Program (CAP) at NIAID**
- **Establish a Strategic Investment (SI) Fund to increase investments in commercial ventures with multi-use potential (BARDA & NIAID)**
- **Establish Centers for Innovation in Advanced Development and Manufacturing (BARDA)**
- **Investment in upgrading science capacity at FDA**



CDC's Strategic National Stockpile



- A repository of antibiotics, chemical antidotes, antitoxins, vaccines, antiviral drugs and other life-saving medical materiel designed to supplement and re-supply state and local public health agencies in the event of an emergency.
- During an emergency, a State may request federal assistance for CDC to deploy SNS assets. CDC works with federal, state and local health officials to determine what assets are needed.
- Each state has developed plan to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible.
- Major metropolitan areas receive support from CDC to increase their ability to rapidly dispense medical assets in an emergency
- CDC can deploy support teams to assist state and local officials during a public health emergency



CDC's SNS Mission



- Use the PHEMCE requirements to ensure SNS contains the most appropriate countermeasures
- Move the materiel to the area of need in a timeframe that is clinically relevant
- Provide technical assistance to state/local partners to help them to plan to effectively receive, distribute and dispense SNS assets
- Maintains materiel in a manner that assures viability



SNS Phased Operational Approach



- Forward-placed caches
- 12-hour Push Package
- Vaccines, antiviral drugs, and other managed inventory
- Just-in-time purchase through existing contracts



Conclusions



- The PHEMCE is in place to provide for preparedness and response for public health emergencies
- It operates on a continuous basis to ensure dialogue and coordination across the federal government
- The PHEMCE governance structure operates through committee and consensus from staff level through senior leaders
- The enterprise proved its value during the H1N1 crisis, and has been important in response to all ensuing major public health events
- The PHEMCE is tackling tough issues that require an all of government approach and is making great progress