



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

# **Development and Acquisition of High Priority Radionuclide Medical Countermeasures – HHS/BARDA Roles and Responsibilities**

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**Senior Policy Analyst**

**Biomedical Advanced Research & Development Authority (BARDA)**

**17 September 2007**



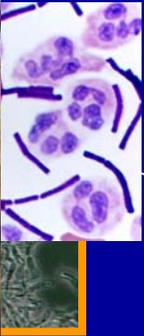
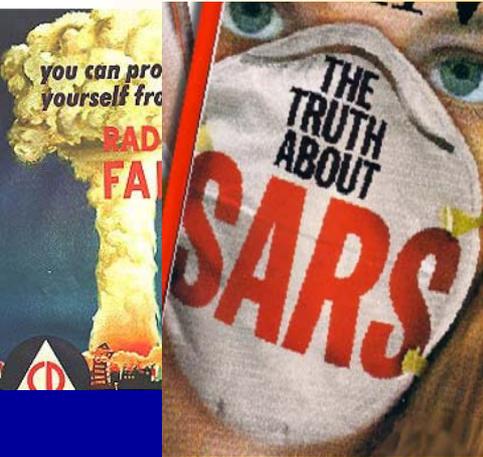
# Overview

- Scoping the Mission
- ASPR and the Biomedical Advanced Research & Development Authority (BARDA)
  - HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)
- Setting HHS Medical Countermeasure Research, Development, and Acquisition Priorities
- Path Forward: Transparency and Engagement with Stakeholders



ASPR/BARDA

# Defining and Prioritizing Medical Countermeasure Development and Acquisition Programs



**Scoping the Mission**



MCM development is fraught with uncertainties regarding timelines, cost, and probability of success



Resources are significant, but limited.



Federal, state, local, & tribal response capabilities

## THE BOTTOM LINE

Establishing and prioritizing MCM development and acquisition programs demands a deliberative approach that is informed by, and transparent to, all stakeholders engaged in the mission of public health emergency preparedness and response.



ASPR/BARDA

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

**LEAD THE NATION IN PREVENTING,  
PREPARING FOR, AND RESPONDING  
TO THE ADVERSE HEALTH EFFECTS  
OF PUBLIC HEALTH EMERGENCIES  
AND DISASTERS, NATURAL OR  
MANMADE, FOR THE CIVILIAN  
POPULATION.**



# BARDA Roles and 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*
  - *Draft BARDA Strategic Plan*
- **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**



ASPR/BARDA

# Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

- 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 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





ASPR/BARDA

# CBRN Medical Countermeasures: Strategic Planning & Policy Milestones

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

**July 2007:** HHS releases the Draft *BARDA Strategic Plan for Medical Countermeasure Research, Development and Procurement* and second Stakeholders Workshop convened

Federal Register / Vol. 71, No. 174 / Friday, September 8, 2006 / Notices 53997

Public Law 109-417—DEC. 19, 2006 120 STAT. 2833

THE WHITE HOUSE  
PRESIDENT  
GEORGE W. BUSH

For Immediate Release  
Office of the Press Secretary  
February 7, 2007

Federal Register / Vol. 72, No. 53 / Tuesday, March 20, 2007 / Notices 13189

January 31, 2007

Subject: Medical Co

BACKGROUND

(1) Weapons of Mass (CBRN) – in the past, challenges facing the compromise critical infrastructure damage that could result.

(2) Our National Strategy for the 21st Century ability to manage this but we must be fully prepared to respond to any eventuality. Community Bank & Corporation, Bank, Maryland origin and sale of residential mortgage loans in the secondary market pursuant to section 225.208(b) Regulation T.

(3) It is not presently possible threat. The caused by exposure process. This directly to Combat Weapons Nuclear's medical countermeasures:

(a) Target the are subject to

(b) Yield a range evolving threat

Federal Register / Vol. 72, No. 77 / Monday, April 23, 2007 / Notices 20117

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Meeting of the National Vaccine Advisory Committee  
AGENCY: Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response  
ACTION: Notice

Interested persons (identified above) and their representatives are invited to attend the meeting of the National Vaccine Advisory Committee. The meeting will be held on Monday, April 23, 2007, at 10:00 a.m. in the Conference Room, 10th Floor, Department of Health and Human Services, 4600 Reservoir Road, Rockville, Maryland 20850. The meeting is open to the public. Public comment will be invited to discuss the meeting agenda. For more information, contact the person identified above and will be posted online to provide members of the public the opportunity to provide comments to the Committee. Meeting agenda will be posted to the public website at [www.hhs.gov/ohrt](http://www.hhs.gov/ohrt).

Biomedical Advanced Research and Development Authority (BARDA)  
Office of the Assistant Secretary for Preparedness and Response (ASPR)  
U.S. Department of Health and Human Services (HHS)

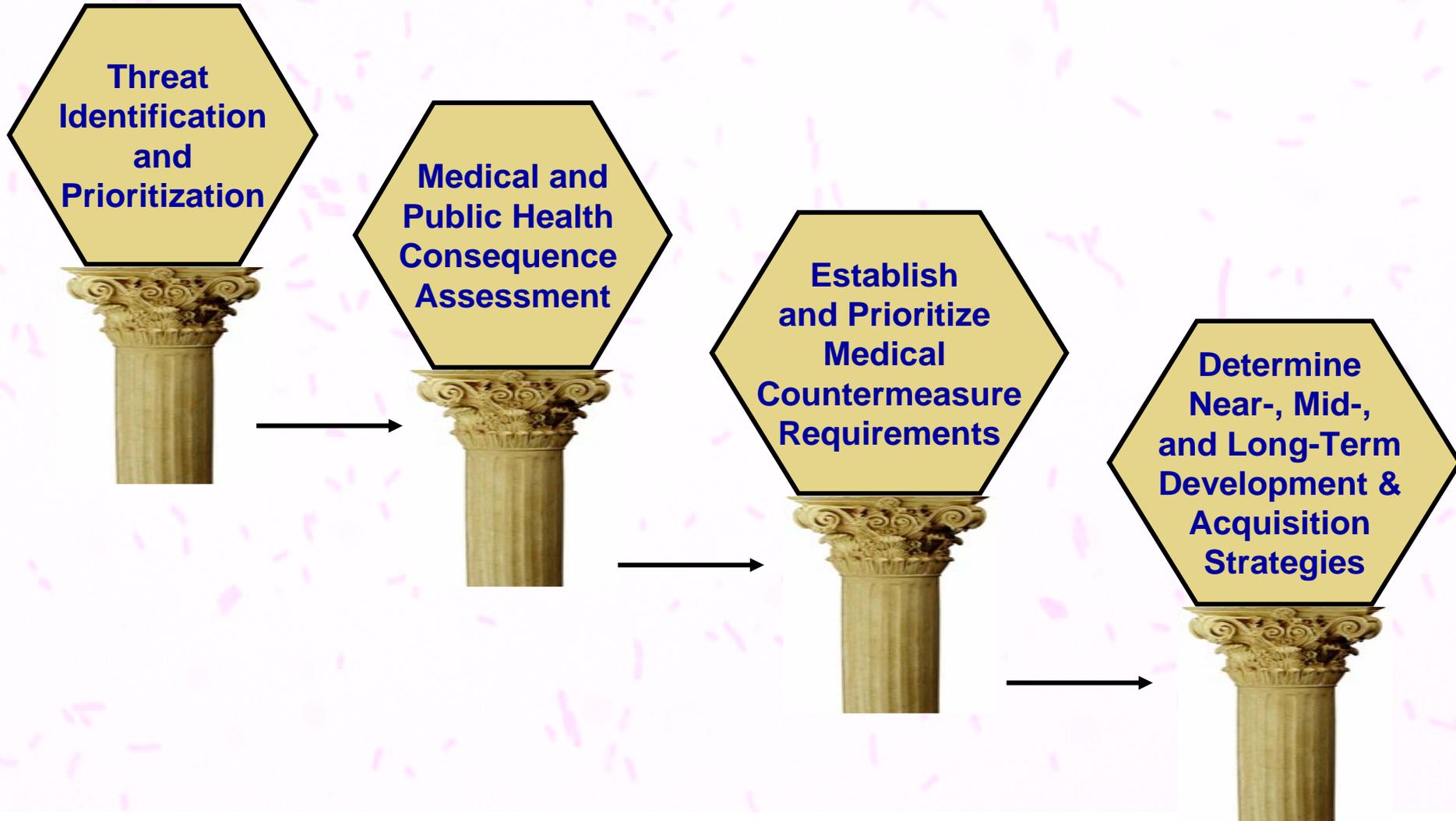
**Draft BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement**

July 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES



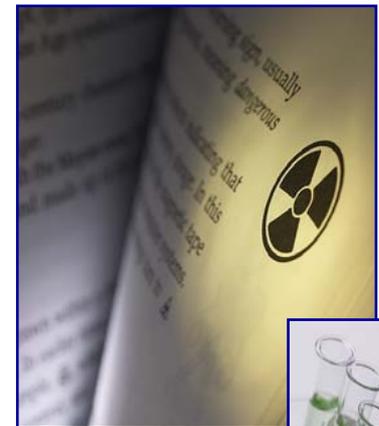
# Requirements → Acquisition Strategies



# Material Threat Determinations and Population Threat Assessments - Department of Homeland Security

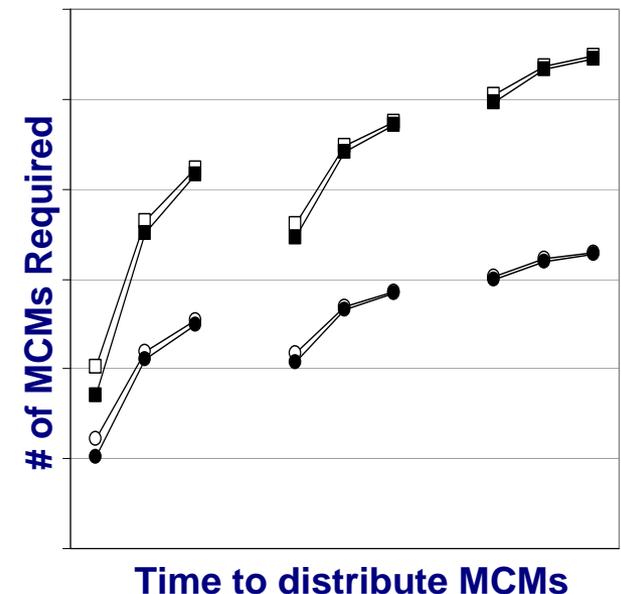
- Radiological and Nuclear agents
- *Bacillus anthracis* (anthrax)
- *Bacillus anthracis*- Multi-drug resistant (MDR anthrax)
- Botulinum toxins (botulism)
- Variola virus (smallpox)
- *Yersinia pestis* (plague)
- *Franciscella tularensis* (tularemia)
- Hemorrhagic Fever Viruses - Ebola , Marburg, Junin
- *Burkholderia mallei* (glanders)
- *Burkholderia pseudomallei* (melioidosis)
- *Rickettsia prowazekii* (typhus)
  
- Volatile nerve agents [PTA only]

**Pillar 1**  
Identify  
and Assess  
CBRN  
Threats



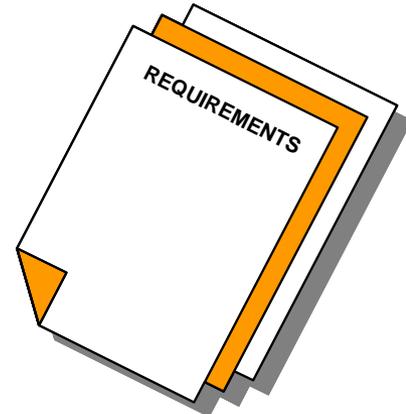
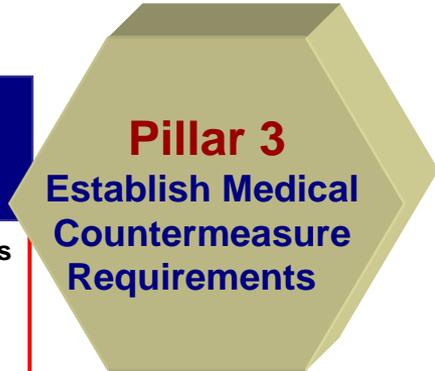
# HHS Medical and Public Health Consequence Assessment

- **Civilian medical and public health consequence assessments based on Department of Homeland Security (DHS) scenarios of CBRN threats:**
  - How many people will be exposed (DHS)?
  - How many people will require diagnoses and medical countermeasures (HHS)?
  - What is the potential public health impact (i.e., morbidity, mortality) of existing or future medical countermeasures (HHS)?
  - How do response times at the federal, state and local levels affect medical countermeasure requirements (HHS)?



# Factors Considered in Establishing Medical Countermeasure Requirements

<p><b>The Threat</b></p> <ul style="list-style-type: none"> <li>✓ Population Exposure Assessment (PEA)</li> <li>✓ Material Threat Determination (MTD)</li> </ul>	<p><b>Target Population</b></p> <ul style="list-style-type: none"> <li>✓ Military</li> <li>✓ Civilian</li> </ul>	<p><b>Product Specifications</b></p> <ul style="list-style-type: none"> <li>✓ Composition</li> <li>✓ Formulation</li> <li>✓ Doses per course; are booster doses necessary?</li> <li>✓ Formulation and Packaging</li> <li>✓ Storage requirements/ Stability – shelf-life</li> <li>✓ Desired product specifications for a future generation candidate</li> </ul>	<p><b>Deployment and Utilization (CONOPs)</b></p> <ul style="list-style-type: none"> <li>✓ Deployment logistics</li> <li>✓ Utilization policy</li> <li>✓ Pre-event</li> <li>✓ Day of event</li> <li>✓ Post-event</li> </ul>
<p><b>Scientific/Medical Characteristics of Threat Agent and Resultant Disease</b></p>	<p><b>Available and Next-Generation Countermeasures</b></p> <ul style="list-style-type: none"> <li>✓ Available medical countermeasures             <ul style="list-style-type: none"> <li>- Prevention</li> <li>- Treatment</li> </ul> </li> <li>✓ Available non-medical countermeasures (PPE, etc.)</li> <li>✓ Next-generation ideal medical countermeasures</li> </ul>		<p><b>Estimated Requirements</b></p> <ul style="list-style-type: none"> <li>✓ Near-term</li> <li>✓ Long-term: replenishment of expired product vs. next-generation vs. fill/finish from bulk</li> <li>✓ Multiple events?</li> <li>✓ Forward deployment?</li> </ul>
<p><b>Medical Consequence Modeling</b></p>			





# CONOPS

- HHS will establish **Concept of Operations**, including storage, maintenance, utilization policies and deployment plans for each MCM in the context of all available consequence mitigation strategies.



- HHS will define specific medical countermeasure requirements, including product specifications consistent with USG storage plans and operational capabilities for deployment and utilization by federal, state, and local authorities.



# Top-Priority PHEMCE Medical Countermeasure Programs

## BIO

### Anthrax Antitoxin(s)

*Bacillus anthracis* (anthrax)  
*Bacillus anthracis*- multi-drug resistant (MDR anthrax)

### Anthrax Vaccine

*Bacillus anthracis* (anthrax)  
*Bacillus anthracis*- multi-drug resistant (MDR anthrax)

### Broad-Spectrum Antibiotic(s)

*Bacillus anthracis* (anthrax)  
*Bacillus anthracis*- multi-drug resistant (MDR anthrax)  
*Burkholderia mallei* (glanders)  
*Burkholderia pseudomallei* (melioidosis)  
*Francisella tularensis* (tularemia)  
*Rickettsia prowazekii* (typhus)  
*Yersinia pestis* (plague)

### Broad Spectrum Antiviral(s)

Filoviruses [Ebola and Marburg] (hemorrhagic fever)  
Junin virus (Argentine hemorrhagic fever)  
Variola virus (smallpox)

### Filovirus Medical Countermeasure(s)

Filoviruses [Ebola and Marburg] (hemorrhagic fever)

### Smallpox Antiviral(s)

Variola virus (smallpox)

### Smallpox Vaccine

Variola virus (smallpox)

## Diagnostics

*Bacillus anthracis* (anthrax,MDR anthrax)  
Botulinum toxins (botulism)  
*Burkholderia mallei* (glanders)  
*Burkholderia pseudomallei* (melioidosis)  
Filoviruses [Ebola and Marburg] (hemorrhagic fever)  
*Francisella tularensis* (tularemia)  
Junin virus (Argentine hemorrhagic fever)  
*Rickettsia prowazekii* (typhus)  
Variola virus (smallpox)  
*Yersinia pestis* (plague)

## RAD/NUC

### ARS/DEARE Medical Countermeasure(s)

Radiological/Nuclear Agents

### Biodosimetry, Bioassay

Radiological/Nuclear Agents

### Radionuclide-Specific Countermeasure(s)

Radiological/Nuclear Agents

## CHEM

### Enterprise CHEMPACKs

Volatile nerve agents

### Volatile Nerve Agent

### Single Antidote

Volatile nerve agents

# PHEMCE Implementation Plan: Acquisition Forecast

## 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



**Pillar 4**  
Identify and Prioritize  
Near-, Mid-, and Long-  
Term Development &  
Acquisition  
Programs

## Long-Term Beyond FY 2013

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



# Projected Acquisitions for Top-Priority MCMs

Near-Term (FY 2007-08)  
Funding Source & Level

Mid-Term (FY 2009-13)  
Funding Source & Level

## Medical Countermeasures (MCMs) for Biological Threats

	Near-Term (FY 2007-08) Funding Source & Level	Mid-Term (FY 2009-13) Funding Source & Level
Diagnostics		SRF ≤ \$100 M
Broad spectrum antibiotic(s)	DSNS ≤ \$100 M	DSNS ≤ \$100 M SRF > \$100 M
Anthrax antitoxin(s)		SRF > \$100 M
Anthrax vaccine(s)	SRF > \$100 M	
Filovirus MCMs		SRF > \$100 M
Smallpox antiviral(s)		SRF ≤ \$100 M
Smallpox vaccine	SRF > \$100 M	

## Medical Countermeasures for Radiological and Nuclear Threats

ARS/DEARE	SRF > \$100 M	SRF > \$100 M
Biodosimetry, Bioassay		SRF ≤ \$100 M
Radionuclide-specific agent(s)		SRF ≤ \$100 M

## Medical Countermeasures for Chemical Threats

Enterprise CHEMPACKs		DSNS > \$100 M
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Reference: HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats, April 2007.

# PHEMCE Implementation Plan: Execution

## HHS PHEMC ENTERPRISE GOVERNANCE BOARD

### CBRN Working Groups, SIPWG & BARDA staff

#### MCM Requirements

- Threats
- Consequences
- PHEMCE Strategy & Implementation Plan
- BARDA Strategic Plan
- Technology watch

Requirements

PHEMCE  
Strategy & IP

BARDA  
Strategic Plan

### Integrated Program Teams (IPTs)

#### Threat-Specific MCM Portfolio Development and Acquisition

- Strategic Planning & Policy
- Acquisition Management

Threat-Specific  
PHEMCE Plans

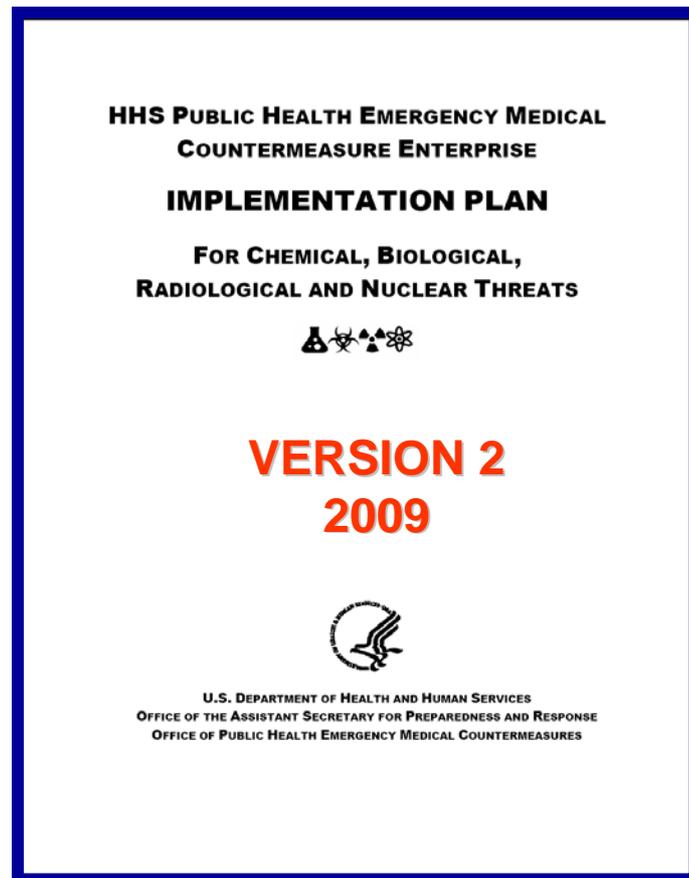
### Product Coordination Teams (PCTs)

#### MCM-Specific Solicitation and Procurement

SSNs,  
BAAs  
and RFPs

# PHEMCE Implementation Plan: Path Forward Version 2

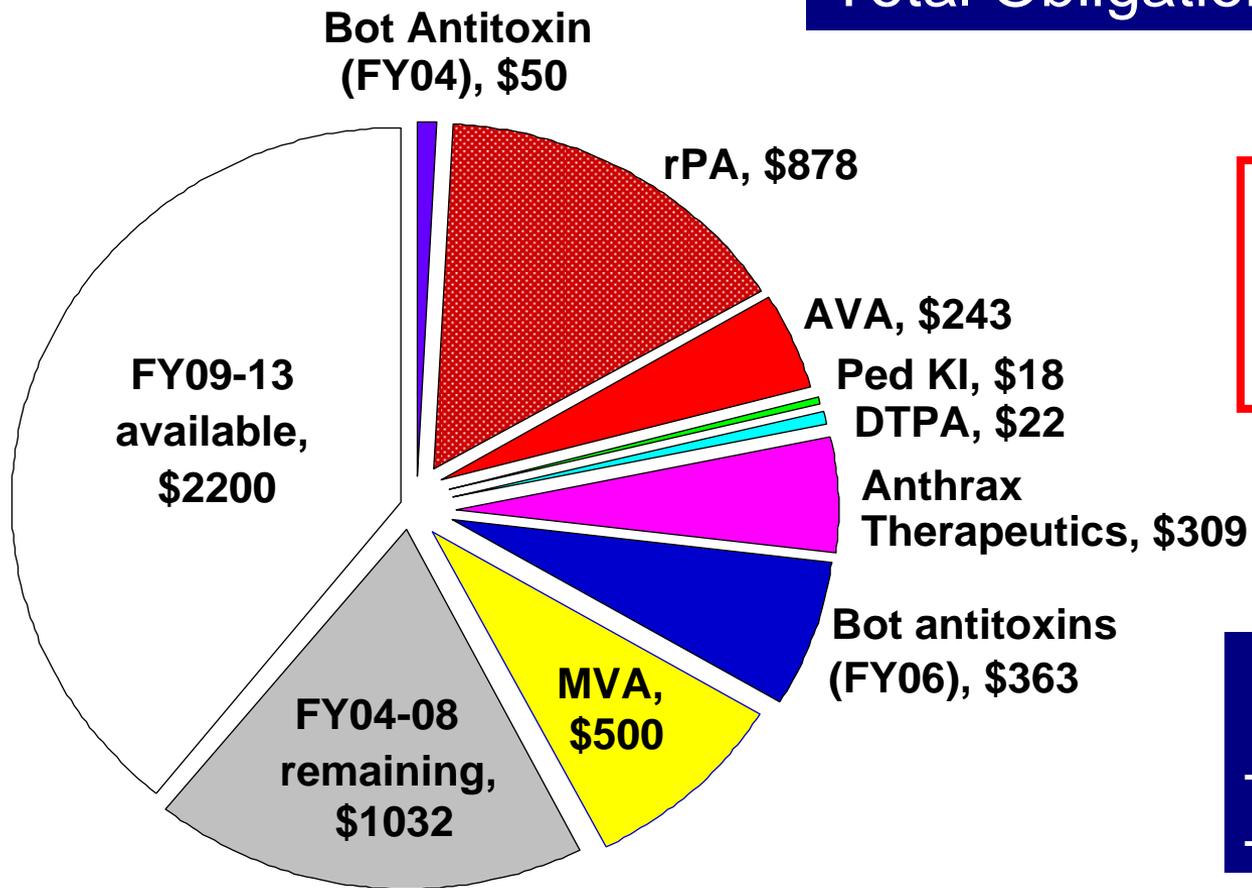
- Biennial review process
  - Version 2 of the PHEMCE Implementation Plan to be released in 2009
- DHS integrated CBRN threat assessment (to be completed 2008)
- Medical countermeasure requirements will more fully consider:
  - Multiplier effects
  - Enhanced, emerging or advanced threat agents
  - State/local/tribal delivery capabilities and event response planning (CONOPs)





# Project BioShield Special Reserve Fund: Obligations as of July 2007 (\$ millions)

**Total Obligations = \$2384 million**



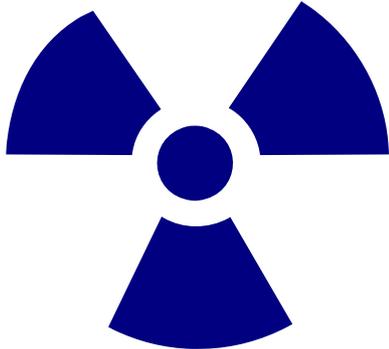
**NOTE: rPA Contract de-obligated \$877.5M in Dec 06; ARS RFP cancelled in March 2007: re-acquisition strategies ongoing**

**Programs approved, but not yet (fully) obligated:**

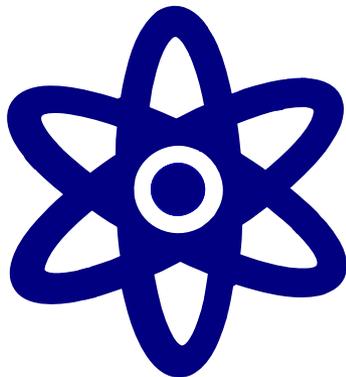
- Acute Radiation Syndrome
- Anthrax Vaccines

# Project BioShield: Acquisition Activities

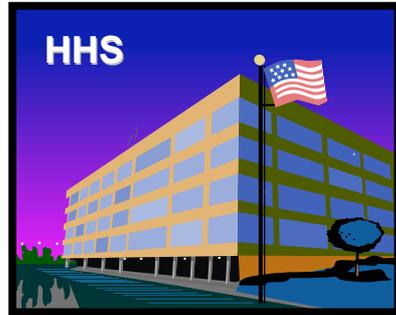
- Radiological and Nuclear Threats



- **Pediatric Potassium Iodide (Contract awarded March 2005; 1.7M units: \$5.7M)**
  - ❖ **Contract option exercised in 2006 for an additional 3.1 million bottles: \$11.8M**
- **Ca-DTPA and Zn-DTPA (Contract awarded Feb 2006; 390,000 doses of Ca-DTPA, 60,000 doses of Zn-DTPA: \$22M)**
  - ❖ **Contract modified in 2006 for additional 5,370 doses of Ca-DTPA and 19,369 doses of Zn-DTPA**
- **Medical Countermeasures to mitigate and/or treat acute radiation syndrome: Sources Sought Notice issued May 2007**



# Stakeholder Engagement



**Briefings**



**Federal Register  
Notices/ Draft RFPs/  
RFPs**



**PHEMC Enterprise Stakeholders  
Workshop; BARDA Dialogues;  
BARDA Industry Day**

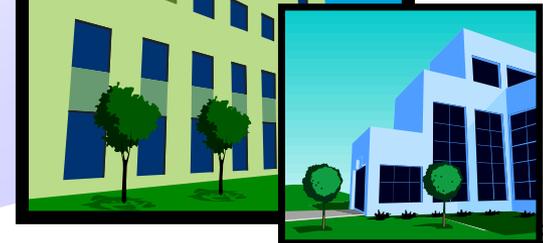
**RFIs  
Sources  
Sought Notices**



**Stakeholder Portal  
MedicalCountermeasures.gov**



**National  
Biodefense  
Science Board**





**“The Stakeholders Portal will be a web-based system through which those in industry and the research and development community can reach the people they need in the federal government, whether they're looking at a basic level of research or focused on end-stage development.”**

**- Secretary Michael O. Leavitt, September 25, 2006**

- **Mission: MedicalCountermeasures.gov facilitates communication between federal government agencies and public stakeholders to enhance the Nation's public health emergency preparedness.**
- **Benefits:**
  - **More effective meeting management**
  - **Central resource for information on USG initiatives**
  - **Improved transparency**
- **Participating Federal Entities: ASPR, NIH, CDC, FDA.**



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### Request a Meeting

▶ Coming Soon



### Procurement and Grant Opportunities

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### Public Meetings and Conferences

▶ More

### Announcements

- **HHS PHEMCE Strategy and Implementation Plan**
- **HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop (July 31- August 2, 2007)**
- **2007 Biomedical Advanced Research and Development Authority (BARDA) Industry Day (August 3, 2007)**
- **PDA/FDA Joint Regulatory Conference, Exhibition and Training Courses (September 24-28, 2007)**
- **Anthrax Vaccines - Bridging Correlates of Protection in Animals to Immunogenicity in Humans (November 8-9, 2007)**

MedicalCountermeasures.gov provides a central source of information on U.S. Department of Health and Human Services (HHS) initiatives regarding research, development, and acquisition of [medical countermeasures](#) for public health emergencies, both naturally occurring and intentional. MedicalCountermeasures.gov can also help you keep informed of the latest developments in federal medical countermeasures activities, with information on [upcoming and past events](#), [funding opportunities](#), and other federally-sponsored [resource programs](#). MedicalCountermeasures.gov also provides links to [regulatory guidance](#) on the development of medical countermeasures and to key federal [strategies and reports](#).

**Coming Soon:** MedicalCountermeasures.gov will enable stakeholders to submit information on products in development and request meetings with government departments or agencies. Please e-mail us at [BARDA@hhs.gov](mailto:BARDA@hhs.gov) if you are interested in receiving notification when this functionality is live.



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Preparedness and Response (ASPR)**

**More Information:**

**[www.hhs.gov/aspr/barda](http://www.hhs.gov/aspr/barda)**