



United States Department of
Health & Human Services

Office of the Secretary

Office of Public Health Emergency Preparedness (OPHEP)

Establishing and Prioritizing Medical Countermeasure Requirements for Chemical, Biological, Radiological, and Nuclear (CBRN) Threats

**BioShield Stakeholders' Workshop
26 September 2006**

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Office of Public Health Emergency Medical Countermeasures**



OPHEP

Office of Public Health Emergency Medical Countermeasures

OPHEP Vision:

A nation prepared to prevent and respond to the health effects of disasters natural or manmade.

OPHEMC Mission:

Develop and acquire medical countermeasures to prepare the nation to prevent and respond to the health effects of disasters natural or manmade.



Project BioShield:

Approved Acquisition Programs (as of 26 Sept 2006)

- **Anthrax**

- Anthrax rPA Vaccine
- Anthrax Vaccine Absorbed (AVA)
- Anthrax Therapeutics

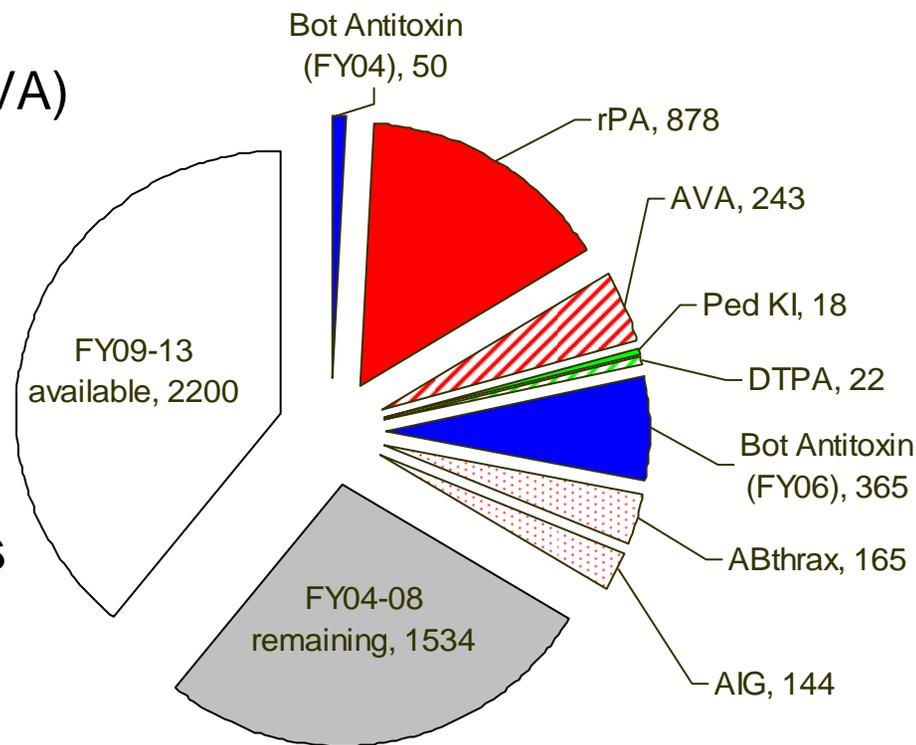
- **Botulinum Antitoxins**

- ***Modified Vaccinia Ankara (MVA) Smallpox Vaccine**

- **Radiological/Nuclear Threats**

- Pediatric KI
- DTPA
- *Medical Countermeasures to Treat and/or Mitigate Acute Radiation Syndrome (ARS)

Special Reserve Fund Obligations (\$M)



****Contracts pending for MVA and ARS***



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The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for CBRN Threats

Published in the
Federal Register
September, 2006



Draft

Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats

The ultimate goal of the HHS PHEMCE Strategy is to establish the foundational elements and guiding principles that will support medical countermeasure availability and utilization for the highest priority CBRN threats facing our nation.



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The PHEMCE Plan for CBRN Threats: A Two-Stage Approach

STAGE 1—STRATEGY:

Define the overarching guiding principles and pillars, or foundational elements, that will inform the analysis and prioritization required for the Implementation Plan.



STAGE 2—IMPLEMENTATION PLAN:

Analyze the input data (including threats/scenarios, medical/public health consequences, medical countermeasures technology assessment) to establish and prioritize the REQUIREMENTS.

The outcome will be an Implementation Plan with prioritized near-, mid-, and long-term goals and targets for research, development, and acquisition of medical countermeasures that is consistent with the guiding principles and priority-setting criteria defined in the STRATEGY.



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Pillars of the PHEMCE Strategy

**Threat
Identification
and
Prioritization**

**Medical/Public
Health
Consequence
Assessment**

**Establish and
Prioritize Medical
Countermeasures
Requirements**

**Establish and
Prioritize
Near-, Mid-, and
Long-Term,
Development &
Acquisition
Strategies**



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Establishing and Prioritizing Medical Countermeasure Requirements

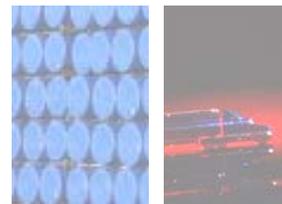
- SCOPING THE MISSION
 - Broad and evolving array of CBRN **threats**.
 - Large and diverse U.S. population that is **vulnerable**.
 - Assessment of medical and public health **consequences** is dependent upon an enormous array of variables and public health emergency response capabilities at the federal, state, and local level.
 - Establishing the ‘readiness’ of any **product development** program is fraught with uncertainties regarding timelines, cost, and probability of success.
 - **Resources** are significant, but limited. Priority-setting is imperative.
- THE BOTTOM LINE:
 - Establishing and prioritizing requirements for medical countermeasures demands a **deliberative approach that is informed by, and transparent to, all stakeholders** engaged in the mission of public health emergency preparedness and response.



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The PHEMC Enterprise Governance

- Serves as the mechanism for implementation of the PHEMC Enterprise.
- Advises Secretary of HHS:
 - Addresses both naturally-occurring and deliberately-induced public health events
 - More fully integrates the SNS, Project BioShield, and Pandemic Influenza missions
 - Plans 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



Regulatory Functions

WMD
Event





Establishing Medical Countermeasure Requirements: Critical Elements

The Threat

- ✓ Threat Assessment
- ✓ Material Threat Determination (MTD)

Scientific/Medical Characteristics of the Threat Agent and Resultant Disease

Medical/Public Health Consequence Assessment, including Modeling

Target Population

- ✓ Military
- ✓ Civilian

Available and Next-Generation Countermeasures

- ✓ Available medical countermeasures
 - Prevention
 - Treatment
- ✓ Available non-medical countermeasures (PPE, etc.)
- ✓ Next-generation medical countermeasures

Product Specifications

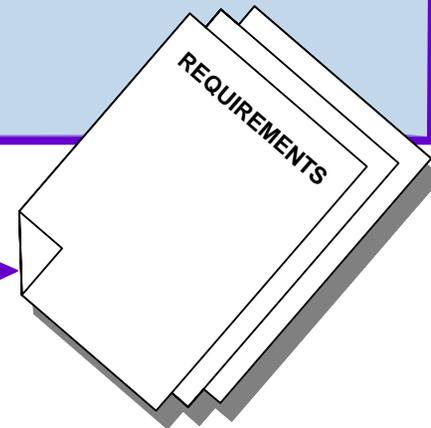
- ✓ Composition
- ✓ Formulation
- ✓ Doses per course; are booster doses necessary?
- ✓ Formulation and Packaging
- ✓ Storage requirements/ Stability
- ✓ Desired product specifications for an "ideal" medical countermeasure

Proposed Utilization Policy/Doctrine

- ✓ Utilization Policy
- ✓ Deployment plan & logistics
- ✓ Pre-event
- ✓ Day of event
- ✓ Post-event

Estimated Requirements

- ✓ Near-, and mid-term
- ✓ Long-term: warm base; replenishment of expired product; next-generation products





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Establishment of Medical Countermeasure Requirements

- Threats will be informed by Department of Homeland Security
 - Material Threat Determinations
- HHS will assess the medical and public health consequences.
 - HHS will establish baseline requirements based on unmitigated consequence assessments.
 - HHS will examine various strategies to prevent and mitigate the health effects of CBRN threats, including medical countermeasures and traditional public health prevention strategies.
 - **Gap analysis:** HHS will assess medical countermeasure requirements vs. candidate and available medical and non-medical countermeasures.

Establishment of Medical Countermeasure Requirements

- 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.



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Biodefense for the 21st Century

1. Threat Awareness/Anticipation of Future Threats
2. Prevention and Detection
3. Surveillance and Detection
4. Response and Recovery
 - Capabilities required for response based on interagency-agreed scenarios derived from plausible threat assessments
 - Mass Casualty Care
 - Risk Communication
 - Decontamination
 - **MEDICAL COUNTERMEASURE DEVELOPMENT**





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Establishing Medical Countermeasure Requirements: “TECH WATCH”

- HHS will monitor and assess the status of medical countermeasures available and in development including:
 - Holdings of the Strategic National Stockpile
 - Relevant commercial products potentially accessible to the USG
 - Candidate medical countermeasures in the developmental pipeline
 - ❖ USG Data Call
 - ❖ RFI for Industry





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Request for Information

Vendors

Federal Business Opportunities



Title: Medical Countermeasures to address chemical, biological, radiological and nuclear threats.

Reference Number: RFI-OPHEMC-06-03

Posted Date: Sep 14, 2006

Response Date: Oct 31, 2006

**Bio, Chem, Rad/Nuc, and Diagnostics
TRLs are appendices to the RFI**

“Data obtained from this RFI will provide critical inputs to the HHS Implementation Plan, with the ultimate goal to acquire the most appropriate medical countermeasures for mitigating the health effects from the highest priority CBRN threats facing the nation.”



TRLs For Biological Medical Countermeasures

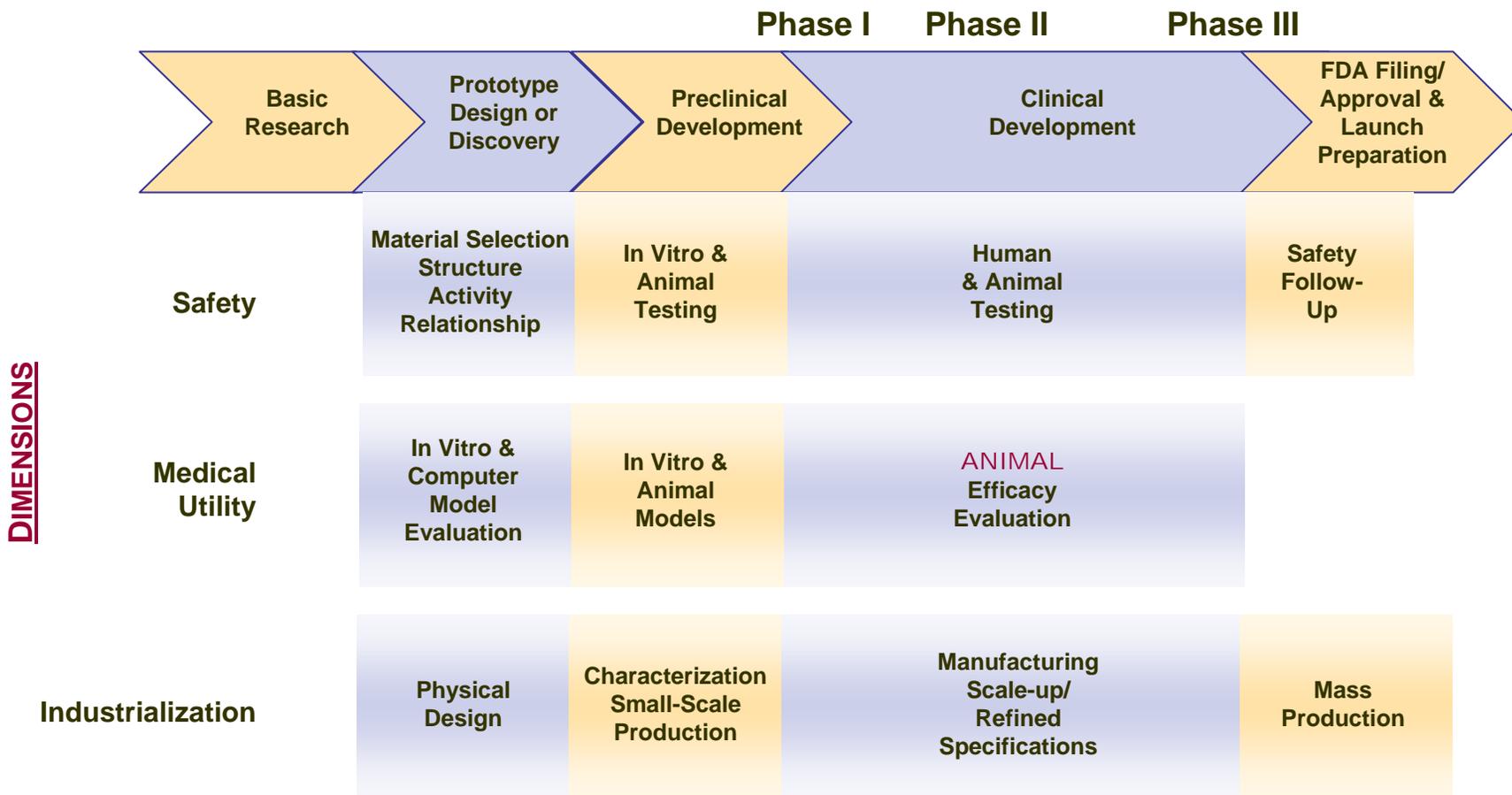
- | | |
|------------------|--|
| Stage 1: | Target Identification |
| Stage 2: | Validated Screening Tool |
| Stage 3: | “Hit” Identification |
| Stage 4: | Preliminary Leads |
| Stage 5: | Optimized Leads |
| Stage 6: | Candidate Drug |
| Stage 7: | IND Ready |
| Stage 8: | Phase 1 |
| Stage 9: | Phase 2 |
| Stage 10: | Phase 3 and Definitive Animal Efficacy |
| Stage 11: | Licensure, Approval, Clearance |
| Stage 12: | Post-licensure, -approval, and -clearance |

TRLs also prepared for Chemical MCMs, Rad/Nuc MCMs, and Diagnostics



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Medical Countermeasures: Challenges to Accelerated Development



Adapted from the FDA Critical Path Report (March 2004)



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The Stakeholders' Portal

Health and Human Services Portal > Home - Microsoft Internet Explorer

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Welcome

Office of Public Health Emergency Medical Countermeasures

The Office of Public Health Emergency Medical Countermeasures (OPHEMC)* has a leadership and coordinating role for the research, development, and acquisition of vaccines, diagnostics, and drugs targeting the chemical, biological, radiological and nuclear (CBRN) threat agents most likely to be used in a terrorist attack on the U.S. homeland. In addition, OPHEMC works to prevent and mitigate the health effects of pandemic influenza through the development and acquisition of vaccines, therapeutics and diagnostics.

Latest Alerts

SARS Alert!

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BIOHAZARD

Done Internet



Strategic Issues that Inform Priority-Setting for Medical Countermeasure Requirements

- CBRN Threats Classes (Bio/Chem/Rad-Nuc): Relative Hierarchy
- Top Priority Threats – All Threats
- Traditional/Known – Emerging/Engineered Threat
- Specific – Broad Spectrum
- Fixed – Flexible defenses
- Prevention – Treatment
- Acute – Chronic
- 1st Available – Next Generation
- General – Special Populations
- Domestic – International



Acknowledgements

- Department of Health & Human Services
 - Office of Public Health Emergency Preparedness
 - ❖ Office of Public Health Emergency Medical Countermeasures
 - National Institutes of Health
 - Centers for Disease Control and Prevention
 - Food and Drug Administration
- Department of Homeland Security
- Department of Defense
- Executive Office of the President
- U.S. Congress
- Industry
- Medical and Public Health Organizations
- Academia