



United States Department of
Health & Human Services

Office of the Secretary

Office of Public Health Emergency Preparedness (OPHEP)

HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise and the PHEMC Enterprise Strategy

**BioShield Stakeholders Workshop
25 September 2006**

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HHS Office of Public Health Emergency Preparedness

Vision:

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

Mission:

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



Public Health Emergency Preparedness: A Case Study - ANTHRAX

Since the anthrax attacks of October 2001 we have built a diverse and continually expanding armamentarium of medical countermeasures. . .

- Our **front line** of response is oral **antibiotics**. We can provide 60-day post-exposure prophylaxis for over 40 million people.
- **Second**, we have acquired 5 million doses of the licensed anthrax vaccine, **AVA**, and have begun to receive a second 5 million doses for which delivery will be completed within a year.
- **Third**, we are aggressively developing a **next generation anthrax vaccine** and have a contract to buy 75 million doses of this new vaccine.
- **Fourth**, we can treat over 800,000 symptomatic anthrax patients with **intravenous antibiotics**.
- **Fifth**, we have two contracts in place to increase our stockpile of anthrax **antitoxins** to treat the toxemia associated with symptomatic anthrax disease.





Project BioShield

The “Project BioShield Act of 2004”
became Public Law 108-276 on 21 July 2004



PURPOSE:

To accelerate the research, development, purchase, and availability of priority medical countermeasures to protect the US population from the effects of chemical, biological, radiological, and nuclear (CBRN) threat agents.

A Bipartisan Effort

- The House version of the bill (H.R. 2122) was passed by a vote of 421-2 on 16 July 2003.
- The Senate version of the bill (S. 15) was passed by a vote of 99-0 on 19 May 2004.



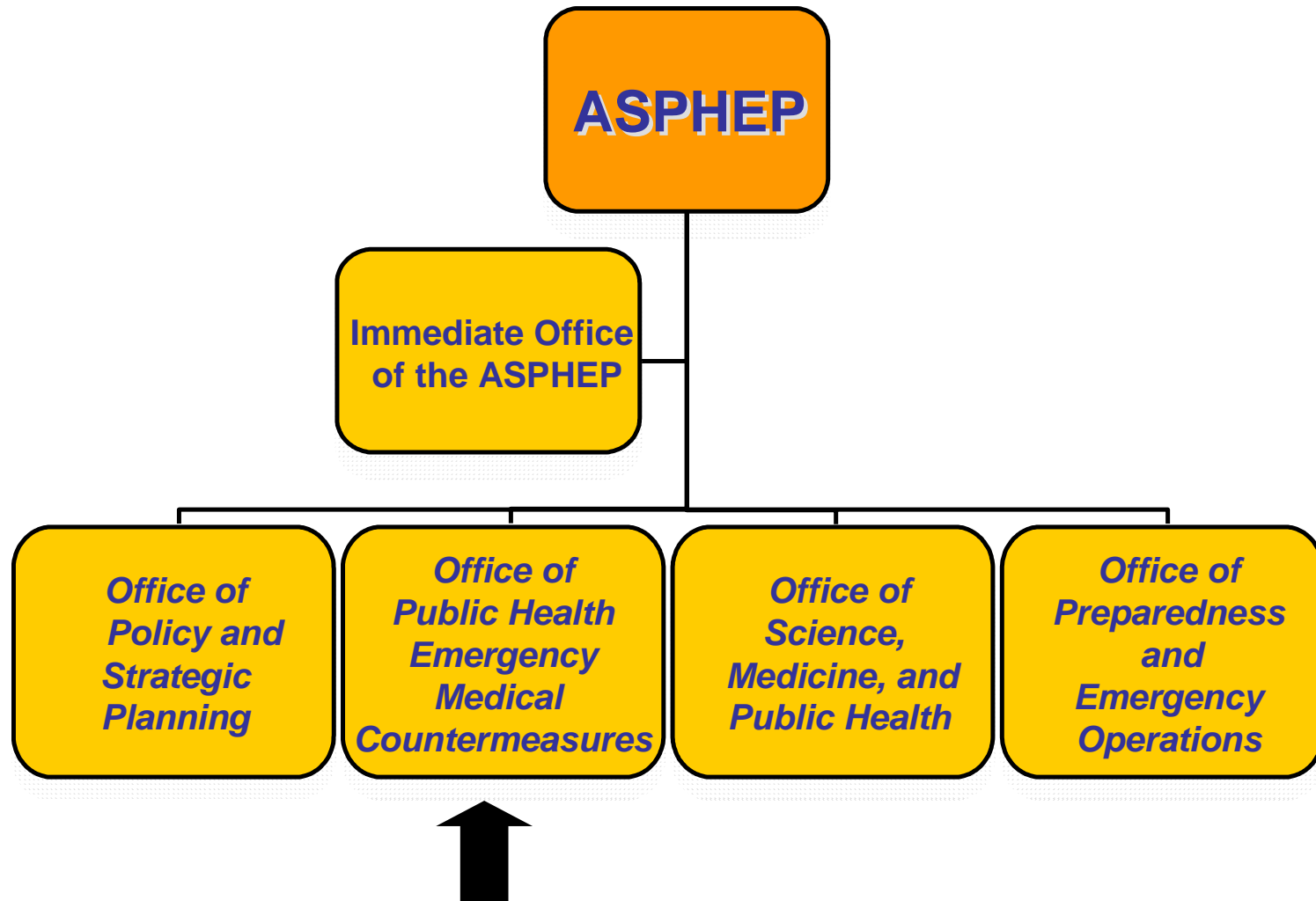
Project BioShield

Three-features of the program:

- **Accelerated** R&D by providing NIH/NIAID with new authorities
- **Availability:** establishes an Emergency Use Authorization for medical products
- **Acquisition:** establishes a secure funding source from FY04-FY13 for purchase of security countermeasures
 - Authorizes utilization of the **\$5.6B Special Reserve Fund** established in the FY04 DHS Appropriations Bill (P.L. 108-90)



Office of Public Health Emergency Medical Countermeasures





Concept of Operations

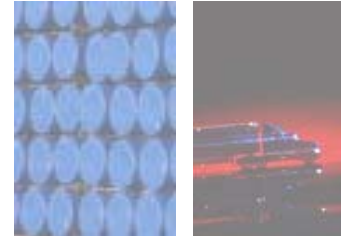
- Concept of Operations include maintenance, utilization policies and deployment plans for each MCM in the context of all available consequence mitigation strategies.





BioShield Stakeholders Workshop

- > 90 pharmaceutical and biotechnology industries
- Professional societies
- 10 State and local public health organizations and emergency response planners
- Academic research and development community
- Public interest groups
- Other stakeholder federal agencies (such as the Department of Homeland Security and Department of Defense) and Congress





Workshop – Engagement with External Stakeholders

- Stakeholder Panels
 - Industry
 - Academia
 - Medicine and Public Health
- Working Sessions
 - Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for CBRN Threats
 - Public Health Consequences and Medical Countermeasure Research, Development, Acquisition and Utilization



Public Health Emergency Medical Countermeasures Enterprise

- Federal Register Notice: 6 July 2006
 - Described the new OPHEP structure
 - Created the Public Health Emergency Medical Countermeasures Enterprise (the Enterprise)
- The Enterprise is a coordinated interagency effort responsible for:
 - Defining and prioritizing requirements for public health medical emergency countermeasures
 - Focusing research, development, and procurement activities addressing the requirements
 - Setting deployment and use strategies for medical countermeasures held in the Strategic National Stockpile



Enterprise Strategy: Defining and Prioritizing Requirements

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:

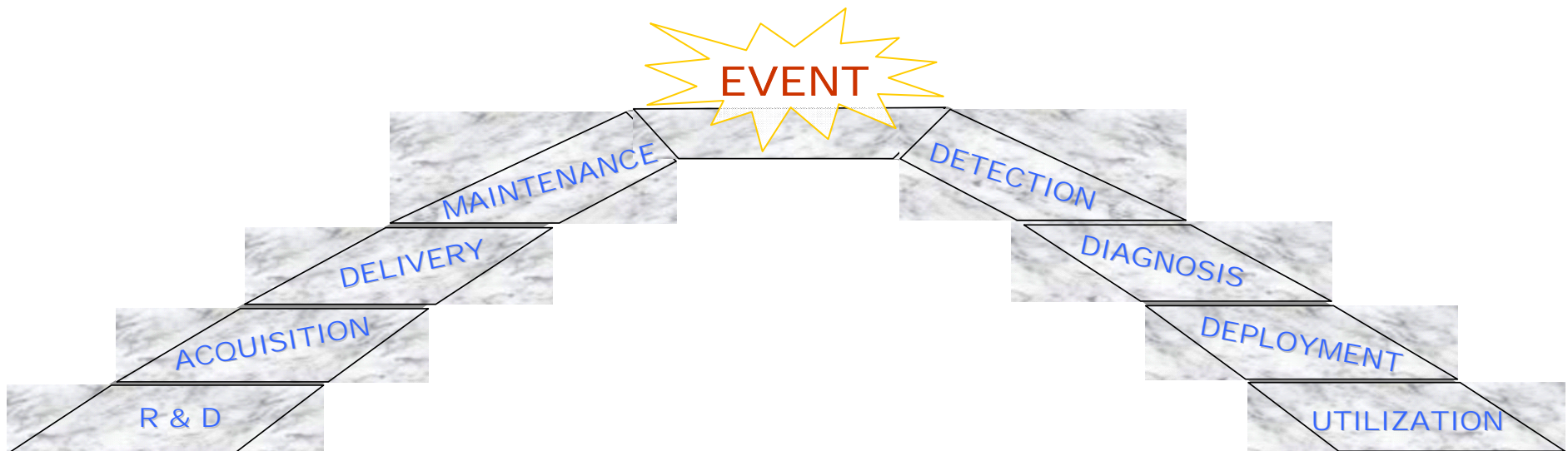
Analyze the input data (including threats/scenarios from DHS, medical/public health consequences from HHS, medical countermeasures technology assessment from the interagency) to establish and prioritize the REQUIREMENTS.

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.



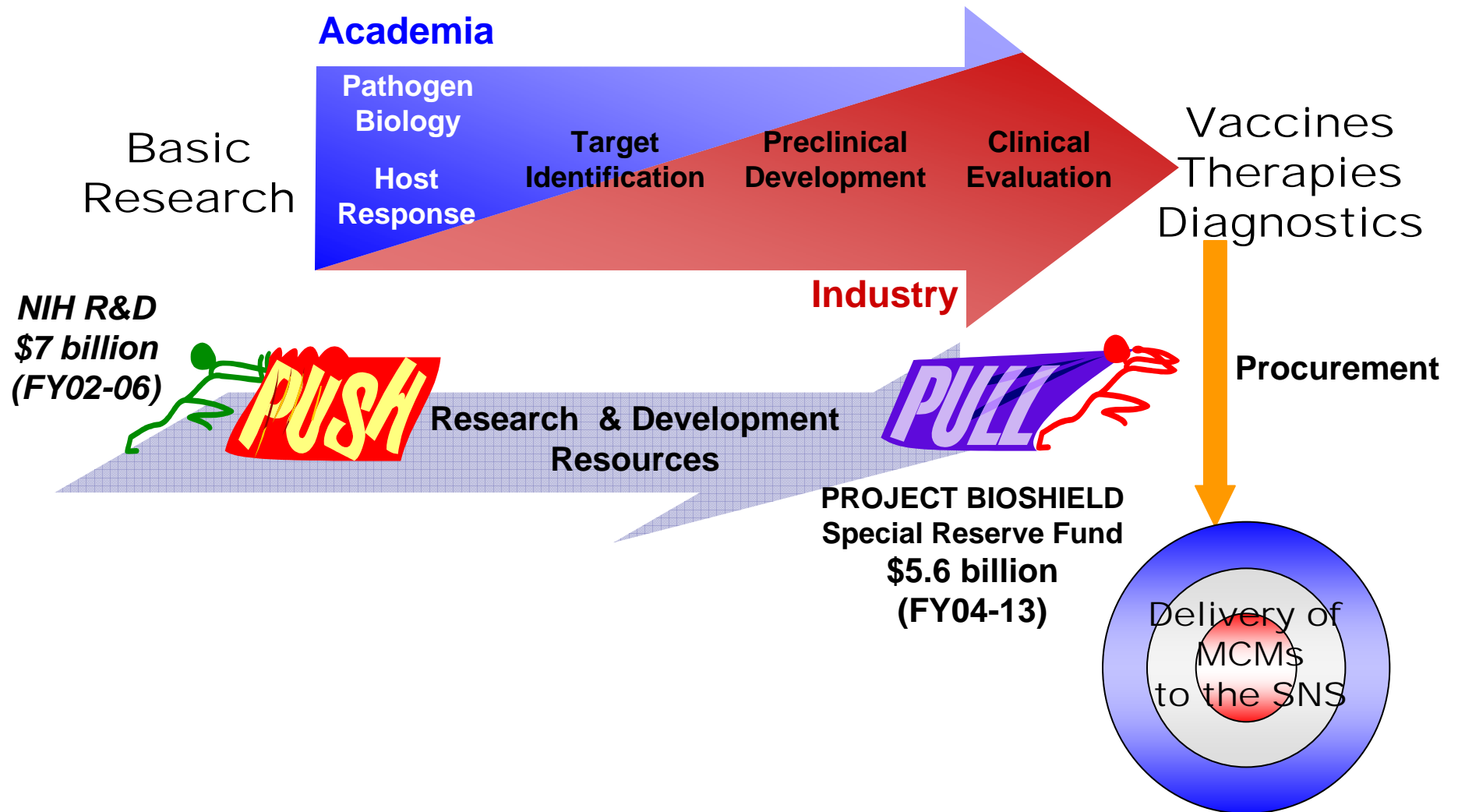
Enterprise: Defining and Prioritizing Requirements

- Government Research and Development “Data Call”
- Request for Information (RFI)





Enterprise: Coordinating Research, Development and Procurement





Enterprise: Establishing Deployment and Use Strategies

- Work with States and Localities, Health Care Providers
- Consider Use Under EUA
- Practice and Test



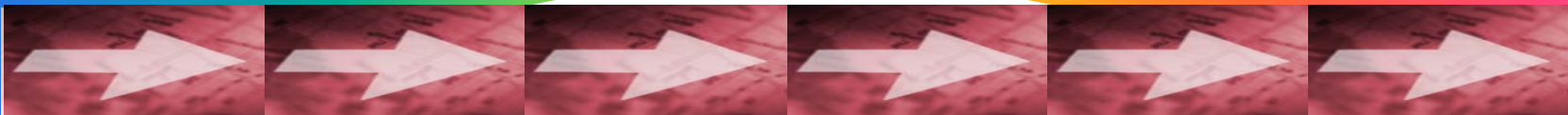


PHEMC Enterprise Governance Body

- Serves as the mechanism for implementation of the Enterprise
- Advises Secretary of HHS:
 - Address both naturally-occurring and deliberately-induced public health events
 - More fully integrate the SNS, BioShield, and Influenza missions
 - Plan beyond the scope and range (\$5.6B; FY04-13) of the Project BioShield Act of 2004
 - Encompass medical countermeasure issues along the full spectrum of the Enterprise



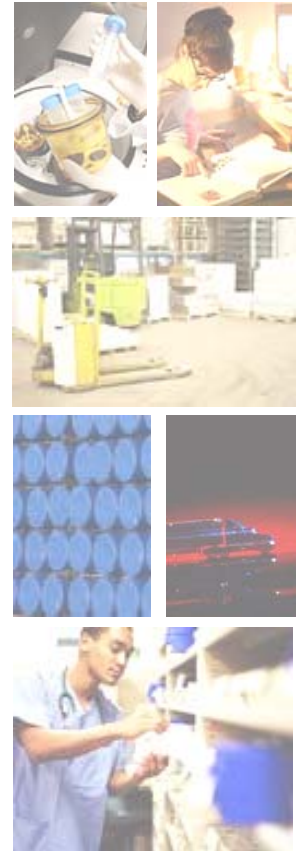
Regulatory Functions





The Enterprise Mission: An Interagency Effort

- OPHEP, CDC, FDA, NIH
- Includes Project BioShield as a critical tool
- HHS Strategic Plan and the subsequent Implementation Plan are road maps
 - Published to increase transparency

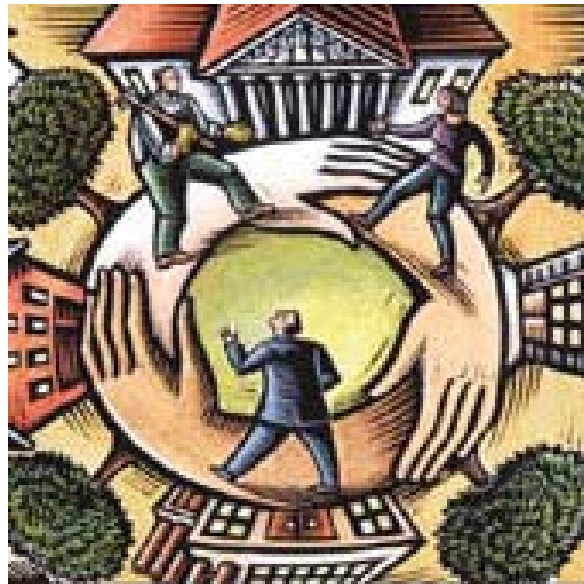




A Call to Action

PHEMC Enterprise Governance

- OPHEP
- CDC
- FDA
- NIH



BioShield External Stakeholders

- Pharmaceutical and biotechnology industries
- Professional societies
- State and local public health organizations and emergency response planners
- Academic research and development community
- Public interest groups
- Other federal agencies
- Congress



“ Science can be effective in the national welfare only as a member of a team, whether the conditions be peace or war. But without scientific progress no amount of achievement in other directions can insure our health, prosperity, and security as a nation in the modern world.”

Excerpt from *“ Science- The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research”* by Vannevar Bush, Director of Scientific Research & Development under President Franklin D. Roosevelt, July 1945.