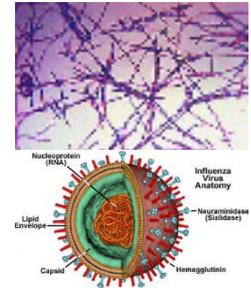


# FDA's Medical Countermeasures initiative (MCMi)



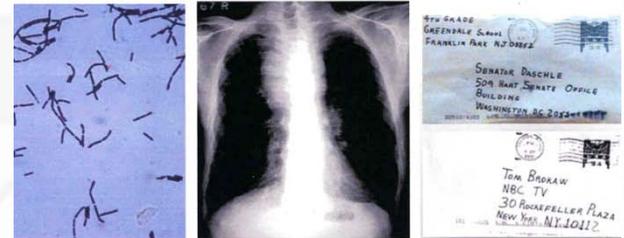
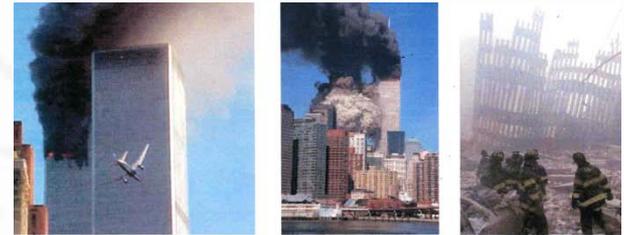
**B I D 2012 – Day 1**



U.S. Food and Drug Administration  
Medical Countermeasures

# The Threat is Real

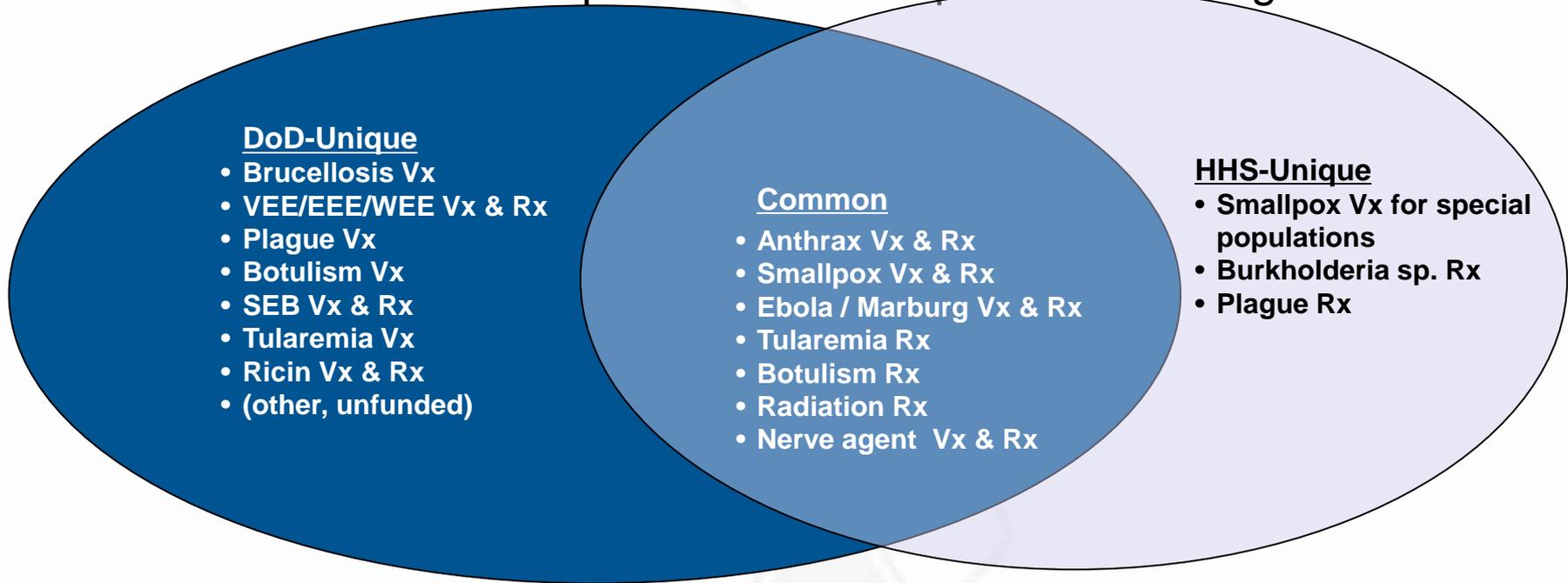
- Our Homeland faces serious CBRN threats, as well as from Emerging Infectious Diseases
- The USA needs to be prepared to respond to many threats, including those from determined and well funded terrorist organizations worldwide



Patient A: 38 yo Index case- post 12 days abs.  
 Much improved clinically. Progression from papule  
 to exudative ulcer (←) edema) to eschar

**Everything Changed  
On Sept 11 2001**

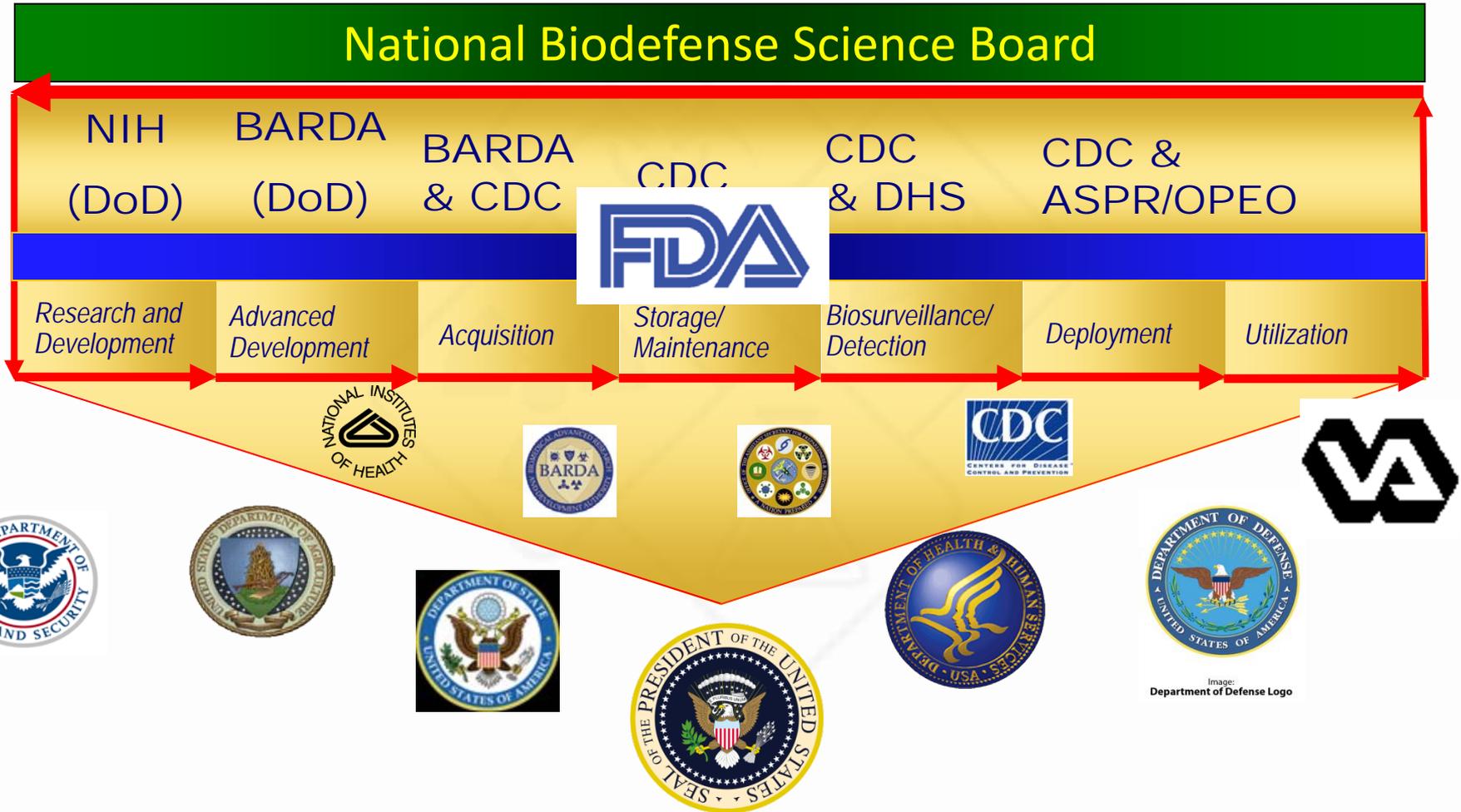
## Integrated Portfolio for CBRN Medical Countermeasures Requirements – Unique and Convergent



***DoD focus is on protecting forces prior to exposure. HHS focus is on response to threats to general civilian population after exposure***

# HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

## National Biodefense Science Board



# What is the FDA MCMi?

- Launched in 2010
- Response to comprehensive year-long review of the Public Health Emergency Medical Countermeasures Enterprise (Enterprise)
- Identified FDA as one of the most critical components of the Enterprise
- \$170M “no-year” one-time funds in FY 2011
- \$20M base funding in FY 2012
- 77 FTEs across FDA
- Leadership provided by OCS/OCET in close collaboration with medical product centers: CBER, CDER and CDRH

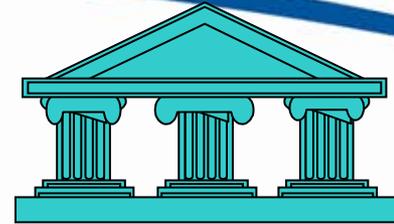


# Goals

1. Enhance the Review Process
2. Advance MCM Regulatory Science
3. Modernize Legal, Regulatory, and Policy Approaches
4. Strengthen workforce expertise in CBRN

**Objective:** Streamline MCM development and regulatory evaluation

# MCMi Program Pillars



- Enhance FDA’s product review/approval processes for the highest priority MCMs and develop cross-cutting systems that support MCM use throughout the product life-cycle (Pillar 1)

- Strengthen the necessary science base for MCM development and identify clear, efficient pathways for developing and manufacturing critical MCMs (Pillar 2)

and

- Modernize the statutory, regulatory, and policy framework to facilitate MCM development and ensure an effective public health response (Pillar 3)

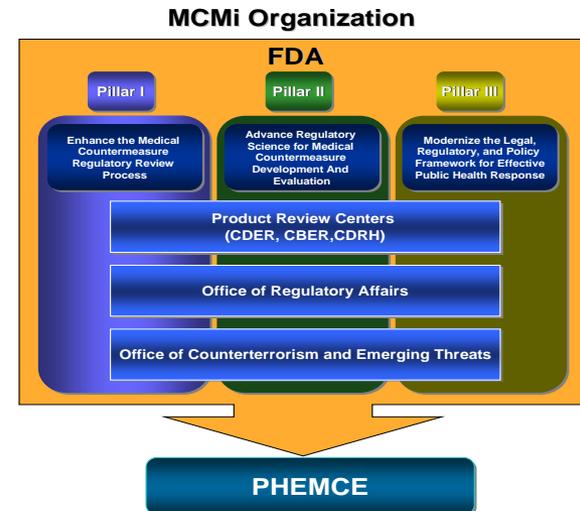
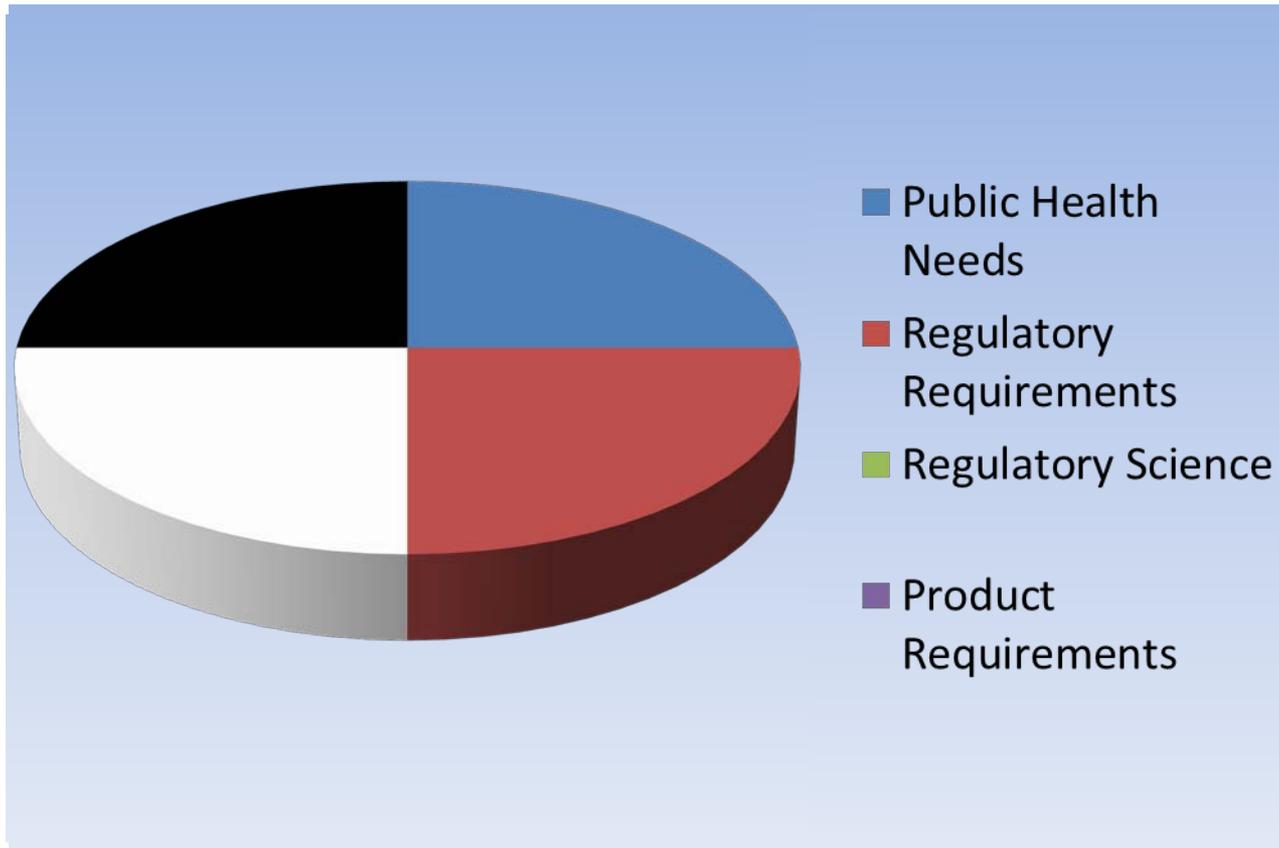


Figure 4

# FDA's Medical Countermeasure (MCM) Development Balance



# MCFI Activities

- November 29-30, 2012: [Public Workshop on Burkholderia](#)
- November 15 - 16, 2012: [Blood Products and Cellular Therapies – A Symposium on Emergency Preparedness](#)
- November 14, 2012: [Vaccines and Related Biological Products Advisory Committee Public Meeting](#)
- November 2, 2012: [FDA Anti-Infective Drugs Advisory Committee Public Meeting](#)
- [Meeting the Challenges of Medical Countermeasure Development](#), FDA perspectives in recent issue of *Microbial Biotechnology*.
- October 29 – 31, 2012: [BARDA Industry Day - Contracting for Countermeasures](#)
- **May 23, 2012: FDA ANNOUNCES BAA 12, 1 YEAR SOLICITATION FOR R&D TO SUPPORT REGULATORY SCIENCE, INCLUDING FOR MCMS.**

Protecting National Health and Security



**Medical Countermeasures Initiative**  
**Strategic Plan 2012 - 2016**



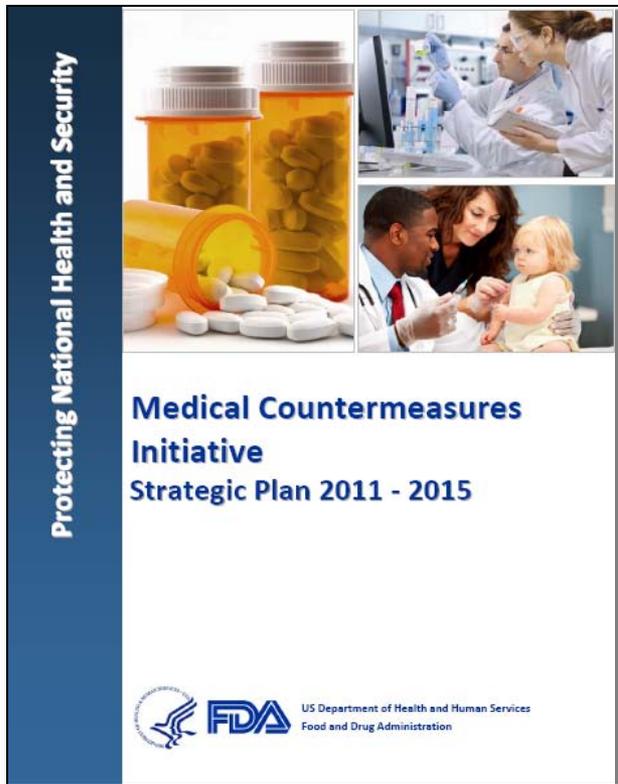

US Department of Health and Human Services  
Food and Drug Administration

# Progress

- ❖ Established multiple Action Teams to identify and address review and approval issues
  - ❖ multiplex in vitro diagnostic tests
  - ❖ acute radiation syndrome
  - ❖ radiological/nuclear event dosimetry
  - ❖ warfighter/trauma
  - ❖ pediatrics and pregnancy
- ❖ Reviewed PHEMCE priorities
- ❖ Focused on outstanding product-specific issues
- ❖ Considered strategies to clarify regulatory pathways for MCM candidates including biodefense vaccines
- ❖ Sponsored/encouraged workshops and advisory committees

# MCMi

## FDA's Medical Countermeasures Initiative Year-1 Status Report — September 2011



— *Protecting National Health and Security*



US Department of Health and Human Services  
Food and Drug Administration

<http://www.fda.gov/medicalcountermeasures>

# In Summary

- FDA MCMi plays a key role in:
  - increasing the speed of development and reducing the high failure rate associated with MCM development
  - transforming the nation's overall MCM system so it can respond faster and more nimbly to emerging threats



# FDA CT Information

Questions? [AskMCMi@fda.hhs.gov](mailto:AskMCMi@fda.hhs.gov)

- **For additional information, please visit our website:**  
[www.fda.gov/MedicalCountermeasures](http://www.fda.gov/MedicalCountermeasures)
- Center Specific Questions
  - CDER: <http://www.fda.gov/cder>
    - Bioterrorism
      - Drug Preparedness and Response
- CBER:  
<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm110311.htm>