FDA’s Medical Countermeasures initiative (MCMi)

B I D 2012 – Day 1
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

Everything Changed On Sept 11 2001
Integrated Portfolio for CBRN Medical Countermeasures
Requirements – Unique and Convergent

**DoD-Unique**
- Brucellosis Vx
- VEE/EEE/WEE Vx & Rx
- Plague Vx
- Botulism Vx
- SEB Vx & Rx
- Tularemia Vx
- Ricin Vx & Rx
- (other, unfunded)

**Common**
- Anthrax Vx & Rx
- Smallpox Vx & Rx
- Ebola / Marburg Vx & Rx
- Tularemia Rx
- Botulism Rx
- Radiation Rx
- Nerve agent Vx & Rx

**HHS-Unique**
- Smallpox Vx for special populations
- Burkholderia sp. Rx
- Plague Rx

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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

NIH (DoD)  BARDA (DoD)  BARDA & CDC  CDC  CDC & ASPR/OPEO

Research and Development  Advanced Development  Acquisition  Storage/Maintenance  Biosurveillance/Detection  Deployment  Utilization

Image: Department of Defense Logo
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)

![MCMi Organization Diagram](image-url)
FDA’s Medical Countermeasure (MCM) Development Balance
MCMI Activities

- November 29-30, 2012: Public Workshop on Burkholderia
- 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.
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

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

• For additional information, please visit our website:
  www.fda.gov/MedicalCountermeasures

• Center Specific Questions
  – CDER: http://www.fda.gov/cder
    • Bioterrorism
      – Drug Preparedness and Response

• CBER: