BARDA Funding Opportunities:
Developing Medical Countermeasures

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Biomedical Advanced Research and Development Authority

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NCI SBIR Workshop on Federal Resources to Accelerate Commercialization

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BARDA's Mission

Develop and provide countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by product development, stockpile acquisition/building, manufacturing infrastructure building, and product innovation.

Renovated 1960's-Era Federal Office Building #8
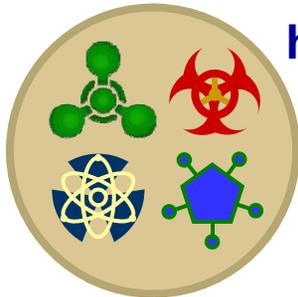**Move in June 2013**

Scoping the Challenge

Define, Design, Develop, Deliver and Dispense Medical Countermeasures to reduce the adverse health consequences of public health emergencies

A Nation Prepared

Complex array of Threats

Diverse population

Lengthy, risky and expensive product development

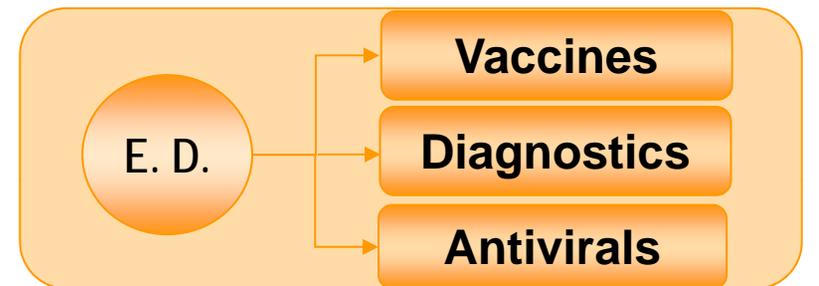**Prioritize medical countermeasure programs to effectively address mission goals**
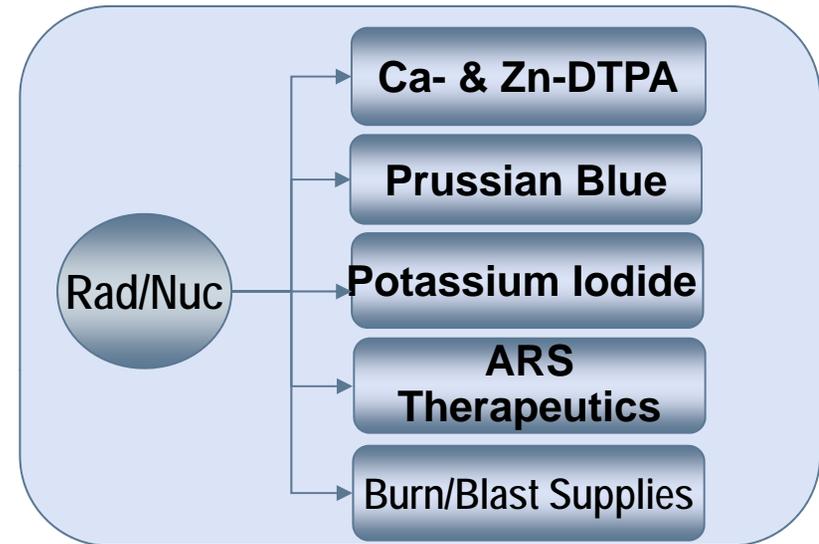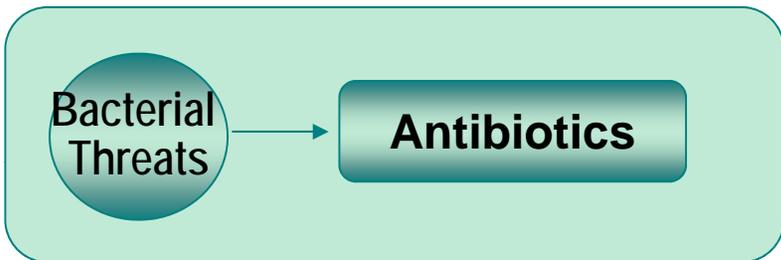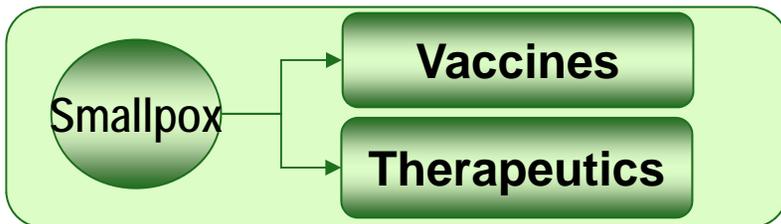
Strategies & dependencies for effective use

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Medical Countermeasures For National Security:
A Toolkit For Public Health Emergency Preparedness

Anthrax
- Antibiotics
- Vaccines
- Antitoxins

Smallpox
- Vaccines
- Therapeutics

Botulism
- Heptavalent Antitoxin

Bacterial Threats
- Antibiotics

Rad/Nuc
- Ca- & Zn-DTPA
- Prussian Blue
- Potassium Iodide
- ARS Therapeutics
- Burn/Blast Supplies

Chem
- CHEMPACKs

E. D.
- Vaccines
- Diagnostics
- Antivirals

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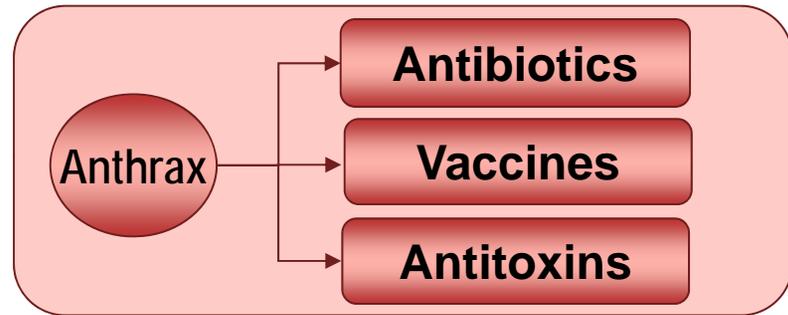
Product Development Challenges

Cost

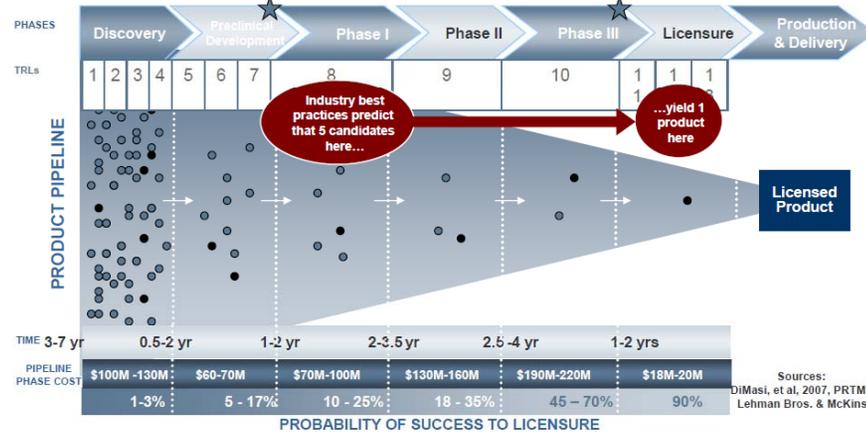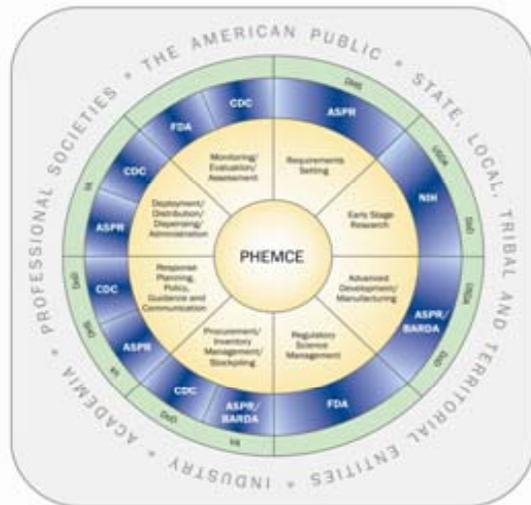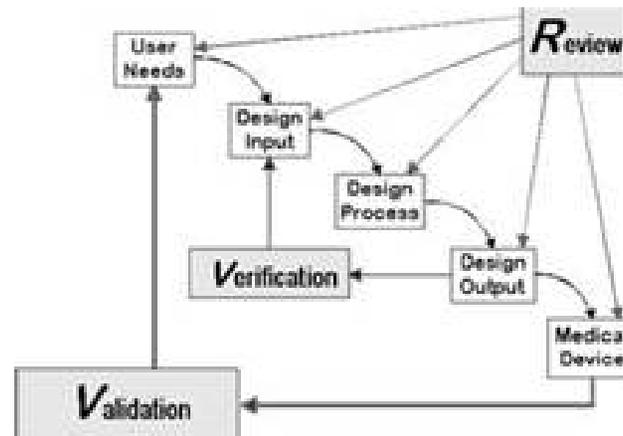|	
Discovery	$$
Development	$$$
Procurement	$$$$
Resupply $$$$	Maintenance $$
Warm Base	$$$

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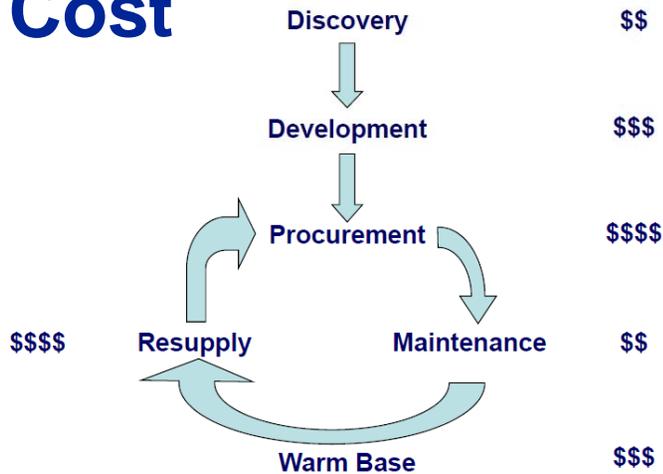
Technical

Administration

Regulatory

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Areas of Risk
for Product Developers

Business Risks

— Lack of commercially viable product pipelines and long-term solvency

— Financing pressures for "start-up" and operating capital

— Lack of integrated business expertise in new organizations

Technical Risk for Product Development

— Lack of ability for translation and incubation of promising ideas from tech base to early product development

— Access to core manufacturing and accessory services

Regulatory Risks

— Uncertain or high risk pathway to product licensure for CBRN

— Need for greater resources at FDA to mitigate risk profile

Governmental Risks

— Coordination across multiple agency and department level programs

— Ability to project and pr ioritize long-range needs through an integrated multi-year program/budget process

BARDA Strategic Issues

✓ Resource constraints afflicting the USG

✓ Many CBRN threats

✓ Maturation of core programs

✓ Pharma industry is changing/restructuring

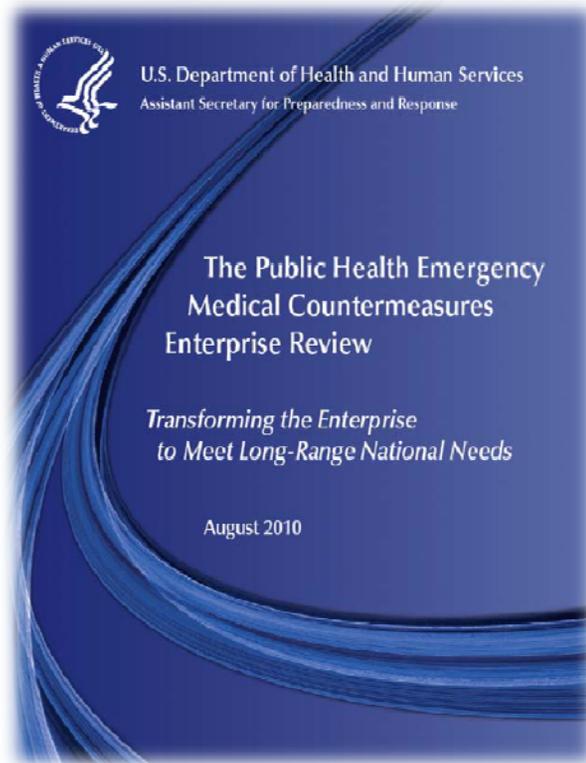✓ Less investment capital then a few years ago

MCM Enterprise Review 2010
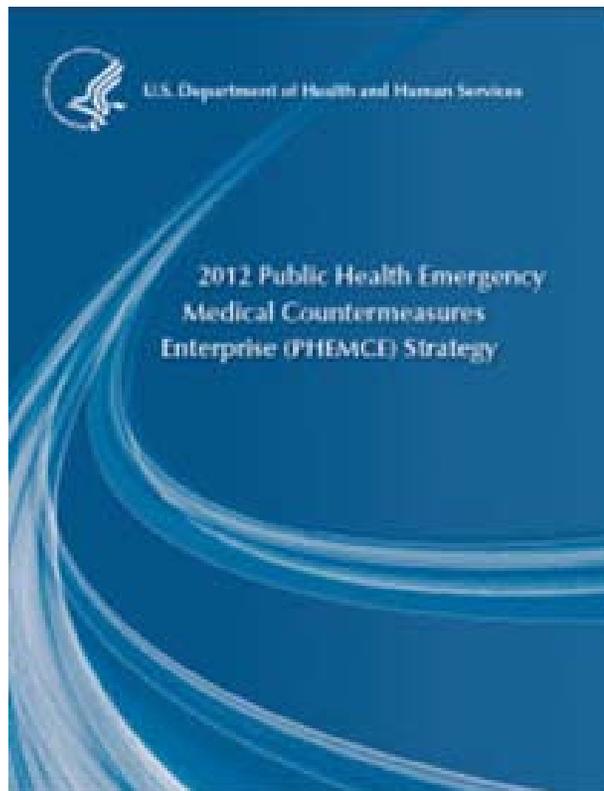
Key Initiatives

- Expand Product Pipeline through Concept Acceleration Program (CAP) at NIAID.

- Establish a Strategic Investment (SI) Fund to increase investments in commercial ventures with multi-use potential (BARDA)

- Establish Centers for Innovation Advanced Development and Manufacturing (BARDA)

- Investment in upgrading science capacity at FDA

- Optimize influenza vaccine development and manufacturing (BARDA, NIAID, FDA, CDC)

- Enhance PHEMCE business practices

U.S. Department of Health and Human Services
Assistant Secretary for Preparedness and Response

The Public Health Emergency Medical Countermeasures Enterprise Review

Transforming the Enterprise to Meet Long-Range National Needs

August 2010

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New PHEMCE Strategy 2012
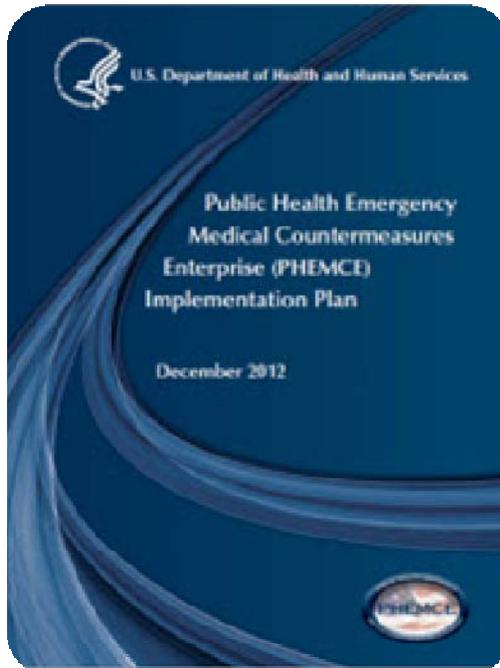
2012 PHEMCE Strategy

- Identify, create, develop, manufacture, and procure critical medical countermeasures

- Establish and communicate clear regulatory pathways to facilitate medical countermeasure development and use

- Develop logistics and operational plans for optimized use of medical countermeasures at all levels of response

- Address medical countermeasure gaps for all sectors of the American civilian population

The 2012 HHS PHEMCE Implementation Plan:
## Identifies Priorities Across the PHEMCE Mission Areas

> a high-level description of programs and initiatives that support the goals and objectives laid out in the Strategy;

> an overview of PHEMCE interagency partner roles and collaborations;

> a detailed description of threat-specific approaches;

> a description of specific capability-based approaches; and

> a summary of key milestones to track progress over the next five years.

This is the blueprint the PHEMCE will follow in the near-, mid-, and long-terms to enhance national health security while making the best use of available resources.

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BARDA Strategic Commitments 2011-2016
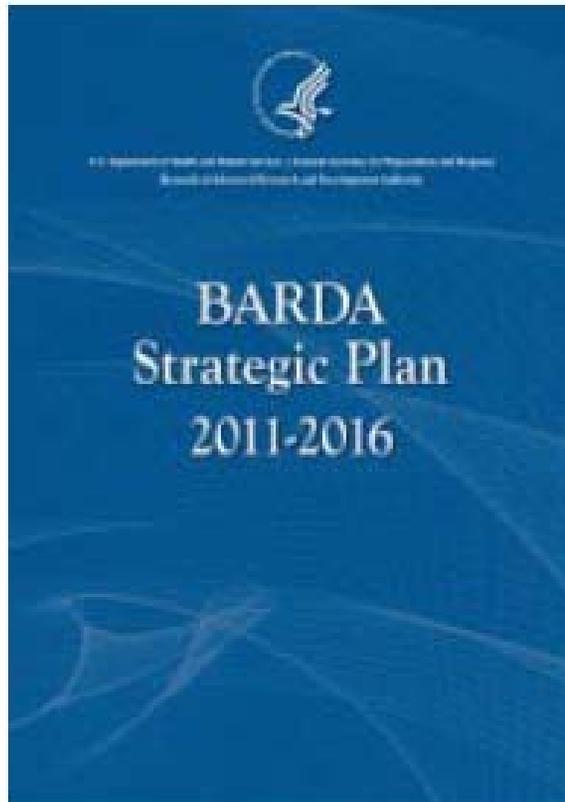
Goals

- Robust advanced development pipeline for all known CBRN threats
- Core service capability
- Robust domestic MCM manufacturing infrastructure
- Address MCM needs for emerging infectious diseases
- Nimble response capability to known & unknown threats
- Consistent with ASPR Strategic Plan, MCM Review, and other national plans

https://www.medicalcountermeasures.gov

CBRN Funding Mechanisms

- **Advanced R&D**
  - Broad agency announcements (BAA)
    - White papers and quad charts (first tier)
    - Full proposals by invitation (second tier)
    - Companies can submit full proposals at any time
    - No procurement of product
    - Cost plus fixed fee
  - Request for Proposals (RFP)
    - Allows for delivery of product in the contract
    - Cost plus fixed fee

- **Procurement Contracts under Project BioShield**
  - RFP
    - Procurement guided contracts
    - Product may be accepted once the sponsor has generated a data set sufficient for the potential use of the product during a declared emergency under Emergency Use Authorization
    - Fixed Price

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Interfacing with BARDA

- **www.hhs.gov/aspr/barda**
  - Program description, information, news, announcements

- **www.fedbizopps.gov**
  - Official announcements and detailed information about all government contract solicitations

- **www.medicalcountermeasures.gov** **(or www.phe.gov)**
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
    - http://www.phe.gov/Preparedness/mcm/phemce/Documents/2012-PHEMCE-Strategy.pdf
    - http://www.phe.gov/Preparedness/mcm/phemce/Documents/2012-PHEMCE-Implementation-Plan.pdf

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