BARDA Funding Opportunities:
Developing Medical Countermeasures

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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

Lengthy, risky and expensive product development

Prioritize medical countermeasure programs to effectively address mission goals

Strategies & dependencies for effective use

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

- **Antibiotics**
  - Anthrax
  - Bacterial Threats

- **Vaccines**
  - Smallpox
  - E. D.

- **Antitoxins**
  - Botulism

- **Ca- & Zn-DTPA**
  - Prussian Blue
  - Potassium Iodide
  - ARS Therapeutics

- **Burn/Blast Supplies**

- **Heptavalent Antitoxin**

- **CHEMPACKs**

Product Development Challenges

**Cost**
- Discovery: $$
- Development: $$$
- Procurement: $$$$ $$$
- Resupply: $$$$ $$$
- Maintenance: $$
- Warm Base: $$$

**Technical**
- Industry best practices predict that 1 candidate here...

**Administration**

**Regulatory**

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 prioritize 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
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
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.

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
Interfacing with BARDA

- [www.hhs.gov/aspr/barda](http://www.hhs.gov/aspr/barda)
  - Program description, information, news, announcements

- [www.fedbizopps.gov](http://www.fedbizopps.gov)
  - Official announcements and detailed information about all government contract solicitations

- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov) (or [www.phe.gov](http://www.phe.gov))
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch