



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response (ASPR)

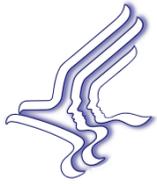


CBRN ADVANCED RESEARCH & DEVELOPMENT AND PROJECT BIOSHIELD (2004-2011)

Biomedical Advanced Research and Development Authority

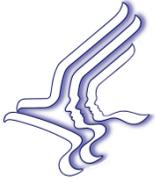
Gerald R. Kovacs, PhD
Director, Division of CBRN Medical Countermeasures
HHS/ASPR/BARDA

7 June 2011



ARE WE PREPARED?





OVERVIEW



- **BARDA Mission and Vision**
- **CBRN Drug Development Through the Years**
- **Key CBRN Legislation**
- **Implementation Plan and MCM Review**
- **Project BioShield Update**
- **New CBRN Portfolio and Strategies**



BARDA MISSION



Ensure the availability of countermeasures to address public health emergencies

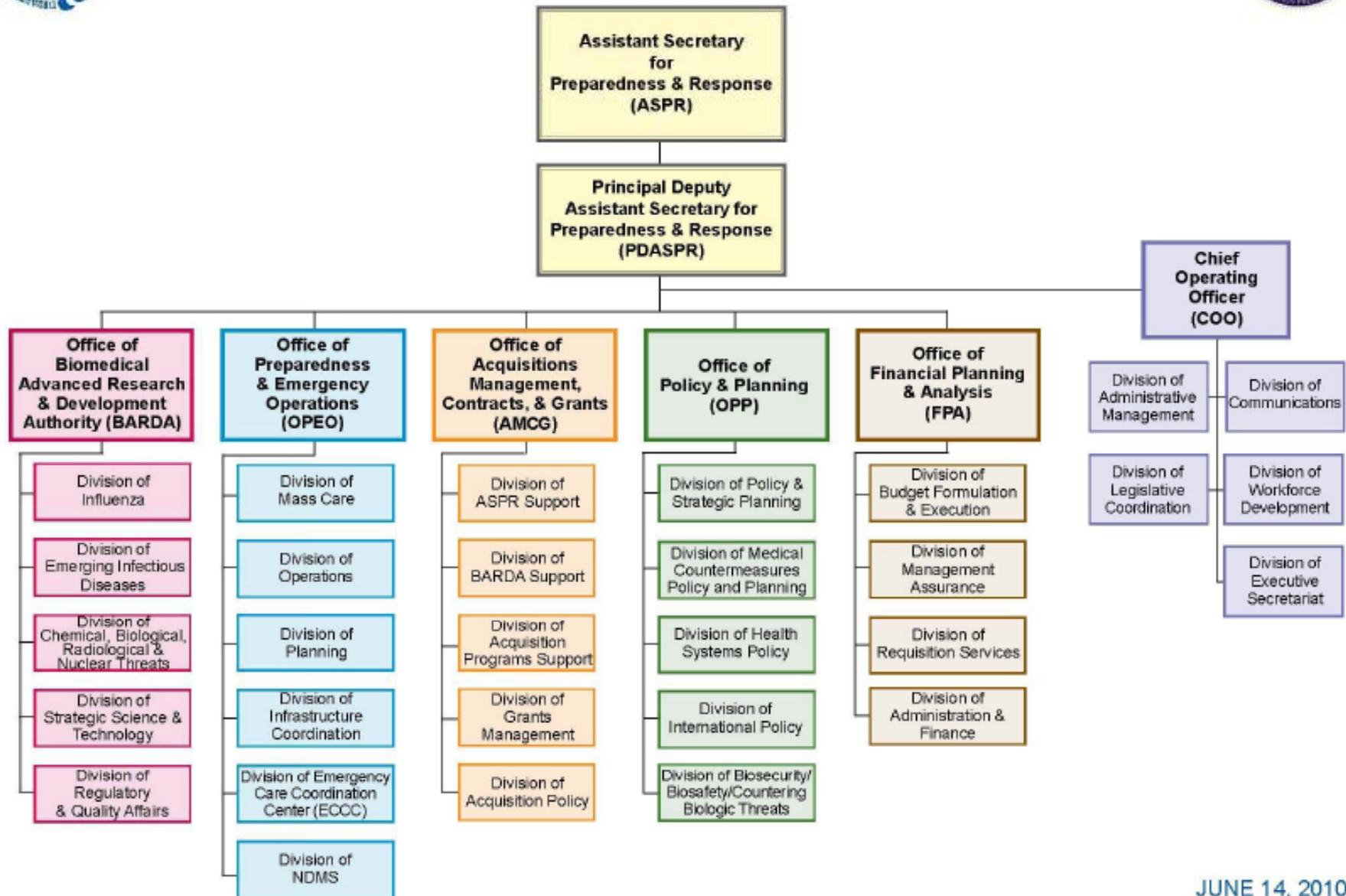
- **Three threat areas: Chem/Bio/Rad/Nuc, Pandemic Influenza, Emerging Infectious Diseases**
- **Comprehensive portfolio approach to development and acquisition of products**
- **Unique niche in USG biomedical R&D**
 - Mid- to late-stage product development
 - Work with industry to progress product candidates through the pipeline
 - Staff with experience in product development and manufacturing





Office of the Assistant Secretary for Preparedness & Response

ASPR ORGANIZATION STRUCTURE AS APPROVED BY THE HHS SECRETARY

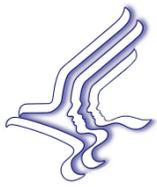


JUNE 14, 2010

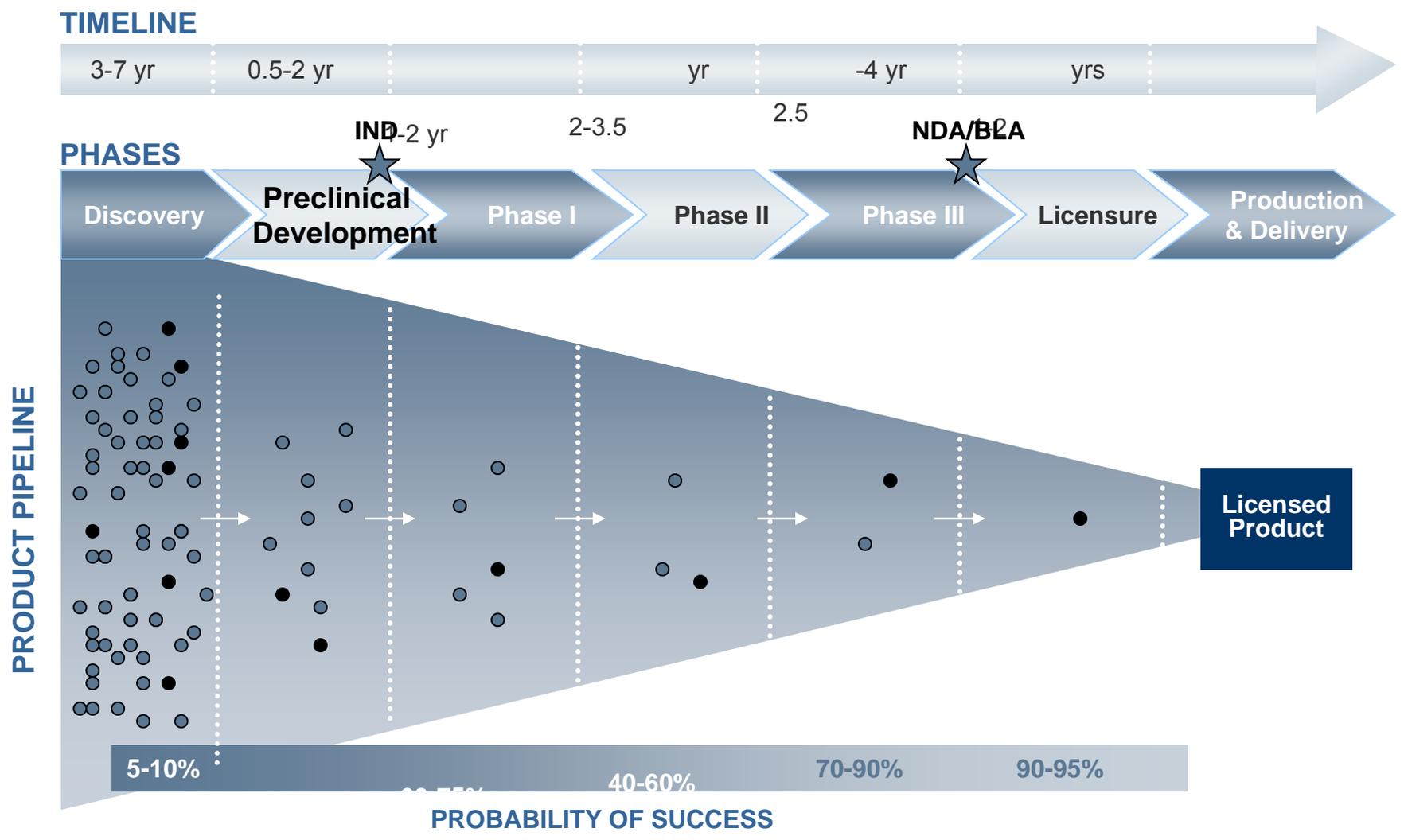


BACKGROUND

- MCM development is characterized by a severe **market failure**
 - Drug development is extraordinarily expensive, takes a very long time, and is associated with a great deal of risk
 - Medical countermeasures (MCMs) address critical threats to national security but have limited if any commercial value or markets
- The Special Reserve Fund of Project BioShield was established by Congress to provide a **market guarantee** to counter this market failure
 - Project BioShield also seeks to expedite MCM R&D and enhance the availability of needed products by providing FDA the authority to issue Emergency Use Authorizations for unlicensed products
- The goals of Congress were to
 - Provide the necessary funds and authority to address pressing public health and national security needs; and
 - Foster the development of a robust biodefense industry



CHALLENGE OF DRUG DEVELOPMENT





CIVILIAN BIODEFENSE



- Chapter 1: pre-9/11, 1950s – 2001
- Chapter 2: post-9/11 to Project BioShield, 2001 – 2004
- Chapter 3: Project BioShield and PAHPA, 2004 – 2006
- Chapter 4: ASPR, BARDA & H1N1, 2007 – 2009
- Chapter 5: Enterprise Transformation, 2010 →

Mid-1950's on:

9/11 terrorist

Project

PAHPA (Dec

2009-H1N1

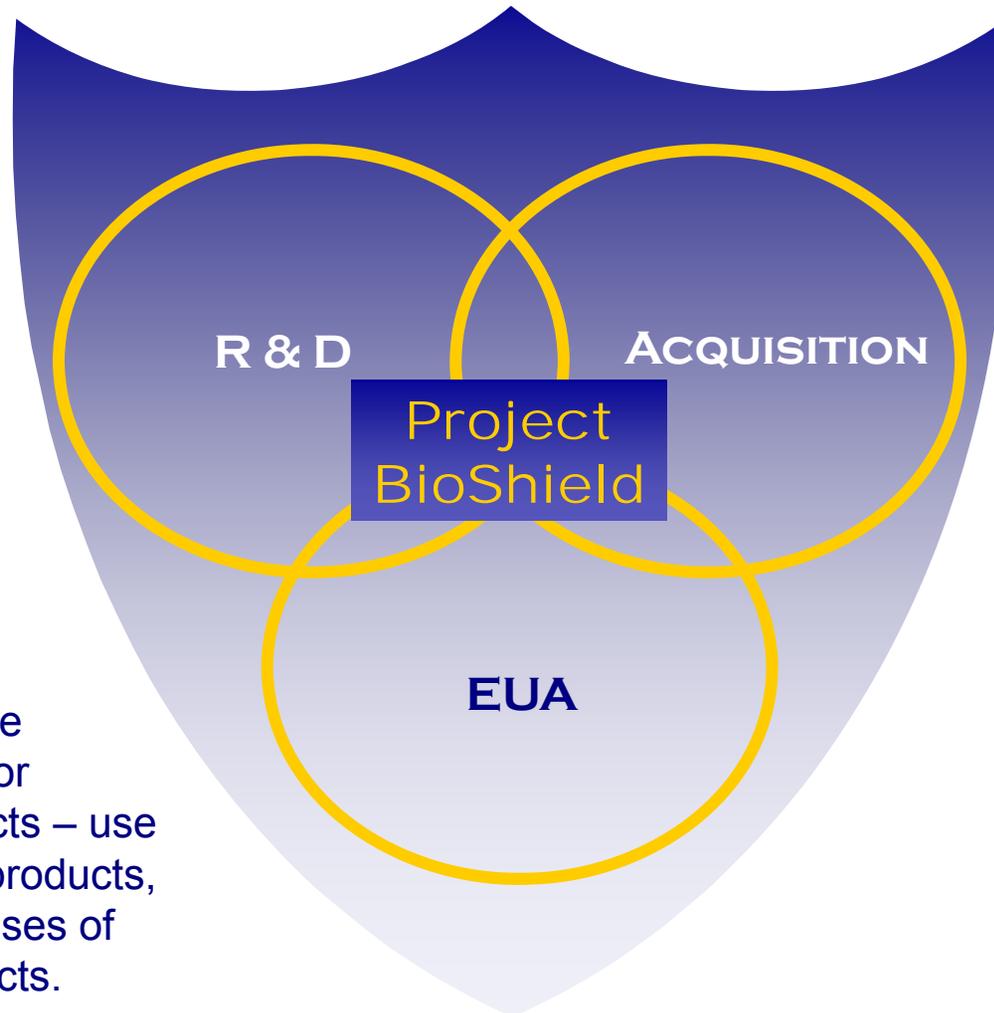


PROJECT BIOSHIELD 2004



Accelerated R&D:
Provided NIH/NIAID with new authorities for review and award of support for R&D of MCM.

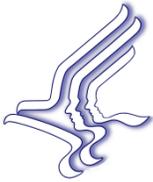
Availability:
Established Emergency Use Authorization for medical products – use of unlicensed products, or alternative uses of licensed products.



Acquisition:
Established secure funding source from FY04-FY13 for purchase of CBRN security countermeasures.

Authorized the \$5.6B **Special Reserve Fund** that had been established in the FY04 DHS Appropriations Bill (P.L. 108-90)

**Virtually all risk placed on the manufacturer.
Pipeline of product candidates not as mature as had been envisioned.
Market guarantee attracted primarily small biotech firms.**

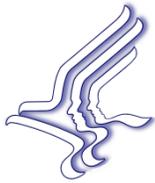


PANDEMIC AND ALL HAZARDS PREPAREDNESS ACT



Title IV: Pandemic and Biodefense Vaccine and Drug Development

- **Establishes the Biomedical Advanced Research and Development Authority (BARDA) to**
 - Facilitate collaboration among USG, industry, and academia
 - Support the advanced research and development of MCMs
 - Promote innovation to reduce time and cost of MCM
- **Establishes the Biodefense MCM Development Fund (Advanced Development)**
 - Fund development of products across so-called “Valley of Death”
 - Authorizes (not appropriated) \$1.07 billion for FY2006-2008
 - Reflects existing commitments in biodefense and pandemic flu initiatives
 - Separate from the preexisting BioShield Special Reserve Fund
- **Reforms to BioShield procurement program / New Authorities**
 - Advanced payments
 - Milestone payments
 - Anti-trust exemption



PHEMCE IMPLEMENTATION PLAN 2007



Near-Term FY 2007-08

- Broad-Spectrum Antibiotics
- Anthrax Vaccines
- Smallpox Vaccines
- Therapeutic Drugs for Acute Radiation Injury

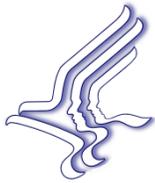
Mid-Term FY 2009-13

- Broad-Spectrum Antibiotics
- Diagnostics
- Anthrax Antitoxins
- Filovirus MCMs
- Smallpox Antivirals
- MCMs for ARS and DEARE
- Radionuclide-Specific MCMs
- Rad/Nuc: Biodosimetry/Bioassays
- Enterprise CHEMPACKS



Long-Term Beyond FY 2013

- Broad-Spectrum Antivirals
- Volatile Nerve Agent Antidotes

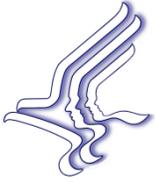


ENTERPRISE MCM REVIEW 2010



Key Initiatives

- 1. Expand Product Pipeline through Concept Acceleration Program (CAP) at NIAID**
- 2. Establish a Strategic Investment (SI) Fund to increase investments in commercial ventures with multi-use potential (BARDA & NIAID)**
- 3. Establish Centers for Innovation in Advanced Development and Manufacturing (BARDA)**
- 4. Investment in upgrading science capacity at FDA**



MCM ENTERPRISE VISION



“Our Nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized naturally occurring emerging infectious disease”

If a product fails, it should only be the result of failure of the product to achieve the desired safety or efficacy thresholds, and not as a function of our inability to provide the proper support from a technical, business and regulatory perspective



MATERIAL THREAT DETERMINATIONS



Material Threat = “sufficient to affect national security”

Radiological and Nuclear agents

Bacillus anthracis (anthrax)

Bacillus anthracis - multi-drug resistant (MDR anthrax)

Botulinum toxins (botulism)

Variola virus (smallpox)

Yersinia pestis (plague)

Franciscella tularensis (tularemia)

Hemorrhagic Fever Viruses - Ebola , Marburg, Junin

Burkholderia mallei (glanders)

Burkholderia pseudomallei (melioidosis)

Rickettsia prowazekii (typhus)

Volatile nerve agents [determination in progress]

Issued by Department
of Homeland Security

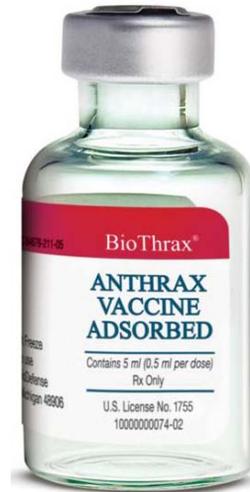
Required for Project
BioShield Contracts



PROJECT BIOSHIELD PRODUCTS



Smallpox



Anthrax

5 mL

Pentetate calcium trisodium injection
1000 mg

For intravenous or inhalation use only. See package insert for use information, and after use.

44639/19/05
Batch no.:
Exp. date:

5 mL

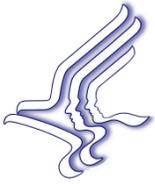
Pentetate zinc trisodium injection
1000 mg

For intravenous or inhalation use only. See package insert for use information. Single-use container - discard after use. Rx only.
hameln pharmaceuticals

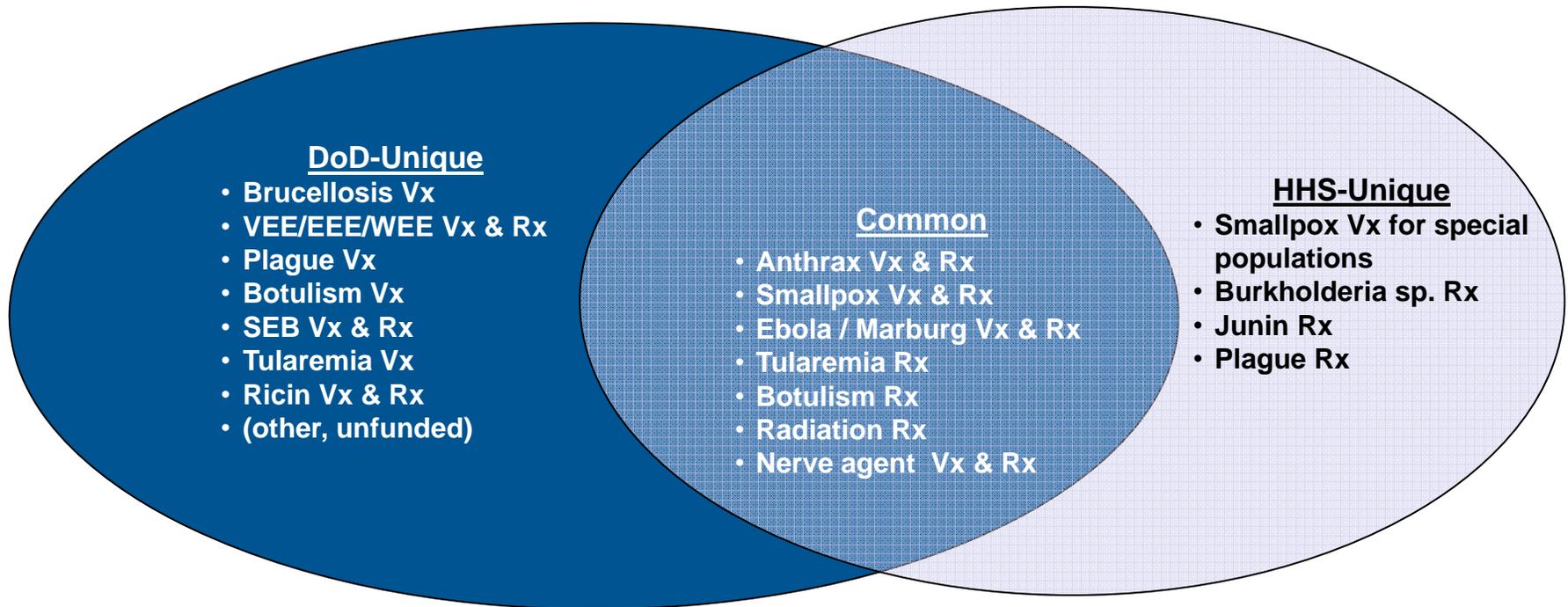
44635/19/05
Batch no.:
Exp. date:

Radiation



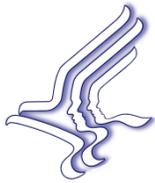


INTEGRATED PORTFOLIO FOR CBRN MEDICAL COUNTERMEASURES REQUIREMENTS



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

V_x = Prophylaxis R_x = Therapeutic



NEW PIPELINE OF PRODUCTS



- **Anthrax**

- Vaccines – novel adjuvants and formulations
- Antitoxins – enhanced affinity



- **Smallpox**

- Antivirals
- Vaccine enhancement



- **Hemorrhagic fever viruses**

- siRNA-based antivirals
- Post-exposure prophylactic vaccines



- **Broad-spectrum antimicrobials**

- Inhalational delivery systems



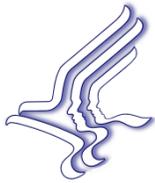
- **Radiation/Nuclear**

- Therapeutics: acute radiation syndrome & thermal burns
- Decorporation agents

- **Biodosimetry**

- Devices and assays





PUBLIC/PRIVATE PARTNERSHIPS FOR ANTIBIOTIC DEVELOPMENT



News Release

FOR IMMEDIATE RELEASE
Monday, August 30, 2010

Contact: HHS Press Office
(202) 690-634

BARDA funds drug development for biothreats, antibiotic resistance

\$27-\$64 million contract supports development of novel antibiotic with multiple uses

The U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) today awarded a contract to develop an antibiotic that could be used against possible two types of bioterrorism as well as common infections that are becoming resistant to antibiotics.

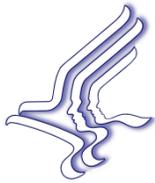
The contract to Achaogen Inc. of San Francisco is for \$27 million in the first two years. The contract can be extended annually for up to three years for a total of \$64 million.

The planned antibiotic, ACHN-490, would be a broad-spectrum antibiotic to treat plague and tularemia infections, both of which are possible bioterrorism agents. The antibiotic also could treat many infections that are becoming resistant to antibiotics. Antibiotic-resistant infections include some of the infections people get when they are hospitalized, including pneumonia from prolonged use of a ventilator and urinary tract infections from using a catheter for an extended period of time. Also under the contract, the company will conduct studies to show that the new antibiotic is safe for children, the elderly, and other special populations.

The contract uses the federal government's new approach to producing medical countermeasures – the medications, vaccines, medical equipment and supplies needed for a health emergency. On Aug. 19, HHS Secretary Kathleen Sebelius released an examination of the federal government's system to produce medical countermeasures, along with recommendations for a better approach. The recommendations included developing drugs that can be used for bioterrorism as well as common illnesses, and to develop more countermeasures that are safe for children, the elderly, and other vulnerable populations.

"This new antibiotic is part of our push against antibiotic resistance for certain bacterial infections, and at the same time could provide a new treatment for plague and tularemia biothreats," said BARDA Director Dr. Robin Robinson. "It's the first time BARDA research and development funds have been used in a multi-use approach like this."

The contract is the first under BARDA's Broad Spectrum Antimicrobial Program, one of six areas of advanced research and development that use a contracting tool called a broad agency announcement. The broad agency announcement provides a way to identify innovative and promising technologies that can be developed to protect Americans from chemical, biological, radiological and nuclear threats.



ENHANCING ANTHRAX VACCINE MANUFACTURING CAPACITY



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ASPR Awards \$54 Million to Support Making Anthrax Vaccine in U.S.

July 13, 2010

The U.S. Department of Health and Human Services' Assistant Secretary for Preparedness and Response today announced a \$54 million multiple year contract with Emergent BioDefense Operations Lansing (EBOL), a subsidiary of Emergent BioSolutions Inc., to support the development of domestic manufacturing capacity for anthrax vaccine.

The contract supports development of a process to manufacture vaccine in the company's Lansing, Mich. facility by funding studies to support validation of the process and by funding scientific studies of the safety and effectiveness of vaccine manufactured under this contract. This data will support the filing of a supplement to the FDA license for BioThrax anthrax vaccine manufactured in the new facility. If product is licensed from the Michigan facility, the manufacturing capacity for anthrax vaccine will increase manifold.

"Today we are taking an important step in anthrax preparedness," said Dr. Robin Robinson, director of ASPR's Biomedical Advanced Research and Development Authority (BARDA) which will oversee the contract. "The current requirement is to have vaccine available for 25 million people – enough for the largest U.S. cities – in the event of an anthrax incident. This facility will help achieve this goal by building domestic manufacturing capacity for this product."

The contract also represents a public-private partnership, part of BARDA's strategy to support public health preparedness and emergency response. In a bioterrorism attack, the nation would need surge capacity to make medications, vaccines, medical equipment and supplies quickly.

BARDA, within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides a comprehensive integrated portfolio approach to the advanced research and development, stockpile acquisition, innovation, and manufacturing infrastructure building of the necessary vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health medical emergencies including chemical, biological, radiological, and nuclear threats, and pandemic influenza, and emerging infectious diseases.

Information on medical countermeasures, including this contract, can be found at <https://www.medicalcountermeasures.gov>.

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DEVELOPMENT OF TECHNOLOGIES THAT ACCELERATE THE IMMUNE RESPONSE TO BIODEFENSE VACCINES
 Solicitation Number: BAA-NIAID-DMID-NIHAI2010103
 Agency: Department of Health and Human Services
 Office: National Institutes of Health
 Location: National Institute of Allergy and Infectious Diseases

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GENERAL INFORMATION
 Notice Type: Presolicitation
 Original Posted Date: March 10, 2011
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Mar 10, 2011
3:02 pm
- Changed
Mar 23, 2011

Solicitation Number: BAA-NIAID-DMID-NIHAI2010103
 Notice Type: Presolicitation
 Synopsis:
 Added: Mar 10, 2011 3:02 pm Modified: Mar 25, 2011 4:36 pm [Track](#)



BARDA-CBRN-BAA-11-100-SOL-00009
 Solicitation Number: BARDA-CBRN-BAA-11-100-SOL-00009
 Agency: Department of Health and Human Services
 Office: Office of the Secretary
 Location: Acquisitions Management, Contracts, & Grants (AMCG)

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 Solicitation 1
 Mar 04, 2011
 BARDA CBRN BAA- 11-1...
 Presentation from Pre-proposal Meeting - 3/23/11
 Mar 23, 2011
 Presentation Slides...

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Presolicitation
Feb 18, 2011
4:59 pm
- Changed
Mar 04, 2011
7:42 pm
Solicitation

Solicitation Number: BARDA-CBRN-BAA-11-100-SOL-00009
 Notice Type: Solicitation
 Synopsis:
 Added: Feb 18, 2011 4:59 pm
 BARDA encourages the advanced research, development and

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Science and Technology Platforms Applied to Medical Countermeasure (MCM) Development
 Solicitation Number: BARDA_BAA_11-100-SOL-00001
 Agency: Department of Health and Human Services
 Office: Office of the Secretary
 Location: Acquisitions Management, Contracts, & Grants (AMCG)

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 Posted Date: February 28, 2011
 Response Date:

- Original Synopsis
Presolicitation
Nov 22, 2010
3:17 pm
- Changed
Dec 09, 2010
4:08 pm
Solicitation
- Changed
Feb 28, 2011
2:54 pm

Solicitation Number: BARDA_BAA_11-100-SOL-00001
 Notice Type: Solicitation
 Synopsis:
 Added: Nov 22, 2010 3:17 pm Modified: Feb 28, 2011 2:50 pm [Track](#)
[Changes](#)
 BARDA - Strategic Science and Technology Division
 Broad Agency Announcement Synopsis Notice
 Science and Technology Platforms Applied to Medical Countermeasure (MCM) Development



BARDA Broad Agency Announcement for Advanced Research and Development of Medical Countermeasures for Pandemic Influenza
 Solicitation Number: BAA-BARDA-11-100-SOL-00013
 Agency: Department of Health and Human Services
 Office: Office of the Secretary
 Location: Acquisitions Management, Contracts, & Grants (AMCG)

Notice Details Packages Interested Vendors List Print Link

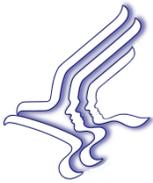
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 Original Posted Date: March 10, 2011
 Posted Date: April 5, 2011
 Response Date:
 Original Response Date:
 Archiving Policy: Manual Archive
 Original Archive Date:

- Original Synopsis
Presolicitation
Mar 10, 2011
5:32 pm
- Changed
Apr 05, 2011
3:27 pm

Solicitation Number: BAA-BARDA-11-100-SOL-00013
 Notice Type: Presolicitation / Cancelled
 Synopsis:
 Added: Mar 10, 2011 5:32 pm
 BARDA is the lead federal agency for the advanced development of medical countermeasures (MCM) to protect the United States against public health emergency threats, including chemical, biological, radiological and nuclear agents, emerging infectious diseases, and pandemic



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BARDA Animal Model Development of Chemical, Biological, Radiological, and Nuclear; Influenza; and Emerging Infectious Disease Medical Countermeasures

Solicitation Number: RFP-BARDA-10-100-SOL-00025
 Agency: Department of Health and Human Services
 Office: Office of the Secretary
 Location: Acquisitions Management, Contracts, & Grants (AMCG)

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Aug 13, 2010 2:15 pm
- [Changed](#)
Sep 17, 2010 5:06 pm
- [Changed](#)
Sep 17, 2010 5:12 pm
- [Changed](#)
Sep 23, 2010

Solicitation Number: RFP-BARDA-10-100-SOL-00025
Notice Type: Presolicitation

Synopsis:
 Added: Aug 13, 2010 2:15 pm
 The Department of Health and Human Services(HHS) through the Biomedical Advanced Research and Development Authority (BARDA) requires the development of animal models for the development of medical countermeasures for Chemical, Biological, Radiological, Nuclear (CBRN); Influenza; and Emerging Infectious Diseases. The mission and priorities of the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) are articulated in the PHEMCE

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Centers for Innovation in Advanced Development and Manufacturing

Solicitation Number: 11-100-SOL-00011
 Agency: Department of Health and Human Services
 Office: Office of the Secretary
 Location: Acquisitions Management, Contracts, & Grants (AMCG)

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- [Original Synopsis](#)
Presolicitation
Mar 02, 2011 10:25 am
- [Changed](#)
Mar 30, 2011 2:29 pm
Solicitation

Solicitation Number: 11-100-SOL-00011
Notice Type: Solicitation

Synopsis:
 Added: Mar 02, 2011 10:25 am
 TITLE: Centers for Innovation in Advanced Development and Manufacturing
 SOLICITATION NO: 11-100-SOL-00011

NAICS Code: 236210

Closes June 29, 2011

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Mar 30, 2011
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- [HHS RFP 11-100-SOL-0...](#)

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Notice Type:
Solicitation

Original Posted Date:
March 2, 2011

Posted Date:
March 30, 2011

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