



**United States Department of**

**Health & Human Services**

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

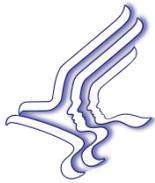
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# **Anthrax Vaccine Countermeasures**

**Biomedical Advanced Research and Development Authority (BARDA)**

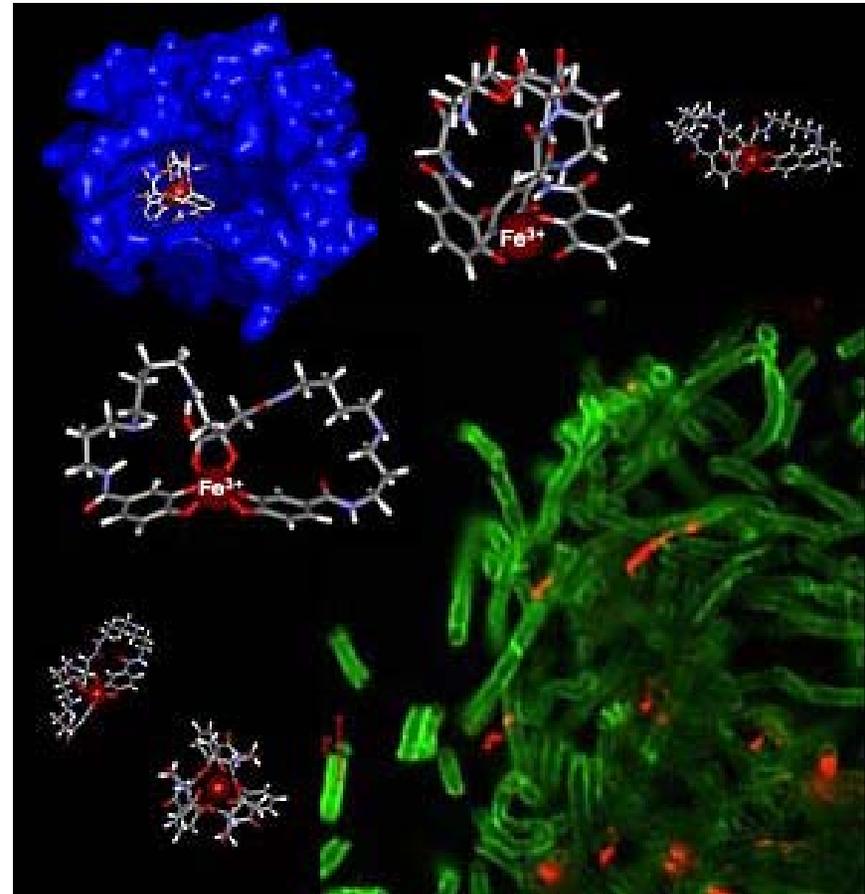
**Tom Dreier, PhD  
Subject Matter Expert  
HHS/ASPR/BARDA**

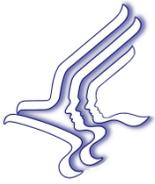


# Outline



- *The Threat*
- Requirements
- Current Program
  - Near term
  - Mid term
  - Long term
- Technical Issue of BAA
- Working with BARDA



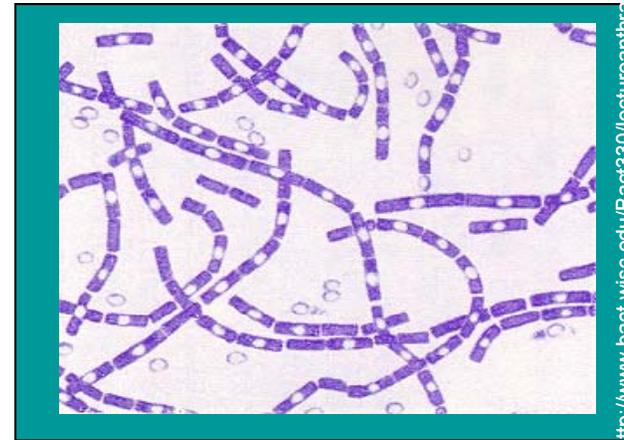


# *Bacillus anthracis* the Threat

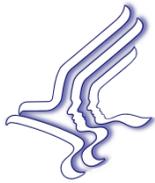


- **General**

- Gram positive spore forming bacterium
- Resulting disease – Anthrax
- Naturally occurring zoonotic disease



- ID50 – 3000 spores
- 1-6 day incubation period
- Non-contagious
- Highly stable
- Easily mass produced

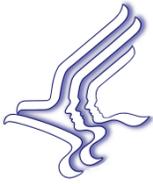


# Anthrax Vaccines Program Alignment with Overall CBRN Strategies

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- **BARDA is building a balanced and diversified portfolio of anthrax countermeasures**
  - Antibiotics
  - Antitoxins
  - Vaccines
- **HHS Requirement to procure sufficient vaccine to protect 25M people**
- **Programs are supported by:**
  - Advanced Research and Development
  - Project BioShield Special Reserve Fund



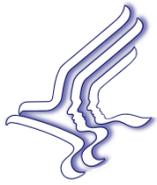
# Anthrax Vaccines

## *Current and Near Term Preparedness*



- **Procurement of BioThrax® (AVA) has transitioned to the SNS**
- **Obtain extended expiry dating**
- **Label claim for PEP**
- **Evaluating Public Health Preparedness**



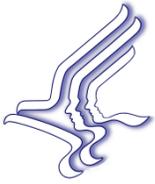


# Public Health Preparedness



- **Evaluation of dose and antigen sparing**
- **Schedule**
- **Pediatrics and other special populations**



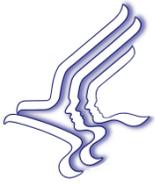


# Anthrax Vaccine Adjuvant and Stabilization - Mid Term



- Potential to decrease antigen and/or dose
- Expands stockpile





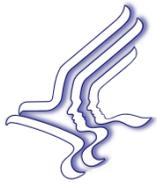
# Expanded Manufacturing – Mid Term



- Builds on AVA database
- Facility Validation
- Increases capacity to from 8 M to 26M doses/yr



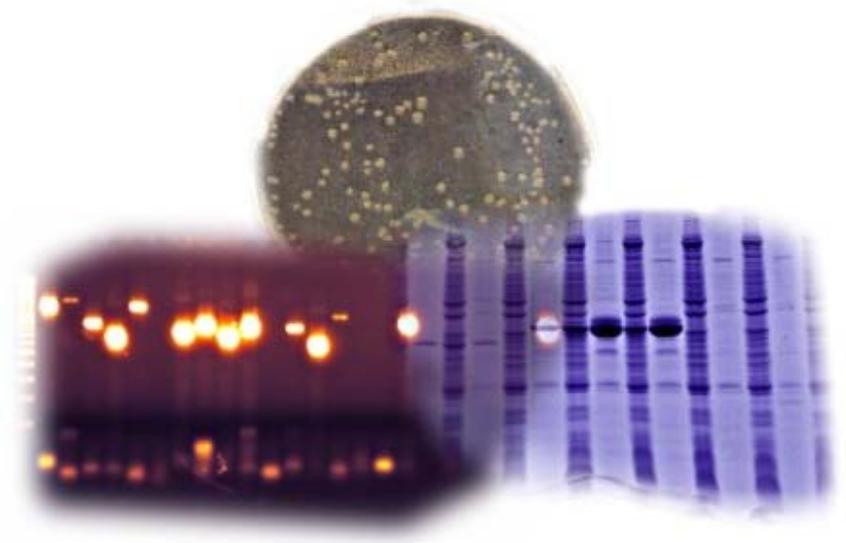
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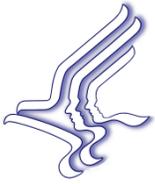


## rPA Based LongTerm



- Broadens manufacturing capabilities
- Reduces reliance on one product/manufacturer



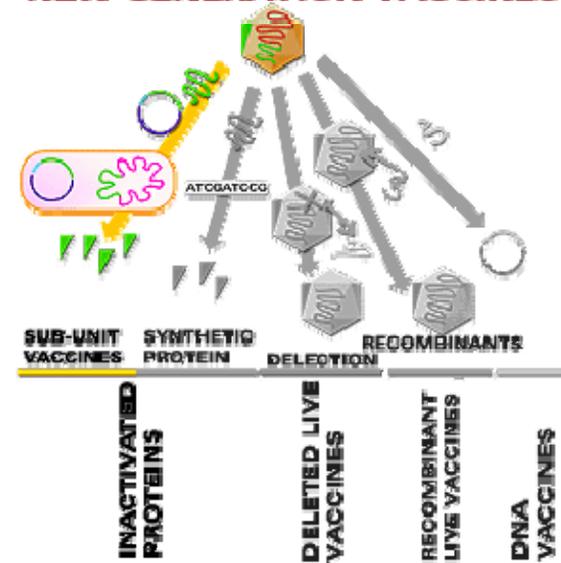


# Novel Technologies – Long Term



- Maintains pipeline of MCMs for future platforms
- Better delivery systems
- Supported by the NIH Tech Base

## NEW GENERATION VACCINES



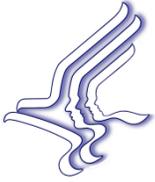


# Working with BARDA Advanced Development—CBRN BAA

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- **Opportunities to address anthrax vaccine needs within the CBRN BAA**
  - **Area 1: Vaccines and vaccine enhancements**
    - Improvements to current vaccines and other vaccine candidates at TRL-6 and above (pending availability of funds)
    - Interested in new approaches
    - Organizations should:
      - Demonstrate immunogenicity in one animal
      - Understand the manufacturing process at small scale
      - Determined one year stability
      - Define appropriate assay for potency, stability, and manufacturing



# Anthrax Vaccine Successes



- **PEP animal model**
- **New rPA vaccine contracts**
- **In conjunction with NIH several contract evaluating adjuvant and stability enhancing capabilities**
- **Under the platform BAA – evaluating another rPA expression platform**
- **BARDA resources available to support contractors**



# Working with BARDA

- **BARDA awards contracts**
  - Generally one year base with option years
  - Milestones
  - Deliverables
- **Project Coordination Team (PCT)**
  - Each contract has a unique BARDA PCT
  - Structure (matrix organized)
    - Contracting Officer (CO)
    - Project Officer (PO)
    - Manufacturing SME
    - Animal Model SME
    - Assay SME
    - Quality
    - Earned Value Management

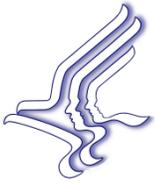




# PCT Objectives



- **PCT provide recommendation to the CO related to the contract**
  - Only the CO can change the contract (should be done in writing)
- **PCT provides technical information up the chain of command**
  - Assessment project status
  - Justification for funding
  - Coordination of intra-agency concerns
- **Intent of PCT is to leverage what has been learned**



# Interaction with PCT for Success

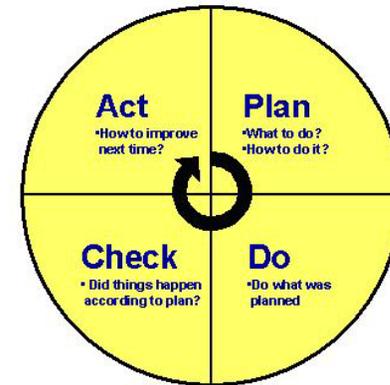


- **Plan ahead**

- Map out all major projects
- Be realistic

- **Communications**

- Provide honest and timely information
- Inform BARDA of problems
- Support path forward with data
- Oral presentations should be supported by a written report
- Scheduled meetings should include the key players





- **How to apply:**

- Go to [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Click on Procurement and Grant Opportunities
  - Scroll down and click on CBRN Funding Activities
  - Click on link for 2011 Broad Agency Announcement
  
- Or go to <https://www.fbo.gov/>
  - Search **BARDA-CBRN-BAA-11-100-SOL-00009**
  
- Technical POC for Research Area #1: Vaccines  
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