

# **Anthrax Working Group**

**Dale Morse, MD, MS**

**Advisory Committee on Immunization Practices**

**October 23, 2008**

# Working Group Members

- Rob Beck - ACIP
- Col Ciselak – DoD
- LTC Garman – DoD
- Col Hachey - DoD
- Jeff Duchin – NACCHO
- Nelson Arboleda – ISO
- David Kimble – AAP
- Rich Beigi - ACOG
- Ed Nuzum – NIH
- Julianne Clifford – FDA
- Alexandra Worobec – FDA
- Christopher Chase - AVMA
- Monique Mansoura - HHS
- Ken Miller – IAB\*
- Ken Chase – ACOEM\*
- Jennifer Wright
- Nancy Messonier
- Conrad Quinn
- LTC Cynthia Thomas
- Brian Plikaytis
- Stacey Martin
- Chuck Rose
- Mike McNeil
- Mary Ari
- Nikki Pesik
- Renee Funk - NIOSH
- Rita Traxler
- John Grabenstein
- Paul Offit

\*consultants for responder discussion

# Anthrax Vaccine Adsorbed (AVA)

- **Anthrax Vaccine Adsorbed, USP (AVA)**
  - Only FDA approved product to prevent anthrax pre-exposure
  - Made from a sterile, cell-free filtrate of avirulent, non-encapsulated *B. anthracis*\*
  - Aluminum hydroxide precipitate
  - Manufactured by Emergent BioSolutions
- **Primes the immune system to recognize and block “protective antigen”**

\*[http://www.emergentbiosolutions.com/pdf/emergent\\_biothrax\\_us.pdf](http://www.emergentbiosolutions.com/pdf/emergent_biothrax_us.pdf)

# **Terms of Reference**

## **Anthrax Vaccine Adsorbed (AVA), Emergent BioSolutions**

- 1. Review existing 2000 statement and 2002 supplement**
- 2. Review new data on AVA including:**
  - a. Safety and immunogenicity data from an interim analysis of CDC's dose reduction and route change study in anticipation of FDA evaluation of Emergent Biosolutions' BLA**
  - b. Recently published safety studies**
  - c. Publications detailing the 2001 anthrax attacks**
  - d. Post exposure prophylaxis with vaccine and antibiotics**
  - e. Pre-exposure vaccination**
- 3. Revise existing statement and supplement into a single document**

# 2000 ACIP Recommendations\*

- **Pre-exposure vaccination**
  - Routine vaccination indicated for groups at high risk of exposure to *B. anthracis*
  - 6 doses administered subcutaneously, annual boosters
- **Post-exposure prophylaxis**
  - Recommended following aerosol exposure to *B. anthracis* spores
  - If available, 3 doses of vaccine (0, 2, 4 weeks)
  - Antimicrobial therapy up to 60 days

\*CDC. Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep. 2000 Dec 15;49(RR15):1-20.

# 2002 Supplement\*

- Recommendations on using anthrax vaccine in response to terrorism
- Recommended that groups at repeated risk for exposure (i.e., LRN personnel in certain situations, remediation workers) be given priority for pre-exposure vaccination
- Endorsed the use of a 3-dose vaccine regimen plus antimicrobials under an IND for post-exposure use in civilians

\*CDC. Use of Anthrax Vaccine in Response to Terrorism: Supplemental Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep. 2002 Nov 15;51(45):1024-6.

# Activities of Working Group

## Since October 2007 formation

- Reviewed:
  - Clinical trial data evaluating AVA safety and immunogenicity
  - Recent publications of DoD safety experience, to include ongoing Vaccine Healthcare Center (VHC) research
  - DoD programmatic experience
  - Concerns surrounding vaccine safety and efficacy
  - 2000/2002 recommendations regarding first responders
  - Data on birth outcomes for women inadvertently vaccinated during pregnancy
  - Post-Exposure Prophylaxis regimen

# Objectives of Today's Anthrax Session

- Review data regarding potential licensure change
  - Suspense date December 2008
  - If approved, brought before ACIP in February 2009
- Present data regarding birth outcomes for women inadvertently vaccinated during pregnancy
- Present WG recommendations for:
  - Pre-event use of AVA
  - Post-exposure use of AVA
  - Use of AVA in Pregnant/Breastfeeding Women
- Request a vote on new recommendations