

Anthrax Working Group

Dale Morse, MD, MS

Advisory Committee on Immunization Practices

June 26, 2008

Working Group Members

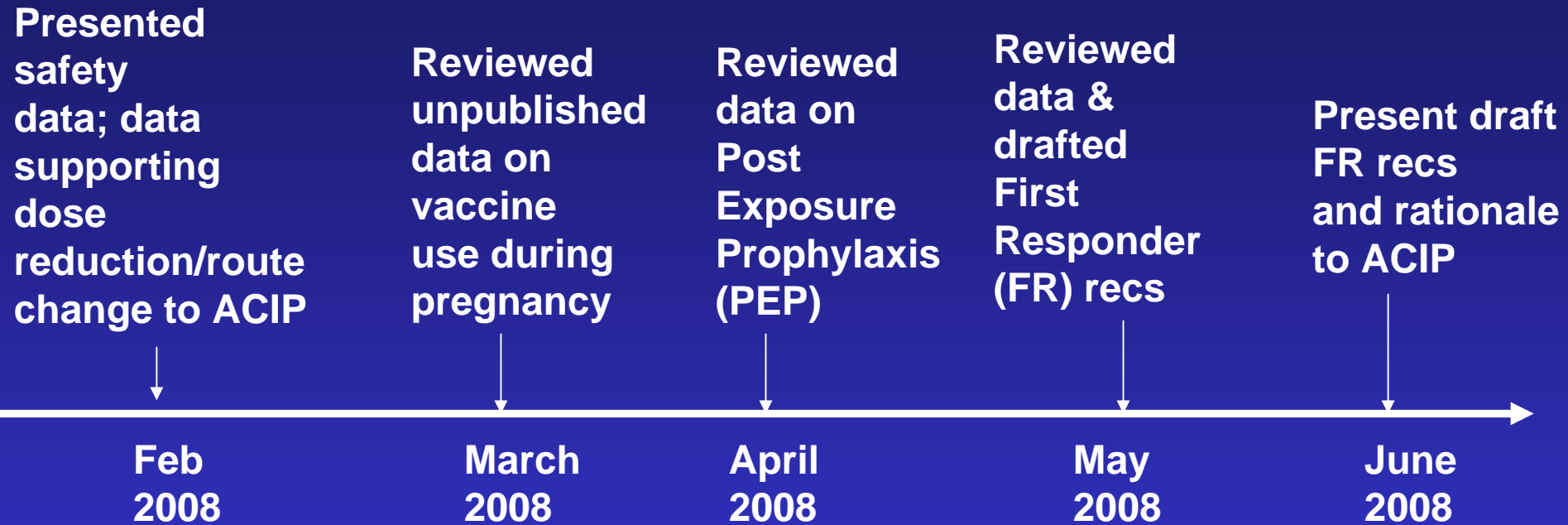
- Rob Beck - ACIP
- Col Ciselak – DoD
- LTC Garman – DoD
- Col Hachey - DoD
- Jeff Duchin – NACCHO
- David Kimbell – AAP
- Richard Beigi - ACOG
- Nelson Arboleda – ISO
- Ed Nuzum – NIH
- Julianne Clifford – FDA
- Alexandra Worobec – FDA
- Christopher Chase - AVMA
- Jennifer Wright
- Nancy Messonnier
- Conrad Quinn
- Brian Plikaytis
- Stacey Martin
- Chuck Rose
- Mike McNeil
- Kate Glynn
- Nikki Pesik
- Renee Funk
- Rita Traxler
- John Grabenstein
- Paul Offit

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**

Timeline and Activities



Timeline and Activities

Continue
work
on new
statement

Review
information
regarding
“missed
doses” &
draft recs

Draft
PEP
recs;
review
statement

Present to ACIP:

1. Draft statement
2. Draft pregnancy recs
3. Draft missed doses recs
4. Draft PEP recs
5. Vote on FR recs
6. Vote on other draft recs?

July
2008

August
2008

September
2008

October
2008

Objectives of Today's Anthrax Session

- **Provide background information on the use of vaccine pre-event in additional populations**
 - Present draft recommendations for the use of AVA in first responder organizations
- **Receive feedback from the ACIP on the option recommended by the WG**
 - Vote expected in October