Anti-Infectives Advisory Committee
July 28, 2000

- How we got here
- What is different

Dianne Murphy, MD

Bioterrorism
Presidential Directive 62
May 18, 1998

Orders federal agencies to take significantly expanded and better coordinated steps to protect against the consequences of biological and other unconventional attacks.

HHS Efforts

- Improving the nation's surveillance network
- Strengthening medical response capacities
- Creating and maintaining a stockpile of pharmaceuticals for mass treatment
- Expanding research into the disease agents and into improved treatment

Research & Development

- Expand support for agents related to bioterrorism
- Emphasis on anthrax, tularemia and plague

National Pharmaceutical Stockpile

- Determine Products
- Development of Stockpile
  - **Deliverable within 24 hours**
  - **adequate monitoring and record-keeping**
  - **FDA: IND products**

IND Products

OPTIONS

1. Identify "streamlining" of IND process for use in mass casualty event
2. Identify marketed products which do not have the indication for treatment of the agent in bioterrorist event but which may be appropriate for labeling
3. Identify marketed products which may need additional other studies

How is the Process Different

1. This was a FDA initiated process
   - FDA reviewed public data and professional recommendations
   - FDA determined a need for submission of data
   - FDA requested:
     - Sponsor's submission of an application
     - Investigators and sponsors participation

How is the Process Different
(continued)

2. Unique indication for unique situation
   - questionable appropriateness of an IND process for a marketed product with extensive safety record and
   - additional other studies including significant animal study of inhalation anthrax
   - ethically unacceptable to conduct trials with the organism in humans

How is the Process Different
(continued)

3. The body of evidence is different
   - large body of clinical safety information
   - animal studies
   - PK/PD data: Animal and Human
   - In vitro microbiologic data

How is the Process Different
(continued)

4. FDA will provide both its assessment of the body of evidence and recommendation:
   - usually we do not provide a recommendation
   - seeking an expert discussion of our assessment

FDA Scientists

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