Asked to offer a few introductory comments. From soon after the events of 9/11, I have been personally immersed in assuring that the U.S. had sufficient smallpox vaccine to meet its own needs and to assure control of outbreak wherever. Plus we have been concerned re: anthrax vaccine; off-label use of antibiotics for various diseases. Development of a new recombinant anthrax vaccine. I have been astonished by the difficulties we have encountered in our regulatory system to accomplish the simplest initiatives, however well-founded scientifically. The system isn't broken but it has become clear that it is ill-constructed to deal with emergency issues.

Ethics and Bioterror Vaccines

World Vaccine Congress
Lyon, France
29 September 2003

D.A.Henderson, MD, MPH
Johns Hopkins University

Problem 1:

The testing and licensure of products that have little utility absent an exposure to rare or emerging biological agents.

- Smallpox, plague, anthrax vaccines
- Antibiotics against plague and anthrax
- Antiviral substances vs. smallpox
- SARS vaccine or antiviral drug

Problem 2:

- The emergency use of unlicensed products
  - Smallpox vaccine
  - Off-label use of antibiotics for anthrax, plague, other bacteria
  - SARS vaccine or drug

The Basic Dilemma

"Balancing incommensurable values and uncertain societal risks"

Taylor and Faden "Ethical Considerations in the Formation of Smallpox Vaccine Policy" *Biosecurity and Bioterrorism 1:47-52, 2003*

Ethical Considerations

- Respect for individual choice
- Minimize harms; maximize benefits
- Distribute benefits and burdens equitably
- Honor ethical research standards
- Enhance and preserve the public trust
- Distribute benefits and burdens fairly

- Judgments may need to be made in the face of extraordinary uncertainties. Moral considerations can help inform these judgments but there is no substitute for public debate and careful deliberation.

Taylor and Faden

- Under epidemic circumstances "it may not only be morally permissible, but even morally obligatory, to step back from standard IND consent practices in the interest of stopping an epidemic"

Taylor and Faden

- For the burden of decision making to rest primarily or ultimately with regulatory authorities is unfair and unwarranted.
- Decision-making must weigh the substantive inputs from the national security, public health and bioethics communities

from Moreno, A New World order for Human Experiments (2002)