

# NBSB

## Pandemic Influenza Working Group

Arlington, VA  
June 18<sup>th</sup>, 2008



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## WG Charge & Representation

**MISSION:** The NBSB working group on Pandemic Influenza (PIWG) will consider scientific progress and policy options regarding the research and development portfolio of medical countermeasures, supplies, and product utilization to prevent, treat and mitigate the effects of a novel strain of human influenza during a pandemic. Other issues related to pandemic influenza may be considered by the PIWG as they arise.

**NBSB Voting Members:**

Andrew Pavia, Chair  
  
Ruth Berkelman  
Roberta Carlin  
Stephen Cantrill  
Albert Di Rienzo  
John Grabenstein  
Eric Rose

**Federal Representatives:**

Joseph Anelli, USDA  
Bruce Gellin, HHS/NVPO  
Robin Robinson, HHS/BARDA  
Stephen Redd, HHS/CDC  
Dorothy Wawrose, HHS/FDA  
Hillery Harvey, HHS/NIAID  
Carter Mecher, HSC



1. Evaluate the process and coordination of scientific and funding decisions across HHS to ensure that there is thoughtful development of a coordinated strategy.
2. Assess the capabilities of HHS advisory bodies to review and provide rapid advice on emerging data and issues such as vaccine efficacy, adverse events related to antivirals, vaccines, or real-time epidemiological data. Develop recommendations for improved rapid evaluation and response.



- Within the basic research area, about 50% of the grant portfolio is investigator-initiated grants and 50% is in response to RFAs (requests for applications, a grant mechanism).
- Initiatives such as RFAs and RFPs (requests for proposals, a contract mechanism) have to go through multiple layers of comment and review prior to their issuance.



# NBSB Strategic Planning at NIAID

- NIAID has an internal coordination through a frequently updated document that provides Dr. Fauci with an overview of coordination, progress, and plans.
  - Any project that is planning to go forward in the Vaccine and Treatment Evaluation Units (VTEU) is vetted by senior NIAID staff, clinical staff and regulatory staff who make sure that the investigators have the work at the appropriate point for use in the VTEU.
- If HHS has a particular interest in a particular area, that area assumes priority.
  - The Director of DMID meets on a monthly basis with the Respiratory Disease's Branch Chief and the Director of BARDA to go over progress, needs and priorities.
- NIAID has been working with BARDA on a study to compare the immunogenicity of different commercial adjuvants when mixed with different influenza vaccines (mix and match study)

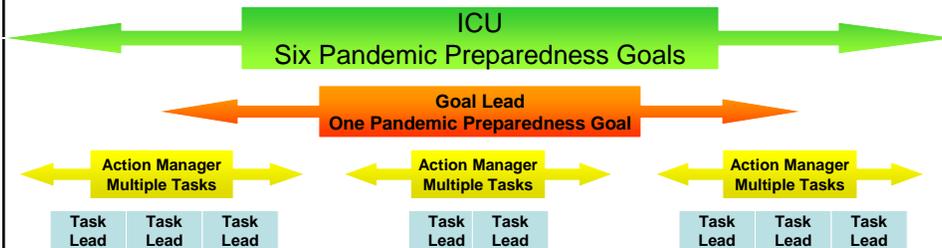


# NBSB Strategic Planning at FDA

- FDA's Role in Pandemic Influenza Preparedness
  - Facilitate development and availability of medical countermeasures.
  - Protect the safety and security of regulated medical products.
  - Enhance emergency preparedness and response capabilities.
  - Implement comprehensive food and feed security strategy.
  - Ensure safety and security of agency assets.
- FDA Task Force on Pandemic Influenza Preparedness
  - Cross-functional, intra-agency team
- Focus on initiatives to proactively facilitate or accelerate development, production and regulatory review of:
  - Vaccines, antivirals, diagnostics and other devices, including personal protective equipment
- Food and animal feed issues in coordination with USDA
- Collaboration with foreign counterpart regulatory agencies and international organizations
- Emergency Preparedness, Response and Communication
- Enforcement
  - Actions to curtail marketing and distribution of counterfeit or mislabeled products



**Project Management Hierarchy**



- CDC Influenza Pandemic Preparedness Responsibilities: > 900 tasks
- Six Pandemic Preparedness goals derived from Nine All-Hazards Preparedness Goals
- Exercise program designed to test operational plan. Reviews and After Action Reports generate new tasks
- > 70% of tasks completed



- **Assess the capabilities of HHS advisory bodies to review and provide rapid advice on emerging data and issues such as vaccine efficacy, adverse events related to antivirals, vaccines, or real-time epidemiological data.**
  - *The role and ability of committees to provide rapid advice during a pandemic is unclear. Only ACIP has experience in rapid evaluation and response*



**Sources of Expertise within HHS:**

- Vaccines
  - Advisory Committee on Immunization Practices (CDC)
  - National Vaccine Advisory Committee (HHS)
  - Vaccines and Related Biological Products Advisory Committee (FDA)
- Antivirals
  - Advisory Committee on Immunization Practices (CDC)
  - Antiviral Drugs Advisory Committee (FDA)
  - Drug Safety and Risk Management Advisory Committee (FDA)
- Infection Control, Secondary Infections
  - Anti-infective Drugs Advisory Committee (FDA)
  - Health Infection Control Practices Advisory Committee (CDC)
- Broader Scientific Expertise
  - National Biodefense Science Board (HHS)
  - NIAID Scientific Council
  - Centers of Excellence in Influenza Research and Surveillance Network Executive Committee (NIAID)
- Legal, liability, payment:
  - Practicing Physicians Advisory Council (CMS)
  - Emergency Medical Treatment and Labor Act Technical Advisory Group (CMS)
  - Others?

**Additional Sources of Expertise Outside of HHS:**

- Defense Health Board (formerly Armed Forces Epidemiological Board; AFEB)
- DHS National Infrastructure Advisory Council



**Considerations:**

- Timing
  - May only have 2-4 weeks from declaration of WHO phase 5 overseas before a pandemic virus causes outbreaks within the U.S.
  - Assessments and recommendations will need to occur on short notice
  - Federal Advisory Committee Act—Legal and regulatory requirements for public disclosure and participation
- Expertise available on individual committees
  - Specialization of committees
  - Possible gaps in expertise for antiviral guidance, nonpharmaceutical interventions
- Coordination
  - Need for over-arching view of issues and recommendations?
- Level to which recommendations would be provided
  - Secretary or Agency Director
- Input from non-health related sectors (government and private)



■ **Working group objectives**

- Examine historical performance of advisory committees in emergency situations
- Identify key decision points for government activity and guidance before, during and after a pandemic wave in which advisory committee input would be advantageous
- Identify gaps in committees' expertise and charters for decisions and recommendations relating to the above
- Consult with existing committees to develop roles and responsibilities during a pandemic and identify, if necessary, a coordination mechanism among them



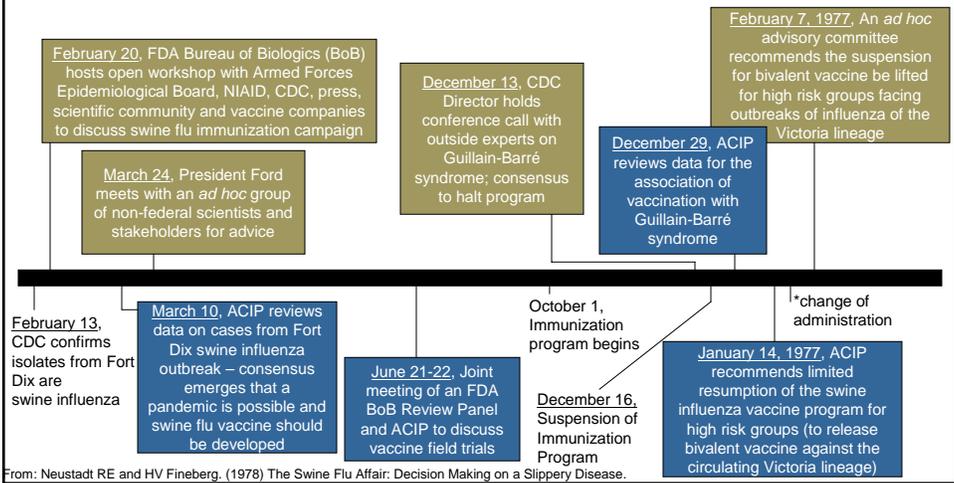
**Historical use of advisory committees during crises:**

- 2003 Smallpox Vaccination Program –
  - On March 28, 2003, CDC reported cases of cardiac adverse events among persons vaccinated recently with smallpox vaccine in MMWR.
  - ACIP held an emergency meeting on March 28 to make recommendations to CDC about medical screening of potential vaccinees and follow-up of persons with cardiovascular risk factors after vaccination.
- 2004/2005 Influenza Vaccine Shortage
  - On October 5, 2004, Chiron Corporation, announced that they could not supply influenza vaccine to the U.S. The U.S. influenza vaccine supply is reduced by nearly 50%. Of the remaining vaccine, 50% had already been distributed to various locations around the country.
  - ACIP held emergency teleconference to identify priority populations who would be targeted to receive the vaccine first and issue guidance.
- Other cases to examine:
  - 1999 Rotavirus vaccine adverse effects on infants
  - Vioxx and COX-2 Inhibitors
  - HIV
  - SARS



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**NBSB** Advisory Committee Roles

Swine Flu Vaccination Program (1976):



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**NBSB** Possible Future Activities

- Recommendations regarding CDC evaluation criteria for State Operations Plans
- Antiviral MedKits
- Rapid Diagnostics
- Novel therapeutics and vaccines



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## Questions?



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