### Pandemic Influenza Preparedness: Complementary Roles within DHHS

CDC



■ Train local response teams

Maintain vaccine/antiviral stockpiles

Disease control/prevention

NIH



Develop medical interventions (vaccines, antivirals)

Conduct clinical evaluation of vaccines and antivirals

FDA

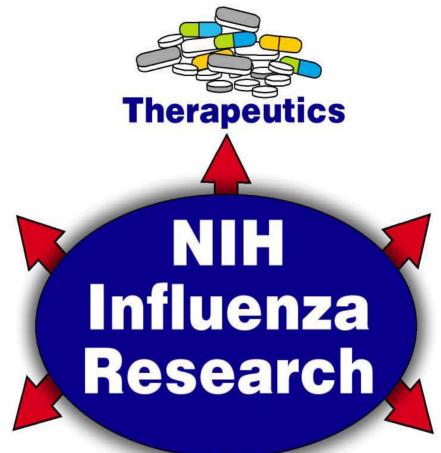


Regulatory approval – vaccines, therapeutics, diagnostics

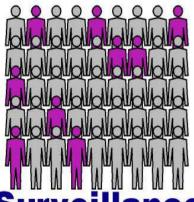
**OPHEP** 

Office of Public Health Emergency Preparedness coordinates HHS-wide emergency preparedness activities









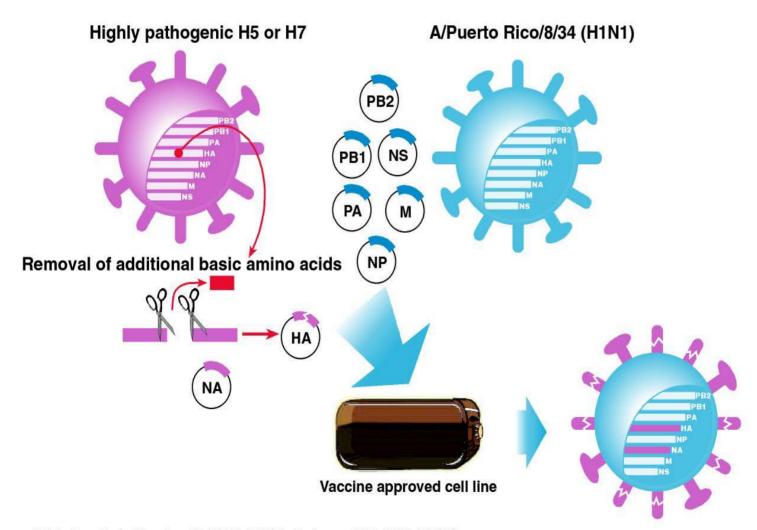
Surveillance and Epidemiology





Expansion of Research Capacity

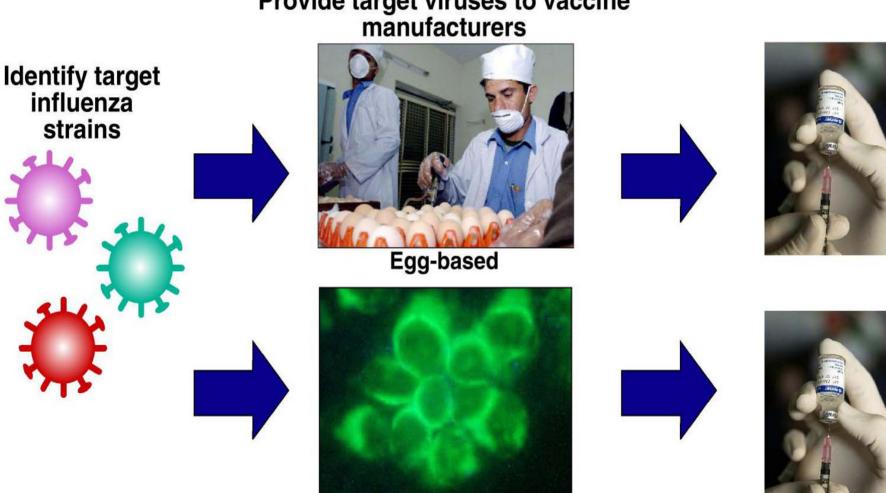
# Influenza Seed Virus for Inactivated Virus Vaccine Production Using a Reverse Genetics System



Source: Webster et al: Vaccine 20:3165 (2002); Science 302:1519 (2003)

### **Influenza Vaccine Production: Cell Culture** as an Alternative to Chicken Eggs

Provide target viruses to vaccine



Cell culture-based

## Reuters

March 24, 2005

## U.S. Starts Human Tests of Bird Flu Vaccine

Phase 1 trial on 450 adults will determine safety of shots

U.S. health officials said on Wednesday they have started human tests of a vaccine against avian flu, which experts believe could kill tens of millions of people if it becomes easily passed from person to person.



### **Clinical Trials for Pandemic Influenza**

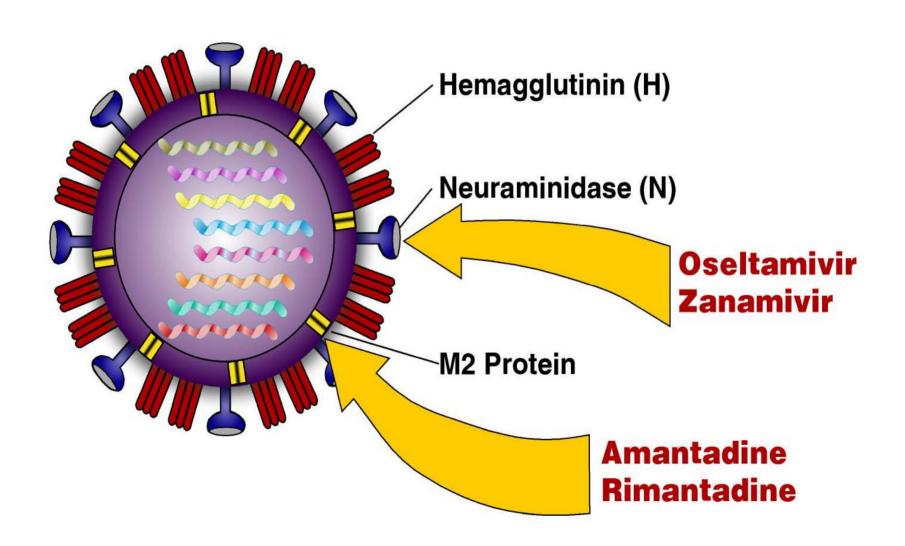
### **H5N1**

- Inactivated vaccine trial began April 4, 2005
  - Stage 1: fully enrolled (118 healthy adults)
  - Stage 2: fully enrolled (333 healthy adults)
  - Upon review of safety and preliminary immunogenicity data, plan to conduct trials in healthy elderly and children in late summer 2005
- Attenuated vaccine trial planned for late 2005

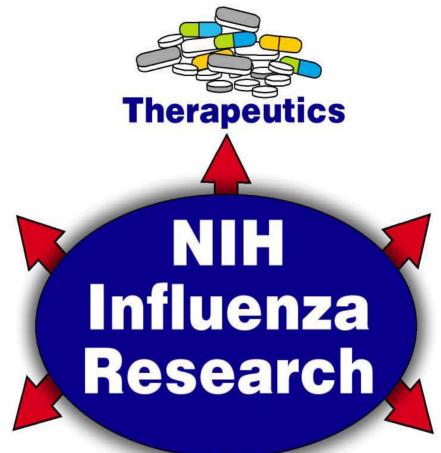
### **H9N2**

- Inactivated vaccine trial began March 31, 2005
  - Fully enrolled (96 healthy adults)
- Attenuated vaccine trial planned for summer 2005

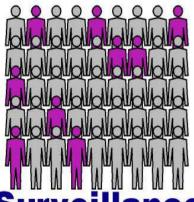
## **Antiviral Therapies for Influenza**











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