

## Vaccines and Vaccine Production Capacity

Vaccination remains a critical defense against pandemic flu. Major efforts are underway to increase our ability to produce a vaccine against a pandemic virus strain when needed, and work on “pre-pandemic” vaccines continues.

### Cell-based Production

Total reliance on egg-based production methods for mass-production of a pandemic flu vaccine is a recognized vulnerability, and on May 4, HHS invested more than \$1 billion in the advanced development of cell-based vaccine technologies. Cell-based production of influenza vaccine offers a number of significant benefits.



- In order to produce 300 million doses of vaccine, egg-based production would require an estimated 900 million eggs. In the case of an avian flu pandemic, egg-producing flocks could decline, jeopardizing vaccine production capabilities.
- While eggs are perishable and must be ordered months ahead of time, cell lines can be safely kept frozen indefinitely, increasing the capability to rapidly produce vaccines if an influenza pandemic were to occur.
- Vaccine manufacturers are able to bypass some of the steps needed to adapt the virus strains to grow in eggs.
- Certain people allergic to eggs cannot receive vaccines produced from chicken eggs, but can be immunized with a cell-based vaccine.

A total of five contracts were awarded for cell-based vaccine technology development:

- Solvay Pharmaceuticals, \$299 million;
- GlaxoSmithKline (GSK), \$275 million;
- Novartis Vaccines & Diagnostics, \$221 million;
- MedImmune, \$170 million; and
- DynPort Vaccine, \$41 million.

Previously, HHS awarded Sanofi Pasteur a \$97 million contract for development of a cell-based vaccine in April 2005. This company was the first

*“We will continue our essential work to increase our domestic capacity to produce pandemic influenza vaccine and antiviral medications.”*  
–Secretary Mike Leavitt

March 2006 – Release of Medical Offices and Clinics Pandemic Influenza Planning Checklist  
 March 2006 – Release of Home Health Care Checklist  
 March 2006 – Release of Child Care and Preschool Checklist  
 March 2006 – Release of Colleges and Universities Checklist  
 March 2006 – 19 State Summits SC, SD, ND, WY, WI, PA, IL, NC, VA, IN, PR, CO, UT, ID, TX, NM, OR, CA and the Virgin Islands  
 March 2006 – Results published demonstrating that inactivated H5N1 vaccine induces immune responses in healthy adults  
 March 2006 – RFP issued for advanced development of antigen sparing technologies  
 March 2006 – Pandemic flu supplemental guidance sent to states  
 March-April 2006 – FDA approves Relenza for the prevention of influenza A and B in adults and children

## Vaccines and Vaccine Production Capacity (cont.)

to be awarded a federal contract for commercial scale production of newer influenza vaccine methodology.

HHS recognizes the need to also expand the nation's capacity to produce vaccines utilizing traditional egg-based technology. This summer, the Department will issue Requests for Proposals (RFPs) for the construction of new facilities and/or the expansion or retrofitting of existing facilities. HHS has also issued RFPs for antigen-sparing technologies, seeking ways to stimulate protection using a smaller amount of vaccine. Contracts for antigen-sparing technologies are expected to be awarded this fall.

### Vaccine Availability

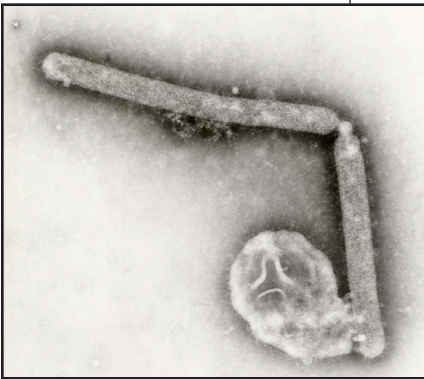
HHS has stockpiled roughly 8 million doses of vaccine against an H5N1 virus strain isolated from Vietnam in early 2004, referred to as the clade 1 virus.

Given a two-dose vaccination schedule, this would allow vaccination of 4 million people. Progress has also been made toward development of a vaccine against an H5N1 strain isolated from Indonesia in 2005 (clade 2 virus) that has circulated in Europe, Africa, and parts of Asia.

While the efficacy of these pre-pandemic vaccines cannot be predicted, there is reason to believe they may provide some level of protection for priority personnel and those at greatest risk. It is probable that H5N1 will continue to evolve, making it necessary to continuously evaluate the development of pre-pandemic vaccines.

### Vaccine Distribution

The *Implementation Plan for the National Strategy for Pandemic Influenza*, released by the Homeland Security Council (HSC) in May, directs HHS to coordinate federal efforts to prioritize vaccine allocation during pre-pandemic and pandemic periods. HHS has also been directed to coordinate federal efforts to list personnel and high-risk groups who should be considered for priority access to medical countermeasures. We are currently working closely with federal departments and agencies, states and other experts to define priority groups for access to pandemic influenza vaccine.



Details of two avian influenza A (H5N1) virions, a type of bird flu virus, which is a subtype of avian influenza A.

March 2006 – States receive initial grant funding for pandemic preparedness

March 2006 – Order of 16.2 million courses of Tamiflu and 3.9 million courses of Relenza

April 2006 – 7 State Summits TN, AK, WA, HI, LA, MI, and the District of Columbia

April 2006 – Government leaders from the Freely Associated States and Pacific Territories participate in the Hawaii and Guam summits

April 2006 – Computer model examines strategies to mitigate potential US flu pandemic

April 2006 – FDA issues guidance for industry on diagnostic devices to detect influenza A viruses for humanitarian agencies

March 2006

April 2006

## Antiviral Drugs

Progress continues to be made in developing a national stockpile of antiviral drugs that could lessen the impacts of influenza. As of June 1, 2006, the Strategic National Stockpile (SNS) contains:

- approximately 6.2 million regimens of Tamiflu capsules (oseltamivir) with an additional 15.4 million on order and expected to arrive through December 2006.
- approximately 8,600 regimens of Tamiflu oral suspension (oseltamivir).
- approximately 84,000 regimens of Relenza (zanamivir) with an additional 3.9 million regimens on order and expected to arrive through December 2006.

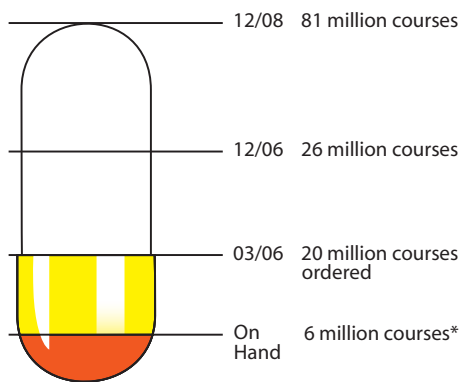
In sum, there will be an approximate stockpile of 26 million antiviral drug courses in the SNS by the end of 2006. At least 20 million of these treatment courses are to be allocated to states in proportion to population. Up to six million courses are reserved for possible opportunities to quench isolated outbreaks through community-wide preventive administration (mass prophylaxis).

HHS is also enabling states and other entities to purchase up to 31 million treatment courses of Tamiflu and Relenza at a 25% subsidy off the federal contract price. The FY06 HHS budget includes \$170 million from the supplemental appropriation to provide this subsidy. To this end, HHS is finalizing basic agreements with Roche and GlaxoSmithKline, respectively, that the states may use for subsidized purchases in accord with each state's population.

### Antiviral Drug Distribution

States are responsible for the management of the antiviral drugs they receive from the SNS. States are required to develop distribution plans that cover initial storage, dividing the allocation into distribution units, and arranging for delivery of these units to the organizations responsible for local distribution of the drugs. HHS, in collaboration with the Healthcare Distribution Management Association, is developing a model distribution plan to help states with their planning that utilizes existing private infrastructure for the distribution of antivirals and other supplies.

## Antiviral Stockpile



\* a course is the number of doses needed to treat one person

April 2006 – NIH researchers discover interregional spread of influenza through United States as described by virus type, size of population and commuting rates and distance

April 2006 – HHS Assistant Secretary Simonson travels to Bangladesh and India to enhance planning for a potential influenza pandemic

May 2006 – Release of National Strategy for Pandemic Influenza: Implementation Plan

May 2006 – HHS awards contracts totaling more than \$1 billion to develop cell-based influenza vaccine

May 2006 – Department of State establishes Avian Influenza Action Group to coordinate US international effort

May 2006 – Release of Long-Term Care and Other Residential Facilities Checklist

April 2006

May 2006

## Antiviral Drugs (cont.)

### First-defense Deployment

One strategy for containing or slowing the spread of a pandemic virus calls for the administration of Tamiflu to patients and their close contacts as well as to people in the area surrounding an initial outbreak. As noted above, Tamiflu was supplied to people in contact with the family cluster in Indonesia. In May, HHS sent a stockpile of Tamiflu to Asia to be pre-positioned for first defense containment efforts in the event of a pandemic flu outbreak.

### Stockpiling Other Supplies

HHS will spend \$162 million to procure essential medical supplies for dealing with a pandemic. Planned purchases in 2006 include 6000 ventilators, 100 million N95 respirators, and 50 million surgical masks as well as face shields, gowns and gloves. To date, 20.2 million respirators have been stockpiled with another 87.2 million on order through September 2007 and 12.3 million surgical masks are on hand with another 39.2 million on order through September 2006.

## State and Local Preparedness

State and local preparedness is crucial to pandemic readiness. An influenza pandemic will likely occur simultaneously or in waves across every community in our nation. All functions of society could potentially be disrupted by a pandemic. Every level of our communities must be prepared to be self-sufficient in the event of a pandemic outbreak.

Congress allocated \$350 million this year to assist with state and local preparedness. Of this, \$100 million has been allocated to states to begin their planning process by identifying gaps in preparedness. States are now submitting applications for how they will spend the remaining \$250 million. The plans are expected to cover three areas:

- Prioritize the gaps identified in an earlier funding application and propose a work plan to address them,
- Develop a distribution plan for antivirals, and

*“If this happens, it’s not going to be business as usual. If it’s a pandemic, it’s going to affect the entire world. We can’t look for outside help.”*

–Fire Chief Bob Painter,  
Homer, Alaska

May 2006 – 7 State Summits MS, OK, NJ, KS, NH, MT, and Tribal Leaders  
May 2006 – HHS Secretary addresses the WHO on pandemic flu preparedness  
May 2006 – Congressional Budget Office report on possible macroeconomic effects and policy issues in preparation of potential influenza pandemic

June 2006 – Secretaries Leavitt of HHS and Johanns of USDA hold national briefing with print, wire, broadcast and news media outlets on US preparations for avian influenza  
June 2006 – HHS Secretary addresses health ministers of Central America on pandemic preparedness

June 2006 – CDC issues updated Interim Guidance for Laboratory Testing of Persons with Suspected Infection with Avian Influenza A (H5N1) virus in the US

May 2006

June 2006

## State and Local Preparedness (cont.)

- Design a full-scale state/local pandemic influenza response exercise.

We have convened state summits in all but two states, and the remaining two summits are now scheduled. Summits have also been held in Puerto Rico and the Caribbean and Pacific territories, and with Tribal leaders. In each state, the governor, state, local and federal officials and members of the community have come together to strategize planning for a potential influenza pandemic. Most states have worked with HHS to complete a planning agreement detailing shared and independent responsibilities for pandemic planning.

The Minnesota Department of Health followed its summit by holding a TV call-in show, during which 12 public health and public safety experts answered more than 200 calls from citizens who wanted more information about bird flu and pandemic flu.

Many states have already carried the planning process to the next level, holding regional, cross-state and community pandemic planning meetings. West Virginia organized seven regional pandemic flu summits with members of local communities. Rhode Island is hosting a cross-state pandemic planning meeting with New York, Maine, Connecticut, Massachusetts, New Hampshire, and Vermont. Many other states are also coordinating their strategic plans with neighboring states.

This fall, HHS will begin holding risk communications training sessions for state and local public health professionals and community leaders in each of the ten HHS regions. Tabletop exercises will also be held, testing both planning and training by having officials interact through scripted scenarios. States are already submitting proposals detailing state pandemic planning exercises. State by state, we are moving from awareness to preparedness.

## Communications

Communications is at the heart of our planning. The free and rapid flow of information both domestically and internationally is critical to everything from education to decision making.

All communications materials, from fact sheets to checklists, from text to video, are made available 24/7 to a world wide audience via [www.pandemicflu.gov](http://www.pandemicflu.gov).

June 2006 – Indonesia holds avian influenza expert consultation

June 2006 – USAID announces \$5 million award to enhance international efforts to track avian influenza pandemic preparedness

June 2006 – Congress passes \$2.3 billion funding for influenza diagnostic testing

July 2006 – USDA trains foreign scientists on avian

July 2006 – New York City Summit

August -September 2006 – Contract awards expected on advanced development of promising antivirals

June 2006

July 2006

Aug-Sep 2006

## Communications (cont.)

Our cross-government Web site is growing exponentially, with content increasing more than 25 percent in the past three months alone.

Highlights include the addition of a question & answer database, additional checklists, an updated *Guide for Individuals and Families* and the translation

of key documents into Spanish. With cross-government content ownership, a coordination council meets regularly to insure that information is current, consistent and coordinated across all related pages.

Over the last several months, we've held roundtable discussions on avian and pandemic flu with the major broadcast and cable television networks and national wire services. Reporters, producers and media executives were told of government planning efforts.

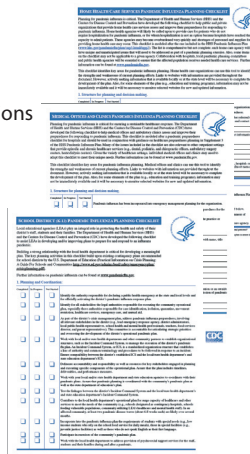
Discussion explored how the government and media would act and interact in different H5N1 scenarios. Growing out of these discussions, plans are now being drafted to conduct a tabletop exercise involving the media and health officials in a mock pandemic flu situation.

### Available Checklists:

- State and Local
- Individuals and Families
- Business
- Schools
- Faith-based and Community Organizations
- Medical Offices and Clinics
- Home Health Services
- Long-Term Care and Other Residential Facilities
- Emergency Medical Services

### Upcoming Checklists:

- Law Enforcement
- Health Insurers
- Travel Industry
- Correctional Facilities



Broadcasters stressed their need for video content, and HHS plans to meet that need by building a library of video interviews and footage. Broadcast facilities in Washington and at CDC in Atlanta are being upgraded to expand emergency broadcast capabilities. Convergence technologies will allow video content to be webcast directly to the public.

We are working to communicate to all the peoples of the world the essential information they need to plan, prepare and ultimately cope with pandemic flu and its impacts. The WHO has modeled its draft communications operational plan on the HHS plan. Since March, we have supported or provided risk communications training for ministry of health communicators from twelve nations, and in April, HHS met with its Canadian and Mexican counterparts to coordinate communications in an open, timely and transparent manner.

### Federal Preparedness

A response to a pandemic will require national coordination. HHS is only one of many federal departments and agencies that are taking preparatory measures to ensure that they can adequately support state and local officials in the event of an outbreak. Working with the DHS, USDA, the White House, and our other federal partners, HHS will utilize the multi-agency coordinating structures of the National Response Plan should an outbreak require a synchronized federal response.



## Addendum

---

---

**Since this report was published in June 2006 there are new developments detailed below:**

**[Page 2, paragraph 2 and chart:](#)**

On August 8, 2006, the World Health Organization (WHO) confirmed that China retroactively reported a fatal H5N1 human case for 2003. This increases the number of human cases at the time of publication to 229. The chart should also reflect this increase with four human H5N1 deaths in 2003.

**[Page 5, paragraph 2:](#)**

On July 26, 2006, the World Health Organization reported a new case of H5N1 in humans in Thailand.

