# Feds Prepare for Next Flu Season

**Flu Shot** *from page 1*

Although the final language was still being worked out at press time, ACIP voted in principle to support a three-tiered prioritization system in which high-risk groups are ranked based on rates of influenza-associated mortality and hospitalization in the United States. (See box.)

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**Dr. Keiji Fukuda, of the CDCs influenza branch testifies at the ACIP meeting.**

The tiering scheme applies only to the inactivated influenza vaccine, and the document is expected to contain a strong recommendation for the preferential use of LAIV for healthy persons aged 5-49 years—particularly health care workers—in the event of a vaccine shortage next flu season.

During periods of vaccine shortfall, persons listed in tier 1 should be vaccinated preferentially, followed by tiers 2 and 3.

The subdivisions within tier 1 would be used only in the unlikely event that the local vaccine supply is extremely limited.

Should that occur, state and local health officials should vaccinate the two populations in tier 1A—those aged 65 and older with comorbid conditions and long-term care facility residents—before all other populations.

In all other vaccine shortfall situations, populations falling into tiers 1A, 1B, and 1C should be considered equivalent and should be vaccinated simultaneously.

Eligible individuals in tiers 1C, 2, and 3 should be encouraged to receive LAIV (those in tier 1C—health care personnel and close contacts of children less than 6 months of age—could receive either the injectable vaccine or LAIV, depending upon supply circumstances).

The committee also voted to include much stronger language about immunization of health care workers overall, regardless of vaccine supply status.

Among the likely recommendations are that campaigns be organized to encourage workplace efforts to improve immunization rates among health care workers, and that such rates be regularly measured and reported.

"Giving the influenza vaccine to health care workers keeps them at work. It becomes a quality issue," said ACIP member Jon S. Abramson, M.D. "When you increase the number of patients a nurse has to take care of [due to absenteeism], it affects patient outcome." ■

## Proposed Tiering For Shortages

**Group 1A**
- ▶ Aged 65 years and older with comorbid conditions.
- ▶ Long-term care facility residents.

**Group 1B**
- ▶ Aged 2-64 years with comorbid conditions.
- ▶ Aged 65 years and older without comorbid conditions.
- ▶ Aged 6-23 months.
- ▶ Pregnant women.

**Group 1C**
- ▶ Health care personnel.
- ▶ Close contacts of children less than 6 months of age.

**Group 2**
- ▶ Contacts of high-risk children, adults.
- ▶ Healthy persons aged 50-64 years.

**Group 3**
- ▶ Aged 2-49 years without high-risk conditions.

Source: Dr. Fukuda

# FDA Panel Echoes WHO in 2005-2006 Flu Vaccine Choice

BY MARK S. LESNEY
*Associate Editor*

BETHESDA, MD. — A federal advisory panel unanimously recommended that only one of the current virus strains be changed in the production of the 2005-2006 influenza vaccine.

At last month's meeting of the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee, the decision was made to retain the influenza A (H1N1) A/New Calendonia/20/99 strain, and the influenza B/Shanghai/361/2002–like strains.

The only change recommended was to replace the influenza A (H3N2) strain with an emerging contender, one of the California-like influenza strains that were first identifed as new by the Centers for Disease Control and Prevention.

Designated A/California/7/2004, because it originated in a patient from Santa Clara County last year, the new strain proved to be one of a family of strains identified as emerging in various locations across the globe. The decision to maintain two strains and to change one in response to the emerging California-like viruses "harmonizes"—in the words of one advisory panel member—the U.S. recommendation with the identical recommendation given mere days before by the World Health Organization as to next year's vaccine mix.

Retaining last year's choices seemed appropriate for the influenza A (H1N1) and influenza B strains because there was no significant change in predominance of the strains seen in the current season, said Roland Levandowski, M.D., of the FDA's division of viral products. But there was a noticeable migration of strains of influenza A (H3N2) with the appearance of the new California strain first identified in January.

The CDC is currently trying to grow four variations of the California-like influenza virus in eggs—the first step in seeing if vaccine can be produced from the virus—with low to moderate results, said Zhiping Ye, M.D., of the FDA. Dr. Ye also noted that six national laboratories in the United States, the United Kingdom, and Japan also are working to develop A/California/7/2004–like candidates in anticipation of demand. These would be made available as candidate viruses for manufacturers to test for their suitability for bulk vaccine production.

Dr. Levandowski noted that no California-like strain had yet reached the manufacturers. But previous experience indicated that there should be no particular problem for the industry to adapt to such a recommendation in time for the next flu season, given those strains under development.

One political issue surfaced during the meeting when a number of the panelists indicated that the nearness in time of the WHO decision might make it appear that the U.S. panel was acting simply as a rubber stamp. But according to Nancy Cox, Ph.D., chief of the CDC's influenza branch, when the FDA panel meeting was held earlier than the WHO meeting, the rest of the world thought that the United States was preempting the global initiative.

Since then, the meeting has been deliberately scheduled as soon as possible after the WHO deliberations in which, according to Dr. Cox, CDC always plays a significant role. This timing, she said, was especially important because the CDC was able to return with and process the most up-to-date global information in time for presentation to the FDA panel.

Panelists and speakers alike reiterated the difficulties that manufacturers face in producing a trivalent vaccine within the short turnaround period dictated by the timing of the committee's recommendation.

A presentation by Albert Thomas, director of viral manufacturing for Sanofi Pasteur, detailed the process used by manufacturers, and emphasized how companies, seeking to accelerate the process, actually started producing the first of the monovalent strains before the committee met. That entailed an "at-risk decision" because of the economic repercussions should they prove wrong in picking which strain was the most likely to be used.

Federal authorities also are concerned about the potential spread of avian influenza. Last September, the Department of Health and Human Services awarded a contract to Aventis Pasteur to manufacture and store 2 million doses of vaccine against avian influenza A (H5N1).

The CDC has developed and distributed a test kit to detect the currently circulating H5N1 strain and is collaborating with the WHO and the National Institutes of Health on the development of additional vaccine strain candidates. ■

## A 'B'-Deviling Problem When Caring for Children

Dealing with the B strains of the influenza virus remains a continuing problem, especially in children, according to the vaccine advisory committee.

Influenza B viruses that are currently circulating can be divided into two distinct lineages represented by B/Yamagata/16/88 and B/Victoria/2/87 (www.cdc.gov/flu/weekly). Before 2001, the Victoria strains were not seen outside of Asia, but by October 2003, they had become predominant in many countries, including the United States.

But for the current season, Yamagata-lineage strains were predicted to predominate once more and the vaccine strain recommendation was changed to B/Shanghai/2002–like viruses, a subset of the Yamagata strains.

In adults and even the elderly, choice of which of these strain candidates to include in the final vaccine is less critical, as it has been noted that each provides some measure of immunity to the others.

But this is not the case in children, making proper prediction of which strain will predominate far more critical, especially as B virus outbreaks have been known to cause pediatric deaths.

Advisory panel members who specialize in the care of children, including Philip S. LaRussa, M.D., professor of clinical pediatrics, Columbia University, New York, and Gary D. Overturf, M.D., professor of pediatrics and pathology, University of New Mexico, Albuquerque, questioned if it would be possible for the panel to propose the development of a pediatric vaccine which would combine both types of B viruses in a single formulation. In discussion, the consensus was that such a formulation would need clinical testing, and initiating such testing did not fall under the authority of the panel, nor even of the FDA. Any such new vaccine would have to be initiated by a manufacturer and brought to the FDA through channels.

If necessary, it would be appropriate to recommend a monovalent vaccine with the alternative B strain to be given in addition to the trivalent standard for pediatric patients. It is well known that such vaccines are effective, Dr. Levandowski said.