

FLUVIRIN® INFLUENZA VIRUS VACCINE RELEASE DELAY

The National Influenza Vaccine Summit believes that this delay reported by Chiron on 8/26/04 will not have a significant impact on the administration of influenza vaccine during the 2004-05 influenza season, if the affected vaccine begins to be released as expected in early October (see accompanying fact sheet). This year's projected supply of vaccine is substantially greater than last year's. Most influenza vaccinations occur between October and February so the release of Chiron's vaccine supply in October should not affect the public's ability to be vaccinated this season.

This is not a potential health crisis. What is known at this point is that there will be a delay in the delivery of the vaccine from one manufacturer. That manufacturer has about half of the market share for influenza vaccine and on time delivery of vaccine is expected from the other influenza vaccine manufacturers. A significant supply of vaccine will be on hand at the beginning of the season for immunizations to get started. People who are high risk of complication from influenza should not panic or defer vaccination out of safety concerns.

The following information is intended to address frequently asked questions regarding current influenza vaccine supply:

What is the issue?

In conducting final internal release procedures for Fluvirin® vaccine, Chiron identified a small number of lots that do not meet product-sterility specifications. Some production problems related to the sterility of a small number of doses manufactured in Chiron's Food and Drug Administration (FDA)-approved Liverpool, England, plant. While ongoing internal investigations into the root cause indicate no widespread issues with the manufacturing process, Chiron has delayed releasing any Fluvirin® vaccine doses until additional release tests have been completed. The doses identified with sterility problems will be destroyed.

Chiron previously expected to deliver 50 million Fluvirin® vaccine doses to the U.S. market for the 2004-2005 flu season, as well as 2 million doses to the U.S. Centers for Disease Control and Prevention (CDC) national stockpile of influenza vaccine. Assuming satisfactory results from ongoing release testing, Chiron now expects to deliver between 46 and 48 million doses to the U.S. market beginning in October, as well as the 2 million doses for the CDC stockpile. That number of doses is 20 to 25 percent more than the 38 million doses supplied to the U.S. market last year.

Chiron expects that Fluvirin® vaccine doses will be available in time for recommended influenza vaccination time frames, as a majority of Americans are vaccinated in October. Aventis-Pasteur, has begun releasing its supply of vaccine, and is on schedule to deliver about 52 million doses by November. Medimmune, manufacturer of nasal flu vaccine, will release 1.5-2 million doses in October.

Will this affect access to pediatric flu vaccine?

The Chiron vaccine is not indicated for children less than 4 years of age and therefore is not expected to have an impact on flu vaccine access for the newly targeted group of 6 – 23 month olds.

What steps are being taken to resolve the issue?

Chiron is following a three-step plan:

1. Root Cause: internal investigations to determine the root cause.
2. Retest: applying the precautionary principle, Chiron is retesting all the lots to ensure they are sterile.
3. Release: once confident the product is sterile and meets all quality-control standards, Chiron will release flu vaccine to the market.

The delay in the delivery is related to some sterility production problems in a small number of doses in Chiron's manufacturing plant in Liverpool. CDC remains in regular contact with Chiron. Right now, Chiron believes they have identified exactly what the source of the production problem was and they're aggressively pursuing all steps to assure that they have the safest and effective vaccine on the market in time for the upcoming influenza season. Our public health system has had problems with delay in vaccine delivery in the past, as recently as 2001. During that time vaccine supply was delayed until October, so this is a problem that CDC and the Summit have experienced before and now have the experience at staying on top of it. It is expected that we will end up with more vaccine doses than we have ever had before.

How many flu vaccine doses are projected to be produced and shipped this year?

Aventis Pasteur: Estimates are that approximately 52 million doses will be distributed by Aventis Pasteur. Vaccine distribution began in August and the majority of vaccine is expected to be distributed by November.

Chiron: Their previously stated goal was to manufacture 50 million doses for the U.S. market, as well as 2 million doses for the CDC stockpile for the upcoming flu season. Assuming satisfactory results from ongoing release testing, they now expect to deliver between 46 and 48 million doses to the US market, as well as 2 million doses to the CDC stockpile.

Medimmune: Expects to distribute up to 2 million doses of the nasal influenza vaccine in October.

Was any Fluvirin® vaccine shipped prior to Chiron's announcement?

As announced in their press release of July 23, Chiron had already shipped 1 million doses to a distributor in the United States. However, all of these doses remain under Chiron's control. No Fluvirin® doses will be released for vaccination until Chiron has completed their testing program.

Will any of the Fluvirin® vaccine shipped prior to the announcement need to be recalled?

No. As part of the annual preparation for the influenza season, the FDA's Center for Biologics Evaluation and Research (CBER) tests samples from each batch of influenza vaccine. Upon passing this regulatory testing step, CBER officially releases the vaccine. CBER has begun this process and released the first million doses of Fluvirin® vaccine. However, those doses have not yet been released for distribution and are currently under Chiron's control.

Will the shipment delay impact the 2004-2005 flu season?

As indicated in Chiron's August 26 press release, assuming satisfactory results from ongoing release testing, it is anticipated that shipment of Fluvirin vaccine will begin in early October – in time for the 2004-2005 influenza season.

Will the supply problem have an impact on the 2 million Fluvirin® doses Chiron is suppose to deliver to the CDC stockpile?

No, Chiron plans to supply the CDC national stockpile of influenza vaccine with 2 million Fluvirin® doses. Delivery of these doses remains on schedule for the end of the regular influenza season.

What does this mean for the American public? Is there a risk there won't be enough flu vaccine this season to protect everyone from the flu?

The vaccine manufacturers, FDA and CDC are committed to protecting people from influenza. All involved parties are working to meet the projected demand in the United States for influenza vaccine during the upcoming 2004-05 season. Overall, assuming delivery occurs as currently expected, the market will have nearly 100 million doses available this year – approximately 20 percent more doses than last year.

What impact will this have on consumers' ability to get their flu vaccine this fall?

Assuming delivery occurs in early October, as currently expected, anticipation is that there will be minimal effect on consumers' ability to obtain their vaccine this fall. We're expecting more than 100 million doses of influenza vaccine this year. So, ultimately, all people who desire influenza vaccines should be able to get their immunizations and can be protected. Some people who are used to receiving their vaccine in early October clinics may find that their clinics are delayed because they are receiving the Chiron vaccine and it hasn't arrived in time to be distributed to those clinics. CDC and the Summit are committed to keeping the public and providers updated on the status of the delivery and also keep people informed of when they can expect to have the delivery in their communities.

For individuals who are trying to plan now for their immunization, the best thing is to stay tuned and to be alert to the messages from your local health officers and your health care provider, who will advise you when those flu clinics get opened.

What message should consumers be told about the importance of flu vaccination?

It's really important that people get the influenza vaccine, especially if they're in the high risk categories. Those categories include: people who are 50 years of age and older, patients who have any kind of chronic medical condition or conditions that weaken their immune system, people who expect to be pregnant during influenza season, children between the ages of 6 months and 23 months, and persons in long term care facilities. Those in contact with high risk persons, including healthcare workers, other caregivers, and household contacts should also be vaccinated. Influenza is a serious disease in this country with 36,000 people on average dying, even in a non-pandemic year. Last year, 152 children under the age of 18 died from influenza. The disease is preventable and certainly its complications, even among children, can be reduced by immunization. So, nothing about the announcement from Chiron should discourage individuals or caregivers from receiving the influenza vaccine.

We don't want people to race out and stand in the head of the line to get their vaccine at the beginning of October because there is not expected to be a shortage of vaccine. On the other hand, people who need to be vaccinated should not avoid it with unnecessary concerns about the availability of the product. CDC recommends that people get their influenza vaccine as early as possible -- typically in October and

November, but December is not too late. Even January or February is not too late to receive the vaccine. CDC advises people to get it earlier in the season rather than later so that you're protected when it arrives, not after it's already present.

When Chiron vaccines are cleared for shipment, who will get priority for vaccination?

According to Chiron they do not prioritize vaccine recipients. They ship to their distributors to fulfill contractual obligations. These distributors fill their orders from medical personnel.

If I am a hospital or other provider who ordered from Chiron is there any way to get earlier vaccine in order to protect health care workers and vulnerable patients?

The manufacturers work with various vaccine distributors. Health care professionals are encouraged to contact their vaccine distributor(s). Manufacturers are committed to fulfill its contracted obligations to the people who had already ordered vaccine. Some are exploring their ability to add additional supply to those places that are still waiting for their Chiron vaccine. Manufacturers of the influenza vaccine (injectable and nasal) are working closely with CDC and FDA to try to assure a continuous supply of vaccine in places where it's needed the most.

Is the current flu vaccine supply issue related to recently released Pandemic Plan?

CDC has posted its draft pandemic influenza plan on the Internet. It represents a comprehensive strategy that the department of Health and Human Services has put together. The plan has been in development for over 3 years and was scheduled to be released before knowledge of the current supply issue was received.

How will we ever be able to supply influenza vaccine for all that need it?

Typically in the United States the estimates are that more than 180 million people should receive influenza vaccine. We have never come anywhere close to vaccinating that number of people. Even last year where we had an aggressive immunization program because there were concerns about the rapid spread of disease, we ended up the season with some doses of vaccine unused. So the issue here is not the ability to protect people who need vaccinations. The issue is simply when will clinics start in a given community. October and November are the times when most people receive their influenza vaccine. As many people as possible should be vaccinated before Thanksgiving. So, this current vaccine supply issue is likely to not have an impact on our ability to protect people, at least based on what we know from the manufacturers so far. This is simply an issue of convenience and meeting expectations about when vaccine will be available.

Has CDC reinstated the tiered recommendation for flu vaccination programs?

No. CDC has recommended vaccination for people who are at high risk for the complications of influenza, those who are in contact with at-risk people and for healthcare workers. CDC has always emphasized the importance of those people receiving their vaccine and receiving their vaccine as early as possible. If CDC identifies any additional delays or any unexpected shortages in vaccine, then it will revisit whether or not to ask certain people to be vaccinated first and others to delay their immunization.

Is the problem experienced by Chiron linked to the thimerosal concern?

According to CDC, there is no link between this problem and the production of thimerosal preservative, or thimerosal containing vaccine.