

## **Flu vaccine maker's shipments suspended, raising fears of flu shot shortage at start of season**

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(London-AP, Oct. 5, 2004 Updated 12:22 PM ) \_ The maker of half the United States' flu vaccine said it would supply none this year after British health officials pulled its license Tuesday.

The news means the United States will face "a significant shortage" just as the flu season begins, said Dr. Anthony Fauci, the National Institutes of Health's infectious disease chief.

Other countries will likely face similar problems.

"The implications may be significant," said Dr. Klaus Stohr, influenza chief the World Health Organization.

British authorities suspended the license of [Chiron](#) Corp. for three months because of problems at its vaccine manufacturing plant in Liverpool, England. The action means the company can't supply any flu vaccines to any market during that time, and Chiron said it would provide none during this year.

U.S. health officials were caught off-guard, learning of the developments only during a midmorning phone call. "We need to regroup," Fauci said shortly afterward.

Chiron had planned to ship 46 million to 48 million doses, but that already had been delayed by a contamination problem discovered in August in the English factory where the vaccine is made. At the time, the company said only 4 million doses were tainted but that the entire supply would be held up and re-tested.

About 1 million doses already had arrived in the United States, but it remains under Chiron's control and has not been released for use.

Flu shot campaigns usually start in October, a month before the flu season typically begins in the United States. In an average year, flu kills 36,000 people and hospitalizes another 114,000, mostly the elderly.

Less than two weeks ago, top U.S. health officials assured the public that close FDA monitoring of the rest of Chiron's supply suggested it was fine and that there would be plenty of supplies.

Dr. Walt Orenstein, formerly the top flu expert at the U.S. Centers for Disease Control and Prevention and now the associate director of the Emory Vaccine Center, said the government may have to ration available vaccine.

"It's a very serious concern. We're already in October, which is vaccine season. If we have to ration at this stage, it becomes more complicated."

If problems prevent the Chiron vaccine from being used at all this year, it's unlikely that other manufacturers could fill the gap. Aventis Pasteur, which expects to supply 52 million doses, said earlier that federal officials had asked it to make additional vaccine but that it already was at capacity and couldn't produce more until after November when existing orders are filled.

A third manufacturer, MedImmune, which makes FluMist, a new nasal spray flu vaccine for use in healthy 5- to 49-year-olds, said it couldn't produce more than the 1.5 million doses it had planned to make for this year's flu season.

That vaccine is made from modified live virus and isn't considered safe for the elderly or people with medical problems.

Worldwide, Chiron is the second leading flu vaccine manufacturer, behind French pharmaceutical company Aventis, which makes about 45 percent or 50 percent of the world's supply, Stohr said.

Chiron, based in California, makes four influenza vaccines, including Fluvirin, the top flu vaccine in Northern Europe and the No. 2 vaccine in the United States

The timing of the license suspension is particularly worrying because vaccine production goes in cycles. The manufacturing cycle for the Northern Hemisphere vaccine finished in August and manufacturers are now gearing up to make the shots for the Southern Hemisphere.

Vaccine makers do not have a lot of spare stock because they produce on demand.