

[Will the grand jury be allowed to hear testimony about (i) the CDC's original findings of thimerosal's adverse neurologic effects, and (ii) the CDC's altering of those data? Should letters request that the US attorney's office in Manhattan ought expand its investigation to include the CDC's scientific fraud and the FDA's and AAP's complicity therewith? -Teresa]

Flu Vaccine Shortage Prompts U.S. Probe

A grand jury may want to know whether drug firm Chiron misled regulators or investors. Shots are being steered to people most at risk.

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October 13, 2004

<http://www.latimes.com/business/la-fi-chiron13oct13,1,2356968.story>

<<http://www.latimes.com/business/la-fi-chiron13oct13,1,2356968.story?coll=la-home-business>>

<<http://www.latimes.com/business/la-101204flu-fl,1,7903189.flash?coll=la-home-business>>

[Imposing the long-term need for neurologic pharmaceuticals.]

(AP)

U.S. health officials said Tuesday that they planned to steer scarce flu vaccine supplies to nursing homes, pediatricians and hospitals as the company that caused the disruptive shortage disclosed that it was under investigation by the Justice Department.

Chiron Corp. said it had received a grand jury subpoena from federal prosecutors in New York seeking materials on its Fluvirin influenza vaccine and its regulatory problems in Britain.

The Emeryville, Calif.-based company said it would cooperate with the investigation but offered no other details. Federal officials declined to comment.

Legal experts speculated that the government could be looking for evidence that the company misled regulators or investors about its ability to provide its vaccine this year.

The grand jury subpoena was issued by the U.S. attorney's office in Manhattan, which is known for its high-profile Wall Street probes and its successful prosecutions of lifestyle entrepreneur Martha Stewart and investment banker Frank Quattrone.

The Oct. 5 shutdown of Chiron's Liverpool factory by British regulators eliminated almost half of this country's expected vaccine supply for the coming flu season and prompted U.S. health officials to ask healthy adults not to get shots this year.

The officials said they were working with another vaccine supplier, French drug maker Aventis Pasteur, to allocate 22.4 million unshipped doses of its flu shots to the most vulnerable groups in the U.S. population, including babies, the elderly and residents of nursing homes, veterans hospitals and long-term care facilities. But details were sketchy.

"This plan will help ensure that vaccine gets to those people who need it most," said Julie Gerberding, director of the Centers for Disease Control and Prevention. "This is a troubling, frustrating situation for all of us, and we need for all Americans to pull together in the weeks to come to meet this challenge head-on."

Aventis Pasteur is asking customers to accept smaller shipments so it can divert more flu shots to public-health efforts, said Damian Braga, president of the firm's U.S. division.

Health officials said that during the next six to eight weeks, they would deliver about 14.2 million vaccine doses made by Aventis Pasteur to healthcare providers that treat high-risk groups. They plan to stockpile an additional 8.2 million doses for use later in the flu season.

"We'll have a great deal of flexibility to move that vaccine around in a way that best serves the people with the highest risk," Gerberding said at a briefing for reporters.

Small amounts of the flu vaccine may also be available from other producers outside the U.S., although the shots would first have to be approved by U.S. regulators.

Still, Gerberding acknowledged that it was unlikely that everyone who wanted a flu shot -- even those in high-risk groups -- would be able to get one. The government estimates that 100 million Americans fall into the high-risk categories.

"There will be some people who will not be able to get vaccine who need it," Gerberding said.

Amid the uncertainty, tales of price gouging have started to spread. On Tuesday, Kansas Atty. Gen. Phill Kline sued a Florida company for allegedly trying to gouge a Kansas City pharmacy buying flu shots.

Meds-Stat, based in Fort Lauderdale, is accused of proposing to deliver and sell a vial of five doses of flu vaccine to the pharmacy for \$900, knowing that the vaccine was intended for a nursing home. The same vial was listed at \$85 on Oct. 1, according to a statement issued by Kline's office. Meds-Stat officials couldn't be reached for comment. The company faces two counts of deceptive acts and two counts of unconscionable acts.

Chiron's stock price has tumbled 26% since British regulators suspended vaccine production at the company's plant last week because of potential vaccine contamination amid a host of manufacturing problems. Just a week earlier, Chiron Chief Executive Howard Pien had told a U.S. congressional committee that the company stood ready to ship more than 40 million vaccine doses by early October.

Legal experts said the Justice Department might be looking for evidence of securities fraud -- whether the company intentionally misled

investors with rosy predictions about vaccine deliveries. The department also could be investigating whether Chiron lied to a government agency, such as the Food and Drug Administration, legal experts said. The FDA has said that Chiron never warned that its flu vaccine supply was in danger.

"The fact that they messed up in England and had a plant that was not acceptable does not offend U.S. criminal law normally," said John C. Coffee, a professor of law at Columbia University.

"What may be of interest to federal prosecutors is whether false statements were made to the FDA about lab conditions, internal controls or the company's ability to meet [delivery] schedules."

The legal experts said they were surprised at how swiftly the Justice Department started looking into Chiron, just one week after the company announced that it could not supply the vaccine.

"Prosecutors are becoming a lot more aggressive at the federal level," said Jamie Wareham, a partner at Paul Hastings. "They don't want to look like they've been blindsided by the Eliot Spitzers of the world," he added, referring to the New York state attorney general who led high-profile litigation against brokerage firms.

Meanwhile, throughout the nation, healthcare providers remained worried about the outlook for the flu season and awaited details about specific allocation decisions.

Denise Ratcliffe, chief operating officer for Christian Health Care Center, which has about 600 patients in its nursing home in Wyckoff, N.J., said the shutdown of Chiron's production had cost her facility its entire allotment of 1,300 shots.

"Virtually all of the long-term facilities in New Jersey had contracted with Chiron," Ratcliffe said, adding that there were "big questions" about the details of reallocation and how the priority for vulnerable populations would be carried out.

CDC officials said states that had relied on Chiron for all of their flu shots this year would get priority, but the names of those states weren't released.

The California Department of Health Services has received only about a quarter of the vaccine it ordered from Aventis and none from Chiron. State officials said they were working overtime trying to get what remained of the vaccine to the most needy.

"We're not quite sure how it's going to work out," said Robert Miller, a spokesman for the department. "We're having a lot of meetings and conference calls" with the CDC.

CDC officials urged at-risk patients to see doctors if they developed flu-like symptoms so they could receive medicine, if necessary. Gerberding said the CDC was stockpiling Tamiflu and Flumadine, drugs that treat the flu if taken in the early stages of infection.

Chiron's shares closed Tuesday at \$33.74, down 51 cents, on Nasdaq.

Times staff writers Emma Schwartz, Julie Tamaki, Marc Lifsher and David Pierson contributed to this report.

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