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Baxter, Supplier Say Heparin Taint Was Deliberate (Update4)

By Justin Blum - Apr 29, 2008

April 29 (Bloomberg) -- Baxter International Inc. said its blood thinner heparin, linked to 81 deaths, appears to have been deliberately contaminated.

The drug's main ingredient was contaminated before reaching the Chinese factory of Baxter's supplier, Scientific Protein Laboratories, executives of both companies testified at a U.S. House hearing today. The Food and Drug Administration suspects the contamination was deliberate, though there isn't proof, according to the agency.

Baxter recalled heparin, used to prevent blood clots, in January of this year after reports of harmful side effects. Since January 2007, 81 people have died after allergic reactions, the FDA said on April 21. Tainted heparin made by other drugmakers has been found in more than a dozen countries since Baxter's recall, and regulators have said they don't know how it was introduced.

``We're alarmed that one of our products was used in what appears to have been a deliberate scheme to adulterate a lifesaving medication,'' Baxter Chief Executive Officer Robert Parkinson told the House Energy and Commerce Committee's investigative subcommittee.

Baxter, based in Deerfield, Illinois, rose 37 cents to $63 at 4:15 p.m. in New York Stock Exchange composite trading and has gained 8.5 percent in 2008. Heparin accounted for about $30 million in annual sales for Baxter, which reported $11.3 billion in revenue last year. The company hasn't decided whether to resume selling heparin, Parkinson told analysts this month.

Some samples of Baxter's heparin were found contaminated with a cheaper substance known as over-sulfated chondroitin sulfate, according to the company and the FDA.

`Upstream' Act

``It seems to us that it's an intentional act upstream in the supply chain,'' said David Strunce, the chief executive officer of Waunakee, Wisconsin-based Scientific Protein, during the hearing. ``We don't know specifically where.''

Scientific Protein, majority owned by American Capital Strategies Ltd., started to inspect its suppliers of raw heparin and stopped when the Chinese government ``took over,'' Strunce said. The ingredient is

derived from pig intestines and originates in workshops in China.

The FDA says the contaminant can lead to deaths. The Chinese government has publicly disputed that, saying the side effects haven't been reported in all countries where the contaminant was found.

Half of Supply

Baxter sold about half the U.S. supply of injectable heparin before the recall. APP Pharmaceuticals Inc., of Schaumburg, Illinois, whose products remain on the market, produced the other half. The FDA says heparin currently sold in the U.S. is safe.

People who said they lost family members to tainted heparin today described their emotional pain to committee members.

``My wife, Bonnie, died in December after receiving heparin that was later recalled by Baxter,'' said LeRoy Hubley, of Toledo, Ohio, as he choked back tears. ``My son, Randy, died a month later under similar circumstances.''

Bonnie and Randy Hubley both were given heparin during dialysis to treat an inherited kidney disease. Family members filed two lawsuits against Baxter.

Lost Wife, Son

``Now I am left to deal not only with the pain of losing my wife and son, but anger that an unsafe drug was permitted to be sold,'' Hubley said.

The FDA would need an additional $225 million annually to inspect overseas drugmakers every two years, said Janet Woodcock, head of the FDA's drug division. The agency plans to spend $11 million this year for overseas inspections, according to the Government Accountability Office, the investigative arm of Congress.

The FDA conducts annual inspections of about 7 percent of overseas drugmakers that ship to the U.S., a pattern suggesting it would take 13 years to visit them all, according to the GAO.

The FDA failed to complete an inspection of the Scientific Protein plant in China that should have been conducted in 2004 because regulators confused the plant with another with a similar name, according to the agency.

FDA Faulted

The FDA may have been able to prevent contaminated heparin from reaching the U.S. if the agency had completed the 2004 inspection, said David Nelson, an investigator for the energy and commerce panel, who testified before the panel. While there wasn't contamination at the time, Nelson said an inspection

may have identified shortcomings, including procedures to ensure the ingredients it purchased were pure.

Baxter inspected the plant in September and found no major deficiencies, said Nelson. In February, the FDA sent inspectors to the plant and uncovered ``significant deviations'' from standard practices, he said. He questioned whether the Baxter inspection was sufficient.

The inspections were done ``at different points in time'' for different reasons, Baxter's Parkinson said. The company's inspection was routine, while the FDA's was ``for cause'' after the recall.

``That leads to a very different type of inspection,'' Parkinson said.

Lawmakers said the FDA needs more money and power to do its job.

``Our investigations have revealed an FDA woefully lacking in the personnel, effective policies, and the will at the highest level to perform the duties entrusted to it by the Congress and the American people,'' said Representative John D. Dingell, a Michigan Democrat, during the hearing.

Representative Michael Burgess, a Republican from Texas, also raised alarm that heparin appeared to have been intentionally contaminated.

He called the contamination ``thuggery'' and ``thievery'' and said it was an ``knife in the back'' of the American public.

To contact the reporter on this story: Justin Blum in Washington at jblum4@bloomberg.net.

To contact the editor responsible for this story: Reg Gale at rgale5@bloomberg.net.