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Widower sues drug company over heparin his wife used

A Toledo man yesterday filed a lawsuit against a major drug manufacturer selling heparin, accusing Baxter Healthcare Corp. of failing to issue a warning of adverse reactions to its product until a month after his wife's death.

Leroy Hubley filed the lawsuit in U.S. District Court in Toledo against the Illinois-based company.

In the lawsuit, Mr. Hubley said his wife, Bonnie, had been receiving hemodialysis and, in doing so, was administered heparin, a prescription drug known as a blood thinner.

Mrs. Hubley died Dec. 19.

The company voluntarily recalled the drug Jan. 17 and began issuing warnings that there were several cases of severe and life-threatening reactions to the drugs.

Earlier this week, Baxter announced it has temporarily suspended the manufacture of multidose heparin vials.

"I just think it's outrageous that this drug company, one of the largest drug companies in the country, wasn't ensuring that the product it puts in its medicines isn't safe," said Toledo-based attorney David Zoll, who filed the lawsuit on Mr. Hubley's behalf.

"This product is given to some of the most susceptible patients, those with kidney problems and who are on dialysis."

According to the lawsuit, the Food and Drug Administration estimates that more than 1 million multiple-dose vials are sold each month in the United States. About 50 percent of that product is made by Baxter, the lawsuit said.

Heparin is most often administered intravenously to decrease the clotting ability of blood. Patients undergoing medical procedures, such as cardiac surgery and kidney dialysis, often are given the drug to help with the procedure.

On Jan. 25, Baxter issued a news release informing the public of the voluntary recall, saying that it was a "precautionary measure due to an increase in the number of reports of adverse patient reactions that may be associated with the product."

It added that the company was conducting a "thorough investigation" to "identify the cause of the increase in allergic-type reactions."

Reactions to the drug ranged from stomach pain and vomiting to fainting and unresponsiveness. According to the lawsuit, reports of the reactions began as early as Nov. 19 "from more than 19 dialysis facilities in more than 12 states."

"An estimated 40 percent of the adverse reports have been categorized as serious by the FDA, and there have

been at least four reported deaths," the lawsuit said.

When reached by phone, Mr. Hubley declined to comment on the lawsuit, only saying that he believes the company must be held responsible.

The lawsuit asks for damages in excess of $75,000.

A spokesman for Baxter pointed out that several companies manufacture the drug and that it would need to be investigated where the heparin given to the patients in Toledo was made.

"It's a generic drug," Erin Gardiner said, adding that it has had widespread clinical use since the 1930s. "Several manufacturers make it. Baxter is one of them."

She declined to comment on the lawsuit, noting that the company had not yet been served.

Ms. Gardiner said the company issued a release Monday to provide an update on the reactions. The release said that since the recall, Baxter received additional reports of adverse reactions.

"Nearly all reported adverse reactions have occurred in three specific areas of product use - hemodialysis, invasive cardiovascular procedures, and apheresis procedures," the release said.

Apheresis is when blood donors give select components, most commonly platelets and plasma.

Although the company voluntarily suspended the manufacture of the multidose heparin vials, it said it will continue to distribute the product to "assure adequate supply in the market."

The decision, the company wrote, was made in agreement with the FDA.

"Given the widespread use of the critical anticoagulant - frequently called a blood thinner - and the impact a product shortage would have on operating rooms, dialysis centers, and other critical care areas, the removal of Baxter's heparin from the market would create more risk to the population of patients requiring heparin therapy than the increased potential for experiencing an adverse reaction," the release stated.

According to the lawsuit, the active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines. One of the plants used to produce the enzyme for the Baxter product is in China, the lawsuit said.

The complaint further alleges that the plant had not met the "requisite requirements for importation and/or sale within the United States."

"This plant was never inspected by the FDA," Mr. Zoll said.

He added that additional lawsuits may follow as a result of other deaths in Toledo.

The case has not yet been assigned to a judge.

- Erica Blake