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Local family still seeks answers in loved ones' deaths; drug company cited in lawsuit

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Dawn Turk is fearful of her own treatment after her mother and her brother died within three weeks of each other.

Dawn Turk lives in fear.

With no kidneys because of a hereditary condition that rendered them useless, Mrs. Turk had become accustomed to her life in and out of hospitals and hooked to machines.

It was a life that she somewhat came to expect - after all, her mother, Bonnie Hubley, had a kidney transplant and was slated for another, and her brother, Randy Hubley, was beginning to undergo regular dialysis as well.

But what Mrs. Turk and her family - father Leroy Hubley and sister Barbie Patton - did not anticipate was that the regular treatment that was supposed to keep their family members healthy may have led to their deaths.

The Toledo-area family has filed one lawsuit in federal court and intends to file a second against one of the drug companies that manufactures heparin, a blood thinner used in hemodialysis treatments. The family believes that the heparin manufactured by Baxter Healthcare Corp. of Deerfield, Ill. - which recently has recalled much of the product - was administered to Bonnie Hubley and Randy

Hubley just prior to their deaths.

The drug has not been identified as the cause of the deaths in the Hubley family. However, recalled heparin and the facilities that manufactured it are being investigated by the Food and Drug Administration and the Centers for Disease Control and Prevention.

To date, there are no answers, and that is something that Hubley family members said they cannot accept.

"They pulled through brain surgery and the removal of their kidneys and then this is it," Mrs. Turk, 46, said of her mother's and brother's deaths within three weeks of each other.

"It's so scary," she added, full of emotion knowing that she, too, requires drugs to stay alive. "I don't want to take anything anymore."

Heparin is most often administered intravenously to

Dawn Turk, left, and her sister, Barbie Patton, sit with their father, Leroy Hubley. The family believes the faulty heparin in kidney dialysis caused the deaths of two family members.

decrease the clotting of blood. Patients undergoing medical procedures such as cardiac surgery and kidney dialysis are often given the drug to help with the procedure.

Reports of adverse reactions to heparin began surfacing in November. In January, the CDC and FDA were notified, and on Jan. 17, Baxter voluntarily recalled portions of the product. The day before the recall, the FDA initiated an inspection of Baxter's manufacturing plant in Cherry Hill, N.J.

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."

Reported reactions to the drug have ranged from stomach pain and vomiting to fainting and unresponsiveness. The FDA noted that four people have died after receiving heparin, although the relationship to the drug is unclear.

The FDA further noted that about 350 adverse reactions were reported by people using the Baxter product since the end of last year as compared to fewer than 100 reports in 2007.

Suspected - but not confirmed - as the source of the contaminated product is a plant in China that the FDA admitted recently "fell through the cracks" and never had been inspected by U.S. officials. This week, the FDA and CDC sent a team to the facility for an inspection.

"We do not know the root cause of this problem. We don't know where it's coming from, what plant it's coming from. We don't know," FDA spokesman Mary Riley said in a telephone interview. "We don't know it was the China facility. We are trying to find out, but we don't know."

An active pharmaceutical ingredient in heparin is an enzyme found in pig intestines. According to FDA policies, drug manufacturers and any plants supplying them with components are inspected before an application to produce a drug is approved. Because the plant in China had a name similar to one that had recently been inspected, FDA regulators inadvertently approved the application without an inspection, Joseph Famulare, deputy director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research, said in a conference call early last week.

He reiterated that it has not been determined where the contaminated product originated.

Since its initial alert was released, the FDA continues to receive information about reactions, Ms. Riley said. Because there is an ongoing investigation, she added, the agency will not update numbers - including deaths - until the data are substantiated.

When first contacted by The Blade, a representative 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.

Spokesman Erin Gardiner said heparin is a generic drug that has been in widespread clinical use since the 1930s and that Baxter is one of several manufacturers that produces it.

However, according to the FDA Web site, Baxter produces about half of the more than 1 million multiple-dose vials of heparin sold each month in the United States.

And it will continue to do so, although at a reduced rate, to ensure a shortage of the essential drug does not occur, the FDA said.

When contacted initially about the Hubley lawsuit, Ms. Gardiner said the company had no comment because it had not received it. A company spokesman did not return phone calls last week for additional comment.

It's a drug that patients such as members of the Hubley family know well. Injected into the blood stream during dialysis and used in the tubes leading into the body, heparin thins the blood and prevents blood clots.

The Hubley family is plagued with polycystic kidney disease, a genetic disease that passed from Mrs. Hubley to her three children.

Those with the mutated gene are likely to grow cysts in their kidneys, eventually interfering with normal kidney function.

When enough cysts develop, a kidney that has worked for nearly 40 years of the patient's life eventually is rendered useless.

Mrs. Hubley had the disease, as did her son, Mr. Hubley, and daughter, Mrs. Turk.

A third daughter, Ms. Patton, has been diagnosed with the gene but has not developed symptoms.

Mrs. Hubley died Dec. 19 at age 65. According to Toledo-Lucas County Health Department records, the official cause of death was septicemia.

Three weeks later, Mr. Hubley, a retired employee of Crown Battery as well as a husband, father of three, and grandfather of one, died on Jan. 15 at age 47.

The cause of death, records show, was electrolyte imbalance.

Family members said that each was experiencing reactions prior to their deaths consistent with the warnings released by the FDA but because the warnings were not yet public, no one could figure out what was going wrong.

They said they believed they finally understood when told by employees of the dialysis center where the two were being treated that recalled heparin was pulled from the shelves in January.

Representatives of Fresenius Medical Services, which operates the Laskey clinic where the Hubleys received treatment, declined to comment on the situation. The center is not a party in the pending litigation.

Toledo attorney David Zoll filed the lawsuit on behalf of the family in U.S. District Court, Toledo, on Feb. 14. He said the lawsuit on behalf of Mr. Hubley's widow will be filed shortly.

Although not yet substantiated, he said his office is looking into seven death claims in the Toledo area. Calling it "an extraordinary number of deaths in a small time in a small town," Mr. Zoll said he must confirm that those who died suffered the symptoms identified by the FDA and that they each received a dose of heparin from one of the

recalled lots.

"It's circumstantial evidence," he conceded. "We have deaths of people under circumstances that are consistent with the FDA published data and information. It seems to me that it is worth pursuing and worth investigating."

For members of the Hubley family, the pain of reliving these deaths is worth someone possibly being held responsible.

"The only thing we want is for someone to be held accountable, for someone to take responsibility for what happened," Mrs. Patton said.

"They were overcoming the odds of this illness. They were getting by."

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