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Families tell U.S. lawmakers of heparin deaths

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By Lisa Richwine and Susan Heavey

WASHINGTON (Reuters) - A man who said he lost his wife and a son to reactions from tainted heparin made with ingredients from China urged U.S. lawmakers on Tuesday to protect patients from other unsafe drugs.

Leroy Hubley said his wife, Bonnie, and son, Randy, had undergone kidney dialysis at an Ohio clinic and were given heparin that was later recalled by Baxter International Inc. Both had reactions to the blood thinner and died within one month of each other.

"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 in this country," Hubley, who frequently choked back tears and wiped his eyes, told a U.S. House of Representatives subcommittee hearing.

A U.S. Food and Drug Administration probe found a contaminant in some batches of Baxter's heparin. Officials said tests showed the chemical could have caused the reactions reported in 81 deaths of patients treated with some brand of heparin since January 2007.

Lawmakers questioned Baxter and its ingredient supplier, Scientific Protein Laboratories LLC (SPL), about why they failed to detect the heparin contamination. Both companies said it appeared the chemical was deliberately added before either company received the ingredients.

Baxter, which had supplied about half of the U.S. heparin market, recalled most of its heparin products in February.

The action followed a string of U.S. recalls linked to China last year, ranging from tainted pet food and toothpaste to excessive lead in paint that swept millions of toys from stores.

The heparin contaminant has been detected in 13 countries, FDA officials have said, but only the United States and Germany have seen reports of an increase in allergic reactions.

The FDA says all heparin imported into the United States is now tested for contamination and the current supply is safe.

NEW STEPS URGED

Hubley and other relatives of heparin victims urged new steps to keep medicines free of contamination.

"I want to know what is going to be done to rectify the matter. I want to know if my daughter, Dawn, and the millions of others who continue to receive dialysis are safe," Hubley said.

Baxter Chief Executive Robert Parkinson said the company was "alarmed that one of our products was used, in what appears to have been a deliberate scheme, to adulterate a life-saving medication, and that people have suffered as a result."

"We deeply regret that this has happened, and I feel a strong sense of personal responsibility for these circumstances," he said.

Heparin -- used in dialysis and some surgeries to prevent blood clots -- is derived from pig intestines and often collected from small, mostly unregulated farms in China.

FDA tests found the recalled drug contained an altered form of chondroitin sulfate that mimics raw heparin. Chinese officials have said the chemical was present but is not to blame for the reactions or deaths.

Rep. Bart Stupak, a Michigan Democrat, said it remained uncertain whether the contamination was intentional or accidental. He said both companies should have done more to assure their products were safe.

"Both Baxter and SPL have failed the American public," said Stupak, chairman of the House of Representatives Energy and Commerce Committee's oversight and investigations panel.

Using the contaminant would be about 100 times cheaper than real heparin, said committee investigator David Nelson.

FDA CRITICIZED

Lawmakers attacked the FDA for failing to inspect SPL's plant in Changzhou, China, before approving Baxter's heparin. Agency inspectors found a series of manufacturing problems during a visit in February, after Baxter'S recall.

Baxter officials audited the facility five months earlier and said they found acceptable conditions, Nelson said.

"I'm really baffled by that. How is it you can have two divergent findings from the same plant?" Stupak asked.

Baxter's Parkinson said the visits happened at different times, and the drug maker's audit was routine while the FDA visit was in response to a specific problem.

Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, said the agency needed more tools and better technology to hold companies accountable.

"FDA needs the help of Congress to make sure that a tragedy like this does not happen again," Woodcock said.

Woodcock said it would cost about $225 million annually for the FDA to inspect, every other year, all pharmaceutical plants around the world that supply the U.S. market.

Lawmakers are considering legislation that would charge drug and device makers fees to boost inspections.

(Editing by Tim Dobbyn)
