Grieving Families Blame Heparin for Deaths

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April 29, 2008

Dennis Staples, a radio announcer in Toledo, Ohio, slipped into a coma the day before his 60th birthday. He had been on dialysis for more than two years because of kidney failure, but had fared well with t reatment. Then one day, while on dialysis at the doctor's office, Staples went into cardiac arrest. Despite a quick medical response, he never recovered.

Today, his wife Johanna attributes his death to the blood-thinner drug heparin that he received to prevent clotting during treatment.

"My husband and many other ailing patients who received that drug suffered needlessly," Staples said.

Dennis Staples may be one of at least 81 patients who died from bad heparin between January 2007 and March 2008, in addition to hundreds of others who have experienced severe allergic reactions like low blood pressure, vomiting and shortness of breath.

The U.S. Food and Drug Administration is now investigating whether the drug's ingredients that came from China became contaminated on purpose or by accident, and where in the supply chain that contamination occurred.

Staples was among several people who provided emotional testimony Tuesday at a Capitol Hill hearing on how the medication became tainted and whether the FDA's inspection procedures for foreign drug plants fueled the problem.

Drug Makers Say Deliberate Contamination Happened Early in Supply Chain

Both the CEO of heparin manufacturer Baxter and the CEO of Scientific Protein Laboratories, the U.S. firm that operates the Chinese plant from which Baxter and others got their heparin, suggested the contamination was deliberate and happened before the drug's ingredient reached the lab.

"We are greatly concerned that our heparin product appears to be the target of a deliberate adulteration scheme," Robert L. Parkinson, Jr., chairman, CEO and president of Baxter International, Inc., said in a written statement to the House Energy and Commerce Committee's oversight and investigations panel.

David Strunce, CEO of Scientific Protein Laboratories, likewise said, "It seems to us that it's an intentional act upstream in the supply chain."

"This is thuggery," said Rep. Michael C. Burgess, R-Texas. "This is thievery. This is high crimes and a direct assault on the American public. I mean, this is not just testing for normal product manufacture, in my opinion, for what it's worth. Someone did this deliberately. They found a product much cheaper than the active ingredient."

Still subcommittee chairman Bart Stupak, D-Mich., pointed fingers at those companies for not ensuring the product that passed through their hands was safe.

"Make no mistake about it: Both Baxter and SPL have failed the American public," Stupak said.

Inspections Aim To Monitor Complex Supply Chain

Derived from pig intestines, often from farms in rural

China, heparin is processed and manufactured in various plants in China, the United States and abroad before it is finally administered to patients.

Experts have since created a new test to detect the previously undetectable contaminant in that complex supply chain. The FDA has also ramped up efforts to test heparin shipments coming from overseas to find out whether they're safe.

Deborah M. Autor, director of the FDA's Center for Drug Evaluation and Research's Office of Compliance expressed confidence in that effort. But Stupak said without immediately recognizing the names of the 12 companies still in the contaminated heparin supply chain, officials monitoring heparin at the border would be ineffective.

Meantime, the Hubley family, too, told lawmakers heparin was responsible for their losses.

Leroy Hubley, also from Toledo, lost both his wife, Bonnie, and his son, Randy, after they received heparin during dialysis for a genetic kidney disease. Bonnie Hubley died in December 2007 and Randy died in January 2008. Both experienced symptoms associated with the contaminated heparin after receiving Baxter's heparin. Other members of the Hubley family continue to receive dialysis for their kidney disease.

"As a nurse, I thought that I would be there to save my husband from any errors, but I guess I was naïve," Randy Hubley's wife, Colleen Hubley, a dialysis nurse, told lawmakers. "I never thought the lifesaving medication we were relying on might be contaminated."

Last week, the same panel blasted FDA Commissioner Andrew von Eschenbach in regard to contaminated heparin at a hearing on the broader issue of the agency's foreign drug-inspection program.

Though estimates suggest more than 80 percent of all active ingredients used by U.S. drug manufacturers come from abroad, the FDA only inspects foreign drug plants about once every 13 years, according to the Government Accountability Office.

The GAO finds that China's drug plants are inspected once every 30 to 40 years. The FDA plans to establish permanent overseas offices in numerous countries, including China, to help address the problem.

The House Energy and Commerce panel is considering ways to better ensure that food and drug imports are safe. The panel is considering proposing that drug and drug device makers be required to register annually with the FDA. The committee is also thinking of proposing that drug labels be required to include details about drugs' country of origin, source of the ingredients and place of manufacture.