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Heparin patients' suffering recounted

- Story Highlights
- Families testify about problems for those who got contaminated blood thinner
- Lawmakers blast FDA, heparin makers over contamination
- Contaminated heparin traced from China to 11 countries, including U.S.
- FDA has linked 81 U.S. deaths to contamination symptoms; no causal link confirmed

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WASHINGTON (CNN) -- In emotional testimony before a congressional subcommittee Tuesday, relatives of people who died after being injected with contaminated heparin expressed anger and sadness at the failure of the manufacturer and government regulators to ensure the drugs were safe.

"I watched my husband and my best friend slip away before my eyes," Colleen Hubley of Toledo, Ohio, told the House Subcommittee on Oversight and Investigations. "My husband was a fighter until the bitter end ... I know that he would want me to make sure this doesn't happen to anyone else."

The dialysis nurse said she had felt competent to handle any issues her husband, Randy, might have faced as he underwent dialysis.

He died in January as she frantically performed CPR to save him.

"I thought that I would be there to save my husband from any errors, but I guess I was naive," she said.

Randy's father, Leroy, also testified, breaking down frequently into sobs. His wife and Randy's mother, Bonnie, died a month before her son, also from contaminated heparin received at the same clinic. Dr. Sanjay Gupta reports on the heparin hearing »

"The FDA and Baxter have not done their job," he said. "Somebody sure the hell didn't."

Contaminated shipments of heparin, a blood thinner commonly used by dialysis patients and in heart surgery, have been traced from China to 11 countries including the United States.

Investigators have identified oversulfated chondroitin sulfate (OSCS) -- a compound made from animal cartilage -- as a contaminant linked to hundreds of serious adverse events, including allergic reactions causing nausea, vomiting, shortness of breath and a severe drop in blood pressure.

It is not yet known how the product became contaminated. But in a prepared statement to the subcommittee, Dr. Janet Woodcock, director of the Food and Drug Administration's Center for Drug Evaluation and Research, said, "(The) FDA's working hypothesis is that this was intentional contamination, but this is not yet proven."

The Food and Drug Administration has tallied 81 deaths related to those symptoms in the United States, though China disputes a causal link. Woodcock said last week the severe reactions seem to be more likely among patients who were given high doses of the drug.

The raw ingredient for heparin sold by Baxter International and ordered recalled came from Scientific Protein Laboratories, a Wisconsin company that owns Changzhou SPL Co. Ltd., a Chinese factory.

The FDA last week sent Changzhou SPL a warning letter, saying the company had not instituted proper safeguards to ensure the raw materials were free of impurities. The letter said shipments of the company's materials made at the plant would be refused admission into the United States until the matter is corrected.

However, on Tuesday members of Congress blasted the FDA for approving the plant as a heparin supplier without first inspecting it. Committee Chairman Bart Stupak, D-Michigan, said a "series of FDA blunders" led to the approval in 2004.

FDA was not the sole object of his wrath. "Make no mistake about it: Both Baxter and SPL have failed the American public," he said.

Johanna Staples, also of Toledo, Ohio, who lost her husband Dennis, told subcommittee members, "In this land of freedom and opportunity, we've come to expect to be protected and safe. It's overwhelming to discover that there are circumstances beyond our control from which you are not sheltered.

"We have a false, empty sense of security, and we are neither safe from harm nor catastrophe."

Robert L. Parkinson, Jr., president and CEO of Baxter International, testified that his company had tested every lot of heparin it received from China. However, OSCS, a heparin-like contaminant, could not be detected with standard testing until recently. In the wake of the incident, he said, Baxter is "methodically re-examining our global supply chain practices."

Parkinson said the addition of OSCS "appears to have been a deliberate scheme to adulterate a lifesaving medicine."

David Strunce, SPL's president and CEO, offered similar testimony.

"The recent worldwide contamination appears to be the result of a deliberate act upstream, not SPL or Changzhou SPL-specific," he said.

Asked how the contaminant got into the company's China plant if the suppliers were being monitored, he said, "Monitoring is not exactly the same thing as living in the facility."

He called the addition of OSCS "a very insidious act that attacked the supply chain of most companies producing heparin."

Strunce said the counterfeiting appeared to have occurred at a time when the price for Chinese heparin was rising. The drug is made from pig intestines, and an outbreak of blue-ear disease in 2006 wiped out much of the swine population in China, driving up the price.

"I believe that that provided some additional incentive" for a supplier to add a contaminant, he said.

At $1.75 per unit, heparin carries razor-thin profit margins, testified Dr. Clive Meanwell, chairman and CEO of the Medicines Company, which markets an alternative to heparin.

He called for FDA to recruit, train and support enough staff to ensure it can properly inspect the various small producers of the product.

Parkinson said he still does not know whom to blame. "This is a very complex supply chain," he said.

Chinese officials have disputed that OSCS was the source of the adverse events in patients, suggesting that uncontaminated heparin may also have been to blame.

But a study published last week in the New England Journal of Medicine found that the impure product caused the symptoms that led to the deaths.

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