As families recall deaths, FDA investigates deliberate heparin contamination

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As families of loved ones tell of their deaths due to heparin contamination, the U.S. Food and Drug Administration investigates the deliberate contamination of the blood thinner.

The widow of a man who died after receiving contaminated heparin told a congressional subcommittee Tuesday "we have a false sense of security" in a land where people expect to be protected and safe.

Brushing away tears, Johanna Marie Staples of Toledo, Ohio, said her husband, Dennis, was looking forward to his 60th birthday party on the last day of his life.

Contaminated heparin, a blood thinner used in dialysis and other treatments, has been connected to 81 deaths and 785 severe allergic reactions, said Rep. Bart Stupak, Democrat chairman of the House Energy and Commerce subcommittee on oversight and investigations.

The heparin, made from ingredients imported from China, has been recalled by Baxter International, and the Food and Drug Administration has blocked imports from the Chinese company.

The FDA found the drug was contaminated with oversulfated chondroitin sulfate, which mimics heparin and thus was not detected in routine testing, Stupak noted.

When, and how, it was introduced into the product has not yet been determined.

"FDA's working hypothesis is that this was intentional contamination, but this is not yet proven," Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, told the panel in her prepared testimony.

Staples told the subcommittee that her husband was looking forward to an evening birthday party at a steakhouse with friends after receiving his dialysis treatment.

But during the treatment he become unresponsive, stopped breathing and went into cardiac arrest, she said. Paramedics rushed him to a nearby hospital but he never regained consciousness, she said.

Colleen Hubley, a dialysis nurse whose husband, Randy, died after receiving heparin, told of a desperate struggle to save his life with cardiopulmonary resuscitation.

"We were certain that no matter what came our way we could handle it together," she said. "Despite our hope, this man died while I did CPR on him, powerless to save him."

When her husband came home from a dialysis treatment he suffered diarrhea, abdominal pain and had problems breathing, she said.

At 2 a.m., she said, she awoke to him clutching his abdomen and grabbing his chest, unable to breathe. She did CPR and called paramedics, who struggled to get a breathing tube in his throat because of swelling.

"I watched my husband and my best friend slip away before my eyes," she said. "I never thought the lifesaving medication we were relying on could be contaminated."

Randy Hubley's death came just a month after that of his mother, Bonnie, under the same circumstances.

Leroy Hubley, dabbing his eyes with a handkerchief, told of losing both wife and son, adding: "I want to know if my daughter, Dawn, and millions of others who continue to receive dialysis are safe."

He told, too, of Bonnie suffering diarrhea, pain and trouble breathing and being rushed to a hospital where doctors recommended removal of her breathing tube to end her suffering.

"Christmas music played in the background as each one of us said our goodbyes," said a shaking Leroy Hubley. "And the nightmare

returned only weeks later when my son, Randy, started dialysis at the same clinic."

The Hubleys also reside in the Toledo area.

Changes have been made in recent years

The FDA's Woodcock told the subcommittee that in recent years major changes have occurred where drugs are made.

For example, in 2007 the agency received only about 150 applications for approval to make generic drugs in the United States compared to nearly 500 from China and more than 400 from India, she said.

"Great vigilance is required to maintain" drug safety, she said.

Chinese officials have argued that the contaminant could not be the root cause of the allergic reactions and suggested that problem may have occurred in the United States.

Baxter president Robert L. Parkinson Jr. said in testimony prepared for the subcommittee that his company is "greatly concerned that our heparin product appears to be the target of a deliberate adulteration scheme."

"The complexity of the global drug supply chain creates new and emerging risks that call for new ways of thinking about, identifying and addressing vulnerabilities, and that resting on old standards — even ones that have worked for decades — is no longer enough," Parkinson said.

David Strunce, president of Scientific Protein Laboratories, said in testimony that the worldwide problem with contaminated heparin cannot be traced to how heparin was processed at the Changzhou SPL factory in China which supplied the material to Baxter. His company holds a majority interest in Changzhou SPL.

Rather, Strunce said, there appears to be deliberate and widespread contamination of the crude heparin supply in China affecting many manufacturers.

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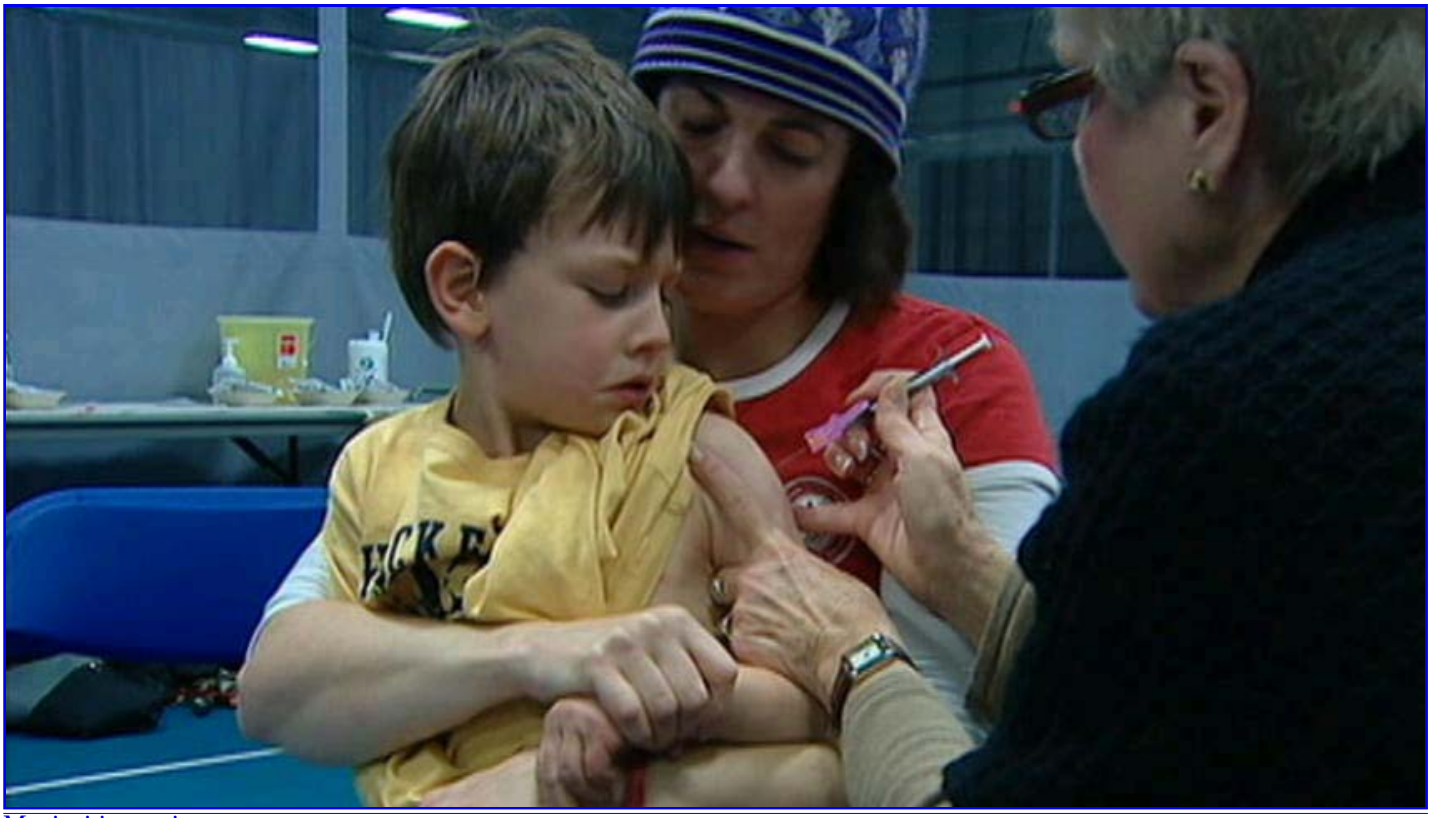

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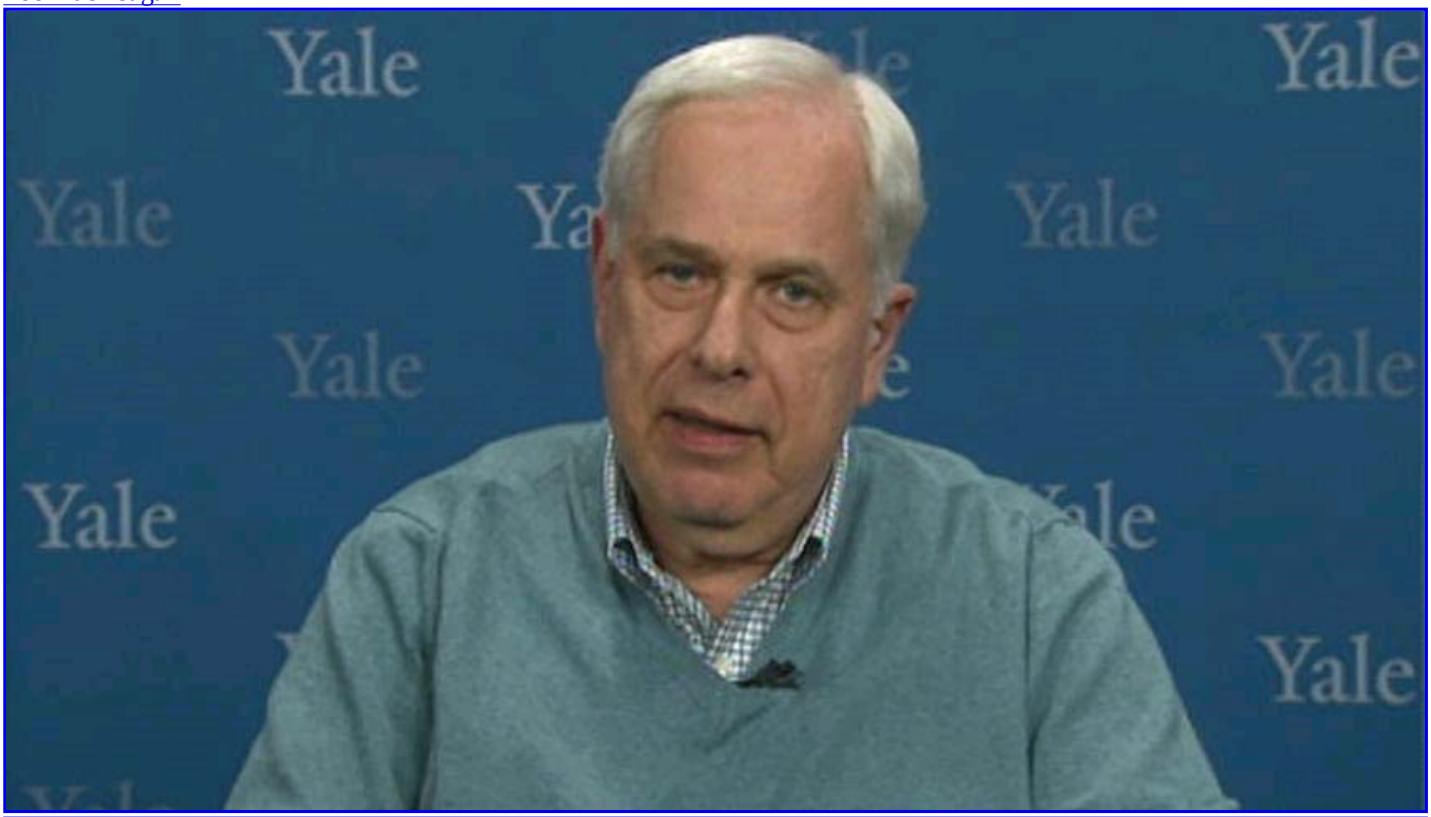

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