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Heparin Testimonies Before House Committee

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Emotions ran high in Washington yesterday, Tuesday 29th April, as a congressional panel listened to tearful and angry testimonies from family members of how their loved ones died after being given contaminated heparin. Manufacturers and industry regulators also told their story, but panel members were very unhappy with their failure to stop the unsafe blood thinner from entering the US from China.

Families expressed sadness at their loss, and anger at manufacturers and regulators.

One man, Leroy Hubley of Toledo, Ohio, lost his wife Bonnie and his son Randy, within weeks of each other. They both had an inherited kidney disease and had undergone kidney dialysis at an Ohio clinic and received heparin from a batch made by Baxter International.

The New York Times reported how Hubley described his feelings:

"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."

Randy Hubley's wife, Colleen, a dialysis nurse, also gave tearful testimony describing how she watched her husband die:

"I watched my husband and my best friend slip away before my eyes."

She told panel members of the House Subcommittee on Oversight and Investigations that her husband fought to the "bitter end", and that she knew he would want her to make sure nobody else had to go through what he did, reported CNN.

Earlier this year, the US Food and Drug Administration (FDA) found that some heparin products made by Baxter International contained a contaminant that was entering the country via shipments of a main ingredient made in China. The agency said tests had shown contaminated product was linked to 81 deaths reported since January 2007, of patients who had used the contaminated product.

Although nobody knows how the contaminant got into the product, Dr Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research told the committee that the agency's "working hypothesis is that this was intentional contamination, but this is not yet proven".

According to CNN, after describing how he lost his wife and son, Hubley said:

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

Heparin is used to stop blood clots forming during surgical procedures and kidney dialysis. As well as the deaths, hundreds of other surgical and dialysis patients have reported serious allergic reaction after using contaminated heparin made by Baxter. Baxter, who supplied half of the US annual demand for heparin, recalled their products in February 2008.

The authentic ingredient in raw heparin is made from the lining of pig intestines and costs about 900 dollars a pound, said a congressional investigator, whereas the contaminant, oversulfated chondroitin sulfate, is made from animal cartilage and costs 9 dollars a pound.

The contaminant has a similar combination of chemical elements as the correct ingredient and the difference between them can only be detected with technology that is more sophisticated than that being used by inspectors when the problem was discovered. According to the FDA, more sophisiticated technology is now used to check all heparin entering the country and the current supply is safe.

The FDA traced the source of the contaminated heparin to Changzhou SPL, a Chinese subsidiary of Wisconsin-based Scientific Protein Laboratories (SPL). SPL supplied the raw ingredient that was used by Baxter in its heparin products.

Thirteen countries, including the US, have now detected the contaminant in heparin products, said the FDA, but only the US and Germany have reported an increase in adverse events linked to their use. The adverse events consist of allergic reactions with symptoms like difficulty breathing, excessive sweating, nausea, vomiting, and sudden fall in blood pressure that can lead to life-threatening shock.

When questioned, representatives from Baxter and SPL said they believed the contaminant was already in the product when it entered the US.

CEO of Baxter International, Robert Parkinson, said that his company tested all the heparin it received from China, but the contaminant, oversulfated chondroitin sulfate, could not be detected with the testing equipment they were using. The equipment they now use can, he said.

Parkinson said Baxter were going through all their supply chain practices, and described the discovery of the contaminant as a "global and industry-wide crisis", with a root cause that was "novel and insidious", so much so that it escaped the notice of some of the world's most sophisticated drug regulatory agencies and avoided the quality systems of many companies.

According to a statement issued by SPL, David Strunce, president of Changzhou SPL, testified that heparin contamination is a global issue, affecting many manufacturers and appeared to be deliberate and widespread in China. He said the counterfeiting probably started after blue ear disease killed many pigs in China in 2006 and drove up the price of pig intestines from which the authentic heparin raw ingredient is derived.

Last week the FDA said that the counterfeit ingredient came from 12 Chinese suppliers of crude heparin spread across a broad area of China.

The agency wrote to Strunce last week, saying the company had failed to implement safeguards to ensure heparin raw ingredients were free of impurities. An inspection of the plant by the FDA had found irregularities in procedures and contaminated tanks at the plant. The agency informed the company that materials made at the plant will not be allowed into the US until they correct their procedures.

Members of the congressional panel expressed their anger at the FDA for approving the plant without inspecting it. An earlier report from the agency admitted they had confused the name of the company with another supplier that had already been inspected.

If the FDA had inspected the plant before approving it in 2004, they may have uncovered the problems thzat have now only come to light after the deaths were reported, said Subcommittee Chairman Bart Stupak (Democrat, Michigan), who described the FDA's actions as a "series of blunders", reported CNN.

However, he did not hold the agency solely responsible, and said the manufacturers were also to blame, "Both Baxter and SPL have failed the American public," said Stupak.

Earlier this month, Chinese health officials, who had run their own tests, said that the contaminant found in the heparin ingredient sourced from China was not to blame for the deaths and severe reactions reported in the US because some of them were linked to batches of product that did not contain the contaminant.

But this claim was disputed by the FDA, who were confident of their verdict because it was supported by results from several labs, who found contaminant in batches that had passed the Chinese tests.

Woodcock said the FDA needed another 225 million dollars every year to carry out biennial inspections of all overseas plants making drugs that enter the US market.

According to the New York Times, there is a growing consensus on Capitol Hill that the agency's budged should be hiked up to allow it to ensure the safety of the nation's drugs, medical devices and foods, but this is at odds with the Bush Administration which has only proposed increasing the budget next year by 3 per cent, which won't even cover its expected cost increase.

It appears that all stakeholders eagerly await the outcome of this hearing.

Sources: CNN, New York Times, Reuters, Baxters, SPL, MNT archives.

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