What Went Wrong With Heparin?

By LISA STARK (@LisaStark) and DANA WACHTER

Feb. 21, 2008

It's become all too common these days to hear about recalls of foreign-made products — everything from pet food to toys.

This time, it's heparin, a blood-thinning drug often used during dialysis and surgery.

All of the recalled heparin was sold by New Jersey's Baxter Pharmaceuticals, which produces half of the nation's supply. The drug has an active ingredient that comes from a plant in China and is under investigation in connection with at least four deaths and hundreds of allergic reactions.

LeRoy Hubley, of Toledo, Ohio, believes heparin was responsible for the deaths of his wife and son. Both died in recent months after receiving dialysis, and Hubley is suing the company.

"I don't know what to say. I just, I'm so damn mad," Hubley said. "There's nothing I can do about it."

The Food and Drug Administration has admitted it never inspected the Chinese plant that made the active ingredient for heparin, because officials there confused the plant with another in China that has a similar name.

"This is an agency that is charged with safeguarding the public health, but it's being run like the keystone cops," said Rep. Rosa DeLauro, D-Conn., chairwoman of the House Agriculture, Rural Development, Food and Drug Administration Appropriations Subcommittee. "That is unacceptable."

It's not clear yet whether the problems tied to the heparin are related to the ingredient produced in the Chinese plant, but the case underscores growing concerns many people have about the drugs we use today.

"Roughly 80 percent of active pharmaceutical ingredients are made outside our country," former FDA official Peter Barton Hutt said.

The nations that make the most drugs for the U.S. market are China, with 714 plants registered to make pharmaceuticals for the United States, and India, with 410. But the FDA says many of those facilities don't currently ship drugs to the U.S.

The agency is required to inspect U.S. plants every two years, but that isn't the case with foreign plants. Those facilities are put on priority lists based on the last time they have been inspected, or if they have new drugs being put on the market, versus drugs that are currently being manufactured.

There are two kinds of inspections - one is done when a plant first begins manufacturing a drug for the U.S. - the other are ongoing inspections. The FDA insists it certifies the good manufacturing process of all plants - foreign and domestic - when they begin manufacturing a drug. It was only because the agency confused the Chinese Heparin plant with another facility, that this was not done in this case, the FDA says.

It's also a staffing issue — the actual staff inspecting the plants overseas are mostly volunteers, and have c ertain schedules to follow when traveling and inspecting. It is estimated that the FDA inspects just 7 percent of foreign plants a year, and at that rate, it could take 13 years to check each plant.

ADVERTISEMENT

PRINT POWERED BY FormatDynamics™

Last year, for example, the FDA inspected only 14 plants in China, and 65 in India.

Another problem: The FDA doesn't even know exactly how many plants there are making drugs that wind up being prescribed for patients in the United States.

According to two different research databases, there are two very different numbers for overseas plants. One lists about 3,000 plants that are recorded to be inspected, and the other indicates there are about 6,800. The FDA has concluded there are about 3,249, but it still isn't sure.

FDA office of compliance director Deborah Autor said the FDA is working to improve its presence in foreign countries.

"We recognize that, at the FDA, we need to do everything possible that we can to assure Americans that the drugs that they're getting from anywhere, are safe," she said.

Those who follow the FDA say a big problem is that the agency lacks the resources it needs.

"If they had an absolutely perfect list, and if it was all computerized, they still don't have the money and personnel to do what we expect them to do," Hutt said.

ADVERTISEMENT