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Heparin Contamination May Have Been Deliberate, F.D.A. Says

By GARDINER HARRIS

WASHINGTON — Federal drug regulators believe that a contaminant detected in a crucial blood thinner that has caused 81 deaths was added deliberately, something the Food and Drug Administration has only hinted at previously.

“F.D.A.’s working hypothesis is that this was intentional contamination, but this is not yet proven,” Dr. Janet Woodcock, director of the Food and Drug Administration’s drug center, told the House Subcommittee on Oversight and Investigations in written testimony given Tuesday.

A third of the material in some batches of the thinner heparin were contaminants, “and it does strain one’s credulity to suggest that might have been done accidentally,” Dr. Woodcock said.

Two weeks ago, Food and Drug Commissioner Andrew C. von Eschenbach told a Senate subcommittee that the contamination was done “by virtue of economic fraud,” but he quickly withdrew the remark, saying he had “probably gone too far.”

Dr. Woodcock’s statement on Tuesday was part of growing chorus that has labeled the heparin contamination as perhaps the most brazen poisoning episode since 1982, when seven people in the Chicago area died after taking Tylenol that had been laced with cyanide.

The Tylenol case led to substantial changes in product packaging, and the heparin contamination has led both Democratic and Republican committee members to call for major changes in the way the F.D.A. functions and is financed.

Tuesday’s hearing was also the first in which family members of those who died were asked to testify.

LeRoy Hubley of Toledo, Ohio, described how both his 65-year-old wife and his 47-year-old son died within a few weeks of each other. Both suffered from a genetic kidney disease that required constant dialysis, for which heparin is routinely used.

“As Christmas music softly played in the background, we each said our goodbyes,” Mr. Hubley said, breaking down in tears. “Then my wife and love of 48 years drifted away.”

He did not know for weeks after their deaths that his wife, Bonnie, and son, Randy, had been given contaminated heparin.

“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,” he said.

David G. Strunce, chief executive of Scientific Protein Laboratories, the company that supplied contaminated heparin material to Baxter International, which manufactured and distributed the finished

drug, described the contamination as “an insidious act” that “seems to us an intentional act upstream in the supply chain.”

The F.D.A. has identified Changzhou SPL, a Chinese subsidiary of Scientific Protein Laboratories, as the source of the contaminated heparin. A Congressional investigator said the contaminant, oversulfated chondroitin sulfate, cost $9 a pound compared with $900 a pound for heparin.

Mr. Strunce said that his company tried to find the original source of the contamination but was stopped by the Chinese authorities.

Robert L. Parkinson, Baxter’s chairman and chief executive, told the committee, “We’re alarmed that one of our products was used in what appears to have been a deliberate scheme to adulterate a life-saving medication.”

Chinese officials have disputed the F.D.A. contention that the contaminant caused death and injury, and they have insisted on the right to inspect American drug plants if the F.D.A. insists on inspecting Chinese ones.

David Nelson, a Congressional investigator, told the House panel that had the F.D.A. inspected the Chinese plant, the contamination could have been averted.

F.D.A. officials have admitted that they mistakenly failed to conduct an inspection of the Changzhou SPL plant but said that an inspection would not have been able to uncover the contamination.

The agency finally conducted an inspection of the facility in February and found so many problems that the F.D.A. blocked the plant from exporting to the United States. Mr. Nelson was even more critical of Baxter International, which bought heparin ingredients from Changzhou SPL from 2004 through 2008 but did not inspect the facility until September 2007.

The company sent one person who spent one day in the plant, Mr. Nelson said. Five months later, the F.D.A. discovered myriad problems, he said.

“It really is impossible for a plant to have fallen that far out of compliance in five months,” Mr. Nelson said.

Under withering questioning, Dr. Woodcock said that the F.D.A. would need another $225 million annually to inspect every foreign drug plant every other year, the frequency most say is needed. The agency will spend $11 million this year on foreign drug inspections.

There is a growing bipartisan consensus on Capitol Hill that the F.D.A. needs a rapid increase in its budget to ensure the safety of the nation’s drugs, medical devices and food.

The Bush Administration has proposed increasing the agency’s budget next year by only 3 percent to $1.8 billion, not enough to cover even its expected cost increases.