FDA should tighten up

by The Milwaukee Journal Sentinel

The U.S. Food and Drug Administration has some explaining to do after four deaths and hundreds of adverse reactions to the popular blood thinner heparin. The FDA has acknowledged that it failed to inspect a Chinese facility that produced the drug after confusing it with another firm. The Chinese government did not inspect the plant, either.

The facility that should have been inspected is part of a joint venture operated by Scientific Protein Laboratories of Waunakee, Wis., which supplies heparin to Baxter International Inc. It's not known whether problems with Baxter's drug were caused by the heparin made in China by SPL. The Waunakee firm says its supply chain is safe and that it is cooperating with the FDA and doing everything it can to ensure patient safety. Neither SPL nor Baxter have been accused of wrongdoing. But whatever the source of the problem, the episode raises concerns about the FDA's ability to manage a global inspection program. It comes after a critical Government Accountability Office report in November that found "FDA's effectiveness in managing the foreign drug inspection program continues to be hindered by weaknesses in its databases." The report found that the FDA inspects only about 7 percent of foreign establishments a year.

Heparin, in common use as a blood thinner since the 1930s, is manufactured from pig entrails. More than half of the global supply comes from China. In a report last week on the small and often rudimentary Chinese workshops that make the product, The Wall Street Journal found that it can be difficult to trace the heparin back to individual animals from which the product is derived. Yet products must be traceable so that if problems arise, they can be contained quickly. The FDA must answer for why it has been slow to adapt to the increase in imported food and drugs. Congress also should look at toughening requirements for the FDA's inspection of foreign producers of drugs and consider boosting funding for inspections. Michigan Democratic Reps. John Dingell and Bart Stupak charge that the FDA, under its own guidelines, should have inspected the plant before any shipments entered the United States.

But while that is FDA policy, it is not federal law. It needs to be.