

\$225 million price for safety

FDA officials state cost to stop tainted drug imports

By Jonathan D. Rockoff *Baltimore Sun* April 30, 2008

WASHINGTON The government needs \$225 million and a range of new powers to protect Americans from unsafe drug imports, federal health officials said yesterday under tough questioning by lawmakers investigating a contaminated blood thinner from China.

"We currently have a crisis and an opportunity to make real change," Deborah M. Autor, director of the Food and Drug Administration's drug compliance office, said at a House oversight subcommittee hearing.

Autor joined Dr. Janet Woodcock, director of the FDA's drug division, in asking Congress to give the agency the power to inspect foreign companies that ship drugs to the U.S., stop imports at the border if they come from factories not inspected and require American drug makers to police their overseas suppliers.

Woodcock said the FDA would need \$225 million in additional funding to inspect the 3,300 foreign drug-making plants as frequently as it reviews plants in the U.S. That is more than 20 times the agency's current foreign drug inspection budget and about one-tenth the agency's overall budget.

The officials offered their most specific assessment of the agency's needs during the latest congressional inquiry into the contamination of the blood thinner heparin, which has been found in 11 countries and caused as many as 81 deaths in the U.S.

FDA officials have said the contaminant, an unapproved chemical modified to look like heparin's main ingredient, was introduced in China. Agency officials have repeatedly said they can't tell whether the contamination was deliberate, but Woodcock said at the hearing that it probably was.

After Chinese imports of pet food and toothpaste were found to be tainted, the Bush administration proposed basing inspectors overseas. The administration has refused to put a price tag on its plan and emphasizes relying on American companies and foreign governments to assure the safety of products made abroad.

FDA officials have been reluctant in previous import safety hearings to stray from the administration message, even under hostile questioning. House Democrats are drafting legislation that would expand the agency's powers and make foreign firms shipping drugs to the U.S. pay user fees to cover the cost of inspections, up to \$300 million a year.

The tough questioning continued at the subcommittee hearing as two Michigan Democrats, Rep. John D. Dingell and Rep. Bart Stupak, interrupted FDA officials to determine the limits on the agency's authority to prevent unsafe imports from entering the U.S. and learn what reform legislation should contain.

Unhappy with the answers he was getting, Dingell told FDA officials they should be "embarrassed" by their testimony and stressed the agency needed to become a tougher watchdog. "You folks are more trusting than a kindergarten class," he said.

Later, Woodcock and Autor provided the specifics about extra funding and authority. "Hallelujah," Stupak said after the FDA officials detailed needs. "We're making progress."

Heparin is widely used during kidney dialysis and open heart surgery to prevent dangerous clots from forming. After scattered reports of serious side effects, Baxter International recalled most of its heparin products in February. Baxter had gotten a tainted ingredient from a plant in eastern China jointly owned by a Wisconsin company, Scientific Protein Laboratories.

The hearing began with relatives of three victims describing in tearful detail how routine dialysis led to trouble breathing, severe diarrhea and chest pain, and death.

Leroy Hubley of Toledo, Ohio, recalled how hospital doctors took his wife of 48 years, Bonnie, off life support in December while Christmas music played in the background. A few weeks later, his son Randy, 47, died, also from the side effects of heparin.

Baxter and SPL executives apologized to the families. The company officials blamed Chinese suppliers and stressed that standard quality testing couldn't detect the contaminant.

Last September, Baxter inspected the plant in Changzhou, China, and deemed the facility OK after getting one problem fixed. Five months later, as the heparin scare intensified, an FDA inspector visiting the same plant found numerous violations of good manufacturing practices.