A shot in the dark

by The St. Louis Post-Dispatch

Two massive product recalls - one involving beef, the other a life-saving drug - demonstrate that the regulatory framework Americans depend on for protection from unsafe food and dangerous drugs is badly broken.

On Sunday, a California meat packer issued the largest beef recall in U.S. history. It covered 143 million pounds of meat, including 37 million pounds that had been used for school lunches.

The recall occurred after the Humane Society of the United States, a private organization, uncovered dangerous practices at the Westland/Hallmark Meat Company slaughterhouse. The United States Department of Agriculture, which is supposed to prevent diseased animals from getting into the food supply, had an inspector at the plant but he never detected the practices. Workers at the plant were using forklifts and cattle prods to force so-called downer cows, which cannot walk and are at increased risk of disease, onto the killing floor.

Last week, meanwhile, federal officials acknowledged that they failed to inspect a Chinese plant that produced the active ingredient for a crucial blood-thinning drug called heparin. The U.S. Food and Drug Administration is supposed inspect foreign plants before permitting them to ship drugs or chemicals into the country. But FDA officials said this week that they mistook the plant for another with a similar name that already had been inspected. Chinese regulators also failed to inspect the plant. The first reported victims were eight Missouri children experiencing kidney failure. Last November, while getting dialysis at a pediatric hospital, they had life-threatening allergic reactions.

Within weeks, the U.S. Centers for Disease Control and Prevention had reports of more than 350 similar cases from 12 states, most of them adults. Four people died. The culprit turned out to be contaminated heparin, a drug used in surgery and dialysis to prevent blood from clotting.

The FDA is so short-staffed and underfunded, the Government Accountability Office reported last month, that it would need 13 years to inspect every foreign drug plant that ships products into this country. Its record in China is even worse.

That country has more than 700 plants approved to ship drugs to the U.S. Between 2002 and 2007, the FDA inspected just 88 of them. At that rate, it would need 40 years to inspect every Chinese plant now shipping drugs into this country.

The drug safety agency conducts no unannounced plant visits overseas. Even when it does visit, inspectors

have no independent translators. Obviously, the agency's lack of language skills played a role in this tragedy. But so did the FDA's faulty databases; the agency has conflicting information about the number of foreign plants shipping into the United States in two databases it maintains.

Because much of the inspection budget comes from user fees paid by drug companies, the FDA does far more inspections in countries with well-developed regulatory systems such as Switzerland and Germany than it does in China. The head of the Chinese drug safety office was executed last year after the country was rocked by scandals tied to counterfeit, unsafe or worthless drugs marketed there.

Waves of similar problems in this country a century ago prompted the formation of an oversight system that was, for many years, the envy of the world. But in recent decades, Congress and successive presidential administrations repeatedly have underfunded the FDA, the USDA and the Consumer Product Safety Commission, which has been forced to recall record numbers of unsafe toys over the past year. A new regulatory philosophy that depends on industry self-policing has come into fashion, with tragically predictable results.

Government agencies that are consistently starved of resources are incapable of doing the job we expect them to do: ensuring that the drugs we take are effective and the food we eat is safe. Trusting our safety to the current, weakened system is like trying to hit targets with a shot in the dark.

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