

Is the FDA a broken agency?

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WASHINGTON -- Every few months, the Food and Drug Administration goes into fire-brigade mode, rushing to get control over another safety crisis.

Tainted peanuts. Unsterilized syringes. Salmonella in Mexican chili peppers. A contaminated blood thinner from China that sent patients into life-threatening shock.

Some say the FDA is broken.

"Bet yourself a new hat or a fine dinner that you are going to have a scandal a month," said Rep. John Dingell, D-Mich. "They are running around like a lot of headless chickens."

Others, even some critics, see tentative improvements. Many defenders acknowledge the FDA is struggling.

"'Broken' is the kind of word that's sort of a fighting word," said Dr. Frank Torti, the cancer researcher serving as acting FDA commissioner. "We have recognized for a long time that more is needed. Because of a lack of [legal] authorities and inadequate resources, it's really hard to do the job."

Restoring the FDA's reputation will be a major challenge for an Obama administration that strode into town promising competent government.

"You've got an agency that quite frankly is either nonfunctional, or dysfunctional, or maybe all of the above," said Dingell, who as the longest serving member of the House has investigated many agencies, including the FDA.

The decline didn't happen overnight. There's no single cause. In 2007, an independent group of science advisers concluded that the FDA was in danger of failing in its mission. "American lives are at risk," said their report. It wasn't the first alarm.

As the pharmaceutical and food industries went global, the FDA fell behind on inspections. Its legal powers failed to keep up with fast-changing industries. Its own scientists said it grew too cozy with drug companies and tuned out signals of safety problems.

Money for research grew scarce. Internal computer systems were allowed to decay, although they are essential to monitoring drug safety trends or blocking shady imports.

The FDA drifted. During the Bush administration, it went long periods without a permanent commissioner who could be an advocate before Congress. Lawmakers piled new responsibilities on the agency, often without the funds to carry them out.

This past year's safety problems -- homegrown and imported -- illustrate the FDA's weakness.

Last winter, heparin from China contaminated by a mysterious ingredient prompted an international recall. The blood thinner was triggering life-threatening allergic reactions.

Summer brought a salmonella outbreak blamed first on tomatoes and later on hot peppers as well.

This winter it was salmonella again, in peanut products. A small company's apparent disregard for basic sanitation led to the recall of more than 2,800 foods that used its ingredients.

More than 2,100 people were sickened in these incidents. At least nine deaths have been blamed on tainted peanuts alone.

In late February, another problem surfaced. Federal prosecutors in North Carolina obtained guilty pleas from two employees of AM2PAT, a company that manufactured syringes in unsterile conditions and covered it up with phony paperwork.

Prosecutors say hundreds of patients were sickened and five died. The feds are looking for the company's owner, who may have fled the country.

Different products were involved in the incidents, but they shared some of the same FDA shortcomings: inspections, legal authority and technology.

Although the FDA is supposed to inspect overseas plants, the pharmaceutical factory in China that made the heparin was never visited, partly because the agency confused its name with a similar name belonging to another drug factory.

The tomato outbreak last summer underscored other kinds of gaps. Produce companies are not required to have a food safety plan. And the FDA lacks legal authority to require a system for tracing foods back to the farm.

In the peanut butter outbreak, FDA inspectors quickly focused on a small Georgia processing plant. But they didn't get the whole story immediately. The FDA had to invoke bioterror laws to get lab reports that ultimately showed the company shipped tainted peanuts. Meanwhile, the agency had no authority to order a food recall.

Congress has been pumping more money into the FDA. And the Obama administration seems willing to consider big changes.

The two leading candidates for FDA commissioner are physicians from outside the agency. One is Baltimore health commissioner Joshua Sharfstein, a pediatrician who has taken on the FDA over risks in children's cough and cold drugs. The other is Margaret Hamburg, a bioterrorism expert who served in the Clinton administration and as New York's health commissioner.