

Recall exposed:

FDA upset about Recalls



By [Jonas Paulauskas](#) , freelance writer: August 2, 2011: AM ET

Washington DC -- High-profile recalls are shining a spotlight on food and drug product safety lapses, and prompting the government to consider bringing criminal charges against corporate executives.

The Food and Drug Administration is serious about identifying and potentially prosecuting senior individuals at companies that have issued a number of recalls due to manufacturing violations, said people familiar with the agency's thinking.

FDA officials have dropped public hints lately. Eric Blumberg, FDA's deputy chief counsel for litigation, told an industry gathering in April that the agency would go after executives at companies that seem to be flouting the FDA's rules.

"Very soon, and I have no one particular in mind, some corporate executive is going to be the first in a long line ... So it's going to happen. Do what you can and do the right thing before we find out about it," Blumberg said.

And FDA Commissioner Margaret Hamburg wrote to Sen. Chuck Grassley, R-Iowa, in March to say that the agency intends to consider "the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable."

The FDA's Office of Criminal Investigations is investigating the **successive recalls** of Tylenol and other over-the-counter drugs made by Johnson & Johnson's (**JNJ, Fortune 500**) McNeil Consumer Healthcare unit.

Sharpening up dull knives. Over the past thirty years, the FDA's enforcement arm has atrophied.

The FDA hasn't been aggressively punishing companies for manufacturing violations that spurred product recalls, said Lewis Grossman, professor of law at American University.

Now industry insiders say the FDA seems intent on reviving a tough law that has been dormant since the '80's. Its aim: To send a strong signal to companies.

The FDA gets its authority from the "Park Doctrine," which allows it to seek criminal convictions for violations of the federal Food, Drug and Cosmetic Act against executives, even if they're unaware of specific manufacturing violations but are in a position of authority to prevent or correct the problems.

"The FDA has generally avoided resorting to court to enforce their actions," said Grossman, an expert in food and drug law. That wasn't always the case. According to Grossman, the agency brought more than 600 criminal prosecutions against companies in 1939, but that the number plummeted to about 16 in 1989.

The number of criminal prosecutions climbed again in 1991 after the OCI was formed, but those were mainly for fraud and not based on food and drug manufacturing violations, he said.

Food and drug recalls have climbed in recent years.

The FDA reported more than 1,742 drug recalls in 2009, skyrocketing from 426 in 2008, according to the Gold Sheet, a trade publication on drug quality that analyzes FDA data. The fast pace is continuing in 2010 with drug recalls totaling 296 from January through June.

Recalls of food products are also increasing. In 2006 there were more than 200 recalls. That number jumped to about 305 in 2008 and more than 500 in 2009, according to the FDA.

So far there have been 684 food product recalls in 2010.

Grossman said there seems to be a perception at the agency that "working it out with the company and the company doing a voluntary recall is not enough."

"No one is really getting into trouble," Grossman said. At the same time, the number of citations for violations and warning letters that the FDA is issuing companies is going up.

David Rosen, who worked at the FDA for 14 years and is now with the law firm Foley & Lardner, agreed.

"The FDA is developing a tougher compliance attitude because companies are ignoring warnings from the FDA. It appears the agency does want to send a clearer message to people now," said Rosen, who advises major pharmaceutical companies on FDA regulations and compliance.

Punishments for a misdemeanor conviction can range from a \$1,000 fine to a year in jail, while a felony conviction can result in a \$10,000 fine or three years in prison, Grossman said.

Although the FDA has yet to bring any criminal charges against high-ranking executives, experts say there are a lot of sleepless nights right now in the industry. There's a lot a company can do for its executives, but one thing it can't do is serve their jail time. ■

