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## All Eyes On J&J Case As FDA Tests Criminal Powers

By **Elaine Meyer**

Law360, New York (June 09, 2010) -- A criminal investigation into a Johnson & Johnson unit's product recall is the latest sign that the U.S. Food and Drug Administration is willing to hold corporate executives' feet to the fire in its efforts to crack down on manufacturing violations, attorneys says.

Revelations of the investigation came out at a May 27 U.S. House of Representatives hearing, where FDA officials said their criminal unit was looking at penalties against J&J for a pattern of noncompliance with good manufacturing practices related to recalls of popular children's medicines including Tylenol, Motrin and Zyrtec.

Coming just a few months after FDA Commissioner Margaret Hamburg declared that the agency was going to step up misdemeanor prosecutions of company executives, the J&J investigation is the latest sign that things are tougher under the Obama administration than its predecessor, attorneys say.

"Even though criminal charges are far from the norm for [good manufacturing practices] issues, enforcement generally, and especially when it relates to safety issues, is probably the number 1 policy priority for this FDA," said James Czaban, the chair of Wiley Rein LLP's food and drug and product safety practice.

"Johnson & Johnson has run into a bad situation at a bad time, in terms of potential criminal prosecution," he added.

J&J subsidiary McNeil Consumer Healthcare announced the most recent recall of 43 children's medicines on April 30, following its decision to shut down a plant in Fort Washington, Pa., where the products at issue were manufactured.

Just days after the closure, FDA inspectors found several violations of good manufacturing

practices at the facility.

The medicines that were recalled could have a higher concentration of active ingredients, McNeil said, as well as tiny particles that the FDA identified as nickel, chromium and cellulose — violations of good manufacturing practices.

The timing could not have been worse for J&J, as it followed FDA Commissioner Margaret Hamburg's plans to take increased action against companies and their executives.

In a letter in March to Sen. Charles Grassley, R-Iowa, that received widespread attention from food and drug attorneys, the commissioner said the agency planned to increase strict liability criminal prosecutions of corporate executives.

Prosecutions under this misdemeanor provision of the Federal Food, Drug and Cosmetic Act allows the government to hold corporate officers liable without having to prove they intended to commit violations.

The commissioner said the agency had developed criteria for how to select cases to prosecute under this provision but did not reveal those standards.

But attorneys are looking at the J&J action as an opportunity for the FDA to reveal these criteria, painting a better picture of what future criminal prosecutions might look like.

"Anything that comes out of this obviously could be helpful information, particularly anything the FDA is going to give us in terms of further information on their criteria for potentially stepped-up criminal misdemeanor prosecutions of responsible corporate officials under the Food, Drug and Cosmetic Act," said Laurie Strauch Weiss, a litigation partner at Orrick Herrington & Sutcliffe LLP.

The FDA declined to comment on the nature of the criminal investigation for this article, and representatives for J&J did not respond to a request for comment.

But there is widespread belief that J&J's own mistakes, including the perception the company has repeatedly failed to comply with good manufacturing practices and not always been upfront with regulators, may have contributed to the FDA's decision to open a criminal investigation, attorneys said.

In December 2009, J&J broadened a recall it had issued the previous month of Tylenol arthritis-pain caplets from a few lots to all available lots. The recall was motivated by

concerns about possible chemical contamination related to a strange odor that was linked to nausea and stomach pain in some consumers.

The company expanded the recall even further in January to include certain lots of products including Rolaids, Children's Tylenol, Regular and Extra Strength Tylenol, Motrin IB and Benadryl. Soon after, the FDA sent a letter to a McNeil plant in Puerto Rico warning it of good manufacturing practices violations.

Making matters worse, in May hearings, the House Government and Oversight Committee revealed that J&J may have hired a contractor in 2008 to carry out a "phantom recall" of certain types of Motrin instead of disclosing problems with the medicine to regulators.

"This is the kind of action by a pharmaceutical company that will almost always lead to an investigation," said Matthew Leckman, an attorney from Pogust Braslow & Millrood LLC who represents plaintiffs in complex pharmaceutical injury cases.

That the most recent recall involved widely used children's medicines like Tylenol, Motrin, Zyrtec and Benadryl "that are probably as common as bread, butter and milk in the average American home with young children" makes the case even more urgent to regulators, Leckman said.

Part of the appeal of opening a criminal investigation is that there are limited civil penalties the agency can assess in this kind of case, according to Peter Reichertz, the leader of Sheppard Mullin Richter & Hampton LLP's food and drug law group.

Criminal penalties, on the other hand, could amount to millions of dollars or imprisonment for individual executives, he said.

Although lawyers are uncertain what to expect, the J&J investigation has echoes of recent criminal actions taken against KV Pharmaceutical Co. In March, the company's Ethex unit pled guilty for failing to report manufacturing problems to the FDA involving two of its prescription drugs. The company agreed to pay a \$25.8 million fine and forfeit \$1.8 million to resolve the allegations.

One thing working in J&J's favor is the fact that FDA officials have said repeatedly that the health risks posed by the recalled products was remote.

And despite the Motrin phantom recall, FDA officials have said that J&J executives have

been good about meeting with the agency.

But the larger message remains that the FDA will go after companies that have been messy with compliance, Leckman said, adding, "The FDA is not naive to the reality that it is understaffed and outresourced by the industries it regulates," Leckman said.

And, according to Reichertz, "The era of informal compliance is over with."

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