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THE WALL STREET JOURNAL.

WSJ.com

MARCH 4, 2010

FDA Criminal Division to Increase Prosecutions

By ALICIA MUNDY

WASHINGTON—The Food and Drug Administration plans to increase prosecutions of pharmaceutical and food industry executives as part of an effort to refocus its criminal division, which has been under attack in Congress and is criticized in a new government report.

In a letter to Sen. Chuck Grassley (R., Iowa), the FDA says an internal committee has recommended that the FDA and its Office of Criminal Investigations "increase the appropriate use of misdemeanor prosecutions, which allows responsible corporate officials to be held accountable and is a valuable enforcement tool."

An FDA official said the agency has the authority to prosecute corporate executives for criminal actions within their companies under a provision called "strict liability." He said the government doesn't have to show intent to defraud in order to get a conviction. He added that the provision is an important tool that hasn't been used much in recent years.

The agency intends to apply the provision thoughtfully and doesn't want to be viewed as overly aggressive, the official said. He declined to name specific kinds of wrongdoing the FDA wants to pursue. Currently, drug counterfeiting and improper marketing of narcotic drugs are among the areas the office investigates.

A report set to be released Thursday by the Government Accountability Office, Congress's watchdog arm, says the Office of Criminal Investigations has operated autonomously for years with little or no accountability to top FDA officials. The criminal office doesn't have to explain what it is investigating or how it uses funds, according to the report. It said the office's budget rose 73% between 1999 and 2008 to \$41 million, and the number of employees increased by about 40%.

The report said the FDA "has relied largely on the OCI director to determine which aspects of OCI's operations and investigations are made known to FDA's top management."

The GAO also said the FDA's criminal unit has fallen short compared with other agencies in developing performance standards.

The FDA officials largely agreed with the assessment and in the letter said the agency is "developing meaningful performance measures" for the criminal office as part of an initiative begun in August. The FDA said it wants the criminal office to share information with FDA leaders regularly, and to do a better job picking cases.

Last year federal appellate Judge Richard Posner in Chicago slammed the government in a case against a salad-dressing wholesaler that originated in the FDA's criminal office. The government charged the wholesaler with changing the labels on 1.6 million bottles of salad dressing to extend their shelf life, and in 2007 won a conviction for "misbranding."

The wholesaler contended that the FDA had no regulations covering such labeling, and Judge Posner agreed. "The testimony of the FDA's employee was not just improper and inadmissible but incoherent," the judge said in his opinion. He also said, "There is no suggestion that selling salad dressing after the 'best when purchased by' date endangers human health; so far as [it] appears [that] Salad Dressing is edible a decade or more after it is manufactured."

According to a 2009 article co-authored by former FDA Chief Counsel Sheldon Bradshaw in an online legal publication, the criminal office brought the case to the Justice Department for prosecution against the advice of top FDA lawyers. He wrote that there's nothing in food law about "best when purchased by" dates on labels.

In 2008, Rep. Joe Barton (R., Texas) criticized the Office of Criminal Investigations, saying its budget had increased while its workload stagnated. Mr. Barton also complained that the office's director since 1992, Terrell Vermillion, a retired Secret Service agent, was receiving cash and retention bonuses of about \$40,000 which added to his \$160,000 salary gave him a higher annual income than that of an associate justice on the Supreme Court.

At the time, the FDA defended itself and Mr. Vermillion, saying his office was productive. Mr. Vermillion couldn't be reached for comment Wednesday.

Mr. Barton said of the new report, "You know something is wrong when the GAO finds that they haven't even told FDA's leadership what they're doing."

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