

FDA to Increase Use of Criminal Prosecutions

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The U.S. Food and Drug Administration (FDA) said it plans on stepping up its prosecutions of pharmaceutical and food industry executives as part of its work to revamp the agency's criminal division said the Wall Street Journal. It seems the division has been derided by Congress and was recently condemned in a government report, added the Journal.

The FDA recently wrote to Senator Chuck Grassley (Republican-Iowa), saying that an internal committee recommended that the agency and its Office of Criminal Investigations (OCI) "increase the appropriate use of misdemeanor prosecutions, which allows responsible corporate officials to be held accountable and is a valuable enforcement tool," quoted the Journal. According to the FDA, it has authority to "prosecute corporate executives for criminal actions" under a provision entitled "strict liability." Although not enacted to a great extent in recent years, the FDA spokesman said that the government is not required to prove intent to defraud in order to convict.

Although the agency is not naming the wrongdoing it intends on pursuing, drug counterfeiting and improper narcotic drug marketing are among some of its areas of investigation, said the Journal.

The recent Government Accountability Office (GAO) report said the OCI has operated relatively separate from the FDA with no minimal accountability to the agency and with no requirement to explain its investigations or use of funds, explained the Journal. The GAO is a so-called "watchdog arm" of Congress.

The report noted that 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," quoted the Journal. The report also noted that the OCI's budget increased a huge 73 percent from 1999 to 2008 to \$41 million and also experienced a 40 percent increase in staffing, reported the Journal.

The FDA agreed, in most part, with the report's assessment, including that the GAO said its criminal unit was not up to par with other agencies and the development of performance standards, according to the Journal. The FDA said, in a letter, that it wants the criminal office to share information with key members at the FDA, explained the Journal.

According to FDA Commissioner Dr. Margaret A. Hamburg, said Thompson Publications, the misdemeanor prosecutions are "a valuable enforcement tool" and that the agency had come up with some criteria for consideration in its choice of misdemeanor prosecution cases. Dr. Hamburg added that, the criteria "will be incorporated into the

revised policies and procedures that cover appropriate use of misdemeanor prosecutions,” quoted Thompson.

Dr. Hamburg also told Grassley, in a letter, that the agency “is currently developing meaningful performance measures for OCI, as part of an agency-wide initiative,” adding that it is also “implementing other significant efforts” to address the issues identified by the GAO, reported Thompson.