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## FDA to Bring More Criminal Charges Against Executives for Companies' FDCA Violations

by Daniel R. Margolis, Mark R. Hellerer and Aaron S. Dyer

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*The Food and Drug Administration ("FDA") recently announced its intention to bring more misdemeanor criminal actions against corporate executives. This confirms a disturbing trend in FDA enforcement—charging corporate executives with crimes committed by employees or agents of their companies even if the executives had no knowledge of the criminal activity. Executives at pharmaceutical and medical device companies should be especially concerned, given that these companies often have hundreds or thousands of employees capable of violating the Food, Drug and Cosmetic Act ("FDCA") every day.*

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### **The FDA's New Initiative**

On March 4, 2010, the FDA released a letter it sent to Senator Chuck Grassley (R-Iowa) responding to a report by the Government Accountability Office released the same day. The GAO report criticized, among other things, the FDA's oversight of its Office of Criminal Investigation ("OCI").<sup>1</sup> In response, the FDA noted, among other things, that as of August 2009, the FDA had already formed a committee to consider ways to "enhance coordination and strategic alignment between OCI and other Agency components."<sup>2</sup> One of the FDA committee's recommendations was to "increase the appropriate use of misdemeanor prosecutions." The FDA noted that it had already developed criteria for use in selecting in which cases misdemeanor charges would be brought. Indeed, though the FDA had not previously announced this initiative, it had already begun to use this controversial weapon in its arsenal.

### **Background of the "Responsible Corporate Officer" Doctrine**

In 1975, the United States Supreme Court in *United States v. Park*,<sup>3</sup> permitted misdemeanor convictions against company executives for violations of the FDCA,<sup>4</sup> even if the executive had no knowledge or involvement in the offense as long as he or she was a "responsible corporate officer." The theory behind the *Park* Doctrine was that, given the importance of public safety, executives who manage companies regulated by the FDA have a positive duty to not only seek out and remedy violations, but also to imple-

ment preventative measures. The FDCA and *Park* effectively created one of the few strict liability crimes in federal law where an individual can be convicted of a federal crime based solely on their position in a company. Actual knowledge or personal participation in the offense is unnecessary to secure a conviction. It is enough that the violation took place by company employees and the executive had the authority either to prevent the violation or to correct it.

### Application of the Doctrine

Until recently, the Department of Justice had not pursued charges under the *Park* doctrine, likely because of the low penalties and sentences associated with misdemeanor crimes. In May 2007, however, several top executives of the Purdue Frederick Company pleaded guilty to charges of misbranding the painkiller OxyContin. Three of those executives pleaded guilty to misdemeanor charges as “responsible corporate executives” under *Park*.<sup>5</sup>

Further, the government did not stop at convicting these executives of federal crimes. Although federal law did not require it, the Department of Health and Human Services’ Office of the Inspector General exercised its permissive authority to bar the executives from securing public contracts for 12 years, effectively ending their careers in the industry. They are currently appealing that decision in federal district court.<sup>6</sup>

This trend continued on February 9, 2010, when Sally Qing Miller and Stephen S. Miller pled guilty to strict liability misdemeanors.<sup>7</sup> Their company, ChemNutra, Inc., purchased wheat gluten from a Chinese trading company which, in turn, purchased the product from two Chinese manufacturers, one of which illegally added melamine to boost the protein content of the wheat gluten. The government alleged that the defendants knew that the wheat gluten was being shipped into the U.S. from China under a code that would allow the product to avoid mandatory inspection leaving China. Although the Millers claimed it was impossible for them to know that melamine was added to the wheat gluten, the government charged them criminally.

The government may be more likely to bring criminal misdemeanor charges given recent amendments to the U.S. Sentencing Guidelines (the “Guidelines”) governing federal criminal prosecutions. In 2008, the U.S. Sentencing Commission revised the Guidelines to provide for an enhanced sentence where the offense created a “substantial risk of bodily injury,” rather than actual death or injury, which the prior version required. The government may well take the position that FDCA violations satisfy this new standard, thus making it more likely that even a misdemeanor conviction can result in a sentence of imprisonment.<sup>8</sup>

### Potential Impact on Life Sciences Companies

The *Park* doctrine can be applied in any criminal investigation of FDCA violations, which can include everything from misbranding dietary supplements and diagnostic tests to false statements regarding hazardous food products. The FDA’s recent initiative, however, may be of particular concern to executives in pharmaceutical and medical device companies. Over the past decade, the FDA and the Department of Justice have dramatically stepped up their investigations into the off-label promotion of prescription drugs and violations of the Medicare Anti-kickback Statute. The government has alleged violations of these laws based on the actions of, among others, sales representatives and marketing personnel. Large multinational companies can have thousands of individuals in such positions operating across the country with minimal daily oversight. While most companies have compliance programs in place prohibiting the violation of federal laws, it is virtually impossible to monitor the activities of every sales representative. Even with a strong compliance program, it is not necessarily the case that the specific conduct the Department

of Justice believes to have violated the prohibition on off-label promotion or the anti-kickback statute would have been specifically addressed by the companies' compliance policies.

## Conclusion

Charging individuals with a crime where they had no knowledge or involvement in criminal activity, and potentially ending their career in the healthcare industry, is a drastic exercise of prosecutorial discretion. Neither the FDA nor DOJ has announced what guidelines will be followed in deciding whether misdemeanor charges or an industry bar is appropriate. Until Congress revises the FDCA misdemeanor statute or the Supreme Court revisits the *Park* doctrine, corporate executives are left to hope that the government only considers such charges where the executive exercised egregiously bad judgment or deliberately failed to implement or enforce a compliance program. Despite the fact that no compliance program can fully ensure that the company's conduct will not raise government suspicion, companies marketing products approved by the FDA should regularly check the strength and efficacy of its compliance program so it can be sure it is doing everything it can to keep its executives out of the government's crosshairs.

If you have any questions about the content of this client alert, please contact the Pillsbury attorney with whom you regularly work or the authors below.

Daniel R. Margolis (bio)  
New York  
+1.212.858.1758  
daniel.margolis@pillsburylaw.com

Mark R. Hellerer (bio)  
New York  
+1.212.858.1787  
mark.hellerer@pillsburylaw.com

Aaron S. Dyer (bio)  
Los Angeles  
+1.213.488.7321  
aaron.dyer@pillsburylaw.com

- <sup>1</sup> General Accounting Office, Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal Misconduct Investigations. GAO-10-221 (Washington, D.C.: March 1, 2010) available at <http://www.gao.gov/new.items/d10221.pdf>.
- <sup>2</sup> Letter to Senator Charles E. Grassley, ranking Member, U.S. Senate, Committee on Finance, March 4, 2010, from Dr. Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, available at <http://freepdfhosting.com/91f613dd58.pdf>.
- <sup>3</sup> 421 U.S. 658 (1975).
- <sup>4</sup> 21 U.S.C. § 331
- <sup>5</sup> Plea Agreement as to Michael Friedman, *United States of America vs. Purdue Frederick Company, Inc., et. al.*, No. 07-CR-00029 (W. Va. filed May 10, 2007), available at <http://www.vawd.uscourts.gov/PurdueFrederickCo/Main-Document.pdf>; Plea Agreement as to Howard R. Udell, *United States of America vs. Purdue Frederick Company, Inc., et. al.*, No. 07-CR-00029 (W. Va. filed May 10, 2007), available at <http://www.vawd.uscourts.gov/PurdueFrederickCo/Plea-Agreement-Udell.pdf>; Plea Agreement as to Paul D. Goldenheim, *United States of America vs. Purdue Frederick Company, Inc., et. al.*, No. 07-CR-00029 (W. Va. filed May 10, 2007), available at <http://www.vawd.uscourts.gov/PurdueFrederickCo/Plea-Agreement-Goldenheim.pdf>.
- <sup>6</sup> *Michael Friedman and Howard R. Udell v. Kathleen Sebelius*, No. 309CV01741RNC (D. Conn. filed Oct. 28, 2009).
- <sup>7</sup> Plea Agreement as to Sally Qing Miller and Stephen Miller, *United States of America vs. Sally Miller, Stephen Miller and ChemNutra Inc.*, Case No. 08-00023-01CR-W-DW; Government's Sentencing Memorandum for *United States of America vs. Sally Miller, Stephen Miller and ChemNutra Inc.*, Case No. 08-00023-01CR-W-DW (W.Mo).
- <sup>8</sup> 2008 Federal Sentencing Guidelines, Section 2N2.1 available at [http://www.ussc.gov/2008guid/2n2\\_1.htm](http://www.ussc.gov/2008guid/2n2_1.htm).

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