

Corporate Officials Put on Notice as Regulators Seek to Increase Personal Accountability

Officials Should Be Mindful of Potential Individual Misdemeanor Liability under FFDCA

In an already intense enforcement climate, regulators are now focusing on corporate officials at pharmaceutical companies in an effort to increase personal accountability for industry compliance. Responding to criticism related to its criminal investigations operations, the Food and Drug Administration (FDA) announced earlier this year that it intends to increase its use of criminal prosecutions against individuals under the responsible corporate official doctrine.

FDA officials have suggested that off-label promotion may be a target area for the agency's increased use of individual prosecutions.¹ Subsequently, officials with the Department of Justice (DOJ) and the Department of Health and Human Services' Office of Inspector General (OIG) announced similar plans to increase scrutiny and enforcement for corporate individuals in off-label promotion actions.² Corporate officials, therefore, will need to navigate a more precarious enforcement environment while continuing their efforts to ensure compliance throughout their organizations.



Michele L. Buenafe and Lee Rosebush are associates with Morgan, Lewis & Bockius, LLP, Washington, D.C.

INDIVIDUAL PROSECUTIONS AND CURRENT FDA ENFORCEMENT CLIMATE

The FDA's intent to pursue more individual prosecutions is part of a wider effort by Commissioner Dr. Margaret Hamburg to improve the effectiveness of the FDA's enforcement system. Since taking the helm at the FDA in May 2009, Dr. Hamburg has made clear she intends to make enforcement a priority for the FDA.

In one of her first public speeches after being sworn in, Dr. Hamburg outlined for industry stakeholders her goals for improving the effectiveness of the FDA's enforcement system and highlighted the need for the FDA to be "vigi-

lant," "strategic," "quick," and "visible" to ensure an effective enforcement strategy.³ Dr. Hamburg's FDA has been keeping industry on their toes through a number of efforts, including an increase in the number of inspections and warning letters, greater scrutiny of recalls, and renewed focus on product promotion.

More recently, Dr. Hamburg described her efforts to improve the FDA's criminal investigations operations and increase individual prosecutions. In a March 4, 2010 letter to Senator Grassley, responding to concerns raised in a report from the Government Accountability Office (GAO) on the FDA's criminal investigations operations,⁴ Dr. Hamburg outlined several reforms for the Office of Criminal Investigations (OCI), including plans to increase the use of misdemeanor prosecutions "to hold responsible corporate officials accountable."⁵ Other actions taken by the FDA in response to the GAO report included the development of procedures to optimize information sharing between OCI and other FDA offices, better alignment of criminal enforcement and regulatory activities, and enhancement of the FDA's debarment and disqualification procedures.

With respect to the use of misdemeanor prosecutions for individuals, Dr. Hamburg stated that the agency has developed criteria for use in selecting appropriate cases for application of this enforcement tool.⁶ Although FDA officials have stated the agency's intent to publish procedures related to individual prosecutions in its Regulatory Procedures Manual, these procedures have not yet been released publicly. Agency officials, however, have suggested that off-label promotion may be a target area for the FDA's use of misdemeanor enforcement against responsible corporate individuals.⁷

THE PARK DOCTRINE

The use of misdemeanor prosecutions as an enforcement tool against corporate officials for violations of the Federal Food, Drug, and Cosmetic Act (FFDCA) was upheld by the Supreme Court in *United States v. Park*, 421 U.S. 658 (1975). The *Park* doctrine imposes misde-

meanor liability not only for those corporate agents who are directly involved in violative acts but also for corporate officials who could be deemed responsible for the violations.

Thus, responsible corporate officials can be convicted of a misdemeanor even if there is no evidence of intent to violate the law and even if the official was not aware of the violation. The official need only have been in a position of authority to prevent or correct the violation and failed to do so. As stated by the Court, the law "imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not recur."⁸

Although the *Park* doctrine was applied in the 1970s, since then, the government generally has not targeted corporate officials unless there was evidence to support a felony count or the officials directly participated in the violative conduct (*e.g.*, acting as "rogue" employees). However, the recent cases against pharmaceutical manufacturer Purdue Frederick and medical device company Synthes, Inc. illustrate the government's willingness to use misdemeanor prosecutions against individuals for FDA violations, even before Hamburg's announcement that the FDA would increase such prosecutions.

In the case of Purdue Frederick, the company and three of the company's top executives were charged in May 2007 for criminal misbranding violations related to the off-label promotion of the drug, OxyContin. The company pled guilty to felony misbranding, and the three executives each pled guilty to one misdemeanor count of misbranding.

For Synthes, the company and four top Synthes executives were indicted in June 2009 for charges related to alleged off-label promotion and unauthorized clinical trials of bone cement products. The four executives were each charged with one misdemeanor count of shipping adulterated and misbranded devices in U.S. interstate commerce. The Synthes officials each pled guilty but have not yet been sentenced. Misdemeanor sentences can be up to a year in prison and a maximum fine

of \$100,000 per count for an individual (unless the violation resulted in a death, in which case the maximum fine is \$250,000).

OTHER AGENCIES ALSO TARGETING CORPORATE OFFICIALS

The FDA is not alone in its efforts to pursue corporate officials for off-label prosecutions. Officials from the DOJ and OIG also have expressed interest in pursuing corporate individuals as part of their off-label promotion enforcement efforts.⁹ To this end, the OIG published a guidance document on October 20, 2010, concerning the exclusion of individuals from participation in federal health care programs.¹⁰ The new guidance lists factors the OIG will consider in implementing its permissive exclusion authority for officers and managing employees of an entity that has been excluded or convicted of certain offenses.

The guidance describes a *Park*-like doctrine for the permissive exclusion of such officers and managing employees, noting that the statute includes no knowledge element but allows for exclusion “based solely on their position within the entity.” The factors listed in the OIG’s guidance include: the circumstances of the offense; the individual’s role in the sanctioned entity; the individual’s actions in response to the misconduct; and information about the entity (*e.g.*, compliance history, size, corporate structure, et cetera).

Although OIG exclusion is rarely used against individuals in the context of pharmaceutical industry enforcement, it is not unprecedented. In the Purdue Frederick case, the OIG pursued exclusion against the Purdue executives after they pled guilty to misbranding. The OIG’s action was based on its permissive authority under Section 1128(b) of the Social Security Act, which allows for exclusion of an individual convicted of certain criminal offenses, including

offenses related to fraud or to the unlawful distribution of controlled substances. Based on their misdemeanor pleas related to Oxy-Contin (a controlled substance), the executives were excluded from participation in federal health care programs for 12 years.

In summary, corporate officials in the pharmaceutical, biotech, and medical devices fields should be mindful of potential individual misdemeanor liability under the FFDCa when evaluating the sufficiency of their companies’ compliance programs and procedures and in overseeing day-to-day regulated activities. Additionally, any official should be aware that FDA violations may result not only in individual criminal charges under the FFDCa but also could result in individual exclusion by the OIG.

Endnotes:

1. The Pink Sheet, Off-Label Prosecution May Be Where FDA “Parks” Aggressive Enforcement Tools First (Oct. 18, 2010).
2. The Gray Sheet, *Justice Dept., Inspector General To Target Individuals In Off-Label Cases* (Sept. 29, 2010).
3. Margaret A. Hamburg, M.D., Commissioner, FDA, Effective Enforcement and Benefits to Public Health, Remarks at the Food and Drug Law Institute (Aug. 6, 2009).
4. Government Accountability Office, *Food and Drug Administration: Improved Monitoring and Development of Performance Measures needed to Strengthen Oversight of Criminal and Misconduct Investigations* (Jan. 2010), available at www.gao.gov/new.items/d10221.pdf.
5. Letter from Margaret A. Hamburg, M.D., Commissioner, FDA to Charles E. Grassley, Ranking Member, Senate Committee on Finance (Mar. 4, 2010).
6. *Id.*
7. The Pink Sheet, Off-Label Prosecution May Be Where FDA “Parks” Aggressive Enforcement Tools First (Oct. 18, 2010).
8. *United States v. Park*, 421 U.S. 658, 671 (1975).
9. The Gray Sheet, *Justice Dept., Inspector General To Target Individuals In Off-Label Cases* (Sept. 29, 2010).
10. See Office of the Inspector General, Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act (Oct. 20, 2010).

Reprinted from Journal of Health Care Compliance, Volume 13, Number 1, January-February 2010, pages 45-47, with permission from CCH and Aspen Publishers, Wolters Kluwer businesses.

For permission to reprint, e-mail permissions@cch.com.
