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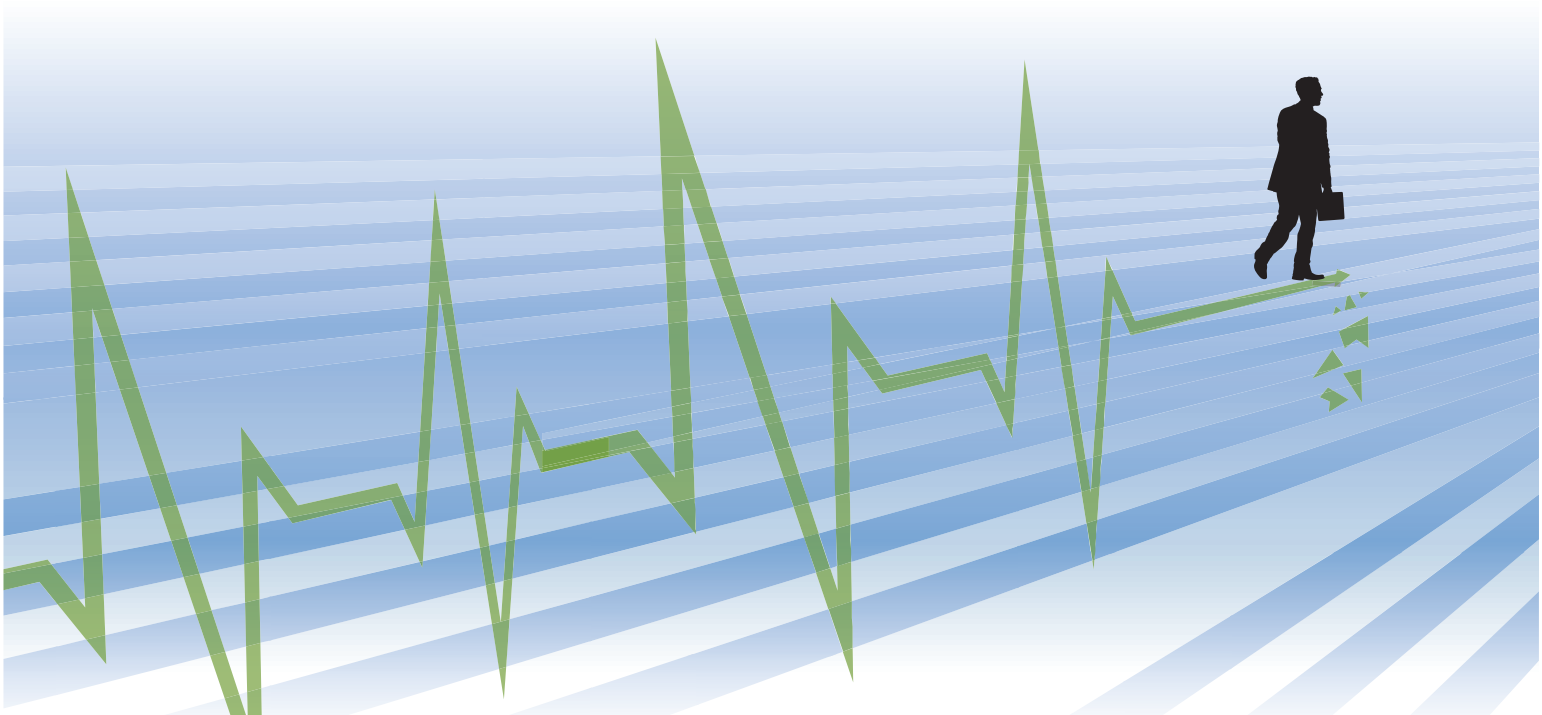

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Revival of the **Responsible Corporate Officer** Doctrine

Strict criminal liability comes to the health care industries.

BY JONATHAN S. SACK AND ROBERT M. RADICK

IN THE PAST SEVERAL years, the Department of Justice (DOJ) has brought a series of cases in which pharmaceutical companies have entered corporate guilty pleas and reached civil settlements with the government for off-label marketing of drugs and biologics, resulting in some of the largest corporate fines and civil penalties in history.

Recently, federal officials have stated their intention to seek prosecution of not just companies engaged in off-label promotion but also individuals responsible for such activity. Both the commissioner of the Food and Drug Administration (FDA) and a senior DOJ official have declared that the prosecution of individuals is a priority of this administration.[1]

This heightened focus on individuals in criminal investigations brings with it the revival of a powerful but little-used tool of federal criminal prosecution: the responsible corporate officer (RCO) doctrine, which provides that corporate officers may be held criminally liable for certain offenses relating to public health and welfare, even if the individual officers neither knew of nor participated in the unlawful activity in question.[2] Under the RCO doctrine, liability turns on an individual's supervisory responsibility over the activities giving rise to the violation of law.

The FDA commissioner has expressly highlighted her agency's support for an increase in prosecutions under the doctrine.[3] The FDA very recently made a corresponding change in written policy as well. Whereas previous policy indicated that the agency would recommend an RCO prosecution only when an individual had actual knowledge of misconduct, a newly-minted policy, added to the

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agency's Regulatory Procedures Manual (RPM) on Jan. 26, 2011, clearly indicates that actual knowledge is no longer a prerequisite for recommending prosecution.[4]

The aggressive prosecution of company executives under the RCO doctrine raises the specter not only of criminalizing alleged failures of supervision but also of tarnishing, and even ending, the careers of corporate officers. The federal government's power over the health care industry includes the power to exclude individuals from participating in government health care programs.

A recent court decision, discussed in detail below, puts a fine point on the marriage of RCO liability and collateral civil and administrative consequences: A federal district court upheld the 12-year exclusion of three former executives of a pharmaceutical company who had earlier pled guilty under the RCO doctrine.

In this article, we discuss the substance and ramifications of this doctrine and the exclusion from government programs that must now be of significant concern to company officials in the pharmaceutical and other health care industries.

The RCO Doctrine and the FDCA

Under the RCO doctrine, an individual may be found guilty of a misdemeanor offense if he "had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and…failed to do so."[5] The doctrine traces its origins to the U.S. Supreme Court's decisions in *United States v. Dotterweich*[6] and *United States v. Park*.[7]

In *Dotterweich*, the Court in 1943 considered whether the president of a company that repackaged and sold medicines could be held criminally liable for a misdemeanor misbranding offense under the Food, Drug and Cosmetic Act (FDCA), despite the fact that the president had no actual knowledge of the misbranding. In upholding the conviction of the company's president, the Court held that the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."[8] In the interests of public protection, the statute "puts the burdens of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[9]

In *United States v. Park*, the Court in 1975 reaffirmed that executives in industries with a direct relationship to the public health and welfare may be held responsible for the acts of corporate employees even if the executive lacks the level of mens rea generally necessary for criminal liability. The *Park* decision arose from the conviction of the president of a supermarket chain for FDCA violations arising out of unsanitary conditions at two of the company's warehouses.

The defendant challenged a jury instruction that stated that the defendant could be liable "even if he did not consciously do wrong," so long as he "had a position of authority and responsibility in the situation out of which the[] charges arose."[10] The Court rejected the defendant's challenge and affirmed his conviction, holding that the FDCA "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 occur."[11]

Recent Prosecutions

In the pharmaceutical context, the RCO doctrine was most recently invoked in 2007, when the U. S. Attorney's Office for the Western District of Virginia charged the drug company Purdue Frederick (Purdue) and certain of its executives with misbranding counts relating to the promotion of the painkiller OxyContin.[12] The Information charged Purdue with felony misbranding for its promotion of OxyContin as less addictive and less subject to abuse and diversion than other painkillers.

The Information also charged Purdue's president and CEO, its executive vice president and chief legal officer, and its chief scientific officer (the "Purdue executives") with misdemeanor counts of misbranding on the theory that they were responsible corporate officers during the period of Purdue's unlawful marketing of OxyContin.

In May 2007, the corporate and individual defendants pleaded guilty to the charges in the Information based upon an agreed statement of facts.[13] That statement set forth in considerable detail the conduct of certain unnamed Purdue supervisors and employees, who, with "intent to defraud or mislead," marketed OxyContin to health care providers by downplaying its risks and falsely describing its addictiveness.[14] The statement of facts also described the Purdue executives as responsible corporate officers during the relevant period, but noted that the executives denied having known of the facts that formed the basis for the company's guilt.

The Purdue case signaled an important shift in the government's approach to prosecuting misbranding cases, a shift which we can now see clearly in the recent statements of government officials and the change in FDA policy, noted above.

First, notwithstanding the strict liability nature of the RCO doctrine, prosecutors had previously limited RCO charges to those cases in which high-level executives were in fact on notice of the misconduct of subordinates but failed to take corrective action.[15] The Purdue prosecution, in contrast, charged individual defendants who were not alleged to have been involved with or to have known of the misconduct that occurred on their watch.

Second, although the RCO doctrine had previously been applied in the context of misbranding, the Purdue case was the first application of the doctrine to the complex and evolving area of off-label marketing, where few, if any, observers anticipated criminal prosecution without allegations of participation in, or at least knowledge of, the underlying offenses.

The RCO doctrine was recently invoked in an indictment brought against the medical device company Synthes Inc., its subsidiary, Norian Corporation, and four Synthes executives. The indictment charges the executives with misdemeanor misbranding offenses and alleges that they were responsible corporate officers during the time period in which Synthes and Norian caused surgeons to use bone cement to treat a form of spinal fractures for which that cement was not approved.[16] The executives have since pleaded guilty to the charges against them, and await sentencing.

Exclusion From Government Programs

The Purdue case not only signalled in 2007 the revival and expansion of the RCO doctrine, but also illustrates the severe collateral consequences that executives can face as a result of RCO convictions.

Under the Social Security Act, the Office of the Inspector General of the Department of Health and Human Services (HHS-OIG) has the authority to exclude individuals from participation in federal health care programs, including Medicare and Medicaid, based on convictions for misconduct related to health care.[17] Exclusion of at least five years is generally mandatory for individuals convicted of crimes such as felony fraud and kickbacks.[18]

The HHS-OIG also has the discretion to exclude individuals convicted of other crimes, including misdemeanor charges of fraud or other unlawful conduct in connection with the provision of health care. The minimum period of exclusion for a misdemeanor involving fraud or other misconduct is three years, but the HHS-OIG may increase or decrease that period as it deems appropriate based on a consideration of aggravating and mitigating factors.[19]

Exclusion from participation in federal health care programs means that the federal government will not

pay for any items or services furnished or ordered by the excluded individual or by any entity that employs him. Any entity that is directly or indirectly involved with federal health care program business is also subject to civil penalties for employing an excluded individual, and may itself be excluded if it employs an excluded individual as an officer, director, agent or managing employee.[20]

Virtually every pharmaceutical company conducts business in some form with federal health care programs, and thus an excluded person is essentially unemployable in the industry during his period of exclusion.

Application to Purdue Executives

Following the Purdue executives' guilty pleas, the HHS-OIG exercised its permissive authority to exclude them from participation in federal health care programs on the basis of their convictions. This was the first instance in which the HHS-OIG imposed exclusion of individuals convicted of misdemeanor FDCA violations under the RCO doctrine.

After considering a number of aggravating factors and mitigating evidence presented by the Purdue executives, the HHS-OIG found that a period of exclusion beyond the minimum three years was warranted, and ultimately imposed an exclusion period of 12 years on each executive.

In *Friedman v. Sebelius*,[21] the Purdue executives challenged the exclusion order in the U.S. District Court for the District of Columbia. Central to the challenge were their claims that they had pleaded guilty to misdemeanor charges predicated solely on their authority as company officers to correct or prevent wrongdoing, that they did not personally engage in any wrongdoing of their own, and that, according to them, the statutory exclusion provisions did not authorize the exclusion of individuals convicted solely of misdemeanor misbranding under the RCO doctrine.

The Purdue executives also argued that the length of the exclusions was unreasonable because the aggravating factors considered by the HHS-OIG related to the actions of the company and others within it, rather than any actions of the executives themselves.

Despite the narrow admissions of the Purdue executives in the criminal case, and despite the absence of an allegation that they knew of or personally participated in affirmative acts of misbranding, the district judge upheld the executives' exclusion, holding that both the fact of the exclusions and their length were authorized and reasonable.

Of particular relevance in the court's decision was its rejection of the executives' claim that they had been subjected to exclusion solely because they committed "status-based" offenses arising from their positions in the company. The court unequivocally held that convictions under the RCO doctrine necessarily entail more than status alone; they also entail the responsibility and authority to prevent or correct illegal conduct, and the failure to do so.

The court also treated the executives' argument that they had not engaged in any wrongful acts as equivalent to asserting one's powerlessness to prevent the criminal conduct of others, an affirmative defense to a charge under the RCO doctrine that, as the court noted, had been abandoned by the executives' prior guilty pleas.

Finally, the court held that the 12-year length of the executives' exclusion was reasonable due to the substantial loss that government health care programs apparently suffered as a result of the misbranding of OxyContin, and due to the company's admission that such misbranding went on for a period of more than five years during which the executives were responsible corporate officers.

The exclusion of the Purdue executives upheld in *Friedman* demonstrates the HHS-OIG's authority, and clear intention, to impose lengthy exclusions against corporate executives who are convicted under the RCO doctrine. Counsel for the executives indicated that they would appeal the ruling affirming the executives' exclusion.[22]

Conclusion

The government maintains that the prospect of RCO prosecutions and subsequent exclusions will deter violations of the FDCA. Yet even the best compliance program cannot prevent every violation.

Only time will tell whether the government's focus on individual prosecutions and exclusions will strike the appropriate balance between punishing and deterring violations of law, and treating individual company officials fairly. If the government goes too far, talented, conscientious and well-meaning executives may decide that the benefits of their positions simply are not worth the risks.

1. See Letter from Margaret A. Hamburg, M.D. to Senator Charles E. Grassley (Hamburg Letter), March 4, 2010, at 2, http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf (last visited Jan. 26, 2011); Remarks by Assistant Attorney General Tony West to Pharma Conference, Oct. 20, 2010, http://www.mainjustice.com/2010/10/20/remarks-by-assistant-attorney-general-tony-west-to-pharma-congress/ (last visited Jan. 26. 2011).

2. In addition to being applicable in cases involving pharmaceuticals, the RCO doctrine also applies in criminal misbranding cases involving medical devices, as well criminal cases brought under the Clean Water Act, see 33 U.S.C. §1319(c)(6), and the Clear Air Act, see 42 U.S.C. §7413(c)(6).

3. See Hamburg Letter, at 2 (noting that a committee of senior FDA leadership recommended an "increase of the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable…").

4. Compare FDA Regulatory Procedures Manual (RPM) §6-5-1 (March 2010), http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf (last visited Jan. 27, 2011) ("[T]he agency ordinarily exercises its prosecutorial discretion to seek criminal sanctions against a person only when a prior warning or other type of notice can be shown.") with RPM §6-5-3 (Jan. 26, 2011), http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm (last visited Jan. 27, 2011) ("Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation").

5. *United States v. Park*, 421 U.S. 658, 673-4 (1975).

6. 320 U.S. 277 (1943).

7. 421 U.S. 658 (1975).

8. 320 U.S. at 281.

9. Id. at 280-81.

10. 421 U.S. at 666 n.9.

11. Id. at 672.

12. *United States v. The Purdue Frederick Co. Inc., et. al.*, No. 07-Cr.-00029 (JPJ) (W.D. Va.).

13 "Agreed Statement of Facts," *United States v. The Purdue Frederick Co. Inc., et al.*, http://www.vawd.uscourts.gov/PurdueFrederickCo/Exhibit-B.pdf (last visited Jan. 26, 2011).

14. Id. at 5.

15. In briefing *Park* before the Supreme Court, the government stated that it was the policy of the FDA to limit its recommendations for criminal prosecution to cases in which the responsible corporate officer was aware of violations but did not correct them. Brief for the United States at 31-32, No. 74-215 (U.S. Jan. 10, 1975). This policy was reflected in the version of the Regulatory Procedures Manual that had been in effect prior to Jan. 26, 2011.

16. See Indictment, *United States v. Norian Corporation, et al.*, No. 2:09-cr-00403-LDD (E.D. Pa. June 16. 2009) (on file with authors).

17. 42 U.S.C. §1320a-7(a)(1)-(4) (mandatory exclusion); id. §1320a-7(b)(1)-(16) (permissive exclusion).

18 Id. §1320a-7(c)(3)(B).

19. Id. §1320a-7(c)(3)(D). 42 C.F.R. §1001.102 sets out numerous aggravating and mitigating factors that may be considered by HHS-OIG.

20. 42 U.S.C. §1320a-7a(a)(6) authorizes civil penalties against anyone who employs an excluded individual and makes any payment, including salary, to that individual using money received from federal health care programs. See OIG Special Advisory Bulletin, "The Effect of Exclusion From Participation in Federal Health Care Programs" (September 1999), http://oig.hhs.gov/fraud/alerts/effect_of_exclusion.asp (last visited Jan. 27, 2011). 42 U.S.C. §1320a-7(b)(8) authorizes the permissive exclusion of an entity that has an excluded person as an officer, director, agent, or managing employee.

21. —F. Supp. 2d—, Civ. Action No. 09-2028 (ESH), 2010 WL 5079937 (D.D.C. Dec. 13, 2010).

22. See Barry Meier, "Ruling Is Upheld Against Executives Tied to OxyContin," New York Times, Dec. 15, 2010, http://www.nytimes.com/2010/12/16/business/16purdue.html (last visited Jan. 26, 2011).