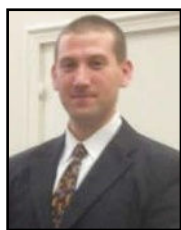




Executives Should Think Twice Before Accepting Pleas ‘Relating to Fraud’: The Expansion of Exclusion Under the *Park* Doctrine

By Abraham Gitterman

Over the last three years, the Health Care Fraud Prevention and Enforcement Action Team (HEAT) has recovered over \$10.2 billion in healthcare fraud settlements, many involving pharmaceutical companies charged with the “off-label promotion” of drugs to healthcare providers.¹ As an effort to change corporate culture, each of these settlements has included a corporate integrity agreement (CIA) with the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS).



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The deterrent effect of CIA’s, however, has been questioned,² and even OIG has demonstrated that billion dollar settlements are not a sufficient deterrent to change corporate culture.³ While some alternatives have been offered,⁴ OIG has responded by indicating its intent to exclude corporate executives in the life sciences industry from federal healthcare programs “under a broader range of circumstances,”⁵ including the responsible corporate officer (RCO) doctrine. FDA has also indicated its intent to use the RCO doctrine in guidance issued in February 2011.⁶ By excluding corporate officers, OIG said it could “influence corporate behavior without putting patient access to care at risk” and “alter the cost-benefit calculus of the corporate executives who run these companies.”⁷

Holding true to their promise, HHS excluded three former Purdue Frederick Company (“Purdue”) executives in 2007 for their misdemeanor misbranding convictions under the RCO doctrine. On July 27, 2012, the U.S. Court of Appeals for the

District of Columbia Circuit upheld their exclusions in *Friedman v. Sebelius* because the executives' misdemeanor convictions were factually related to fraud. The court, however, remanded the case back to the district court regarding the 12-year exclusion length because HHS failed to explain why the penalty was three times longer than penalties imposed in comparable cases in the past⁸ and four times longer than the presumptive baseline in the statute.⁹

Consequently, lawyers and healthcare stakeholders must closely examine this decision because OIG may "expand its use of [permissive] exclusion against individuals"¹⁰ and the decision may encourage more RCO prosecutions. As a result, these exclusions may have the unintended consequence of deterring "talented, qualified, and ethical individuals from working in senior or leadership positions in the"¹¹ life sciences industry for fear of being excluded when they engaged in no wrongful conduct.

Case Background

In May 2007, Purdue pled guilty to felony misbranding, in violation of 21 U.S.C. § 331(a) and § 333(a)(2) of the Food, Drug and Cosmetic Act (FDCA), because some of Purdue's employees made misrepresentations to healthcare providers that the painkiller Oxycontin was less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.¹² Purdue was placed on probation for five years, fined \$500,000, and suffered other monetary sanctions totaling approximately \$600 million, of which approximately \$160 million was earmarked for restitution to Federal and State healthcare agencies.¹³

At the same time, the three executives¹⁴ each pled guilty to a single count of misdemeanor misbranding as "responsible corporate officers" under the RCO doctrine, in violation of 21 U.S.C. § 331(a)

and § 333(a)(1), for their admitted failure to prevent Purdue's fraudulent marketing of OxyContin. Under the RCO doctrine, criminal liability for an FDCA violation does not require "awareness of some wrongdoing" or "conscious fraud."¹⁵ In *Friedman*, the D.C. Circuit reasoned that because the executives, as part of their plea agreements, admitted having "responsibility and authority either to prevent in the first instance or to promptly correct" the off-label promotion, the executives admitted being guilty of misdemeanor misbranding under the RCO doctrine.¹⁶ However, both the presiding judge who accepted the corporate and executive plea agreements and the prosecuting U.S. Attorney recognized the absence of any proof that the executives had any personal knowledge of the misbranding or any personal intent to defraud.¹⁷

Nevertheless, the court's holding established an unfamiliar precedent because unlike the seminal RCO cases, *U.S. v. Dotterweich*¹⁸ and *U.S. v. Park*, in which the penalties were "relatively small" and conviction did no "grave damage" to the person's reputation,¹⁹ the executives in *Friedman* had to disgorge approximately \$34.5 million in compensation and faced what amounted to a lifetime ban from the pharmaceutical industry.

Four months after the executives were sentenced, OIG informed them of its intent to exclude them from participating in any federal healthcare program for 20 years, pursuant to 42 U.S.C. § 1320a-7(b)(1), which authorizes OIG to exclude an individual convicted of a "misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct." The executives appealed OIG's determination to an Administrative Law Judge (ALJ) and ultimately to the Departmental Appeals Board (DAB). While OIG reduced the ex-

clusion to 15 years because the executives had assisted law enforcement authorities to combat abuse of OxyContin, the DAB affirmed the exclusion, only reducing its length to 12 years because there was no substantial evidence that the misbranded Oxycontin had any adverse effect on program beneficiaries and others. The U.S. District Court upheld the exclusion.

Expanding Exclusion Under the RCO Doctrine

The *Friedman* case presented the question of whether the phrase "misdemeanor relating to fraud" in section 1320a-7(b)(1)(A) refers to a (1) generic criminal offense—the categorical approach—or (2) to the facts underlying the particular defendant's conviction—the circumstance-specific approach.

The "categorical approach," according to which the statutory term refers to the generic criminal offense, "prohibits the later court from delving into particular facts disclosed by the record of conviction" and directs that court to "look only to the fact of conviction and the statutory definition of the prior offense," including the elements of that offense.²⁰ Under the "circumstance-specific" approach, by contrast, the statutory term refers to the particular conduct giving rise to the conviction and so the court "must look to the facts and circumstances underlying an offender's conviction" to determine whether that conviction is covered by the statute.²¹ The court reasoned that the text, structure, and purpose of the exclusion statute indicated that the Secretary's circumstance-specific approach was proper. The court, however, noted a "split in authority on the question whether to defer to an agency's interpretation of a term drawn from criminal law but used in a statute the agency administers."²²

The key phrase in the exclusion statute the court used to uphold the executives'

exclusions was “relating to,” which the court broadly defined as “stand[ing] in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.”²³ Using this definition, the court reasoned that “relating to” “includes any criminal conduct that has a factual “connection with” or reference to fraud.”²⁴ The court explained that “relating to fraud” modifies “misdemeanor” and that a “conviction,” meant a particular event on a particular occasion and “so refers to a set of facts, and not to a generic crime.”²⁵ Consequently, the court explained that “Misdemeanor misbranding does not necessarily require a culpable mental state” like generic misdemeanors “because a conviction for the offense may be, and in this case was, predicated upon the responsible corporate officer doctrine, which entails strict liability.”²⁶

Pointing to the “broad scope” of 1320a-7(b)(1)(A), the court used three examples to support its position. First, the court maintained that exclusion for a misdemeanor relating to “other financial misconduct” “expressly refers to a type of ‘conduct,’ not to a genus of criminal offense.”²⁷ Therefore, the term “misdemeanor” refers to the particular circumstances of an individual’s conviction, and “relating to” must denote a factual relationship between the conduct underlying the misdemeanor and the conduct underlying a “fraud.”²⁸

Second, the court reasoned that the limiting clause in section (b)(1)(B) “does not pick out a generic class of offenses because there is no generic crime of defrauding a program other than a healthcare program financed in whole or in part by a government agency.”²⁹ As a result, the court explained that the “criminal offense” must “relate to fraud” because it has a factual relationship to conduct involving a program financed by a government agency, committed on a particular occasion.

Third, the court explained that the phrase “the use of funds” in section 1320a-7(b)(2)(ii) does not refer to a generic offense and therefore must refer to specific facts on a particular occasion. As a result, the court maintained that “related to” in this provision denotes a factual connection between an “investigation or audit” and “the use of funds.” Accordingly, the court asserted that “The only reasonable interpretation is that in all three provisions the phrases refer to a factual relationship.”³⁰ The Court also reasoned that the heading of section 1320a-7(b)(1) (“Conviction relating to fraud”) further supports this reading of the provision.

The court then evaluated the three aggravating factors OIG relied on to exclude the executives for 12 years—(1) the conduct underlying the convictions lasting more than one year, (2) the amount of the financial loss, and (3) the significant adverse physical or mental impact upon program beneficiaries. First, the Court rejected the argument that there was no financial loss because Purdue paid \$160 million in “restitution,” which the executives admitted responsibility for and because Purdue generated almost \$3 billion in revenues from OxyContin during the time it misbranded the drug,” much of which came from Federal and State healthcare programs that would not have been paid for but for the misbranding.³¹

Second, while the executives’ violations consisted solely of omissions, rather than “acts,” the Court concluded that HHS’ interpretation equating the two terms when only “acts” are proscribed was a permissible one.³² Third, the Court rejected the executives’ argument that HHS gave insufficient weight to their cooperation with law enforcement agencies because the executives did not show that the Secretary had abused her discretion.³³

The Court however, agreed with the executives that there was substantial evidence that HHS did not take into account the executives’ lack of “conscious wrongdoing” as a mitigating factor.³⁴ The Court also found that the length of the executives’ exclusion was arbitrary and capricious because (1) every case cited by HHS involved a mandatory exclusion with a presumptive baseline of five years, not a discretionary exclusion with a presumptive baseline of three years; (2) every case cited involved either a felony or Medicare fraud conviction for which the defendant was incarcerated, which was not present in this case; and (3) “none of the cases cited even concerned an exclusion under section 1320a-7(b)(1),” and HHS “had never excluded anyone for more than ten years” based upon a misdemeanor—the longest was four years.³⁵

Conclusion/ Recommendations

While the Purdue executives may file a petition for a rehearing by the entire D.C. Circuit, this case will have significant repercussions for those in the healthcare industry for several reasons. First, the decision likely will deter corporate healthcare executives from agreeing to pleas under the RCO doctrine because doing so could lead to exclusion, which would effectively end their careers even where the exclusionary period is significantly less than 12 years. As a result, it may be more difficult for the government and corporate defendants to resolve these types of cases through pleas, which may lead to increased litigation and related costs. Executives, however, may still be forced to accept a misdemeanor plea because prosecutors may threaten them with indictments under a felony charge, which could result in jail time as well as *mandatory* exclusion. They may also face pressure from corporate boards or shareholders to “take one for the team.”³⁶

Second, a plausible defense under the RCO doctrine is extremely difficult. The government need only prove that the executive had supervisory authority at the time the underlying violations took place to convict senior executives of an RCO offense. Moreover, although *Park* created the defense of objective impossibility,³⁷ such a defense is impractical because “Even if the most thorough and assiduous supervision produced no evidence of a problem, it would always be objectively possible for a CEO, who has authority over an entire company, to have prevented wrongdoing.”³⁸

Third, “before an organization pleads guilty, all counsel should scrutinize language in the statement of the offense to reduce the quantity as well as the quality of admissions that could be used against an executive” not only at sentencing, but also in a debarment or exclusion proceeding.³⁹ Companies that want to protect their executives from exclusion may want to refuse agreeing to plea facts “suggesting false, misleading or deceptive promotional practices by the company.”⁴⁰

Fourth, executives may be less likely to plead to misdemeanors without assurances from OIG as to exclusion. As a result, defense counsel will have to focus on achieving a global resolution early on in the negotiation process by engaging all government agencies involved, and if possible, to negotiate a waiver of exclusion/debarment.⁴¹ Accordingly, counsel should request a decision from OIG about exclusion before any individual or organization pleads guilty, similar to how corporate defendants negotiate the terms of their CIAs before entering criminal pleas or civil settlements. “This request should be made even when an investigation is closed without a guilty plea because the OIG’s authority to seek permissive exclusion does not require a criminal conviction.”⁴²

OIG likely will “resist the request for an advance decision about exclusion by claiming that it cannot exercise its discretion until after the resolution of criminal and civil matters.”⁴³

This argument, however, is problematic because OIG makes decisions about exclusions for companies before such cases are resolved by knowing enough about the investigation to accept the terms of the CIA. Moreover, the case of Michael Dinkel is precedent that OIG will make a decision about exclusion before accepting a settlement.⁴⁴ Additionally, defense counsel may “argue that a timely decision about exclusion is a matter of due process because the parties need to evaluate the true impact of a proposed agreement with the government.”⁴⁵ If OIG continues to refuse, defense counsel should negotiate a way to limit “the number of individuals or the types of positions that might be considered for permissive exclusion,”⁴⁶ and should ask OIG to render exclusion decisions “within a certain period of time so that the organization and the individuals can plan their futures accordingly.”⁴⁷

Ultimately, the *Friedman* case underscores “the government’s expectation that upper management be actively involved in ensuring corporate compliance with federal healthcare laws and regulations.”⁴⁸ Moreover, the case is a warning to individuals that a guilty plea could potentially result in exclusion if OIG finds that there is a factual connection relating to fraud. Accordingly, healthcare stakeholders will need “to work proactively with OIG prior to accepting a guilty plea to better assess whether an exclusion proceeding may occur subsequent to conviction.”⁴⁹ Additionally, corporate executives should become integrally involved in their company’s compliance efforts to ensure

that affirmative steps are being taken to minimize the risk of misconduct. ▲

1. <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>
2. Copeland, Katrice Bridges, *Enforcing Integrity* (October 18, 2011). *Indiana Law Journal*, Vol. 87, No. 3, 2011; The Pennsylvania State University Legal Studies Research Paper No. 22-2011, p.3 (noting that the use of CIAs “has not led to demonstrable reductions in health care fraud”) [hereinafter *Enforcing Integrity*].
3. Testimony of Daniel R. Levinson, Inspector Gen., before U.S. Senate Comm. on Fin. Hearing on Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges (Mar. 2, 2011); Testimony of Lewis Morris, Chief Counsel to Inspector Gen., before Subcomm. on Oversight of U.S. House Comm. on Ways & Means Hearing on Improving Efforts to Combat Health Care Fraud 6 (Mar. 2, 2011) [hereinafter *OIG Testimony*].
4. *Enforcing Integrity* at 50, (for example, “requiring funding for clinical trials, compulsory licensing, corporate officer liability, and a more targeted exclusion remedy”).
5. *OIG Testimony*.
6. FDA, *Special Procedures and Considerations for Park Doctrine Prosecutions*, Regulatory Procedures Manual, 6-5-3, available at <http://tinyurl.com/bp5l7vc>.
7. *OIG Testimony*.
8. Washington Legal Foundation, *Court Declines to Rein in Responsible Corporate Officer Doctrine*, Litigation Update (July 27, 2010).
9. *Friedman v. Sebelius*, No. 11-5028, p. 20 (2012) (citing 42 U.S.C. § 1320a-7(c) (3)(D)).
10. Bloomberg BNA, *Pharmaceutical Law & Industry Report, Experts Say D.C. Circuit’s Ruling May Increase Permissive Exclusion Use*. 10 PLIR 994 (quoting Laura Laemmler-Weidenfeld, Patton Boggs) [hereinafter *BNA Health*].
11. Shannon Thym Kilnger, Patrick M. Kellermann, *Enforcement Corner: Understanding Friedman v. Sebelius: How Might the Government’s Approach to Permissive Exclusion Impact Your Career in the Life Sciences Industry?*, FDLI Update (March 2011).
12. *Friedman*, at 3, 24.
13. *Id.* at 3-4.
14. Michael Friedman (President and CEO), Paul Goldenheim (Executive Vice Presi-

- dent of Medical and Scientific Affairs and former Executive Vice President of Worldwide Research and Development), and Howard Udell (Executive Vice President and Chief Legal Officer).
15. *United States v. Park*, 421 U.S. 658, 672-73 (1975).
 16. *Friedman*, at 4.
 17. *United States v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, 571 (W.D. Va. 2007) (noting that the executives were “not charged with any personal knowledge of misbranding or with any personal intent to defraud,” as well as the “absence of government proof of knowledge by the individual[s] ... of the wrongdoing”); Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing before the S. Comm. on the Judiciary, 110th Cong. 11 (July 31, 2007) (oral testimony of John Brownlee, United States Attorney for the Western District of Virginia).
 18. 320 U.S. 277 (1943).
 19. *See, Morissette v. U.S.*, 342 U.S. 246, 296 (1952); and Brief of Amicus Washington Legal Foundation at 12, *Friedman*, et al., 1:09-cv-02028-ESH (No. 22-2028).
 20. *Friedman* at 8 (quoting *Shepard v. United States*, 544 U.S. 13, 17 (2005)).
 21. *Id.* at 9 (quoting *Nijhawan v. Holder*, 557 U.S. 29, 34 (2009)).
 22. *Id.* at 10. The term “misdemeanor relating to fraud.” The split is between the U.S. Third Circuit Court of Appeals (*Wong Park v. Att’y Gen.*, 472 F.3d 66, 70 (3d Cir. 2006)) and the Second Circuit (*James v. Mukasey*, 522 F.3d 250, 254 (2d Cir. 2008) and *Mugalli v. Ashcroft*, 258 F.3d 52, 56 (2d Cir. 2001)).
 23. *Friedman* at 11 (citing *Morales*, 504 U.S. at 383 (quoting BLACK’S LAW DICTIONARY 1158 (5th ed. 1979))).
 24. *Id.* at 12.
 25. *Id.* at 13.
 26. *Id.* at 8.
 27. *Id.* at 12.
 28. *Id.* at 15.
 29. *Friedman* at 14.
 30. *Id.* at 14-15.
 31. *Id.* at 21.
 32. *Id.*
 33. *Id.* at 22.
 34. *Id.*
 35. *Id.* at 26.
 36. BNA Health (quoting Richard Samp, chief counsel of the Washington Legal Foundation).
 37. *Park*, 421 U.S. at 673.
 38. Brief of Amicus Washington Legal Foundation at 10, *Friedman*, et al., v. Sebelius 1:09-cv-02028-ESH (2010) (No. 22-2028).
 39. Thomas E. Zeno, Kimberly J. Donovan, *Rx for Fraud: The Feds Get Personal*, Criminal Justice, Vol. 26, No. 4, p. 7 (Winter 2012) [hereinafter *Rx for Fraud*].
 40. BNA Health Kelly (quoting John E. Kelly of Bass Berry & Sims PLC).
 41. *Id.*
 42. *Rx for Fraud* at 7.
 43. *Id.* at 8.
 44. Squires Press Release, *OIG, Law Judge Upholds HHS OIG’s Exclusion of Owner of Orlando, Florida, Diagnostic Imaging Services Company* (July 21, 2011).
 45. *Rx for Fraud* at 8.
 46. *Id.*
 47. *Id.*
 48. *Be Careful of the Company You Keep: Corporate Acts Lead to Executives’ Exclusions*. Baker & Hostetler LLP, Health Law Update (Aug. 16, 2012).
 49. *Id.*