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“RESPONSIBLE CORPORATE OFFICER”: BUSINESS EXECUTIVES FACE STRICT LIABILITY UNDER NOVEL CRIMINAL LAW DOCTRINE

by

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In recent years, the federal government has aggressively prosecuted the allegedly improper distribution and promotion of drugs under the federal Food, Drug, and Cosmetics Act (FDCA) and the False Claims Act (FCA). As a result of these prosecutions, drug companies have agreed to civil and criminal settlements worth billions of dollars. Because federal officials suspect that improper distribution and promotion continues, some commentators predict more individual prosecutions under the FDCA’s “responsible corporate officer” doctrine.¹ Under that doctrine, any corporate officer who has the authority and responsibility to prevent violations of the FDCA may be criminally liable for the violations, regardless of the officer’s knowledge or intent.²

The trend towards individual prosecutions is most apparent within the U.S. Food & Drug Administration’s (FDA) Office of Criminal Investigations (OCI). The OCI conducts investigations of suspected criminal violations and collects evidence to support prosecutions by the U.S. Department of Justice.³ In a recent letter to U.S. Senator Charles Grassley, FDA Commissioner Margaret Hamburg announced that OCI intends to “increase the appropriate use of misdemeanor prosecutions ... to hold responsible corporate officers accountable.”⁴ Hamburg also revealed that OCI has developed new criteria for selecting misdemeanor prosecution cases, which will be incorporated into revised OCI policies and

¹Mary Anne Pazanowski, *More Than Compliance Plan Needed to Avoid Enforcement, Attorneys Tell Meeting*, Health Care Daily Rep. (BNA) (Sept. 28, 2009) (Comments attributed to Sara M. Bloom, Assistant U.S. Attorney for the District of Massachusetts in Boston); Mary Anne Pazanowski, *Attorneys: More Than Compliance Plan Needed to Avoid Enforcement*, 13 Health Care Fraud Rep. 788 (BNA) (Oct. 7, 2009); *Government Attorneys Discuss Conduct That Gives Rise to Fraud Investigations*, Health Care Daily Rep. (BNA) (Nov. 12, 2009) (Comments attributed to Gerald Sullivan of the U.S. Attorney’s Office for the Eastern District of Pennsylvania).

²*United States v. Park*, 421 U.S. 658, 673-74 (1975).

³Letter from Margaret Hamburg, Commissioner of Food and Drugs, to Sen. Charles E. Grassley, Ranking Member, Senate Committee on Finance (Mar. 4, 2010), available at <http://finance.senate.gov/press/Gpress/2010/prg030410b.pdf> (last visited Mar. 13, 2010).

⁴*Id.*

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procedures.⁵ While the FDA has not released the new criteria, investigations and prosecutions of responsible corporate officers are almost certain to increase.

Such prosecutions can end the careers of responsible corporate officers because they can lead to exclusion from Medicare, Medicaid, and other federal health care programs. That was the fate of the former CEO, Chief Medical Officer, and General Counsel for The Purdue Frederick Company who pled guilty to FDCA violations based on Purdue's conduct in marketing Oxycontin. The Purdue officers were excluded from the federal health care programs for 12 years, even though they had no personal knowledge of the unlawful actions of several Purdue employees. Their predicament highlights the low threshold for liability under the responsible corporate officer doctrine, as well as the limited avenues for defending against exclusions premised on FDCA violations.

The FDCA and the Responsible Corporate Officer Doctrine

Criminal liability attaches under the FDCA when the defendant "misbrands" a product.⁶ A product is misbranded unless its labeling contains adequate directions for use and warnings against dangerous uses and unsafe dosages or methods of administration.⁷ Alternatively, a misbranded product is one with a false or misleading label.⁸

Misbranding is often characterized as a strict liability misdemeanor.⁹ This is largely true in cases where the responsible corporate officer doctrine is applied. A responsible corporate officer is criminally liable if he or she was in a position to prevent or correct the misbranding and failed to do so.¹⁰ While neither criminal intent nor actual knowledge of the conditions which violate the FDCA is required, the jury may not "find guilt solely on the basis of the [officer's] position in the corporation."¹¹ Rather, the jury must find that the officer "had a responsible relation to the situation and by virtue of his position had authority and responsibility to deal with [it]."¹² The primary, if not the only, defense is impossibility.¹³ That is, a corporate officer is not liable if he or she could not have possibly stopped the misbranding.¹⁴

The Officers' Guilty Pleas

In May 2007, Purdue pled guilty to a felony count of misbranding OxyContin with the intent to defraud or mislead.¹⁵ As part of the guilty plea, Purdue agreed that its sales representatives, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.¹⁶ In conjunction with Purdue's plea, three former senior Purdue officers – the CEO, General Counsel, and Medical Director – all pled guilty to misdemeanor misbranding.¹⁷ Unlike their employer, they were not charged with personal

⁵*Id.*

⁶21 U.S.C. § 331.

⁷21 U.S.C. § 352(f).

⁸21 U.S.C. § 352(a).

⁹*United States v. Articles of Drug*, 825 F.2d 1238, 1246 (8th Cir. 1987) ("Section 331 imposes strict liability for misbranding"); *Rheinecker v. Forest Labs., Inc.*, 813 F. Supp. 1307, 1311 (S.D. Ohio 1993).

¹⁰*Park*, 421 U.S. at 673-74.

¹¹*Id.* at 674.

¹²*Id.* (internal quotations omitted).

¹³*See Id.* at 672-73

¹⁴*Id.*

¹⁵*United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 575-76 (W.D.Va. 2007) (accepting plea agreements).

¹⁶*Purdue Frederick*, 495 F. Supp. 2d at 571.

¹⁷*See id.*

knowledge of the misbranding or any personal intent to defraud.¹⁸ The district court accepted their plea agreements, sentenced them to probation, and ordered them to disgorge millions of dollars of income.¹⁹

Following the sentencing, the U.S. Department of Health and Human Services – Office of Inspector General (OIG) excluded the Purdue officers from participating in federal health programs for 15 years. OIG cited two grounds for the exclusions. First, the Purdue officers’ pleas were convictions “relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct” under 42 U.S.C. § 1320a-7(b)(1).²⁰ Second, the pleas were convictions “relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance” under 42 U.S.C. § 1320a-7(b)(3).²¹ The exclusions were affirmed by an administrative law judge, and then by the Departmental Appeals Board of the U.S. Department of Health and Human Services.²² The Appeals Board reduced the exclusions to 12 years.²³

The Officers’ Action to Overturn the Exclusions

The Purdue officers promptly sued to overturn the exclusions in the U.S. District Court for the District of Columbia, making three arguments.²⁴ First, their convictions are not excludable offenses relating to fraud under 42 U.S.C. § 1320a-7(b)(1) or the unlawful distribution of a controlled substance under 42 U.S.C. § 1320a-7(b)(3).²⁵ Second, their exclusions do not serve the remedial purposes underlying the exclusion statute.²⁶ And third, the 12-year exclusions are unreasonable because they are not supported by substantial evidence of aggravating circumstances.²⁷

The district court may only disturb the U.S. Department of Health and Human Services’ (HHS) ultimate decision if that decision is unsupported by substantial evidence or is arbitrary and capricious given the purpose of the statute.²⁸ Under this liberal standard of review, the Purdue officers may have difficulty prevailing on their first argument. The Purdue officers contend that their convictions do not relate to fraud or an unlawful controlled substances violation, as the convictions are based solely on the Purdue officers’ corporate positions, and the Purdue officers were never charged with an intentional or knowing violation.²⁹ HHS, however, rejected the Purdue officers’ reasoning because at least one federal court has held that a nexus or common sense connection between the conviction and the unlawful conduct suffices.³⁰ Under this case law, the underlying felony conviction of Purdue supplies the intentional or knowing violation for the Purdue officers’ exclusion.³¹ Moreover, the Purdue officers agreed to numerous facts that place the

¹⁸*Id.*

¹⁹*Id.* at 575-76.

²⁰*In the Case of: Paul D. Goldenheim, M.D., Howard R. Udell, Michael Friedman v. Inspector General*, DAB No. 2268, 2009 WL 2957956, at *HHS 6 (H.H.S. Aug. 28, 2009).

²¹*Id.*

²²*Id.* at *HHS 1.

²³*Id.*

²⁴*Friedman v. Sebelius*, No. 1:09-cv-02028-ESH, Docket Entry No. 1 (D.D.C. filed Oct. 28, 2009) (Complaint).

²⁵*Id.* at ¶¶ 33-38.

²⁶*Id.* at ¶¶ 39-47.

²⁷*Id.* at ¶¶ 48-72.

²⁸*Chevron U.S.A., Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837 (1984); *Crews v. Shalala*, 40 F. Supp. 2d 350, 353-354 (E.D. Va. 1999); *Bowers v. Inspector Gen. of the Dep’t of Health & Human Servs.*, No. 1:08-CV-159, 2008 U.S. Dist. LEXIS 103302, at *5 (S.D. Ohio Dec. 19, 2008).

²⁹*Friedman*, No. 1:09-cv-02028-ESH, Complaint at ¶¶ 34-35.

³⁰2009 WL 2957956 at *HHS 9 (citing *In re Carolyn Westin*, DAB No. 1381 (1993), *aff’d sub nom Westin v. Shalala*, 845 F. Supp. 1446 (D. Kan. 1994)).

³¹*Id.* at *HHS 10.

company's conviction within the fraud prong for the exclusions.

The *Park* ruling's inflexible dictates pose challenges to the officers' second argument. The Purdue officers contend that their exclusions are arbitrary and capricious because the purpose of the exclusionary statute is to protect the federal health care programs from untrustworthy individuals, and they cannot be deemed untrustworthy given their lack of personal knowledge.³² But as HHS pointed out, the Supreme Court held in *United States v. Park* that a conviction of a responsible corporate officer requires proof that the officer had the power to stop the unlawful conduct yet failed to do so.³³ In HHS' view, *Park* establishes that convictions of responsible corporate officers import a measure of blameworthiness, which satisfies the remedial purpose of the exclusion statute.³⁴ While the Purdue officers' argument is a reasonable one, the district court could still find that HHS' conclusion is neither arbitrary nor capricious and should be upheld.

The strongest of the Purdue officers' arguments may be their third. They contend that the 12-year period for their exclusions is arbitrary because the aggravating circumstances upon which HHS relied are not supported by the evidence.³⁵ For example, HHS found that aggravating circumstances existed because the acts that resulted in the Purdue officers' convictions were committed over a period of one year or more.³⁶ The Purdue officers, however, were convicted based solely on their holding of corporate officer positions and their failure to stop the misbranding.³⁷ They did not plead guilty to any affirmative, personal acts.³⁸ With no evidence of the Purdue officers committing any affirmative personal acts, the Purdue executives' exclusionary period may be ripe for a reduction to fewer than 12 years.

Challenges for C-Level Executives

The Purdue officers' case raises questions about what can be done to avoid responsible corporate officer liability. With no *mens rea* requirement, the threshold for liability is low. At the same time, there are few guideposts for the "extraordinary care" required for the amorphous defense of impossibility. If the impossibility defense fails and a conviction is obtained, HHS has broad discretion in seeking exclusions from the federal health care programs.

Until the FDA issues guidance concerning the responsible corporate officer doctrine, the best, if not only, defense may be a good offense. That is, an aggressive compliance program with robust reporting mechanisms, led by senior corporate officers, may be the best means for avoiding liability.

³²*Friedman*, No. 1:09-cv-02028-ESH, Complaint at ¶¶ 39-47.

³³2009 WL 2957956, at *HHS 13 (citing *Park*, 421 U.S. at 672-73).

³⁴*Id.* at *16-17.

³⁵*Friedman*, No. 1:09-cv-02028-ESH, Complaint at ¶¶ 58-59.

³⁶2009 WL 2957956, at *HHS 20-23, 26.

³⁷*See Purdue Frederick*, 495 F. Supp. 2d at 570.

³⁸*See id.*