Clues to the Future of the *Park* Doctrine

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Introduction – Responsible Corporate Officer

This article examines three recent cases brought under the controversial *Park* doctrine in search of clues to the doctrine's future. The responsible corporate officer (RCO) doctrine, also known as the *Park* doctrine, allows for criminal prosecution of individuals, typically high-ranking corporate executives of pharmaceutical companies, for violations of the Food, Drug, and Cosmetic Act (FDCA), even absent any proof of the individual defendant's knowledge of or participation in the violation.

The seminal U.S. Supreme Court cases of *United States v. Dotterweich*[1] (1943) and *United States v. Park*[2] (reaffirming *Dotterweich* in 1975) established the RCO/*Park* doctrine, providing that a corporate agent who stands in a "responsible relation" to misconduct may be held criminally liable even without having played any direct role in the misconduct.[3] Standing in such a "responsible relation" means the corporate agent must have "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 that he failed to do so."[4] In essence, *Park* liability provides a mechanism for holding corporate executives vicariously responsible for violations occurring under their watch, even if they did not know of or personally participate in those violations. The

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first occurrence is a misdemeanor, albeit one that is often accompanied by the career-ending consequence of exclusion from participation in federal health care programs by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), with subsequent felony liability for recidivists.

Although this doctrine originated in the food and drug context, it also has been applied in the context of other public health and welfare statutes. For example, the Clean Water Act provides that a "responsible corporate officer" may be held liable for violations of the Act.[5] The same is true of the Clean Air Act[6] and the Radiation Control for Health and Safety Act.[7]

The FDA's View of the *Park* Doctrine

In recent years, the Food and Drug Administration (FDA) has demonstrated an increasingly aggressive view of the *Park* doctrine. In March 2010, FDA Commissioner Margaret Hamburg wrote a public letter to Senator Charles Grassley advising him that the FDA recommended "increas[ing] the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officers accountable."[8] Hamburg's letter also informed Grassley that the FDA had developed criteria for recommending *Park* doctrine prosecutions, but did not specify what those criteria were.[9]

In October 2010, FDA Deputy Chief for Litigation Eric Blumberg echoed Hamburg's sentiment about a planned increase in *Park* doctrine prosecutions, remarking at the Food and Drug Law Institute's Enforcement Conference in Washington, D.C. that pharmaceutical executives whose companies promoted off-label uses of their products could be targeted for misdemeanor prosecutions.[10] Blumberg further stated his view that large monetary settlements, such as a record-breaking $2.3 billion settlement with Pfizer the previous year to settle charges of the company's illegal promotion of the painkiller Bextra, were "not getting the job done" to deter FDCA violations, and he urged federal prosecutors to "show[] more resolve to criminally charge individuals at all levels in the company."[11] In response, the Washington Legal Foundation (WLF) wrote a letter to Blumberg calling these comments "irresponsible" and urging the FDA *not* to seek criminal liability under the *Park* doctrine where the individual in question did not participate in or have knowledge of the alleged violations.[12]

In January 2011, the FDA published its non-binding criteria for recommending *Park* doctrine prosecutions, nearly a year after first alluding to the development of these criteria.[13] They provide, contrary to the WLF's view, that "[k]nowledge of and actual participation in the violation are not a prerequisite to misdemeanor prosecution," but are merely "factors that may be relevant when deciding whether to recommend charging a misdemeanor violation."[14] According to FDA's non-binding criteria, other factors to consider include:

1. Whether the violation involves actual or potential harm to the public;
2. Whether the violation is obvious;
3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
4. Whether the violation is widespread;
5. Whether the violation is serious;
6. The quality of the legal and factual support for the proposed prosecution; and
7. Whether the proposed prosecution is a prudent use of agency resources."[15]

Only time will tell to what extent FDA and federal prosecutors in practice use the *Park* doctrine to prosecute individuals in the absence of knowledge or participation. Three recent cases, however, provide certain clues to the future direction of the *Park* doctrine.

Three Recent Cases

Purdue Executives

In May 2007, the federal government announced that it had reached a settlement with Purdue Frederick Company and its parent company, Purdue Pharma, to resolve a multi-year criminal and civil investigation into the alleged off-label promotion of the narcotic pain reliever OxyContin. The government alleged that certain Purdue Frederick supervisors and employees promoted OxyContin as being less addictive than it was, and that they did so with the intent to defraud or mislead.[16] Purdue Frederick pleaded guilty to felony misbranding, while the parent company paid roughly $600 million in criminal and civil penalties to settle the case.[17]

Two months later, three Purdue Frederick executives—the president and CEO, general counsel, and chief medical officer—each pleaded guilty to misdemeanor misbranding of OxyContin.[18] These executives pleaded guilty "solely as responsible corporate officers"; they were "not charged with personal knowledge of the misbranding or with any personal intent to defraud."[19] In other words, they pleaded guilty under FDA's view of the *Park* doctrine as not requiring personal knowledge or participation. Their non-prison sentences consisted of a combination of probation, community service, and fines.

The most significant consequence for the Purdue executives, however, was their subsequent exclusion by OIG, barring them from working for any company that receives federal health care funds. The period of exclusion was initially set at 20 years but was later reduced to 15 years, and finally to 12 years.

In October 2009, the Purdue executives sued HHS and OIG, arguing that (1) exclusion of individuals convicted under the *Park* doctrine is unauthorized because such convictions do not require any evidence of personal wrongdoing; and (2) a 12-year exclusion was an unreasonable penalty given these executives' lack of culpability.[20] In December 2010, a district court upheld the 12-year exclusion, even where the parties had stipulated that none of the excluded individuals had personal knowledge of the misbranding conduct.[21]

The executives appealed to the D.C. Circuit Court of Appeals. In July 2012, the federal appeals court reversed and remanded, holding that an exclusion of this length is authorized by statute, but ordering HHS to justify the lengthy ban for these particular executives on the ground that the decision was "arbitrary and capricious for want of a reasoned explanation for the length of their exclusions."[22] In its decision, the appeals court endorsed the FDA's view of *Park*, explaining, "Misdemeanor misbranding does not necessarily require a culpable mental state because a conviction for the offense may be, and in this case was, predicated upon the responsible corporate officer doctrine, which entails strict liability."[23]

Synthes Executives

In June 2009, the federal government charged spinal implant manufacturer Synthes, its subsidiary Norian Corporation, and four Synthes executives—two division presidents, vice president of operations, and director of regulatory and clinical affairs—with FDCA violations stemming from clinical trials of a bone filler conducted on roughly 200 spinal surgery patients without FDA approval between 2002 and 2004.[24] The charges included allegations of serious patient harm that may have resulted from the unauthorized clinical trials, including three patient deaths during surgery.[25] Synthes pleaded guilty to misdemeanor misbranding, and Norian pleaded guilty to felony conspiracy as well as misbranding.[26] The two companies also paid roughly $23 million in criminal and civil penalties.[27]

Unlike the executives in the *Purdue* case, the four Synthes executives were charged as responsible corporate officers with knowing and intentional violations of the law – in other words, not a strict liability *Park* doctrine prosecution. The four executives each pleaded guilty to misdemeanor misbranding as responsible corporate officers and, in late 2011, were sentenced to prison terms ranging from five to nine months.[28] At sentencing, the judge found *sua sponte* that the company had caused three patient deaths. The evidentiary basis for this finding remains unclear. Three of the four executives received prison sentences above the 0 to 6 month guideline range suggested by the federal sentencing guidelines. The judge explained that the upward variance was warranted because "a Guidelines sentence would not adequately address the unprecedented nature of the criminal conduct ... The scope of their scheme is without parallel, the risks created for an unsuspecting public were grave, and the scale of the deception of the Food and Drug Administration can only be characterized as extreme. . . . No similar set of facts can be located in the universe of *Park* doctrine cases."[29] Two of the executives were taken directly to prison from the courtroom in handcuffs, an unusual occurrence considering the criminal conduct at issue. Three of the executives initially appealed their prison sentences to the Third Circuit Court of Appeals but voluntarily withdrew their appeals the following month.[30] The reason for the voluntary withdrawals is not apparent from the record.

KV Pharmaceutical CEO

In November 2010, OIG notified KV Pharmaceutical's former CEO Marc Hermelin that it was excluding him from participation in federal health care programs in connection with the company's production and distribution of oversized morphine sulfate tablets.[31] Hermelin did not challenge his exclusion, which came months after KV and its subsidiary, Ethex Corporation, pleaded guilty to two felony counts of failing to report manufacturing problems related to the oversized tablets to FDA.[32] In March 2011, Hermelin pleaded guilty to two counts of misdemeanor misbranding as a responsible corporate officer.[33] He was sentenced to one month in prison and $1.9 million in criminal penalties.[34] Like the *Purdue* executives, Hermelin was not charged with personal knowledge or intent. Paraphrasing from the Supreme Court's language in *Park*, the government argued in its sentencing memorandum: "By virtue of his role at KV, Hermelin had the power, authority, and responsibility to prevent drug manufacturing problems in the first instance and promptly correct any drug manufacturing problems that did occur."[35]

What It All Means

Prosecutions brought under *Park* are few and far between, making it difficult to draw sweeping conclusions about the future of this doctrine. Though the three recent cases discussed above hardly con-

stitute a statistically significant sample, some fundamental observations warrant special mention. First, as in the Synthes and KV Pharmaceutical cases, prison sentences are more than a theoretical possibility under this doctrine. Second, the Purdue and KV prosecutions indicate that the Department of Justice gives credence to FDA's view of *Park* as requiring no knowledge, intent, or personal participation in the FDCA violation. Third, while strict liability could be viewed as being more morally defensible in cases involving serious patient harm, *Park* prosecutions are not necessarily reserved for only those cases. Fourth, given the ability to proceed based on a strict liability theory, as a practical matter, *Park* prosecutions place the burden on the company and executives to prove a *lack* of causation. Finally, the OIG's power of exclusion, with the potential to effectively end careers, remains a powerful threat separate and apart from criminal prosecution.

If the recent developments examined in this article presage the future direction of the *Park* doctrine, one might reasonably wonder how it is possible for even the most conscientious of corporate managers to protect themselves from *Park* liability. The most obvious answer – not working at a company where FDCA violations could conceivably occur – is only partly facetious. Ultimately, the best defense for those in the pharmaceutical industry may be a proactive approach that aims to avoid such prosecutions altogether by implementing effective compliance and training programs and ensuring that such programs continue to reflect new government guidance; practicing proper managerial oversight; conducting internal audits; reinforcing the appropriate use of e-mail and other communication; thoroughly documenting not only identified problems, but also the responses to those problems; and seeking inside and outside legal advice on thorny marketing and regulatory issues as soon as they arise. Taking these measures should greatly reduce the likelihood that the government will exercise its discretion to bring charges, even if something goes wrong at a pharmaceutical company such that strict liability charges could be brought against a responsible corporate officer. ⚠

1. 320 U.S. 277 (1943).
2. 421 U.S. 658 (1975).
3. *Park*, 421 U.S. at 673-74; *Dotterweich*, 320 U.S. at 280-81.
4. *Park*, 421 U.S. at 673-74.
5. 33 U.S.C. § 1319(c)(6).
6. 42 U.S.C. § 7413(c)(6).
7. *United States v. Hodges X-Ray, Inc.*, 759 F.2d 557, 560-61 (6th Cir. 1985) (holding that the RCO doctrine applied to impose civil liability under the Radiation Control for Health and Safety Act of 1968).
8. Letter from Margaret A. Hamburg, FDA Comm'r, to Sen. Charles Grassley (Mar. 4, 2010).
9. *Id.*
10. Anna Edney, *Drugmaker CEOs May Be Targets for U.S. FDA in Off-Label Cases, Lawyer Says*, Bloomberg News (Oct. 14, 2010), http://www.bloomberg.com/news/2010-10-14/drugmaker-executives-may-become-targets-of-fda-for-off-label-promotions.html.
11. *Id.*
12. Letter from Cory L. Andrews, Washington Legal Found. Senior Litig. Counsel, to Eric M. Blumberg, FDA Deputy Chief for Litig. (Oct. 26, 2010).
13. FDA Regulatory Procedures Manual, § 6-5-3, "Special Procedures and Considerations for Park Doctrine Prosecutions" (revised Jan. 26, 2011).
14. *Id.*
15. *Id.*
16. *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 571 (W.D. Va. 2007).
17. *Id.* at 570-72.
18. *Id.* at 570-71.
19. *Id.*
20. *Friedman v. Sebelius*, 755 F. Supp. 2d 98, 105 (D.D.C. 2010).
21. *Id.* at 100.
22. *Friedman v. Sebelius*, No. 11-5028, --- F.3d ----, 2012 WL 3055520, at *1 (D.C. Cir. July 27, 2012).
23. *Id.* at *3.
24. Indictment, *United States v. Norian Corp.*, No. 09-cr-403-LDD (E.D. Pa. June 16, 2009).
25. Peter Loftus, *Former Synthes Officers Receive Prison Sentences*, Wall Street Journal (Nov. 22, 2011), http://online.wsj.com/article/SB10001424052970204443404577052173679627572.html.
26. Settlement Agreement, *United States v. Norian Corp.*, 09-cr-403-LDD (E.D. Pa. Sept. 24, 2010), *available at* http://www.justice.gov/usao/pae/Pharma-Device/synthesnorian_settlementagreement.pdf.
27. Loftus, *supra* note 26.
28. Judgment, *United States v. Higgins*, No. 09-cr-403-LDD-4 (E.D. Pa. Nov. 21, 2011); Judgment, *United States v. Huggins*, No. 09-cr-403-LDD-3 (E.D. Pa. Nov. 21, 2011); Judgment, *United States v. Walsh*, No. 09-cr-403-LDD-6 (E.D. Pa. Nov. 21, 2011); Judgment, *United States v. Bohner*, No. 09-cr-403-LDD-5 (E.D. Pa. Dec. 13, 2011).
29. Memorandum, *United States v. Huggins*, No. 09-cr-403-LDD-3, (E.D. Pa. Dec. 13, 2011).
30. David Sell, *Ex-Synthes Executive Withdraws Appeal of Prison Term*, Philadelphia Inquirer (Jan. 6, 2012), http://articles.philly.com/2012-01-06/business/30598058_1_thomas-higgins-bone-cement-appeal.
31. Anna Edney, *KV Pharmaceutical's Hermelin Resigns After U.S. Ban, Will Sell Stake*, Bloomberg News (Nov. 17, 2010), http://www.bloomberg.com/news/2010-11-17/kv-pharmaceutical-s-hermelin-resigns-after-u-s-ban-will-sell-stake.html.
32. Press Release, Department of Justice, Marc S. Hermelin, Former CEO of KV Pharmaceutical, Pleads Guilty to Misbranding Drugs and Agrees to Pay United States $1.9 Million as Fines and Forfeiture (Mar. 10, 2011) (the "Hermelin Press Release").
33. Information, *United States v. Hermelin*, No. 11-cr-85-ERW (E.D. Mo. Mar. 10, 2011); Hermelin Press Release, *supra* note 33.
34. Hermelin Press Release, *supra* note 33.
35. Government's Sentencing Memorandum, *United States v. Hermelin*, No. 11-cr-85-ERW (E.D. Mo. Mar. 11, 2011).