Bloomberg BNA

Pharmaceutical Law & Industry Report®

VOL. 12, NO. 14 APRIL 4, 2014

Vicarious Criminal Liability in the Executive Suite For Problems on the Manufacturing Floor





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Pharmaceutical executives who bear ultimate responsibility for product safety must beware of a unique occupational hazard—the risk of criminal prosecution as a responsible corporate officer (''RCO'') resulting from violations of Current Good Manufacturing Practice (''cGMP'') regulations. As set forth in the Supreme Court's seminal decision in *United States v. Park*, 421 U.S. 658 (1975), an executive can be subject to liability as an RCO (often termed *Park* liability) if he or she was in a position to prevent a violation of the Food Drug & Cosmetic Act (''FDCA''), including distribution of adulterated products—regardless of whether he or she knew about the violation. Indeed, criminal liability can result from infractions in a manufacturing facility thousands of miles away from headquarters. This article prescribes steps that companies can take to reduce the risk that their senior leaders will be held personally liable under a ''captain of the ship'' theory of liability for cGMP violations that are unrelated to their personal conduct.

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Although the theoretical risk of a *Park* prosecution for an FDCA violation has existed for decades, the intersection of two recent trends creates a clear and present threat for executives, including the CEO, who have ultimate responsibility for ensuring product safety: (1) the government's increased use and threatened use of *Park* prosecutions against executives at pharmaceutical and medical device companies, and (2) several high-profile corporate felony plea agreements involving cGMP violations that resulted in steep fines. The Food and Drug Administration (''FDA'') also cited *Park* in discussing cGMP violations in eight warning letters issued in 2013 to dietary supplement manufacturers – a clear reminder that cGMP violations can implicate *Park* liability. Being subjected to *Park* liability can have catastrophic consequences, including reputational harm; large fines; jail time; and exclusion from federal health care programs—making it virtually impossible to continue working in the health care industry.

What should a CEO and other executives with ultimate responsibility for product safety do to protect themselves from being charged with a crime to which there may be no viable defense? In 2011, the FDA issued guidelines setting forth the circumstances under which it believes that *Park* prosecutions are appropriate—in which the FDA confirmed that knowledge of wrongdoing is not a prerequisite to prosecution—but provided little meaningful guidance as to how executives can avoid prosecution in the first place. Although there are no foolproof solutions to this dilemma, there are steps that companies can take to

 ISSN 1542-9547

limit the risk to their executives, including establishing rigorous and comprehensive compliance policies designed to facilitate the flow of information to and from senior management, ensuring that appropriate reporting channels are in place, setting a strong tone at the top emphasizing the importance of compliance to the company's business mission, and ensuring that executives have appropriate visibility into manufacturing processes and performance. Companies also should consider hiring experienced outside counsel to conduct a thorough examination of the company's compliance processes to ensure that executives are receiving the type of information they need to insulate themselves from possible *Park* liability.

Intensified Government Focus on Criminal Strict and Vicarious Liability

Section 333 of the FDCA criminalizes the distribution of adulterated or misbranded food, drugs, or devices in interstate commerce. A misdemeanor violation under Section 333(a)(1) requires no intent or even awareness of the underlying conditions or wrongdoing, reflecting legislative intent to impose a high standard of care in the name of deterring actions or conditions that may endanger public safety.

In *United States v. Dotterweich*, the Supreme Court sanctioned holding ''responsible officers'' strictly liable for the acts of a corporation, irrespective of the employee's knowledge or personal involvement in any wrongdoing.[1] In *United States v. Park*, the case for which the *Park* doctrine is named, the Court upheld a misdemeanor conviction under Section 333(a)(1) of the president and CEO of a national retail food chain that distributed adulterated products. Expanding on the *Dotterweich* decision, the Court concluded 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*.''[2] The only potential defense the *Park* Court recognized were instances where the corporate agent was ''powerless to prevent or correct the violation.''[3] Thus, under the *Park* doctrine, guilt can be imputed to anyone who, by reason of her position, has the ''authority and responsibility'' to prevent or correct violations, and fails to do so, even if she did not participate in any wrongdoing or had no personal knowledge of the underlying acts or conditions.[4]

From the 1960s through the 1980s, misdemeanor RCO prosecutions were pursued with some frequency, primarily in adulterated food cases known to the Department of Justice as ''dirty warehouse'' cases.[5] Most of the convicted executives in such cases, however, had some degree of awareness or notice of the underlying activity or conditions.

The government's use of the *Park* doctrine took a different turn in 2007, when three executives of the Purdue Frederick Company, Inc. (''Purdue'') pled guilty to misdemeanor counts of misleading the public about the safety of OxyContin. Collectively, the executives were ordered to disgorge $34.5 million in personal funds and were subsequently excluded from federal health care programs for 12 years.[6] What was remarkable about the Purdue case was that, although the government had previously assured the Supreme Court in its *Park* briefing that officials ''who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of their corporate duties'' would not be subject to criminal prosecution—the government admitted that it was not aware of any evidence that the Purdue executives had any knowledge of the sales practices in dispute.[7]

Following the Purdue case, there have been a number of *Park* prosecutions of executives at drug and medical device companies. These include:

- In 2009, four executives at a biotechnology company were charged, among other things, as RCOs based on alleged underlying acts of off-label promotion of a medical device.[8] The government subsequently dismissed the charges against the defendants.[9]

- In 2010, three executives at a medical device company were charged, among other things, as RCOs for conduct involving the importation of adulter-

[1] 320 U.S. 277 (1943).
[2] 421 U.S. 658, 672 (1975) (emphasis added).
[3] *Id*. at 673.
[4] *Id*. at 674.

[5] John R. Fleder, *The Park Criminal Liability Doctrine: Is it Dead or is it Awakening?*, FDLI UPDATE, 48, 49 (Sept./Oct. 2009).
[6] In July 2012, the Court of Appeals for the D.C. Circuit held that the length of the exclusion was arbitrary and capricious and remanded the matter to the Department of Health and Human Services for further proceedings. *See Friedman v. Sebelius*, 686 *F.3d* 813 (D.C. Cir. 2012). There is no further publicly available information regarding the exclusions in that matter.
[7] *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 11, 21 (July 31, 2007) (former U.S. Attorney John Brownlee, in sworn testimony before the Senate Judiciary Committee, acknowledged that he had not found any evidence that the Purdue executives had personal knowledge of any wrongdoing).
[8] DOJ Press Rel., Stryker Biotech and its Top Management Indicted for Illegal Promotion of Medical Devices Used in Invasive Surgeries (Oct. 28, 2009), http://www.fda.gov/ICECI/CriminalInvestigations/ucm271714.htm.
[9] David Voreacos & Janelle Lawrence, Health Care Prosecution Losses Mar U.S. Marketing Probe, BLOOMBERG NEWS, Mar. 14, 2012, http://www.bloomberg.com/news/2012-03-14/health-care-prosecution-losses-mar-u-s-marketing-probe.html.

  PLIR ISSN 1542-9547

ated medical devices.[10] Two executives were subsequently acquitted at trial of the RCO charges and the government subsequently dismissed charges against the other executive.[11]

- In 2011, the chairman and CEO of a pharmaceutical company pled guilty as an RCO based on alleged underlying conduct involving the production of oversized tablets. He was sentenced to 30 days in jail, paid a $1 million fine, and was required to forfeit $900,000.[12]
- In 2011, four executives at a medical device company pled guilty as RCOs based on alleged underlying conduct involving unauthorized clinical trials relating to a medical device that resulted in three deaths. They received prison sentences ranging from five to nine months and were each fined $100,000.[13]
- In 2012, the head of compounding pharmacy pled guilty as an RCO based on alleged underlying conduct involving the shipment of a drug with varying levels of potency, resulting in three deaths. He was sentenced to 90 days of home confinement and was fined $100,000.[14]

Prosecutors continue to threaten *Park* prosecutions, particularly by suggesting that companies are not sufficiently incentivized to ensure compliance, but instead view fines and settlements as merely a cost of doing business. For example, in October 2013, Zane David Memeger, the U.S. Attorney for the Eastern District of Pennsylvania, expressed just such a sentiment at a public conference, characterizing the *Park* doctrine as an effective yet underutilized tool for addressing misconduct.

Government Focus on Steep Criminal Penalties for cGMP Violations

In recent years, the government has entered into two high-profile felony plea agreements with pharmaceutical manufacturers – one branded and one generic – for misconduct involving cGMP violations. The generic manufacturer, admitted that an overseas facility violated cGMP due to, among other things, incomplete testing records, an inadequate program to assess the stability characteristics of manufactured drugs, and the company's disregard of a report from a consulting firm that identified cGMP violations in the company's facilities.[15] The branded manufacturer, admitted that a facility in a U.S. territory failed to ensure that certain drugs were free of contamination from microorganisms; that a manufacturing process caused certain tablets to split, destroying the therapeutic effect of the medication; that other tablets did not always have the FDA-approved mix of ingredients; and that there were drug mix-ups, resulting in different drugs being commingled.[16] In both cases, the consequences were severe: the manufacturers each pled guilty to a felony information and each paid $150 million in criminal fines and forfeiture, as well as hundreds of millions of dollars more to resolve civil claims under the False Claims Act and related state laws.

Federal prosecutors continue to pursue alleged cGMP violations. A pharmaceutical company received a subpoena from the U.S. Attorney's Office in Boston in March 2013 regarding manufacturing practices at an overseas facility.[17] In a speech last year, Deputy Assistant Attorney General Maame Ewusi-Mensah Frimpong warned that the Department of Justice would ''be taking an especially hard look whenever patients are placed at an unacceptably high risk of harm by . . . violations of current good manufacturing practices.'' Similarly, Susan Winkler, an Assistant U.S. Attorney in Boston who has led many health care fraud prosecutions, warned in an October 2013 panel discussion that there will be more prosecutions involving cGMP violations, particularly in cases involving safety issues or fraud.

Intersection of Enforcement Trends: Park Liability for cGMP Violations

Eight warning letters issued by the FDA last year suggest a continued focus on *Park* liability in the context of cGMP violations. Each of these letters, which were issued to dietary supplement manufacturers, included the following language:

Although your firm may contract out certain dietary supplement manufacturing operations, it cannot, by the same token, contract out its ultimate responsibility to ensure that the dietary supplement it places into commerce (or causes to be placed into commerce) is not adulterated for failure to comply with dietary supplement CGMP requirements (see *United States v. Dotterweich*, 320 U.S. 277, 284 (1943)) (explaining that an offense can be committed under the Act by anyone who has ''a responsible share in the furtherance of the transaction which the statute outlaws''); *United States v. Park*, 421 U.S. 658, 672 (1975) (holding that criminal li-

[10] DOJ Press Rel., Spectranetics Executives Indicted for Conspiracy, False Statements, Import Violations and Introduction and Receipt of Misbranded Medical Devices (Aug. 30, 2010), http://www.fda.gov/ICECI/CriminalInvestigations/ucm226466.htm.

[11] Wayne Heilman, Former Spectranetics CEO Acquitted On All But One Charge, The Gazette, Mar. 1, 2012, http://gazette.com/article/134422.

[12] DOJ Press Rel. 11-306, Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case (Mar. 10, 2011), http://www.justice.gov/opa/pr/2011/March/11-civ-306.html. (09 PLIR 328, 3/18/11)

[13] DOJ Press Rel., Former Executives of International Medical Device Maker Sentenced to Prison in Unlawful Clinical Trials Case (Nov. 21, 2011), http://www.fda.gov/ICECI/CriminalInvestigations/ucm280937.htm.

[14] DOJ Press Rel. 12-526, Dallas Compounding Pharmacy Owner Pleads Guilty in Connection with Misbranded Drug Shipment (Apr. 24, 2012), http://www.justice.gov/opa/pr/2012/April/12-civ-526.html. (10 PLIR 586, 5/4/12)

[15] DOJ Press Rel., 13-542, Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA (May 13, 2013), http://www.justice.gov/opa/pr/2013/May/13-civ-542.html. (11 PLIR 626, 5/17/13)

[16] DOJ Press Rel., 10-1205, GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010), GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant.

[17] AstraZeneca gets U.S. subpoena over UK drug factory, Reuters (April 25, 2013), http://uk.reuters.com/article/2013/04/25/us-astrazeneca-results-factory-idUKBRE93O0BM20130425.

ability under the Act does not turn on awareness of wrongdoing, and that ''agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act'' can be held accountable for violations of the Act).

To our knowledge, these eight warning letters represent the first time that the FDA has referenced *Park* and *Dotterweich* in its public correspondence with regulated entities. Although the context of these references is entity liability—not individual liability—the FDA is fully aware that its warning letters are carefully scrutinized and will be read by industry as confirmation of the FDA's position that, in appropriate cases, it will encourage the Department of Justice to seek RCO prosecutions for cGMP violations.

Lack of Clear Guidance About How Executives Can Protect Themselves Against Liability

In 2011, the FDA issued special procedures and considerations for agency personnel considering whether to recommend a *Park* prosecution (the ''Guidelines'').[18] The Guidelines emphasize that knowledge of or participation in a violation is not required for a *Park* prosecution, and instead instruct agency personnel to consider three primary factors: *first*, the individual's position in the company; *second*, the individual's relationship to the violation; and *third*, the individual's authority or ability to correct or prevent the violation. The Guidelines identify additional factors that agency personnel should consider, including:

- Whether the violation involves actual or potential harm to the public;
- Whether the violation is obvious;
- Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- Whether the violation is widespread;
- Whether the violation is serious;
- The quality of the legal and factual support for the proposed prosecution; and
- Whether the proposed prosecution is a prudent use of agency resources.

Although the Guidelines make clear that the FDA will seek to hold executives liable for violations of the FDCA solely by virtue of their company positions, the Guidelines offer virtually no concrete guidance or instruction about how executives can protect themselves from individual liability.

What Companies and Executives Can Do to Minimize Personal Liability for cGMP Violations

What can an executive do to minimize the potential for personal liability? The short answer is be an active leader and take ownership of his or her company's compliance program. More specifically, senior executives should consider taking the following protective measures, at a minimum:

- Ensure that the company's corporate compliance program is sufficiently broad in focus. Corporate compliance programs should include some degree of oversight over manufacturing quality, clinical trials, and foreign operations, in addition to the U.S.-based sales and marketing practices that have dominated government investigations in recent years. Although the involvement of corporate compliance personnel obviously cannot and should not replace experts in cGMP quality compliance, a highly technical and specialized area, corporate compliance personnel can provide a valuable additional layer of oversight and company-wide perspective.
- Set a ''tone from the top'' that compliance is a top priority for the company, takes precedence over profits, and that all personnel are expected to play a role in ensuring compliance. Leaders should emphasize publicly and regularly the company's commitment to quality, compliance, and integrity, and develop effective lines of communication to ensure that the message gets to employees at all levels. For example, executives can emphasize the importance of quality and compliance in speeches, training, and/or written communications to employees. Leaders can also hold meetings, such as town halls, with manufacturing employees and middle managers to emphasize the importance of compliance and to allow employees to voice concerns about quality operations. If there is a compliance or quality incident, executives should address the incident publicly and be visibly active in remediation efforts.
- Create appropriate reporting channels and an environment in which employees feel comfortable reporting potential issues. At a minimum, companies should have a compliance hotline through which employees can report possible compliance and quality issues anonymously or semi-anonymously, and a strong anti-retaliation policy that prohibits any form of retaliation or adverse consequences for employees who report potential compliance issues in good faith. Companies should regularly publicize the compliance hotline and the anti-retaliation policy. Executives should publicly encourage employees to use the reporting hotline and convey to line employees as well as managers that the company has zero tolerance for retaliation. Executives can also consider scheduling plant visits or tours to further emphasize to employees that quality and compliance are top priorities for the company.
- Ensure that senior leadership has appropriate visibility into manufacturing processes. It is not enough that senior leaders talk about manufacturing compliance. Companies should ensure that leaders receive clear and reliable metrics and indicators on manufacturing functions that show past trends and predict future compliance issues before they occur. Executives should also consider joining compliance committee meetings and/or hold-

[18] FDA Regulatory Procedures Manual, § 6-5-3, Special Procedures and Considerations for Park Doctrine Prosecutions (2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3.

  PLIR ISSN 1542-9547

ing regular meetings with manufacturing managers to discuss these metrics, manufacturing performance, and the risks facing the company. Gaining sufficient knowledge of cGMP performance not only places executives in a position to remediate or take precautionary measures when necessary, but allows leaders to make informed decisions about appropriate resource allocation.

- Commission rigorous outside reviews to identify potential weaknesses in the company's cGMP processes. Executives should not rely on internal audits and data alone, but should also enlist objective experts to conduct in-depth reviews and audits of various manufacturing and other processes. Executives should review the findings of those evaluations, ask questions, and ensure that they understand their significance.
- Engage experienced outside counsel to conduct a rigorous examination of the company's compliance program, policies and procedures, and, specifically, the flow of information up and down the chain to identify where executives may be vulnerable to *Park* liability and to identify constructive ways to address those vulnerabilities.
- Address any identified deficiencies. Perhaps most importantly, executives should not ignore warning signals or signs of trouble. Once made aware of a potential issue, executives should investigate the cause of the problem, take steps to remediate it, and continue to follow up until satisfied that the issue has been addressed.