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REPORT

A Perfect Storm: Prosecutors' Increasing Focus on Individual Liability In the Drug and Device Sectors and the Responsible Corporate Officer Doctrine



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Introduction

In connection with the steady drumbeat of prosecutions of pharmaceutical and medical device companies for promotional and other violations, the government has also increasingly targeted individuals at various levels of these companies for violations ranging from misbranding under the federal Food, Drug and

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Cosmetic Act (''FDCA'') to wire fraud and obstruction of justice.[1] A number of examples illustrate this trend:

- In May 2007, as part of the settlement between the Purdue Frederick Company, Inc. and the government regarding the company's promotion of Oxycontin, three of the company's executives—its president and CEO, its executive VP and chief legal officer and its former executive VP and chief scientific officer – pled guilty to misdemeanor misbranding charges under the FDCA.[2]
- On March 18, 2008, W. Scott Harkonen, M.D. was indicted by the U.S. Attorney's Office for the Northern District of California on two felony counts—violation of the wire fraud statute and misbranding under the FDCA—for his role in the creation and dissemination of an allegedly false and misleading press release about the efficacy of InterMune's drug Actimmune as a treatment for idiopathic pulmonary fibrosis (''IPF'').[3] The indictment alleged that, under Harkonen's direction, InterMune engaged in the off-label marketing of Actimmune to treat IPF.[4] On September 29, 2009, Harkonen was convicted on the felony wire fraud count, but acquitted on the misbranding count.[5]
- In March 2009, a former Pfizer District Sales Manager was convicted of obstruction of justice for instructing one of his sales representatives to alter documents and backdate the alterations on his computer to delete evidence of off-label promotion after he learned of a request for documents related to a government investigation.[6]
- Also in March 2009, in connection with the government's investigation of Pharmacia's promotion of Bextra, the government alleged that a former Pharmacia sales manager instructed her sales people to sell Bextra for unapproved uses and at unapproved doses and to tell doctors that Bextra was safer and more effective than its competitors, even though there was insufficient scientific support for that claim.[7] The sales manager subsequently pled guilty to distribution of a misbranded drug.[8]
- On June 16, 2009, four senior executives of Synthes, Inc., a medical device company, were indicted based on allegations that they had helped the company conduct clinical trials of an unapproved use of a medical device without Food and Drug Administration approval and in spite of a warning on the product's label against this use.[9] All four executives subsequently pled guilty.[10]
- On October 28, 2009, in connection with the indictment of Stryker Biotech, two regional sales managers were indicted by the U.S. Attorney's Office for the District of Massachusetts and charged with distributing a misbranded device under the FDCA for their role in an allegedly fraudulent marketing scheme involving the company's products.[11]
- Finally, as recently as November 2010, the federal government indicted a former GlaxoSmithKline Vice President and Associate General Counsel on charges of obstructing an official proceeding, concealing and falsifying documents to influence a federal agency and making false statements to the FDA.[12] Among other factual allegations, the indictment alleged that the in-house lawyer falsely denied that her company had promoted a drug off-label even though evidence indicated that she knew that it had sponsored many programs where the drug was promoted off label.[13]

The increased focus on individual accountability has also led to a significant change in the Corporate Integrity Agreements (''CIAs'') that the Office of Inspector

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[1] It is also likely that prosecutions of individuals at pharmaceutical and device companies under the Foreign Corrupt Practices Act (''FCPA'') will increase. According to Lanny Breuer, Assistant Attorney General of the Department of Justice's Criminal Division, in the past year, ''we tried more individuals for FCPA violations than in any prior year. And we indicted more individuals than ever before. *This is no accident*. In fact, prosecution of individuals is a cornerstone of our enforcement strategy . . . . Put simply, the prospect of significant prison sentences for individuals should make clear to every corporate executive, every board member, and every sales agent that we will seek to hold you personally accountable for FCPA violations.'' Assistant Attorney General Lanny Breuer, Address at the 22nd National Forum on the FCPA (Nov. 17, 2009) (emphasis in original).

[2] Press Release, U.S. Attorney's Office Western District of Virginia, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding Oxycontin; Will Pay Over $600 Million (May 10, 2007) http://web.archive.org/web/20070512174719/www.usdoj.gov/usao/vaw/press_releases/purdue_frederick_10may2007.html (last visited June 17, 2010). This case will be discussed in greater detail *infra*.

[3] Press Release, DOJ, ''W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud (Sept. 29, 2009), http://www.justice.gov/usao/can/press/2009/2009_09_29_harkonen.convicted.press.html (last visited June 17, 2010).

[4] *Id*. Harkonen argued that the press release at issue should be protected under the First Amendment as pure scientific speech or, at a minimum, as mixed scientific and commercial speech. Defendant's Motion to Dismiss (First Amendment) at 1-2, *U.S. v. Harkonen*, No. 3:08-cr-00164-MHP (N.D. Cal. Mar. 23, 2009). Alternatively, he argued that the press release and related communications did not constitute ''labeling'' under the FDCA because they did not ''supplement or explain'' the drug itself and were not part of an ''integrated distribution program.'' Defendant's Motion to Dismiss (''Labeling'') at 5-11, *U.S. v. Harkonen*, No. 3:08-cr-00164-MHP (N.D. Cal. Mar. 23, 2009).

[5] Verdict Form, *U.S. v. Harkonen*, No. 3:08-cr-00164-MHP (N.D. Cal. Sept. 29, 2009) (7 PLIR 1164, 10/9/09).

[6] Press Release, DOJ, Ex-Pfizer Manager Found Guilty of Obstruction (Mar. 17, 2009), http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Mar2009/FarinaconvictionPR.html (last visited June 17, 2010).

[7] Press Release, United States Attorney's Office District of Mass., Pharmaceutical Company Manager Pleads Guilty to Off-Label Marketing (Mar. 30, 2009), http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Mar2009/HollowayMaryPleaPR.html (last visited June 18, 2010).

[8] *Id*.

[9] Indictment at 25-26, 54, *U.S. v. Norian Corp., Synthes Inc., Michael D. Huggins, Thomas B. Higgins, Richard E. Bohner and John J. Walsh*, No. 2:09-cr-004-2-LS-4 (E.D. Pa. June 16, 2009). This case will be discussed in greater detail *infra*.

[10] Government's Amended Presentence Memorandum at 3-5, *U.S. v. Huggins, et al.*, No. 2:09-cr-00403-LS (E.D. Pa Apr. 7, 2010).

[11] Indictment at 26-27, *U.S. v. Stryker Biotech, LLC, Mark Philip, William Heppner, David Ard and Jeffrey Whitaker*, No. 09-cr-10330 (D. Mass. Oct. 28, 2009).

[12] Press Release, DOJ, Pharmaceutical Company Lawyer Charged with Obstruction and Making False Statements (Nov. 9, 2010), http://www.justice.gov/opa/pr/2010/November/10-civ-1266.html (last visited Nov. 10, 2010) (8 PLIR 1427, 11/12/10).

[13] *Id*.

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General (''OIG'') has been negotiating.[14] Since 2008, the OIG has included provisions in CIAs requiring individuals to personally certify compliance with the CIA, federal health care program requirements and FDA requirements. Government representatives have called these individual certifications an important step toward prosecuting more individuals at pharmaceutical and medical device companies.

With respect to misbranding violations in particular, prosecutors wield a potent weapon against individuals—the ''Responsible Corporate Officer'' (''RCO'') or *Park* doctrine. The *Park* doctrine provides for strict liability of individuals under the misdemeanor provisions of the FDCA. In other words, individuals may be found liable for the actions of others in the company merely because their position within the company gave them the responsibility and authority to prevent or correct violations and they failed to do so—even when they had no knowledge of the misconduct.

This article will examine this trend and its implications for executives at pharmaceutical and device companies. First, we discuss *U.S. v. Park*, the Supreme Court case that laid the foundation for strict individual liability under the FDCA. We then highlight recent prosecutions under the *Park* doctrine. The article then analyzes the provisions in recent CIAs requiring personal certifications of compliance and recent statements by government officials that the CIA certifications can be used for prosecutions under the *Park* doctrine. The article then addresses the recently announced criteria for excluding individuals from participating in federal health care programs. Finally, we offer practical suggestions on how to mitigate exposure to *Park* liability.

U.S. v. Park

Liability under the *Park* doctrine stems from the FDCA's misdemeanor provision, section 301, which makes persons strictly liable for ''the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.''[15] Section 303 states that ''[a]ny person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.''[16]

In *U.S. v. Park*,[17] a national food store chain and its CEO, John Park, were charged with violations of the FDCA stemming from allegations that the chain had stored food ''in a building accessible to rodents and [] exposed to contamination by rodents,'' which ''resulted in the food's being adulterated.''[18] The evidence at trial demonstrated that the FDA informed the CEO of the conditions at the warehouse. Although he acknowledged that he was ultimately responsible for the entire operation of the company, he had delegated the responsibility for investigating and correcting the problems identified to others.[19] Even though there was no evidence to suggest that he was personally responsible for the specific conditions in the warehouse, the CEO was convicted.[20]

The Supreme Court upheld the CEO's conviction, holding that the government establishes a *prima facie* case under Section 301 of the FDCA ''when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant 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.''[21] The Court stated that with respect to the duties imposed on RCOs, the FDCA requires ''foresight and vigilance'' and ''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.''[22] Thus, the decision defined the standard required of RCOs.

Significantly, the Court stated that the FDCA does *not* ''make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.' ''[23] Rather, even though an officer cannot be found guilty solely on the basis of his position within the corporation, he can be found guilty if a jury determines that he '' 'had a responsible relation to the situation,' and 'by virtue of his position . . . had . . . authority and responsibility' to deal with the situation.''[24]

The CEO had argued that ''as the president of a large corporation, he had no choice but to delegate duties to those in whom he reposed confidence, that he had no reason to suspect his subordinates were failing to insure compliance with the Act, and that, once violations were unearthed, acting through those subordinates he did everything possible to correct them.''[25] The Court found this argument unavailing given the fact that the defendant had been notified by the FDA of the conditions in the warehouse, which the Court viewed as evidence that the defendant had been ''on notice that he could not rely on his system of delegation to subordi-

[14] A CIA is often required by the OIG in connection with the resolution of a case involving allegations of off-label marketing or kickbacks, and in exchange for the OIG's agreement not to seek exclusion of the company from participation in Medicare, Medicaid and other federal health care programs. Typically, a CIA will require, among other things, that the company hire and maintain a compliance officer; appoint a compliance committee; develop written standards and policies; implement a comprehensive employee training program; and establish a confidential disclosure program.

[15] 21 U.S.C. § 331(a) (2006).

[16] 21 U.S.C. § 333(a)(1) (2006). Additionally, the sentences for convictions under the FDCA have increased. The Patient Protection and Affordable Care Act, which was signed into law in March 2010, redefined the term ''health care fraud offense''—which triggers certain enforcement-related activities—to include misbranding violations under Section 301 of the FDCA. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10606, 124 Stat. 119 (2010). The Act also amended the federal sentencing guidelines to increase the offense level ranges between two and four levels, depending on the total loss, for defendants convicted of a federal health care offense relating to a government health care program. *Id.*

[17] 421 U.S. 658 (1975).

[18] *Id*. at 660.

[19] *Id*. at 663-64.

[20] *Id*. at 666.

[21] *Id*. at 673-74.

[22] *Id*. at 672.

[23] *Id*. at 672-3 (quoting *U.S. v. Dotterweich*, 320 U.S. 277, 281 (1943)).

[24] *Id.* at 674. The Court did note that one possible defense to RCO liability is when a defendant could credibly argue that he was ''powerless'' to prevent or remedy the violations. *Id.* at 673. The defendant bears the burden of coming forward with evidence supporting this affirmative defense. *Id.*

[25] *Id*. at 677.

nates to prevent or correct insanitary conditions at Acme's warehouses . . . .''[26]

In short, *Park* stands for the proposition that the delegation of responsibilities, even within a large organization, will not shield an officer from personal liability—especially if the officer is not demonstrating sufficient personal vigilance in the process. Rather, the FDCA imposes on RCOs a duty to act with ''the highest standard of foresight and vigilance.''[27] Importantly, because *Park* constitutes a strict liability offense under the FDCA, it could apply to virtually every misbranding prosecution, limited only by the discretion of the individual prosecutors involved.

What does this mean in today's large global pharmaceutical and medical device companies with thousands of employees confronting complicated compliance-related issues at all levels of the company? According to the *Park* doctrine, executives of these organizations cannot leave it to their delegates to raise issues and ensure that they are being addressed. Rather, the clear impact of an aggressive use of *Park* is that these executives must drill down themselves into the state of compliance and must themselves ensure issues and challenges are being identified and addressed.

Prosecution of Individuals Under *Park*

The potential for the government to exercise its authority under the *Park* doctrine is no longer an academic one. Since 2007, the government has prosecuted individuals under this doctrine in two notable cases: Purdue and Synthes.

Purdue. In May 2007, the Purdue Frederick Company, Inc. and Purdue Pharma, L.P. entered into a settlement with the U.S. Attorney's Office in the Western District of Virginia, which resolved the government's claims that the companies were marketing Oxycontin, a powerful pain reliever, as being less addictive, less subject to abuse and less likely to cause withdrawal symptoms than other pain medications, even though, according to the government, the company could not support these claims.[28] The settlement included guilty pleas to misdemeanor misbranding charges under the *Park* doctrine by three Purdue Frederick Company, Inc. executives – the president and CEO, the executive VP and chief legal officer, and a former executive VP and chief scientific officer.[29]

The criminal Information filed against the defendants stated in relevant part that the ''defendants . . . were senior executives of The Purdue Frederick Company, Inc., . . . and were responsible corporate officers under 21 U.S.C. §§ 331(a), 333(a)(l), and 352(a) during the time that The Purdue Frederick Company, Inc., introduced and caused the introduction into interstate commerce of quantities of OxyContin from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere, which were misbranded . . . . ''[30] Each of the charged executives pled guilty to this charge.[31] In accepting the plea agreement, the court took note of ''the absence of government proof of knowledge by the individual defendants of the wrongdoing.''[32]

Synthes. On June 16, 2009, Synthes, Inc., a medical device company, its subsidiary, Norian Corporation, and four senior executives were indicted for their alleged involvement in conducting clinical trials of an unapproved use of a medical device without the authorization of the FDA and in spite of a warning on the product's label against this use and serious concerns about the safety of the product for that unapproved use.[33]

The four indicted executives included: (i) the president of a Synthes subsidiary and later, president of one of its divisions; (ii) the president of one of Synthes's divisions and later, Senior VP of Global Strategy; (iii) the VP of Operations; and (iv) the Director of Regulatory and Clinical Affairs of a Synthes division.[34] Although the indictment detailed facts regarding each defendant's specific involvement in the allegedly unlawful conduct, all four executives were charged in the indict-

[26] *Id*. at 678.

[27] *Id*. at 673.

[28] Criminal Information at 5-6, *U.S. v. The Purdue Frederick Company, Inc., Michael Friedman, Howard R. Udell and Paul D. Goldenheim* No. 1:07-cr-00029-jpj-3 (W.D. Va. May 10, 2007).

[29] Press Release, U.S. Attorney's Office Western District of Virginia, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding Oxycontin; Will Pay Over $600 Million (May 10, 2007) http://web.archive.org/web/20070512174719/www.usdoj.gov/usao/vaw/press_releases/purdue_frederick_10may2007.html (last visited June 17, 2010) (5 PLIR 513, 5/18/07).

[30] Criminal Information at 15-16, *U.S. v. The Purdue Frederick Company, Inc., Michael Friedman, Howard R. Udell and Paul D. Goldenheim* No. 1:07-cr-00029-jpj-3 (W.D. Va. May 10, 2007).

[31] This case also illustrates an important collateral consequence of a guilty plea under the FDCA. Each of these executives was also subsequently excluded from participating in the federal health care programs, which virtually precludes them ''from gainful employment in a pharmaceutical or health care company that markets products in the United States so long as their exclusion remains in place.'' Complaint for Declaratory, Injunctive and Other Relief at 9, *Friedman, et al. v. Sebelius, et al.*, No. 3:09-cv-01741 (D. Conn. Oct. 28, 2009). In their complaint appealing that decision, the executives note that this is the first time exclusion has been imposed based on an RCO misdemeanor. *Id*. at 3. They argue that their strict liability misdemeanor pleas are not excludable offenses under 42 U.S.C. § 1320a-7(b)(1) and (b)(3) (relating to permissive exclusion), on which the Secretary of HHS relied, because their pleas ''related to [their] status at Purdue, not to their commission of the fraud and controlled substances violations'' to which these statutory provisions refer. *Id*. Of note, the House of Representatives also recently passed a bill that would expand the government's ability to exclude individuals affiliated with sanctioned entities. H.R. 6130, 111th Cong. (2010). Specifically, the bill would authorize permissive exclusion for individuals: (i) who had an ownership or control interest in a sanctioned entity (defined as an entity convicted of an offense subject to mandatory exclusion or convicted of certain offenses that would subject it to permissive exclusion) or an affiliate of that entity, or had an ownership or control interest at the time that the conduct that formed the basis for the conviction or exclusion of that entity took place; and (ii) knew or should have known of such conduct. *Id*. It would also permit exclusion for any individual who is an officer or managing employee of a sanctioned entity or affiliate of that entity, or was an officer or managing employee of the entity at the time that the conduct that formed the basis for the conviction or exclusion of that entity took place. *Id*.

[32] *U.S. v. The Purdue Frederick Company, Inc.*, 495 F. Supp. 2d 569, 576 (W.D. Va. 2007).

[33] Indictment, *U.S. v. Norian Corp., Synthes Inc., Michael D. Huggins, Thomas B. Higgins, Richard E. Bohner and John J. Walsh*, No. 2:09-cr-004-2-LS-4 (E.D. Pa June 16, 2009).

[34] *Id*. at 2.

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ment solely as RCOs under the FDCA.[35] All four executives subsequently pled guilty to this charge.[36]

Significance of Purdue Case. The individual prosecutions in Purdue stand in sharp contrast to the prosecutions in *Park*. In *Park*, the defendant was on notice as to the specific company conduct giving rise to the FDCA violations; the allegations against him focused on the fact that, after learning of the problem, he had then delegated responsibility for the handling of it and inappropriately relied on his subordinates to correct it. By contrast, in the Purdue case, the government did not allege that the officers had any specific knowledge of the FDCA violations and, in fact, conceded that they were not aware of the violations. (In Synthes, although the executives were charged under the FDCA solely as RCOs, the indictment alleges that they had specific knowledge of the alleged unlawful conduct.) As a result, the imposition of liability on the Purdue executives appears to reflect a harsher application of the RCO doctrine than was applied in *Park*.

As noted earlier, the government's selective application of the RCO doctrine illustrates the practically unfettered discretion a prosecutor has in deciding whether to bring RCO charges against an executive. In its briefs to the Supreme Court in *Park*, the government addressed the issue of its broad discretion. In that regard, as a result of concerns that Congress and the Supreme Court had previously expressed about the exercise of reasonable prosecutorial discretion, the government stated in its brief, ''FDA has applied criteria which do not result in criminal prosecutions for every violation of the statute's strict standard of criminal liability . . . . Accordingly, FDA's standards for reference of cases to the Department of Justice for prosecution embrace the following categories: continuing violations of law . . . ; violations of an obvious and flagrant nature . . . ; and intentionally false or fraudulent violations.''[37]

Similarly, in discussing the guidelines to be followed in recommending prosecutions and referrals for criminal investigations, the FDA Regulatory Procedures Manual notes that:

> With the exception of prosecution recommendations involving gross, flagrant, or intentional violations, fraud, or danger to health, each recommendation should ordinarily contain proposed criminal charges that show a continuous or repeated course of violative conduct . . . . This is because the 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. Establishing a background of warning or other type of notice will demonstrate to the U.S. Attorney, the judge, and the jury that there has been a continuous course of violative conduct and a failure to effect correction in the past.[38]

In prosecuting the Purdue executives, however, the government appears to have deviated from its own standard.

Individual Certifications in Recent CIAs and Statements by Government Officials

In an effort to emphasize the prospect of individual liability, as well as to shore up future cases against individuals, the government has also begun adding provisions to recent CIAs requiring companies' Boards of Directors and senior management to personally certify compliance with the requirements of the CIA. These individual certifications reflect the government's increasing interest in holding individuals accountable for corporate activities, thus reinforcing the theory underlying *Park* liability.

Requirements of Recent CIAs. In September 2008, the Cephalon CIA reflected two major changes from previous pharmaceutical and device company CIAs. First, the CIA required that Cephalon's Board of Directors (or a committee of the Board) certify, via the adoption of a resolution, Cephalon's compliance with the federal health care program requirements, FDA requirements and the obligations of the CIA.[39]

Second, the CIA included a requirement that certain high-level executives personally certify that they are monitoring activities within their area of authority and that their areas are compliant.[40] Certifying employees included Cephalon's Chairman and Chief Executive Officer; Executive Vice President of Worldwide Medical and Regulatory Operations; Executive Vice President of Worldwide Pharmaceutical Operations; all business unit sales vice presidents; all business unit marketing vice presidents; all business unit sales directors; all

[35] *Id*. at 54.

[36] Government's Amended Presentence Memorandum at 3-4, *U.S. v. Michael D. Huggins, Thomas B. Higgins, Richard E. Bohner and John J. Walsh*, No. 09-403-03 – 06 (E.D. Pa. Mar. 30, 2010). It is worth noting that the defendants in both the Purdue and Synthes cases pled guilty to RCO misdemeanor charges pursuant to plea agreements with the government. *Id*. From the perspective of a defendant facing a likely misbranding conviction, a guilty plea under an RCO theory is certainly preferable to a conviction for affirmative violations of the misbranding statute because it enables the defendant to maintain that he or she did not participate in, or even know of, the misconduct at issue. Thus, the government may deploy this doctrine simply to obtain more pleas. Of course, the RCO misdemeanor guilty plea does not preclude the government from revealing the alleged details of a defendant's specific involvement in the misconduct at issue in connection with the guilty plea or at sentencing. *See, e.g., Id*. at 1-43.

[37] Br. for the U.S. at 31, *U.S. v. Park*, No. 74-215 (Jan. 1975).

[38] FDA Regulatory Procedures Manual, 6-5-1 (March 2010), http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm (last visited August 22, 2010).

[39] Corporate Integrity Agreement Between the Officer of Inspector General of the Department of Health and Human Services and Cephalon, Inc., III.A.3.b (Sept. 26, 2008), http://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf (last visited June 16, 2010). At a minimum, the resolution must include the following language: ''The Board of Directors [or a Committee of the Board] has made a reasonable inquiry into the operations of Cephalon's Global Compliance Program, including the performance of the Chief Compliance Officer and the Global Compliance department. Based on its inquiry, the Board [or Committee] has concluded that, to the best of its knowledge, Cephalon has implemented an effective Global Compliance Program to meet the Federal health care program requirements, FDA requirements, and the obligations of the CIA.''

[40] *Id*. at III.A.4. The CIA requires that those employees determined to be ''Certifying Employees'' are ''specifically expected to monitor and oversee activities within their areas of authority'' and to certify annually that their ''area of authority is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA.''

business unit marketing directors; the Vice President of Worldwide Medical Affairs; and all medical directors of communications and medical science liaisons.[41] These changes are noteworthy because they signify the first time that individuals have been required to personally certify compliance in a CIA.

Like the Cephalon CIA, the Eli Lilly CIA relating to the Zyprexa settlement, executed in January 2009, requires both Board (or a committee of the Board) and personal certifications.[42] In the Eli Lilly CIA, however, both the Board resolution[43] and personal certification[44] provisions are more detailed—and more stringent—than what is required by the Cephalon CIA. Specifically, the ''Certifying Employees'' must include, at a minimum, Lilly's President and CEO; Executive VP, Global Marketing and Sales; Lilly USA's President, U.S. Operations; Senior VP, Account-Based Markets; Senior VP, Health Care Professional Markets; VP, Chief Marketing and Operations Officer; and ''all national and executive sales directors, brand leaders, and business unit leaders in the HCP Markets, executive directors and directors in Account-Based Markets, and executive directors and directors in Marketing and Operations.''[45]

The Pfizer CIA relating to the settlement involving Bextra and several other drugs, executed in August 2009, continues this trend, and contains both an Audit Committee certification and a requirement that certain high-level executives personally certify that they are monitoring activities within their areas of authority and that their areas are compliant.[46] With respect to the management certifications, however, the requirements are significantly more rigorous than what was required in either the Eli Lilly or Cephalon CIAs in three main areas.

First, the CIA states that the leadership teams of Pfizer's Business Units ''shall complete a certification indicating that [they] have taken all appropriate steps to ensure compliance, that [they have] not directly or indirectly encouraged policy violation, and that controls are operating effectively.''[47] Certifying employees include the Presidents and Finance Directors of Pfizer's Business Units; representatives of marketing/sales, medical, commercial development, strategy and innovation; and U.S. Primary Care regional business unit presidents.[48]

Second, the CIA identifies the particular documents, including documents relating to promotional quality assessments, speaker programs, advisory boards, consultant payments, travel and entertainment expenses and sales compensation exclusion criteria, that each certifying employee must review prior to completing his certification.[49] Third, the CIA requires each certification to state that ''the signatory understands that the certification is being provided to and relied upon by the United States.''[50]

Other more recent CIAs confirm that these new certification requirements are not limited to cases involving billion dollar settlements like Pfizer and Eli Lilly.[51] In-

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[41] *Id*.

[42] Corporate Integrity Agreement Between the Officer of Inspector General of the Department of Health and Human Services and Eli Lilly and Company, III.A.3.d and III.A.4 (Jan. 14, 2009), http://oig.hhs.gov/fraud/cia/agreements/eli_lilly_and_company_01142009.pdf (last visited June 16, 2010).

[43] *Id*. at III.A.3d. Specifically, the Board Resolution must include the following language: ''The [insert name of Committee] Committee of the Board of Directors has made a reasonable inquiry into the operations of Lilly's Compliance Program**, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Chief Compliance Officer and other compliance personnel. The Board also has arranged for the performance of, and reviewed the result of, the Compliance Program Review**. Based on its inquiry, the Committee has concluded that, to the best of its knowledge, Lilly has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA'' (emphasis added to reflect language that differs from Cephalon CIA). *Id*.

[44] *Id*. at III.a.4. The CIA requires that ''[f]or each Reporting Period, each Certifying Employee shall sign a certification that states: 'I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision**. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.]** To the best of my knowledge, except as otherwise described herein, the_____ [insert name of department or functional area] of Lilly is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA' '' (emphasis added to reflect language that differs from Cephalon CIA). *Id*.

[45] *Id*.

[46] Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Pfizer, Inc., III.A.3.b and III.A.4 (Aug. 31, 2009), http://oig.hhs.gov/fraud/cia/agreements/pfizer_inc_08312009.pdf (last visited June 16, 2010). Of note, this CIA requires that the company's Audit Committee of the Board of Directors complete the certification, which more closely parallels the Cephalon CIA than the Eli Lilly CIA. *Id.* at III.A.3.b.

[47] *Id*. at III.A.4.

[48] *Id*.

[49] *Id*. These employees must certify that each one ''1) has reviewed the following: (a) reports from an internal group within Pfizer formed to conduct promotional quality assessments; (b) summary reports of speaker programs, advisory boards, consultant payments, travel and entertainment expenses (c) sales compensation exclusion criteria; and (d) corporate compliance group statistics; and 2) is currently aware of no violations of law, regulation, Pfizer policy, or the CIA requirements; or, 3) in the event that a potential issue has been identified, the certifying individual has referred the potential violations to the Corporate Compliance Group or a member of the Pfizer legal division for further review and follow-up.'' *Id*.

[50] *Id*.

[51] *See, e.g.*, Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and AstraZeneca Pharmaceuticals LP and AstraZeneca LP, III.A.3.b and III.A.4 (Apr. 27, 2010), http://oig.hhs.gov/fraud/cia/agreements/astrazeneca_04272010.pdf (last visited June 17, 2010); Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Ortho-McNeil-Janssen Pharmaceuticals, Inc., III.A.3.d and III.A.4 (Apr. 28, 2010), http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Apr2010/OrthoMcNeil/CIA.pdf (last visited June 17, 2010); Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Allergan, Inc., III.A.3.b and III.A.4 (Aug. 30, 2010), http://oig.hhs.gov/fraud/cia/agreements/Allerga_Executed_CIA_with_Appendices.pdf (last visited Oct. 5, 2010); Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Forest Laboratories, Inc., III.A.3.d and III.A.4 (Sept. 15, 2010), http://oig.hhs.gov/fraud/cia/agreements/forest_laboratories_inc_09152010.pdf (last visited Oct. 5, 2010); Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation, III.A.3.d and III.A.4 (Sept. 29, 2010), http://oig.hhs.gov/fraud/cia/agreements/

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stead, with some variations, the certification requirements have been woven into the fabric of the standard CIA required in cases involving off-label marketing.[52]

Each of these CIAs provides for a $5,000 stipulated penalty for each false certification submitted by or on behalf of the company.[53] Additionally, flagrant or repeated violation of the CIA, including of the certification obligations, could constitute a material breach of the CIA and lead to the company's exclusion.[54]

The evolution of the requirements in these three CIAs demonstrates that OIG has made a concerted effort not just to hold individuals personally accountable under the agreements, but also to refine these requirements in an effort to make clear what is expected of these individuals and what is at stake if they do not meet these requirements. Specifically, by requiring managers and executives to personally certify compliance, the government's intention is to force them to take personal responsibility for detecting and remedying problems. In addition to enlisting the personal certifications to reinforce this basic principle of the *Park* doctrine, the government is also paving the way for making future prosecutions under the *Park* doctrine easier.

Statements by Government Officials. Lest there be any doubt, recent comments from high-ranking government officials reflect an intention to use the *Park* doctrine aggressively and, in particular, a dedication to the use of CIA certifications to increase accountability by individual officers and employees for the effectiveness of their companies' compliance programs and to support individual liability under the *Park* doctrine.[55]

DOJ

- In September 2009, an Assistant U.S. Attorney from the District of Massachusetts stated that the CIA certifications now being required could make prosecuting individuals easier under the RCO doctrine.[56] The prosecutor stated that requiring individuals to attest that they have conducted a risk assessment and mitigated any problems will be useful in applying this doctrine.[57]
- Also in late 2009, with respect to the medical device area in particular, an Assistant U.S. Attorney in the Eastern District of Pennsylvania stated: ''You are going to be seeing a lot of enforcement with respect to certifications.''[58] Referring to the certifications in the Pfizer CIA, he said, '' 'I think there is going to be a trend towards more enforcement coming out of false certifications.' ''[59]
- In September 2010, a high-level DOJ official stated: ''The department is intent on identifying and, where appropriate, prosecuting the individuals who are responsible for illegal off-label marketing.''[60] She added: ''Our emphasis is going to be much increased in this area.''[61]

FDA

- In a March 4, 2010 letter from Margaret Hamburg, the FDA Commissioner, to Senator Charles Grassley in response to a Government Accountability Office report on the FDA's Office of Criminal Investigations, she stated that an FDA committee had recommended an increase in ''the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officers accountable.''[62] Dr. Hamburg added: ''Criteria have now been developed for consideration in selection of misdemeanor prosecution cases and will be incorporated into the revised policies and procedures that cover the appropriate use of misdemeanor prosecutions.''[63]
- In an October 2010 speech, an FDA official outlined several factors the agency would consider in deciding whether a criminal case should be brought against an individual. These factors included, for example, whether the conduct resulted in harm to the public, the seriousness of the underlying violation and whether the violation reflected a pattern or practice.[64] The official went on to say that, in the past, individuals have generally not been prosecuted under *Park* because of reluctance on the part of U.S. Attorney's Offices to bring charges, but that the government must show more resolve to criminally charge individuals, which he said would increase deterrence.[65] He did say, however, that if corporate executives took certain steps, such as the ones found in recent CIAs (e.g., establishing a company hotline to report off-label promotion and conducting monitoring of promo-

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Novartis_Pharmaceuticals_Corporation_09292010.pdf (last visited Oct. 5, 2010).

[52] Like the Bextra CIA, the AstraZeneca CIA, Forest CIA and NPC CIA require that the employees' certifications state that the signatory understands that the ''certification is being provided to and relied upon by the United States.'' AstraZeneca CIA, at III.A.4; Forest CIA, at III.A.4; Novartis CIA, at III.A.4. The Ortho-McNeil-Janssen CIA and Allergan CIA do not include this requirement. Ortho-McNeil-Janssen CIA, at III.A.4; Allergan CIA, at III.A.4. Only the Bextra CIA identifies the particular documents that each certifying employee must review prior to completing his certification. Pfizer CIA, *supra* note 49, at III.A.4.

[53] *See, e.g.*, the Pfizer CIA, X.A.6.

[54] *Id*. at X.D.1.a.

[55] Remarks during FDLI 21st Annual Advertising & Promotion Conference: Settlements Update from the Office of the Inspector General, Department of Health and Human Services and the Department of Justice (Sept. 21-22, 2009).

[56] *Id*.

[57] *Id*.

[58] ''Federal prosecutor says medical device sector should expect aggressive enforcement stemming from certifications,'' Rx Compliance Report, Vol. IX, Issue 2, Feb. 15, 2010, at 6 (reporting remarks made at the Medical Device Regulatory Reimbursement and Compliance Conference in Washington, D.C on Nov. 10, 2009).

[59] *Id*.

[60] Jessica Bylander, *Justice Dept, Inspector General To Target Individuals In Off-Label Cases*, The Gray Sheet, Sept. 29, 2010 (quoting remarks made the FDLI 22nd Annual Advertising & Promotion Conference (Sept. 20-21, 2010)).

[61] *Id.*

[62] Letter from Margaret Hamburg, FDA Commissioner, to The Hon. Charles Grassley, Ranking Member of the Senate Comm. on Finance (Mar. 4, 2010), http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=25530# (last visited June 16, 2010) (8 PLIR 324, 3/12/10).

[63] *Id*.

[64] ''FDA to Target CEOs Personally in Off-label Promotion Suits'' (Oct. 14, 2010), http://www.fdaweb.com/default.php (last visited Oct. 26, 2010).

[65] *Id*.

tional programs), it would be difficult to bring charges against them.[66]

OIG

- In September 2009, an OIG official remarked that a key aspect of the Pfizer CIA is that it ''continues trends in recent CIAs about increasing accountability, both at the board level and the individual level of some of the managers in the business.''[67] She pointed out that the ''sub-certifications'' in the Pfizer CIA, on which business unit presidents and financial directors must rely, provide ''a way for people to be held personally accountable for compliance in their area.''[68] The official explained that she expected the trend to continue in future CIAs.[69],[70] She subsequently reinforced those comments, stating that ''We're trying to . . . get more individuals within the organization to take responsibility for compliance.''[71]

Significantly, in October 2010, OIG released ''Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act,'' which sets forth nonbinding factors OIG will consider in deciding whether to permissively exclude individuals pursuant to its authority to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses.[72] Specifically, Section (b)(15) provides for the permissive exclusion of an individual officer, owner or managing employee of an entity that has been sanctioned (i.e., convicted of certain offenses or excluded) if that individual: (i) had an ownership or control interest in a sanctioned entity and knew or should have known of the conduct that led to the sanction; or (ii) is an officer or managing employee of a sanctioned entity.[73]

The guidance states that, with respect to owners, ''if the evidence supports a finding that an owner knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion.''[74] The presumption may be overcome, however, if certain factors weigh against exclusion.[75] Similarly, although OIG has the authority to exclude every officer and managing employee of a sanctioned entity, the guidance states that ''OIG does not intend to exclude all officers and managing employees.'' In the presence of evidence that an ''officer or a managing employee knew or should have known of the conduct,'' however, ''OIG will operate with a presumption in favor of exclusion.''[76]

Citing *Park*, the new OIG guidance also sets forth a strict liability standard for excluding individuals. Specifically, in determining whether to exclude an officer or managing employee ''in the *absence* of evidence that the person knew or should have known of the misconduct,''[77] OIG will consider the following factors:

1. *The circumstances of the misconduct and seriousness of the offense*. This factor includes: (i) the ''nature and scope of the misconduct for which the entity was sanctioned'' as well as ''any other relevant misconduct''; (ii) the ''level of the entity [at which] the misconduct occur[ed]''; (iii) the type and amount of any criminal, civil or administrative sanction imposed on the entity; (iv) whether the misconduct resulted in harm to beneficiaries or any federal health care program; (v) whether the misconduct reflected ''an isolated incident or [was] part of a pattern of wrongdoing over a significant period of time''; and (vi) any previous problems the entity has had with the government.[78]
2. *The individual's role in the sanctioned entity*. This factor includes: (i) the individual's current position within the company; (ii) positions the individual previously held within the entity, ''particularly at the time of the underlying misconduct''; (iii) the ''degree of managerial control or authority [] involved in the individual's position''; and (iv) ''the relation of the individual's position to the underlying misconduct,'' i.e., whether the misconduct took place ''within the individual's chain of command.''[79]
3. *The individual's actions in response to the misconduct*. This factor includes: (i) whether the individual took steps ''to stop the underlying misconduct or mitigate the ill effects of the misconduct'' and whether those actions took place before or after the individual knew of an investigation; and (ii) whether the individual disclosed the misconduct to

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[66] *Id*.

[67] *Id*. That same official made similar comments at the FDLI 22nd Annual Advertising & Promotion Conference (Sept. 2010). Jessica Bylander, *Justice Dept, Inspector General To Target Individuals In Off-Label Cases*, THE GRAY SHEET, Sept. 29, 2010 (quoting remarks made the FDLI 22nd Annual Advertising & Promotion Conference (Sept. 20-21, 2010)).

[68] *Id*.

[69] *Id*.

[70] In addition to prosecuting individuals under *Park*, OIG has also indicated that it may require companies to take stock of executives who have the responsibility and authority to exercise control over subordinates within the company but fail to do so. In a March 2010 interview, Lewis Morris, chief counsel to the Department of Health and Human Services OIG, said: ''A corporation is just a corporate fiction. It's a piece of paper.'' Nightly Business Report: A Final Push for Healthcare Reform (PBS Television Broadcast Mar. 19, 2010), http://www.pbs.org/nbr/site/onair/transcripts/final_health_care_push_100319/ (last visited June 16, 2010). ''It's run by people and one of the things we are turning our attention to now is trying to find ways to hold corporate officials responsible for the misconduct of their subordinates.'' *Id.* He added, ''We have been talking to some companies, even as we speak, about executives within their current power structure who we would like to know what responsibility they had when the misconduct took place, what opportunities did they have to stop the problem and why they didn't affirmatively step in and prevent the abuse of our program.'' *Id.*

[71] Jessica Bylander, *Justice Dept, Inspector General To Target Individuals In Off-Label Cases*, THE GRAY SHEET, Sept. 29, 2010 (quoting remarks made the FDLI 22nd Annual Advertising & Promotion Conference (Sept. 20-21, 2010)).

[72] ''Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act'' (Oct. 20, 2010), http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf (last visited Oct. 25, 2010).

[73] *Id*.

[74] *Id.*

[75] *Id.*

[76] *Id*. The guidance defines a ''managing employee'' as ''an individual (including a general manager, a business manager, an administrator, or a director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity.'' *Id*.

[77] *Id* (emphasis added).

[78] *Id*.

[79] *Id*.

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the government and cooperated with any investigation.[80]

4. *Information about the entity*. This factor includes: (i) whether the sanctioned entity or a related entity has previously been convicted of a crime, found civilly or administratively liable or resolved a case with the government; (ii) the entity's size; and (iii) the entity's corporate structure.[81]

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In the aftermath of these recent events, the Washington Legal Foundation (''WLF'') sent a letter to the FDA on October 26, 2010 urging it to abandon its plan to seek increased criminal prosecution of individuals.[82] WLF argued that the increased prosecution of individuals ''has the potential to adversely affect the nation's healthcare delivery system by labeling responsible corporate officials as criminals—even if they never participated in, encouraged, or had knowledge of the alleged violations.''[83] Addressing the recent OIG exclusion criteria, WLF also commented: ''This is especially true with respect to recent efforts to exclude corporate officials from participation in federal health care programs for strict liability convictions under the responsible corporate officer doctrine. Such strict vicarious liability also undermines the due process rights of corporate officials to have minimal notice of criminal culpability.''[84] WLF also argued that ''subjecting every manager and executive in the industry to potential criminal liability every time an off-label promotion occurs is extremely shortsighted. In the wake of such an aggressive use of the FDCA misdemeanor, industry executives will have little incentive to continue working in the pharmaceutical sector.''[85]

Practical Considerations

In sum, the government has made it clear that it will continue to hold individuals, by virtue of their position as RCOs, accountable for compliance violations. The government's message is that executives can no longer delegate responsibilities and expect issues to percolate up to them on an as-needed basis. Rather, the government is placing the onus on these executives to make sure that red flags are identified for them and that they personally ensure that those red flags are adequately addressed.

Park imposes a ''duty to seek out and remedy violations when they occur'' as well as ''a duty to implement measures that will insure that violations will not occur.''[86] In that regard, the possibility of *Park* liability will force pharmaceutical and medical device company executives to see to it that the reach of their compliance departments and risk assessment initiatives are embedded into every aspect of the business, and that important findings from those initiatives are promptly elevated within the company. Additionally, it will be important for executives to document their efforts to identify issues and address them.

Specific Areas of Risk. Executives should begin by working with their compliance departments to identify the particular areas within their company that pose the greatest risk. Clearly, product (safety and products liability), research and development (clinical trials), marketing (fraud and abuse) and manufacturing concerns would be at or near the top of the list. Executives should ask the team to then evaluate and, if necessary, enhance a system that effectively: (i) identifies established and emerging risks within those areas; (ii) formulates appropriate, enforceable policies and standard operating procedures as well as practical training programs for managing those risks; (iii) imposes appropriate controls for ensuring proper execution along with monitoring that regularly examines whether those controls are working; and (iv) remediates when exceptions are identified—including implementing a feedback loop to ensure that the ''lessons learned'' are used to improve the entire system.

The executives need to stay personally apprised of the status of these systems and be satisfied that they are adequately designed to protect against non-compliance. Executives should also consider building a ''dashboard'' reflecting key measures of compliance within these risk areas. The dashboard should be kept current, and executives should monitor it on a regular basis. Executives need to ensure that unsatisfactory findings are pursued until corrected and/or resolved.

Conclusion

In a strict liability regime, there may, in fact, be no practical way for a pharmaceutical or medical device company executive to avoid prosecution when a violation has occurred within the company and an aggressive prosecutor determines that she wants to hold the executive accountable. Nevertheless, taking steps to ensure active vigilance of the company's risks will enable the executive to push back against bringing such a prosecution or to defend against it, if it should happen.

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[80] *Id*. Following the reasoning in *Park*, the guidance notes that ''[i]f the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.'' *Id*. This particular factor is unusual given the context. If the individual did not know of the underlying misconduct, it is hard to understand how he or she could have taken steps to mitigate it.

[81] *Id*.

[82] Letter from Cory L. Andrews, WLF Senior Litigation Counsel, to Eric M. Blumberg, Deputy Chief for Litigation, Office of the Chief Counsel, FDA (Oct. 26, 2010), http://www.wlf.org/litigating/case_detail.asp?id=640 (last visited Nov. 5, 2010) (8 PLIR 1375, 10/29/10).

[83] *Id*.

[84] *Id*.

[85] *Id*.

[86] 421 U.S. 658, 672 (1975).