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The OIG's Continued Focus on Corporate Executives



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There is no doubt that executives of pharmaceutical and medical device manufacturers face increasing risk of personal criminal liability and exclusion from the Federal health care programs should their companies run afoul of Federal health care laws—even if they personally have done nothing wrong. In recent years, the United States Department of Justice (''DOJ'') has increasingly threatened to prosecute individual corporate executives of companies that violate the Food, Drug & Cosmetic Act (''FDCA'') under the Responsible Corporate Officer (''RCO'') doctrine, which holds that ''responsible'' senior executives can be held criminally liable if they fail to prevent certain corporate criminal conduct. On a parallel track, the Department of Health and Human Services' Office of Inspector General (''OIG'') has threatened to exclude individual corporate officers in various circumstances simply because of their status and without proof of individual culpability. The severity and persistency of this risk is such that earlier this year at least one insurance company began offering policies that will cover the defense costs related to RCO prosecutions and administrative debarment/exclusion proceedings to companies in the health care and life science sectors.[1] The availability of a commercial insurance product of this type reflects market recognition of the continued and ongoing risks faced by individual executives in light of the Government's enforcement priorities.

Despite the eye-popping settlement amounts obtained by the DOJ from pharmaceutical and medical device manufacturers in recent years, the OIG has expressed its concern about repeat company offenders and has been explicit in its new strategy. In a Congressional hearing, the long-time Chief Counsel of the OIG, Lewis Morris, announced his concern that some pharmaceutical manufacturers and other health care entities may consider ''civil penalties and criminal fines a cost of doing business'' or consider themselves ''too big to fire'' from the Federal health care programs.[2] Through prosecution and exclusion of corporate executives, the

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[1] Marsh & McLennan Companies, RCO Corporate Response Fact Sheet (2012), available at: http://usa.marsh.com/Portals/9/Documents/RCOCorporateResponseFactSheet.pdf (last visited Nov. 2, 2012).

[2] *Hearing Before the Subcomm. on Oversight of the H. Ways and Means Comm. On Improving Efforts to Combat Health Care Fraud*, 112th Cong. (Mar. 2, 2011) (statement of Lewis Morris, Chief Counsel, Office of Inspector Gen., U.S. Dep't of Health and Human Servs.), *available at* http://

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OIG, he said, seeks to ''alter the cost-benefit calculus of the corporate executives who run these companies.'' In other words, the Government believes it ''can influence corporate behavior without putting patient access to care at risk'' by ''excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud.''[3]

Although Morris, retired earlier this year, his successor—Gregory Demske—plans to continue the OIG's focus on excluding executives of sanctioned entities. In a 2011 interview, Mr. Demske noted that OIG is concerned that ''forcing companies to pay money'' has not changed behavior.[4] According to Mr. Demske, ''[t]he next logical step would be to exclude someone based on the fact they had been in a position of responsibility at a corporation when the a crime occurred.''[5] In light of these statements, the Government's increased emphasis on combating health care fraud, and the new enforcement authorities included in the Fraud Enforcement and Recovery Act of 2009 and the Patient Protection and Affordable Care Act, there is little reason to believe that the Government intends to reduce its efforts to prosecute and exclude executives of health care companies.

The Government's Authority to Target Corporate Executives

The Government's ability to target executives for corporate—rather than personal—wrongdoing rests on two distinct authorities: (1) The RCO doctrine, and (2) the OIG exclusion statute.[6] The RCO doctrine is an exception to the general rule that an individual may only be convicted of a criminal offense upon a showing by the Government that the individual acted with the requisite intent to violate the law. As such, under the RCO doctrine, ''a corporate agent, through whose act, default, or omission the corporation committed a crime in violation of the Food, Drug, and Cosmetic Act may be held criminally liable for the wrongdoing of the corporation whether or not the crime required consciousness of wrongdoing by the agent.''[7] Thus, under the RCO doctrine, a corporate executive may be convicted of criminal conduct by virtue of his or her position held within the corporation, and criminal liability does not turn on ''awareness of some wrongdoing'' or ''conscious fraud.''[8] The idea is to impress upon the corporate executive that the public expects them to act responsibly when they assume positions of authority that affect public welfare.[9]

The Government has yet another tool to use to impress upon corporate executives the gravity of their decisions affecting public welfare—the OIG's statutory and regulatory authority to exclude executives from the Federal health care programs.[10] This statute identifies numerous bases for both mandatory and permissive exclusion from the Federal health care program. In general, the statute mandates that the OIG exclude individuals that are convicted of a crime related to the Medicare and Medicaid program or patient abuse.[11] In addition, there are various grounds for ''permissive exclusion,'' including a conviction ''relating to fraud'' or—critically—simply managing or controlling a sanctioned entity.[12]

OIG exclusion is considered a highly effective tool because exclusion generally is considered a career-ending event.[13] As its name suggests, an excluded individual may not participate in ''any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government,'' including Medicare and Medicaid.[14] In addition, organizations that participate in the Federal health care programs are subject to civil money penalties, should they employ an excluded individual.[15] While certain opportunities remain for an excluded individual, broadly speaking, exclusion effectively precludes an individual from working in the health care industry.

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Notwithstanding the severity of this sanction, the OIG—as noted—has long been authorized permissively to exclude individuals without proof of personal wrongdoing if such individuals own or control a sanctioned entity. Under 42 U.S.C. § 1320a-7(b)(15) (''Section (b)(15)''), the OIG may exclude an individual who has an ownership interest in a sanctioned entity if the individual ''knows or should know'' of the action constituting the basis for the conviction or exclusion.[16] Moreover, the OIG may exclude an officer or managing employee of a sanctioned entity without any evidence that the individual knew or should have known of the conduct that resulted in the exclusion.[17]

The OIG has infrequently exercised this authority. Consistent with its recent focus on corporate executive responsibility, however, the OIG revised its policy for using the Section (b)(15) permissive exclusion author-

oig.hhs.gov/testimony/docs/2011/morris_testimony_03022011.pdf (last visited Nov. 2, 2012).

[3] *Id.*

[4] Pharmalot.com, *The OIG And Excluding Execs: Demske Explains* (June 6, 2011), available at: http://www.pharmalot.com/2011/06/the-oig-and-excluding-execs-demske-explains/ (last visited Nov. 2, 2012).

[5] *Id.*

[6] 42 U.S.C. § 1320a-7.

[7] *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012) (quotations omitted) *quoting U.S. v. Park*, 421 U.S. 658, 670 (1975); *see also U.S. v. Dotterweich*, 320 U.S. 277, 672-73 (1943).

[8] *U.S. v. Park*, 421 U.S. 658, 672-673 (1975).

[9] *Id.* at 672.

[10] 42 U.S.C. § 1320a-7.

[11] 42 U.S.C. § 1320a-7(a).

[12] 42 U.S.C. § 1320a-7(b)(1) & (15).

[13] *Friedman v. Sebelius*, 686 F.3d at 823.

[14] 42 U.S.C. §§ 1320a-7(a) & (b), 1320a-7b (f).

[15] 42 U.S.C. § 1320a-7a(a)(6)

[16] 42 U.S.C. § 1320-7a(b)(15)(A)(i).

[17] 42 U.S.C. § 1320-7a(b)(15)(A)(ii).

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ity in October 2010.[18] Under its revised guidance, the OIG will exercise a ''presumption in favor of exclusion'' where there is evidence that an owner, officer or managing employee knew or *should have known* of the conduct leading to the exclusion or conviction.[19] The OIG guidance outlined four factors it would consider in exercising its discretion to exclude a managing employee of a sanctioned entity under Section (b)(15): (1) the circumstances of the misconduct and the seriousness of the offense; (2) the individual's role in the sanctioned entity; (3) the individual's actions in response to the misconduct; (4) and information about the size and compliance history of the entity.[20] Given the general dearth of OIG guidance in interpreting permissive exclusion bases and limited administrative case law for exclusion proceedings, this 2010 guidance caused quite a stir in the health care enforcement community.

Although not discussed in its 2010 guidance, the OIG appears to take the position that its Section (b)(15) authority extends only to current owners and managing employees. This interpretation is based in the text of the statute—Section (b)(15) is written in the present tense: the OIG may exclude an individual ''who **has** a direct or indirect ownership or control interest'' or ''who **is** an officer or managing employee'' of a sanctioned entity.[21] As a result, OIG's Chief Counsel has noted that ''[t]he way our statute is written, we can only pursue a person who is in office of a convicted entity . . . we can't reach the former CEO, because of the way our statute is written, so that limits the universe of potential subjects of exclusion.''[22] Thus, where a sanctioned entity is under new leadership at the time sanctions are imposed, OIG may only exclude the current executives under its Section (b)(15) authority and it ''has no interest in doing that.''[23]

As a result, OIG often relies on other provisions of the exclusion statute to exclude corporate executives. Notably, the OIG has recently utilized 42 U.S.C. § 1320a-7(b)(1), which authorizes OIG to exclude individuals who have been convicted of a crime ''relating to fraud'' to exclude corporate executives that have been convicted of crimes under the RCO doctrine. Specifically, OIG has excluded the former CEO, CFO, and General Counsel of Purdue Frederick Company,[24] and on October 18, 2012, four former executives of Synthes, Inc. pursuant to this authority.[25] This trend is likely to continue as the United States Court of Appeal for the District of Columbia Circuit recently endorsed the agency's broad reading of this provision of the exclusion statute.

Recent D.C. Circuit Case Addressing Exclusion

The D.C. Circuit's decision in *Friedman v. Sebelius* is the latest—and likely final—decision in the drawn out appeals process related to the exclusion of three Purdue Frederick Company executives. In 2007, Purdue Frederick Company pled guilty to a felony charge of fraudulent misbranding as a result of employees marketing and promoting OxyContin as ''less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.''[26] At the same time, three senior executives—Michael Friedman, Paul Goldenheim and Howard Udell—were convicted under the RCO doctrine of the misdemeanor of misbranding a drug.[27] Based on these convictions, the OIG sought to exclude these executives from participation in the Federal health care programs for 20 years pursuant to 42 U.S.C. § 1320a-7(b)(1) and (3).[28] The length of the exclusion was reduced to 12 years through the administrative appeals process, and the U.S. District Court for the District of Columbia affirmed a 12 year exclusion.[29]

The Purdue Frederick Company executives made several arguments on appeal to the D.C. Circuit including an argument that their misdemeanor convictions for misbranding were not convictions ''relating to fraud,'' as required by the statute. The executives argued that because their convictions rested on the RCO doctrine, and the government did not prove a core element of fraud—intent—the convictions were not criminal offenses ''relating to fraud.''[30] A divided panel of the D.C. Circuit rejected this argument, adopted the agency's view, and held that Section 1320a-7(b)(1)(A) ''authorizes the Secretary to exclude from participation in Federal health care programs an individual convicted of a misdemeanor if the conduct underlying that conviction is factually related to fraud.''[31] In the Court's view, because their convictions were ''predicated upon the company they led having pleaded guilty to fraudulently misbranding a drug,'' their convictions were factually related to fraud.[32] However, the court noted that the OIG had never previously excluded an individual for more than four years pursuant to Section 1320a-7(b)(1), and thus remanded the case back to the agency to justify the length of the exclusion in light of the agency's prior decisions.[33]

This D.C. Circuit case sets an important precedent allowing exclusion of executives who are convicted as responsible corporate officers of misdemeanor misbranding from the Federal health care programs under 42 U.S.C. § 1320a-7(b)(1). In short, the Government has the authority to both convict individual executives of criminal offenses without any showing of intent and may exclude those executives from the Federal health care programs based on those convictions. Given the costs of exclusion, this holding increases the already

[18] OIG Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act (Oct. 20, 2010), available at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf (last visited Nov. 2, 2012).

[19] *Id*. at 1.

[20] *Id.* at 3-4.

[21] 42 U.S.C. § 1320a-7(b)(15)(A)(i) & (ii) (emphasis added).

[22] Pharmalot.com, *The OIG And Excluding Execs: Demske Explains* (June 6, 2011), available at: http://www.pharmalot.com/2011/06/the-oig-and-excluding-execs-demske-explains/ (last visited Nov. 2, 2012).

[23] *Id.*

[24] *Friedman v. Sebelius*, 686 F.3d at 817.

[25] OIG LEIE (List of Excluded Individuals/Entities) Exclusions database, http://exclusions.oig.hhs.gov/ (search for: Michael Huggins, Thomas Higgins, Richard Bohner and John Walsh).

[26] *U.S. v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 571 (W.D. Va. 2006).

[27] *Friedman v. Sebelius*, 686 F.3d at 816.

[28] *Id.* at 817.

[29] *Id.*

[30] *Id.* at 818.

[31] *Id.* at 824.

[32] *Id.*

[33] *Id.* at 827-28.

devastating consequences of a criminal conviction under the RCO doctrine.

Preventive Measures for Corporate Executives

There are concrete measures that executives may implement that will enhance a company's culture of compliance. These efforts will ultimately serve as factors that the OIG would view favorably in its determination of whether to seek exclusion of a controlling person of a sanctioned entity, as reflected in the 2010 guidance. We can easily see the applicability of these actions more broadly to any defensive argument when trying to persuade the OIG from excluding a company or an individual on any statutory or regulatory basis:

1. Develop a robust compliance program consistent with the OIG Compliance Program Guidance for Pharmaceutical Manufacturers[34] and updated to reflect important signals to the industry in certain Corporate Integrity Agreements. An effective compliance program demonstrates a corporate commitment to compliance and will guard against widespread patterns of wrongdoing over a substantial time period.

2. Upon learning of misconduct, take immediate steps to mitigate the ill effects of the misconduct (*e.g.*, take appropriate disciplinary action against the individuals responsible for the activity).

3. Immediately investigate the nature and extent of any reported misconduct using qualified outside counsel, where appropriate.

4. Check employees, contractors and vendors regularly for excluded status.

Taking these steps may form the basis of an argument that any wrongdoing occurred despite the exercise of ''extraordinary care.''[35] The OIG has stated that when prohibited conduct occurs despite the exercise of ''extraordinary care,'' such care is a factor weighing against exclusion.[36]

Conclusion

Executives of pharmaceutical and medical device manufacturers face increasing risk of being excluded from the Federal health care programs should their companies violate any Federal health care laws. In light of these risks, health care company executives must be vigilant about promoting a culture of compliance within their organizations, maintain up-to-date ''effective'' compliance programs, and take immediate steps to investigate and halt any instances of misconduct.

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[34] OIG, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003).

[35] OIG Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act (Oct. 20, 2010), available at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf (last visited Nov. 2, 2012).

[36] *Id.*

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