

A BITTER PILL FOR THE PHARMACEUTICAL INDUSTRY? HHS-OIG'S ENFORCEMENT OF THE RESPONSIBLE CORPORATE OFFICER DOCTRINE

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I. Introduction

On July 27, 2012, the U.S. Court of Appeals for the District of Columbia upheld the decision of the Secretary of Health and Human Services (HHS) to exclude three former Purdue Frederick company executives from participating in federal health programs.¹ The ruling marked a victory for the government, which argued that HHS has the authority to exclude the pharmaceutical executives under the Responsible Corporate Officer (RCO) doctrine.² The Court of Appeals agreed that the exclusion was within the government's powers, although the court held that HHS needed to provide a reasoned explanation for the length of the twelve-year exclusion and remanded the case back to the district court.³ This decision represents a recent trend in which the government has sought to exclude corporate executives in an effort to promote greater corporate compliance with federal

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¹ *Friedman v. Sebelius*, 686 F.3d 813, 824 (D.C. Cir. 2012).

² *Id.* at 816-17.

³ *Id.* at 828.

healthcare laws.⁴

Congress first gave the Secretary of HHS the authority to exclude individuals from participation in federal health care programs in 1977, and HHS delegated this authority to the Office of the Inspector General (HHS-OIG) in 1981.⁵ Over the past 30 years, HHS-OIG has used this authority to exclude individuals who commit fraud against federal health programs.⁶ By HHS-OIG's own count, over 3,000 people are excluded each year.⁷ While HHS-OIG has regularly exercised this authority in the past, several recent exclusion actions have created uncertainty in the healthcare industry.⁸

Historically, HHS-OIG has only used its permissive exclusion authority against individuals who controlled smaller companies.⁹ However, in the past three years, HHS-OIG has brought exclusion actions against corporate officers of large pharmaceutical companies under the RCO doctrine.¹⁰ The RCO doctrine holds that officers and managers are responsible for the actions of their companies whether or not they know of any illegal actions within the company.¹¹ This change in enforcement policy has generated a great deal of controversy, and some commentators have wondered if the government will be prosecuting and excluding individuals who had no personal knowledge of company

⁴ See generally Ricardo Alonso-Zaldivar, *Feds now target execs, not just companies, in health frauds*, USA TODAY, May 31, 2011, http://www.usatoday.com/money/industries/health/2011-05-31-execs-health-care-fraud_n.htm.

⁵ *Exclusions FAQ*, OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUMAN SERVICES, <http://oig.hhs.gov/faqs/exclusions-faq.asp> (last visited Nov. 18, 2013) [hereinafter *Exclusions FAQ*].

⁶ See *OIG Fact Sheet on Forest Laboratories, Inc., and the Inspector General's Exclusion Authorities*, OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUMAN SERVICES (May 10, 2011), http://oig.hhs.gov/publications/docs/press/2011/factsheet_051011.asp (explaining that the Social Security Act authorizes the Secretary of HHS to exclude persons from participation in Federal healthcare programs) [hereinafter *OIG Fact Sheet*].

⁷ *Id.*

⁸ See Ashby Jones, *Does Forest Labs Case Signal New Era in White-Collar Prosecution?*, LAW BLOG, WALL ST. J. (Apr. 26, 2011, 4:04 PM), <http://blogs.wsj.com/law/2011/04/26/does-forest-labs-case-signal-new-era-in-white-collar-prosecution/>.

⁹ *Improving Efforts to Combat Health Care Fraud: Hearing Before the Comm. on Ways and Means, Subcomm. on Oversight*, 112th Cong. (Mar. 2, 2011) (statement of Lewis Morris, Chief Counsel, Office of the Inspector General, Dep't of Health and Human Services), available at <http://www.hhs.gov/asl/testify/2011/03/t20110302h.html> [hereinafter *Improving Efforts to Combat Health Care Fraud*].

¹⁰ See *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).

¹¹ *Id.* at 816.

wrongdoing.¹²

This Article looks at three instances in which HHS-OIG exercised or threatened to use its permissive exclusion authority against executives of pharmaceutical companies. These examples highlight how HHS-OIG interprets the RCO doctrine, and suggest that HHS-OIG is willing to exclude corporate officers under the RCO doctrine. As such, healthcare executives and their counsel need to be aware of potential liability. However, much of the concern about HHS-OIG's interpretation of the RCO doctrine may be overstated. HHS-OIG's track record suggests that it will be judicious when deciding whether to exclude an individual under the RCO doctrine. Of course, corporate officers need to be aware of the RCO doctrine and take appropriate action to ensure that their company is complying with the law, but HHS-OIG's actions thus far do not suggest that the government will exclude someone in the management chain with no personal knowledge of company wrongdoing if the company has robust training and compliance systems in place. HHS-OIG will likely act judiciously under such circumstances for fear of establishing negative judicial precedent, especially because an overly aggressive exclusion paradigm could have negative policy ramifications.

Section II of this Article briefly outlines HHS-OIG's exclusion authority and discusses the law and policy underpinnings of the RCO doctrine. Section III outlines the facts of three case studies dealing with this issue, and Section IV analyzes these three examples. These case studies suggest that all healthcare executives need to understand their potential personal liability and must be aware of potential risks within their corporations. To protect themselves from potential exclusion, executives should make sure that their companies have robust compliance systems in place. HHS-OIG's track record suggests that it will be judicious in the use of the doctrine when bringing (b)(15) exclusions, but HHS-OIG will likely be more inclined to bring action when there is evidence that the corporate officer knew, or should have known, of corporate wrongdoing.

¹² Alonso-Zaldivar, *supra* note 4 (noting that the recent use of the RCO doctrine is "making an entire industry nervous").

II. *HHS-OIG Exclusion Authority and the Resurrection of the RCO Doctrine*

A. *HHS-OIG Exclusion Authority*

HHS-OIG does not have the authority to criminally prosecute individuals who commit healthcare fraud, but it does have a powerful tool at its disposal: the ability to exclude individuals from participating in federal healthcare programs.¹³ An excluded individual is barred from receiving reimbursement for any product or service that is ordered or provided to a beneficiary in a federal program such as Medicare, Medicaid, and TRICARE.¹⁴ The length of exclusion varies depending on the specific basis of the exclusion.¹⁵ This payment prohibition also applies to anyone who employs or contracts with the excluded person.¹⁶ As such, exclusion essentially makes an individual unemployable in the healthcare industry because so many healthcare companies depend on receiving payment from the federal government.

There are two types of exclusions: mandatory and permissive.¹⁷ Mandatory exclusions require that HHS-OIG exclude individuals or entities if their conduct falls under one of four categories.¹⁸ For example, HHS-OIG must exclude an individual following a criminal conviction related to the Medicare or Medicaid program or a conviction related to patient abuse.¹⁹ Conversely, permissive exclusions give HHS-OIG discretion as to whether to exclude an individual or entity.²⁰ Among the 16 permissive grounds for exclusion is § 1320a-7 (b) (15), which grants the Secretary of HHS the discretion to exclude any individual who is an officer or managing employee of a company sanctioned for healthcare fraud.²¹ The (b) (15) provision is a codified version of

¹³ 42 U.S.C. § 1320a-7 (2012).

¹⁴ MICHAEL K. LOUCKS & CAROL C. LAM, PROSECUTING AND DEFENDING HEALTH CARE FRAUD CASES 677 (2d ed. 2010).

¹⁵ *See id.* (noting that in a global resolution entailing a conviction for Medicare fraud, defense counsel should contact HHS exclusion authorities to attempt to negotiate the length of the mandatory exclusion period).

¹⁶ *See Exclusions FAQ*, *supra* note 5.

¹⁷ 42 U.S.C. § 1320a-7(a)-(b).

¹⁸ 42 U.S.C. § 1320a-7(a)(1)-(4).

¹⁹ 42 U.S.C. § 1320a-7(a)(1)-(2).

²⁰ 42 U.S.C. § 1320a-7(b).

²¹ 42 U.S.C. § 1320a-7(b)(15).

the RCO doctrine because it does not require that the officer or manager know about the behavior that led to the sanction.

Until recently, HHS-OIG rarely utilized (b)(15) as a grounds for permissive exclusion. Congress enacted the provision as part of the Health Insurance Portability and Accountability Act (HIPAA), but in the decade after its enactment, the government only brought about 30 exclusion actions under (b)(15),²² a relatively small number considering that over 3,000 individuals are excluded per year.²³ Furthermore, the government tended to bring (b)(15) actions against the owners or managers of small Durable Medical Equipment (DME) companies rather than major pharmaceutical corporations.²⁴

B. *The Responsible Corporate Officer Doctrine*

Just as the (b)(15) provision was underutilized, the RCO doctrine also lay dormant until recent years.²⁵ The RCO doctrine was adopted by the Supreme Court in two cases involving the Food, Drug and Cosmetic Act (FDCA).²⁶ In *United States v. Dotterweich*, the CEO of a company was convicted of shipping adulterated and misbranded drugs.²⁷ The Supreme Court held that the CEO was guilty of violating the FDCA even though there was no evidence that the CEO knew of the violation.²⁸ The Court reasoned that the FDCA was a public welfare statute; therefore, the CEO could be held strictly liable for the crime because of the potential for food and drugs to cause death and injury.²⁹ Similarly, in *United States v. Park*, the government prosecuted the CEO of a food company for failing to maintain sanitary conditions within the company's warehouses.³⁰ The Court reasoned that the CEO violated the RCO doctrine because, as the CEO, he had the "responsibility and

²² *Improving Efforts to Combat Health Care Fraud*, *supra* note 9.

²³ *See OIG Fact Sheet*, *supra* note 6.

²⁴ *Id.*

²⁵ Andrew Longstreth, *Analysis: U.S. court tests liability of healthcare execs*, REUTERS (Dec. 6, 2011, 6:46 AM), <http://www.reuters.com/article/2011/12/06/us-legal-idUSTRE7B50Q420111206>.

²⁶ *See* U.S. v. Dotterweich, 320 U.S. 277 (1943); U.S. v. Park, 421 U.S. 658 (1975).

²⁷ *Dotterweich*, 320 U.S. at 278.

²⁸ *Id.* at 284-85.

²⁹ *Id.* at 280-81.

³⁰ *Park*, 421 U.S. at 660.

authority” to prevent or correct a violation of law but failed to do so.³¹

The government prosecuted several FDCA cases in the 1960s and 1970s that targeted executives for unsanitary warehouses, but by the late 1980s the government stopped bringing cases under the RCO doctrine.³² The government may have ceased relying on the RCO doctrine for fear of overreaching and subjecting the doctrine to unwanted judicial scrutiny. However, in the past few years, the RCO doctrine has been revived by the Food and Drug Administration (FDA), which in 2011 published guidance on the criteria it will follow when recommending RCO prosecutions.³³

Just as the FDA has dusted off the old RCO case law, the HHS-OIG has revived the RCO doctrine in an effort to hold healthcare executives responsible for the behavior of their companies.³⁴ HHS-OIG has changed the enforcement paradigm because civil monetary penalties have not dissuaded companies from committing healthcare fraud.³⁵ In recent years, the fines levied against corporations for violations of the FDCA and other federal laws have grown increasingly larger.³⁶ For example, in 2010, Novartis Pharmaceuticals agreed to pay \$422.5 million to resolve criminal and civil penalties after its owners pleaded guilty to off-label marketing of the drug Trileptal.³⁷ Despite these steep civil

³¹ *Id.* at 673-74.

³² Vanessa O’Connell & Michael Rothfeld, *U.S. Targets Drug Executives: Law Allows Courts to Hold Corporate Officials Responsible for Pharma Violations*, WALL ST. J., Sept. 13, 2011, <http://online.wsj.com/article/SB10001424053111903532804576567003533291480.html>.

³³ U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL 6-49 (2011), available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm> (factors to consider when recommending a charge of a misdemeanor violation include whether the violation involves actual or potential harm to the public, whether the violation is obvious, whether the violation is widespread or serious, etc.).

³⁴ See Alonso-Zaldivar, *supra* note 4; see also O’Connell & Rothfeld, *supra* note 32.

³⁵ *Improving Efforts to Combat Health Care Fraud*, *supra* note 9; see also Alicia Mundy, *U.S. Effort to Remove Drug CEO Jolts Firms*, WALL ST. J. (Apr. 26, 2011, 12:01 AM), <http://online.wsj.com/article/SB10001424052748704123204576283283851626952.html>.

³⁶ For example, in the pharmaceutical industry context, of 165 settlements comprising \$19.8 billion in penalties during a 20-year period from 1991 to 2010, 73 percent of the settlements (121) and 75 percent of the penalties (\$14.8 billion) have occurred in the recent past (2006-2010). See SAMMY ALMASHAT ET AL., RAPIDLY INCREASING CRIMINAL AND CIVIL MONETARY PENALTIES AGAINST THE PHARMACEUTICAL INDUSTRY: 1991 TO 2010, at 2 (2010), available at <http://www.citizen.org/documents/rapidlyincreasingcriminalandcivilpenalties.pdf>.

³⁷ Press Release, Dep’t of Justice, *Novartis Pharmaceuticals Corp. to Pay More Than \$420 Million to Resolve Off-label Promotion and Kickback Allegations* (Sept. 30, 2010), <http://www.justice.gov/opa/pr/2010/September/10-civ-1102.html>.

penalties, HHS-OIG has publicly expressed concern that providers who engage in fraud and abuse might consider “civil penalties and criminal fines a cost of doing business.”³⁸

In the past, HHS-OIG has not applied its exclusion authority to executives of large pharmaceutical companies or device manufacturers.³⁹ Theoretically, HHS-OIG could exclude a company from participating in a federal program, but the government is unlikely to exclude a large corporation because of the profound effect this would have on program beneficiaries who rely on the corporation for a patented device or medicine.⁴⁰ The former Chief Counsel of HHS-OIG, Lewis Morris, testified before Congress that “[s]ome hospital systems, pharmaceutical manufacturers, and other providers play such a critical role in the care delivery system that they may believe that they are ‘too big to fire’ and thus OIG would never exclude them and thereby risk compromising the welfare of our beneficiaries.”⁴¹ Rather than excluding the company, HHS-OIG has shifted focus and has decided that holding the corporate leaders responsible might be more appropriate.⁴² HHS-OIG intends for this shift in focus to pressure business leaders to develop better compliance and monitoring systems because the executives will see how much they stand to lose if they are excluded from the industry.⁴³

The rhetoric of HHS-OIG suggests that it is prepared to aggressively exclude individuals under the RCO doctrine, but in practice HHS-OIG has thus far been judicious in the use of its authority. Indeed, HHS-OIG has indicated that it will weigh factors in favor of exclusion against mitigating factors.⁴⁴ In October 2010, HHS-OIG issued guidance about the four factors it will consider

³⁸ *Improving Efforts to Combat Health Care Fraud*, *supra* note 9.

³⁹ *Id.*

⁴⁰ 42 U.S.C. § 1320a-7 (2012) (“The secretary shall exclude the following individuals and entities”); *see also* LOUCKS & LAM, *supra* note 14, at 677-78.

⁴¹ *Improving Efforts to Combat Health Care Fraud*, *supra* note 9.

⁴² *See id.* (“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, we can influence corporate behavior without putting patient access to care at risk.”).

⁴³ OFFICE OF THE INSPECTOR GEN., GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT (2010), *available at* http://oig.hhs.gov/fraud/exclusions/files/permisive_excl_under_1128b15_10192010.pdf [hereinafter GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION].

⁴⁴ *Id.*

when making an exclusion decision.⁴⁵ The four factors are: (1) the circumstances of the misconduct and seriousness of the offense; (2) the individual's role in the sanctioned entity; (3) the individual's actions in response to the misconduct; (4) other information about the entity.⁴⁶ While factors one and four address the sanctioned company, HHS-OIG will consider the conduct of the individual under factor three. Under the RCO doctrine, the government does not need to prove a mens rea element in order to exclude an individual,⁴⁷ but the healthcare industry should take some comfort that the government will consider the actions of the individual along with the actions of the company.

When HHS-OIG issued its Guidance, it stated for the first time that it would operate on a presumption in favor of exclusion when an owner or executive of a sanctioned entity "knew or should have known of the conduct that formed the basis for the sanction."⁴⁸ This presumption is rebuttable, but the burden is on the targeted individual to present factors that weigh against exclusion.⁴⁹ Some advocates have spoken out against this presumption of guilt in a justice system that provides for due process to protect defendants from being punished when they have personally done nothing wrong.⁵⁰ The stakes are especially high since an exclusion action can effectively end an executive's career in the healthcare industry.⁵¹ Cory Andrews of the Washington Legal Foundation, which filed a friend-of-the-court brief on behalf of the defendants in the Purdue Frederick exclusion case (discussed below), argued that "where the deprivation is very small, the due process violations are not as significant But where the deprivation goes to someone's ability to earn a living – I think that raises the constitutional temperature."⁵² However, these due process arguments may not be very strong because closer examination of the following three examples reveals that HHS-OIG is more likely to rely on the RCO doctrine when there is evidence that the

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012).

⁴⁸ GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION, *supra* note 43.

⁴⁹ *See id.*

⁵⁰ *See generally* Longstreth, *supra* note 25.

⁵¹ *Id.*

⁵² *Id.*

executive knew of corporate wrongdoing. HHS-OIG is willing to exclude individuals who have not personally been convicted of a crime, but HHS-OIG has also exhibited restraint when using its exclusion authority.

III. *Marc Hermelin, Howard Solomon, and the Purdue Frederick Executives*

A. *Marc Hermelin*

As described above, HHS-OIG intends to create corporate accountability at the top of organizations that receive money from the federal health programs. HHS-OIG first exercised its (b) (15) authority against a drug-company executive when it excluded Marc Hermelin, former CEO and Chairman of St. Louis based KV Pharmaceutical.⁵³ Hermelin's exclusion was based on the guilty pleading of Ethex Corporation, a subsidiary of KV Pharmaceutical.⁵⁴ In February 2010, Ethex pleaded guilty to charges that the company failed to promptly inform the FDA about dangerous manufacturing problems when it discovered that it was manufacturing oversized pills.⁵⁵ Manufacturing and shipping the oversized pills across state lines constituted a federal misbranding crime because the actual tablets contained more of the active ingredient of the drug than the stated amount on the package.⁵⁶

Not only was Hermelin the first drug-company owner or executive to be barred from doing business with the government under (b) (15), but he was also the first individual to be excluded before the Department of Justice (DOJ) brought criminal charges.⁵⁷ At age 68, Hermelin's 20-year exclusion amounted to a

⁵³ Anna Edney, *KV Pharmaceutical's Hermelin Resigns After U.S. Ban, Will Sell Stake*, BLOOMBERG (Nov. 17, 2010, 4:51 PM), <http://www.bloomberg.com/news/2010-11-17/kv-pharmaceutical-s-hermelin-resigns-after-u-s-ban-will-sell-stake.html>.

⁵⁴ *Id.*

⁵⁵ Joe Whittington & Andrew Harris, *Ex-KV Pharmaceutical CEO Hermelin Pleads Guilty to Drug Label Law Breach*, BLOOMBERG (Mar. 10, 2011, 4:26 PM), <http://www.bloomberg.com/news/2011-03-10/ex-kv-pharmaceutical-ceo-hermelin-pleads-guilty-to-drug-label-law-breach.html>; see also Bill Koenig, *KV Pharmaceutical Reaches Agreement with U.S. Justice Department*, BLOOMBERG (Feb. 25, 2010, 2:00 PM), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aZAFKmaQWQ_0&pos=6.

⁵⁶ Whittington & Harris, *supra* note 55.

⁵⁷ Edney, *supra* note 53.

lifetime ban from working in the healthcare industry.⁵⁸ Four months after the exclusion action, Hermelin pleaded guilty to two criminal FDCA misdemeanors on grounds that he was a responsible corporate officer at KV at the time that the company shipped misbranded drugs to California and Canada.⁵⁹ A judge sentenced Hermelin to 30 days of imprisonment and ordered him to pay a \$1,000,000 fine and forfeit \$900,000.⁶⁰

B. Howard Solomon

On April 12, 2011, HHS-OIG informed Forest Laboratories CEO Howard Solomon that it planned to bring a (b) (15) exclusion action against him in connection with the guilty pleading of a Forest Laboratories subsidiary, Forest Pharmaceuticals.⁶¹ In March 2011, Forest Pharmaceuticals pleaded guilty to distributing a misbranded drug, distributing an unapproved drug, and obstructing a regulatory inspection by the FDA.⁶² In a global settlement, Forest Laboratories paid \$313,000,000 to resolve the criminal and civil lawsuits.⁶³ It came as a surprise when HHS-OIG announced that it was nevertheless going to bring a (b)(15) exclusion against Solomon, who had led Forest Laboratories since 1977, growing it from a modest drug company into a major corporation.⁶⁴

In April 2011, Solomon declared that he would fight the exclusion action,⁶⁵ and on August 5, 2011, HHS-OIG wrote to Solomon to inform him that it had decided not to seek his exclusion, explaining that “[b]ased on a review of the information in our file and consideration of the information that your attorneys provided to us, both in writing and during an in-person meeting,

⁵⁸ *Id.*

⁵⁹ See Whittington & Harris, *supra* note 55.

⁶⁰ *Id.*

⁶¹ Mundy, *supra* note 35.

⁶² Press Release, Dep’t of Justice, *Drug Maker Forest Pleads Guilty; To Pay More Than \$313 Million to Resolve Criminal Charges and False Claims Act Allegations* (Sept. 15, 2010), <http://www.justice.gov/opa/pr/2010/September/10-civ-1028.html>.

⁶³ *Id.*

⁶⁴ Mundy, *supra* note 35.

⁶⁵ *Forest Laboratories Chairman and CEO to Challenge “Unwarranted and Unprecedented” Potential Action to Exclude Him from Federal Health Programs*, BUSINESS WIRE (Apr. 13, 2011, 5:41 PM), <http://www.businesswire.com/news/home/20110413006882/en> [hereinafter *Forest Laboratories*].

we have decided to close this case.”⁶⁶ The letter gave no indication of what factors influenced HHS-OIG’s decision, but it is likely that Solomon’s attorneys relied upon the factors in the October 2010 Guidance and presented evidence that mitigated against Solomon’s exclusion.

C. *Purdue Frederick Executives*

The final example of HHS-OIG’s use of the RCO doctrine relates to the exclusion of the CEO, the Executive Vice President for Medical Affairs, and the General Counsel from Purdue Frederick.⁶⁷ The facts of this case are different from the previous two examples in that the government used a different basis for exclusion. The executives in this case were excluded under (b)(1) and (b)(3) as opposed to (b)(15) because each of the executives first pleaded guilty to a criminal misdemeanor before they were excluded.⁶⁸ Nonetheless, this is still an illustrative example of the RCO doctrine’s force. Each of the executives was convicted because they were considered responsible corporate officers within the company, not because of personal wrongdoing.⁶⁹

The three executives held their positions at Purdue Frederick at a time in the late 1990s when the company was aggressively marketing OxyContin as a controlled release painkiller.⁷⁰ The government later prosecuted the company for intent to defraud or mislead in violation of the FDCA because the company fraudulently marketed the drug as a painkiller that was less addictive and less subject to abuse.⁷¹ To resolve the civil and criminal charges, the company agreed to pay over \$600,000,000 in

⁶⁶ *HHS-OIG Drops Potential Action against Forest CEO Howard Solomon*, BUSINESS WIRE (Aug. 05, 2011, 5:09 PM), <http://www.businesswire.com/news/home/20110805005983/en>.

⁶⁷ See Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES, May 10, 2007, <http://www.nytimes.com/2007/05/10/business/11drug-web.html?pagewanted=all>; see also Office of Inspector Gen., *Administrative Law Judge Upholds HHS-OIG Exclusions Imposed Against Responsible Corporate Officers in OxyContin Case*, OFFICE OF INSPECTOR GEN. NEWS (Jan. 23, 2009), available at http://oig.hhs.gov/publications/docs/press/2009/hhs_oig_press_01232009.pdf [hereinafter *Administrative Law Judge Upholds HHS-OIG Exclusions*].

⁶⁸ *Friedman v. Sebelius*, 686 F.3d 813, 817 (D.C. Cir. 2012).

⁶⁹ See Meier, *supra* note 67; see also *Administrative Law Judge Upholds HHS-OIG Exclusions*, *supra* note 67.

⁷⁰ Meier, *supra* note 67.

⁷¹ *Id.*

finances, which at the time was one of the largest monetary settlements by a drug manufacturer.⁷² Criminal charges were also brought against the three executives.⁷³ The government did not charge them with being directly involved with the activities that violated the FDCA. Rather, the government argued that because of the position the executives held in the company, the executives had a responsibility to either prevent the misbranding or promptly correct it.⁷⁴ As part of the settlement, the executives pleaded guilty to strict liability misdemeanors under 21 U.S.C.A. § 331(a) as responsible corporate officers of a company that misbranded a prescription drug.⁷⁵ After the resolution of the criminal case, HHS-OIG followed on with an exclusion action under (b)(1) and (b)(3).⁷⁶ In the subsequent administrative proceeding, HHS decided that the convictions of the executives were grounds for permissive exclusion.⁷⁷ As mentioned above, this administrative decision has since been upheld by the U.S. Court of Appeals for the District of Columbia.⁷⁸

IV. Implications for the Pharmaceutical Industry and the Future Outlook of RCO Enforcement

The three examples above provide valuable lessons about HHS-OIG's interpretation of the RCO doctrine. First and foremost, the examples signal that all healthcare executives need to be aware of their potential personal liability. In the past, executives had to worry about civil penalties to the company, but a (b)(15) action presents something far worse. As Judge Williams noted in his dissent in *Friedman*, a (b)(15) action “excludes appellants from pursuing careers in the pharmaceutical industry—where they’ve spent their lifetimes accumulating industry-specific human capital.”⁷⁹ Indeed, counsel for the Purdue executives argued that their twelve-year exclusion “effectively ended

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Administrative Law Judge Upholds HHS-OIG Exclusions*, *supra* note 67.

⁷⁵ *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012).

⁷⁶ *Id.*

⁷⁷ *Administrative Law Judge Upholds HHS-OIG Exclusions*, *supra* note 67.

⁷⁸ *Friedman*, 686 F.3d at 824.

⁷⁹ *Id.* at 831.

appellant's careers."⁸⁰ Even Howard Solomon and Forest Laboratories had to bear legal uncertainty and expenses while his counsel argued against exclusion. Solomon may have eventually won, but the threat of exclusion was unwelcome attention for a publicly traded company.

A. *Importance of Compliance and Reporting Systems*

HHS-OIG's actions demonstrate that executives need to know of potential risks within their corporations. Ignorance is not a defense in FDCA cases that are prosecuted under the RCO doctrine, and ignorance will not keep HHS-OIG from bringing an exclusion action.⁸¹ To protect themselves from liability and potential exclusion, executives should make sure that their companies have robust compliance, training, and reporting systems in place.

It is unrealistic to expect corporate officers to know of *every* activity occurring within the company, but HHS-OIG will hold corporate officers liable for violations that they *should have* known about.⁸² HHS-OIG may not have had proof of personal wrongdoing on the part of the Purdue executives, but there was ample evidence to suggest that the executives should have known that OxyContin was being abused.⁸³ For instance, in 2001 the House Committee on Energy and Commerce held a hearing on the abuse of OxyContin.⁸⁴ The Chief Operating Officer of the company, Michael Friedman (who was CEO at the time he was excluded), submitted testimony saying that it was "early in April of 2000 that Purdue was first alerted to reports of abuse and diversion

⁸⁰ Longstreth, *supra* note 25.

⁸¹ See *Forest Laboratories*, *supra* note 65.

⁸² See GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION, *supra* note 43 ("Individuals who have an ownership or a control interest in a sanctioned entity may be excluded under section 1128(b)(15)(A)(i) if they knew or should have known of the conduct that led to the exclusion.").

⁸³ See Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, CNNMONEY (Nov. 9, 2011, 5:00 AM), <http://features.blogs.fortune.cnn.com/2011/11/09/oxycontin-purdue-pharma/>.

⁸⁴ *OxyContin: Its Use and Abuse: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm on Energy and Commerce*, 107th Cong. 107-504 (2001) (Prepared Testimony of Michael Friedman, COO of Purdue Frederick), available at <http://www.gpo.gov/fdsys/pkg/CHRG-107hrg75754/html/CHRG-107hrg75754.htm>.

of OxyContin”⁸⁵ Nonetheless, in the subsequent lawsuit against the company, emails surfaced that showed that the company was aware of the addictive nature of the drug at a much earlier date.⁸⁶ For instance, in 1997 a marketing executive e-mailed Friedman, stating that discussions about OxyContin abuse on addiction chat sites were “enough to keep a person busy all day.”⁸⁷ The exclusion of Friedman and his fellow executives is a clear warning to industry that HHS-OIG is willing to exclude individuals if the individual had notice of wrongdoing.

B. Corporate Response to Internal Wrongdoing

If a company’s internal investigation or compliance program does uncover any wrongdoing, HHS-OIG will expect corporate officers to act promptly to remedy the infraction.⁸⁸ When making an exclusion decision, HHS-OIG will evaluate how the executive responded to the information of wrongdoing, according to factor three of the October 2010 Guidance (“Individual’s Actions in Response to the Misconduct”).⁸⁹ The mitigating factors that HHS-OIG considered when it decided not to exclude Solomon are not public, but we can infer that Solomon’s counsel presented favorable mitigating evidence under factor three regarding Solomon’s response to the misconduct.

Conversely, it appears that HHS-OIG excluded Hermelin, in part, because he knew about the wrongdoing at KV Pharmaceutical and chose not to act. The court documents submitted by the U.S. Attorney’s office allege that Hermelin had knowledge of the manufacturing problems that were creating the oversized pills.⁹⁰ According to the government, Hermelin “instructed KV employees to minimize communications about KV’s oversized tablet manufacturing problems and the company’s investigation of these issues.”⁹¹ The fact that Hermelin knew of the wrongdoing should be of comfort to the pharmaceutical industry because it suggests

⁸⁵ *Id.*

⁸⁶ Eban, *supra* note 83.

⁸⁷ *Id.*

⁸⁸ See GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION, *supra* note 43.

⁸⁹ *Id.*

⁹⁰ Information at ¶¶ 4, 19, Hermelin, United States v. Hermelin, No. 4:11-CR-1 (ERW) (E.D.Mo. Feb. 10, 2011).

⁹¹ *Id.* at ¶ 19.

that Hermelin was not excluded simply because he was the CEO of KV at a time when the company caused misbranded drugs to enter interstate commerce. Rather, Hermelin was likely excluded because he knew of the wrongdoing and made the decision not to come forward to the government.

C. Responding to Notice of Exclusion

It is likely that the executives in all three examples were caught off-guard when they received notice that HHS-OIG intended to exclude them. Soon after Solomon received notice, the General Counsel for Forest Laboratories, Herschel S. Weinstein, expressed dismay that the government was considering excluding Solomon.⁹² In a press release, Weinstein stated the following:

Numerous other major pharmaceutical companies have plead guilty to much more egregious offenses, and none of them has faced the exclusion of a senior executive who has not himself been convicted of a crime or pleaded guilty to a crime. We believe that HHS-OIG is contemplating using a statute that has never before been used under these circumstances and would be exceeding the bounds of its authority.⁹³

The Purdue Frederick executives were almost certainly surprised by the exclusion action. It is unlikely that they would have pleaded guilty to the strict liability misdemeanor if they anticipated the follow-on action from HHS-OIG. In the future, similarly situated executives will be reluctant to plead guilty to strict liability misdemeanors for fear of being exposed to HHS-OIG exclusion liability. It is probable that HHS-OIG also surprised Hermelin with the timing of his exclusion action. Previously, HHS-OIG had waited until the conclusion of criminal proceedings before bringing an exclusion action.⁹⁴ The Hermelin example should put the industry on notice that executives are not safe from an exclusion action prior to facing criminal charges.

The Solomon example is a good case study of how to respond

⁹² *Forest Laboratories, supra* note 65.

⁹³ *Id.*

⁹⁴ Matthew Hay, *OIG Seeks to Exclude Forest's Chief Executive Officer from Working*, POLICY AND MEDICINE (Apr. 22, 2011, 5:28 AM), <http://www.policymed.com/2011/04/oig-seeks-to-exclude-forests-chief-executive-officer-from-working.html>.

to an HHS-OIG exclusion notice. Corporate officers have two options once they are served with notice that HHS-OIG plans to bring an exclusion action: fight the action or resign. Solomon showed that exclusion actions can be fought and won. HHS-OIG puts the burden on the officer to raise mitigating factors that weigh against exclusion, but this does not mean that it is an impossible burden to surmount. The other option available to Solomon was to resign before he was excluded. HHS-OIG can only exclude an executive or majority shareholder with control of a sanctioned company.⁹⁵ By resigning and selling shares before the proverbial “other shoe drops,” an executive could be shielded from exclusion. This approach has not yet been tried, but resigning before the government brings a (b) (15) action would likely put a corporate officer out of reach from the HHS-OIG’s exclusion authority.

Of course, before deciding whether to fight the action or step down, a corporate officer will need to evaluate their chances of succeeding if they decide to challenge a potential exclusion action. Corporate executives and their counsel should consider any mitigating factors as described in the October 2010 Guidance.⁹⁶ In addition to the executive’s conduct under factor three of the Guidance, HHS-OIG will also consider other information about the corporate entity under factor four (“Information About the Entity”).⁹⁷ This may have been an important mitigating factor in HHS-OIG’s decision not to exclude Solomon. Forest Laboratories had undergone management reorganization the year before, and there was not a clear successor in place to replace Solomon if he was forced to resign.⁹⁸ HHS-OIG may have been reluctant to strip the company of a leader who had been at the helm for 24 years. Conversely, HHS-OIG did not have to force a sitting CEO to resign when it brought an exclusion action against Marc Hermelin.⁹⁹ Hermelin had already stepped down as CEO and Chairman at the time that HHS-OIG brought an exclusion action, but he still held a 52 percent controlling stake in the drug company that had been founded by his father.¹⁰⁰

⁹⁵ 42 U.S.C. § 1320a-7(b)(15)(A).

⁹⁶ GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION, *supra* note 43.

⁹⁷ *Id.*

⁹⁸ *See Forest Laboratories, supra* note 65.

⁹⁹ Edney, *supra* note 53.

¹⁰⁰ *Id.*

D. *Legal Challenges to the RCO Doctrine*

In the coming years, HHS-OIG will likely continue to exercise judiciousness when bringing exclusion actions under the RCO doctrine for fear that overreaching cases will shape the contours of the doctrine. The *Frederick v. Sebelius* decision was a victory for the government, but the RCO doctrine will likely continue to be challenged in the courts. There is not a circuit split on this matter, so it is uncertain whether the Supreme Court will grant certiorari to hear an RCO case anytime in the near future. However, the Court has not ruled on an RCO case since 1975, when it decided *United States v. Park*,¹⁰¹ and it may decide to revisit this area of law at a time when the government is bringing cases under the doctrine with greater frequency. Healthcare executives and their counsel would surely welcome guidance from the Supreme Court regarding the reach of the RCO doctrine. In the meantime, HHS-OIG will likely be selective in bringing exclusion actions for fear of losing in the courts and developing unfavorable case law.

E. *Conflict of Interest*

The HHS-OIG is also unlikely to overreach when bringing exclusion actions for public policy reasons because an overly aggressive exclusion policy would create a conflict of interest for corporate officers. In the aftermath of the Purdue Frederick case, there already appears to be strong disincentives for executives to plead guilty to strict liability misdemeanors for fear of follow-on exclusion actions by the HHS-OIG. Herein lies the potential for a conflict of interest: a global resolution might be in the best interest of the company, but an executive might steer away from such a settlement for fear of personal liability. If corporate officers are unable to make decisions about whether to settle or go to court, it is unclear who would be able to make this decision. Under (b)(15), controlling shareholders can be subjected to exclusion and members of the Board of Directors could also be subject to exclusion if they should have known of corporate wrongdoing.¹⁰² From a policy standpoint, HHS-OIG's new paradigm could create

¹⁰¹ *United States v. Park*, 421 U.S. 658 (1975).

¹⁰² GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION, *supra* note 43.

more accountability at the top, but one unintended consequence would be to discourage settlement of criminal and civil actions. For this reason, it is likely that HHS-OIG will exercise prudence when bringing exclusion actions.

V. *Conclusion*

Commentators have claimed that HHS-OIG's new direction creates unprecedented levels of personal liability for corporate officers.¹⁰³ It is certainly true that HHS-OIG has indicated its intention to hold top management responsible for the activities of their companies. Furthermore, the exclusion actions against the Purdue Executives and Marc Hermelin would not have been brought if it were not for the resurrection of the RCO doctrine. Nonetheless, HHS-OIG's track record suggests that it will be judicious in the use of the doctrine when bringing (b)(15) exclusions. As the Solomon example shows, HHS-OIG will consider mitigating factors when making an exclusion decision.¹⁰⁴ Additionally, the Hermelin case demonstrates that HHS-OIG is more inclined to bring action when there is evidence that the corporate officer knew, or should have known, of wrongdoing.¹⁰⁵ As such, healthcare executives would be wise to strengthen their compliance and reporting systems. Under the new RCO enforcement regime, an ounce of prevention could protect a corporate officer from a career-ending exclusion action.

¹⁰³ Thomas Sullivan, *Government Targeting Pharmaceutical Executives with Renewed Enthusiasm*, POLICY AND MEDICINE (Nov. 14, 2011, 5:06 AM), <http://www.policymed.com/2011/11/government-targeting-pharmaceutical-executives-with-renewed-enthusiasm.html>.

¹⁰⁴ See Hay, *supra* note 94.

¹⁰⁵ See Information, *United States v. Hermelin*, No. 4:11-CR-1(ERW) (E.D.Mo. Feb. 10, 2011).