HEALTHCARE EXECUTIVES IN THE CROSSHAIRS: NAVIGATING THE EMERGING THREAT OF PROSECUTION AND EXCLUSION UNDER THE RESPONSIBLE CORPORATE OFFICER DOCTRINE

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Introduction

Healthcare executives, including officers, managers, and in-house counsel, increasingly face the prospect of derivative criminal prosecution and exclusion from federal health programs for the actions or omissions of others within their companies, despite a lack of personal involvement in or even awareness of the alleged misconduct. The Responsible Corporate Officer (“RCO”) or “Park” doctrine, which underlies such prosecutions and exclusion actions, is enjoying a legal renaissance as the government presses for personal accountability of healthcare executives for significant corporate transgressions to address its growing frustration that enforcement against companies alone is insufficient to deter healthcare fraud and abuse.

Today, what is most troubling to [HHS] OIG is the possibility that some unethical health care corporations build the cost of paying civil fines and penalties and implementing CIAs into their cost of doing business. Some 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. As long as the profits from fraud outweigh those costs, abusive corporate behavior is likely to continue. … [W]hen there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization, OIG will operate with a presumption in favor of exclusion of that executive.¹

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Relying upon the RCO doctrine, a theory of liability that originated in food safety and pharmaceutical enforcement actions, the government has made good on its pledge to pursue prosecutions and exclusions of healthcare executives. In this emerging paradigm of both corporate and derivative individual liability, healthcare companies and their executives must take prudent steps to ensure compliance and minimize risks.

This article traces the origins and modern development of the RCO doctrine; provides an overview of the statutory and administrative authorities governing prosecution and exclusion of healthcare entities and individuals; highlights the latest RCO enforcement actions; and explores best practices and defensive measures for managing exposure for both healthcare companies and their executives.

Origins and Development of the RCO Doctrine

Overview

The RCO doctrine originated in case law as a narrow exception to the general rule that an individual should not be subjected to criminal liability without evidence of a blameworthy mens rea. In short, the doctrine allows conviction of a corporate executive based on the individual's “responsibility,” by virtue of position held within the corporate structure, for activity leading to a violation. In its broadest application, the RCO doctrine dispenses with the requirement of any showing that the individual executive knew or even should have known of the violative conduct. Historically, the doctrine was used primarily in cases brought under the Federal Food, Drug and Cosmetic Act of 1938 (“FDCA”), but it also has been used to enforce other strict liability laws involving the environment, public health and safety.

Supreme Court Affirmation of the RCO Doctrine

United States v. Dotterweich

The United States Supreme Court first addressed the RCO doctrine in the 1943 case United States v. Dotterweich,4 upholding by a 5-4 vote the misdemeanor conviction of a drug company's president for the company's shipping of adulterated drugs in violation of the FDCA. Although the defendant had no knowledge of the unlawful conduct, guilt was imputed “solely on the basis of his authority and responsibility as president and general manager of the corporation.”5 Notably, the jury had acquitted the drug company of the same charges.

The Dotterweich majority reasoned that in the balance of relative hardships, it is preferable to penalize “those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.”6 With no risk of overstatement, the Court acknowledged that “[h]ardship there doubtless may be under a statute which thus penalizes the transaction[,] though consciousness of wrongdoing be totally wanting.”7 At the same time, the majority expressly rejected as “treacherous” the invitation to “attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an act of Congress.”8 It also declined to define “the class of employees which stands in such a responsible relation” to a public danger.9 Instead, the Court noted that such cases depend on the good sense, conscience, and circumspection of prosecutors.10

The dissent in Dotterweich objected that a conviction in the case directly contravened the “fundamental principle of Anglo-Saxon jurisprudence that guilt is personal, and that it ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing.”11

United States v. Park

In 1975, decades after Dotterweich was decided, the Supreme Court, in United States v. Park,12 upheld the misdemeanor conviction of the president of a food chain whose Baltimore warehouse was rat-infested, although the president had delegated the responsibility for warehouse operations to others and did not know of the infestation of that facility. The Supreme Court reaffirmed that criminal liability under the FDCA does not require “awareness of some wrongdoing” or “conscious fraud.”13

In so holding, the Supreme Court described the FDCA-imposed duty of persons with authority and supervisory responsibility as:

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. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and wellbeing of the public that supports them.14

New Prosecutorial Priorities and the Re-emergence of the RCO Doctrine

For years after Park, the RCO Doctrine (or “Park” doctrine as it
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came to be known), was infrequently relied upon, and when it was invoked, it was typically in cases where the individual either participated in or knew of the wrongful conduct. In recent years, however, the U.S. Food and Drug Administration (“FDA”) and U.S. Department of Health and Human Services (“HHS”) have pursued individuals under the RCO doctrine in a variety of cases.

The RCO enforcement trend began with a March 4, 2010 letter from FDA Commissioner Margaret Hamburg to Senator Charles Grassley (R-Iowa). The letter first acknowledged a Government Accountability Office report of the same date that raised concerns about oversight and lack of meaningful performance measures in the FDA’s Office of Criminal Investigations (“OCI”). The Commissioner went on to state that in order to enhance operations of OCI and the entire agency, the FDA had determined to “increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible officials accountable. 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 appropriate use of misdemeanor prosecutions.”

The FDA subsequently updated its Regulatory Procedures Manual to add a new section on Park Doctrine prosecutions, which expanded on the criteria referenced in the Commissioner’s letter. The Manual now provides:

When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual’s position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.

The Manual also added a non-exhaustive list of other considerations, many relating to the nature of the violation:

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

Statutory and Administrative Authorities Governing Prosecution and Exclusion of Healthcare Entities and Individuals

U.S. Sentencing Guideline Amendments for Healthcare Offenses

The Patient Protection and Affordable Care Act of 2010 (“PPACA”) directed the amendment of the U.S. Sentencing Guidelines with respect to, inter alia, the calculation of the amount of intended losses. The intended loss amendment was a reaction to United States v. Isiwele and similar cases.

Enitan Isiwele, a durable medical equipment supplier, was convicted on multiple counts of healthcare fraud in connection with a scheme to bill the Medicare and Medicaid programs for medically unnecessary power wheelchairs. At sentencing, the district court calculated the loss resulting from the fraud as $587 million – the amount Isiwele billed Medicare and Medicaid – and applied a fourteen-level increase to the base offense level under the Guidelines. On appeal, Isiwele argued that the district court should have calculated his intended loss based on the lower amounts that Medicare and Medicaid allowed for the wheelchairs under the respective programs’ fixed fee schedules for durable medical equipment. Isiwele asserted that, despite including full charges on his claims, he knew he would receive the lower, capped amounts per the fee schedule, and therefore did not have the subjective intent to cause a loss equal to the billed amounts.

The Fifth Circuit affirmed the conviction, but remanded the case to the district court on the issue of whether the lower court correctly applied the law when it determined Isiwele’s “intended loss,” stating the record was unclear as to what the district court understood the law to be. The Court stated that the billed amount is prima facie evidence of the “intended loss,” but the parties may introduce additional evidence to establish that the billed amount overstates or understates the defendant’s intent.

Adopting the same standard articulated by the Fifth Circuit in Isiwele and the Fourth Circuit in United States v. Miller, the 2011 amendments supplemented the Sentencing Guidelines to state:

In a case in which the defendant is convicted of a Federal healthcare offense involving a Government
healthcare program, the aggregate dollar amount of fraudulent bills submitted to the Government healthcare program shall constitute prima facie evidence of the amount of the intended loss, i.e., is evidence sufficient to establish the amount of the intended loss, if not rebutted.26

The amendments also established tiered enhancements of two to four offense levels for federal healthcare violations causing losses above $1 million.27

Finally, the Sentencing Guidelines were amended to expressly indicate that certain defendants – including the specifically identified example of nominee owners in a healthcare fraud scheme – may be considered for a downward adjustment on the grounds that their part in the offense renders them substantially less culpable than the average participant. The provision now states:

Likewise, a defendant who is accountable under §1B1.3 for a loss amount under §2B1.1 (Theft, Property Destruction, and Fraud) that greatly exceeds the defendant’s personal gain from a fraud offense and who had limited knowledge of the scope of the scheme is not precluded from consideration for an adjustment under this guideline. For example, a defendant in a healthcare fraud scheme, whose role in the scheme was limited to serving as a nominee owner and who received little personal gain relative to the loss amount, is not precluded from consideration for an adjustment under this guideline.28

As a result, then, this adjustment could ameliorate the sentence of an executive convicted under the RCO doctrine despite limited knowledge of the fraud and personal gain significantly that is far exceeded by the loss to the government.

HHS Mandatory and Permissive Exclusion Authority
Exclusions by HHS’ Office of the Inspector General (“OIG”), often referred to in the industry as the “economic death penalty,” have been described as “remedial in nature, not punitive. They are a payment-related sanction, and if excluded, no payment may be made for any items or services billed to a federal healthcare program.”29

OIG exercises its exclusion authority pursuant to statute and its own administrative policies. Under the Social Security Act (“Act”), OIG must exclude any individual from participation in any federal healthcare program who is convicted of:

• a program-related crime;31
• an offense relating to patient abuse;32
• a felony relating to healthcare fraud;33 or
• a felony relating to controlled substances.34

OIG has permissive exclusionary authority, in contrast, based on a host of lesser offenses and even affiliations with sanctioned entities. In sum, the Act provides that OIG may exclude an individual from participation in any federal healthcare program for:

• Fraud-related conviction (misdemeanor fraud, theft, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with delivery of a healthcare item or service; or similar conviction in non-healthcare program);35
• Conviction relating to obstruction of an investigation or audit;36
• Misdemeanor conviction relating to controlled substances;37
• License revocation or suspension;38
• Exclusion, suspension, or sanction from a federal or state healthcare program for reasons bearing on professional competence, professional performance, or financial integrity;39
• Claims for items or services furnished substantially in excess of usual charges or patient need;40
• Fraud, kickbacks, or commitment of another act subject to civil monetary or criminal penalty pursuant to 42 U.S.C. §§ 1320-7a (CMPs), 1320a-7b (criminal penalties), or 1320-8 (CMPs in other programs);41
• Failure to supply or provide access to information supporting payments;42
• Failure to grant immediate access to information related to compliance with conditions of participation or payment, to OIG, to state Medicaid fraud control units, etc.;43
• Default on loan or scholarship;44
• Individuals controlling a sanctioned entity;45
• False statements in enrollment documentation.46

The newly construed bases for permissive exclusion most relevant to the instant subject, 42 U.S.C. Sections 1320a-7(b)(7), (15), and (16), are explored further immediately below.

42 U.S.C. Section 1320a-7(b) (15): Individuals Controlling a Sanctioned Entity

As noted above, 42 U.S.C. Section 1320a-7(b)(15) authorizes OIG to exclude any individual “who has a direct or indirect ownership or control interest in a sanctioned entity47 and who knows or should know48 of the action constituting the basis for the [sanction]; or who is an officer or managing employee49 of such an entity.”50

Historically, OIG used its 42 U.S.C. Section 1320a-7(b)(15) permissive exclusion authority infrequently, i.e. a total of 29 times. In October 2010, however, OIG issued guidance

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(“OIG Guidance”) on its permissive exclusion authority under this subsection, which encourages greater consideration and use of this power.

The OIG Guidance provides that 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 of the entity, OIG will exercise a presumption in favor of exclusion, barring “significant factors” weighing against exclusion. On the other hand, in the absence of such evidence, OIG will apply the enumerated nonbinding factors in determining whether to exclude an officer or managing employee. Unless owners knew or should have known of the misconduct, they are not be subject to exclusion.

The OIG Guidance enumerates the following factors – which it characterizes as “nonbinding” – to be considered in determinations to exclude officers or managing employees, although the Guidance also states that such persons may be excluded “based solely on their position within the [sanctioned] entity.”

• Circumstances of misconduct and seriousness of the offense, including:
  - The nature and scope of the conduct for which the entity was sanctioned and any related misconduct;
  - The level within the entity at which the misconduct occurred;
  - The nature and scope of criminal and civil sanctions imposed on the entity;
  - Whether the misconduct resulted in actual or potential harm to beneficiaries or financial harm to any persons or programs; and
  - Whether the misconduct was an isolated incident or part of larger pattern of wrongdoing.

• Role of individual within the sanctioned entity, including:
  - The individual’s current and former position(s) in the company;
  - The degree of managerial authority or control exercised by the individual; and
  - Whether the misconduct occurred within the individual’s chain of command.

• Individual’s actions in response to the misconduct, including:
  - Whether the individual acted to stop the underlying misconduct or mitigate the effects of the misconduct;
  - Whether the individual’s actions to stop or mitigate the misconduct occurred before or after the individual learned of the government’s investigation;
  - Whether the individual disclosed the misconduct to the appropriate authorities and cooperated with investigators and prosecutors.

• General information about the entity, including:
  - Size and corporate structure; and
  - Previous sanctions and the nature and scope of any prior misconduct.

Significantly, the OIG Guidance notes that if an individual can demonstrate either that preventing the misconduct was “impossible” or that the individual exercised “extraordinary care” but still could not prevent the misconduct, OIG may consider this as a factor weighing against the individual’s exclusion.

As described below, since issuing the Guidance OIG has invoked its permissive exclusion authority under 42 U.S.C. Section 1320a-7(b)(15) in two notable cases, one against Marc Hermelin, a former director of KV Pharmaceutical Co., and one involving the CEO of Forest Laboratories, Howard Solomon, although OIG later withdrew the exclusionary proceedings against Solomon.

Also, although no action has been taken since its referral to Congressional committee in February 2011, the bipartisan Strengthening Medicare Anti-Fraud Measures Act of 2011 would broaden 42 U.S.C. Section 1320a-7(b)(15) to allow OIG to permissively exclude individuals and entities currently or formerly affiliated with sanctioned entities, rather than only individuals who control sanctioned entities, as provided by law currently. Consistent with the OIG’s Guidance, the legislation permits officers and managing employees – though not owners – to be excluded whether or not they actually knew or should have known of the conduct. It goes further, however, to permit the exclusion of an owner of a non-sanctioned entity that is or was affiliated with a sanctioned entity if that owner knew or should have know of the misconduct. Exclusion would be conditioned on evidence that a relationship existed at the time of the conduct that formed the basis for the sanctioned entity’s conviction or exclusion. No legislative action has been taken on the measure since its introduction and referral to several House committees and subcommittees last year. A similar bill passed the House but not the Senate in 2010.

42 U.S.C. Section 1320a-7(b)(16): False Statements in Enrollment Documentation

PPACA amended the Act to create subsection (b)(16), a new category of permissive exclusionary authority. It authorizes exclusion of any individual or entity that made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a federal healthcare program.

42 U.S.C. Section 1320a-7(b)(7): Civil Monetary Penalty (“CMP”) Liability for Failure to Return Overpayments
with a $37 million penalty, a deferred prosecution agreement, and a five-year corporate integrity agreement (“CIA”) with OIG. At Harkonen’s sentencing, the Department of Justice (“DOJ”) requested a ten-year prison sentence and a $1 million fine. He was sentenced, however, to no jail time, and received only three years’ probation, a $20,000 fine, community service, and six months' home detention. Harkonen’s appeal and the cross appeal of the government are pending in the 9th Circuit Court of Appeals. Briefing was scheduled to be complete in May 2012.

On August 31, 2011, OIG notified Harkonen of his mandatory exclusion under Section 1320a–7(a)(3) from federal healthcare programs for five years. OIG contends that Harkonen’s felony wire fraud conviction was “in connection with the delivery of a healthcare item or service,” a contention the defendant disputes. He has appealed the exclusion and requested a hearing with an administrative law judge, although his exclusion remains in place.

WellCare Health Plans Executives and Officers: Mandatory Exclusion Being Sought Under Section 1320a–7(a) (Trial Pending)

On March 2, 2011, the government indicted several former senior executives of WellCare Health Plans, Inc., a managed care services provider serving exclusively government healthcare programs, including Medicaid and Medicare. The defendants include Todd Farha, WellCare’s former chief executive officer, as well as the former general counsel, chief financial officer, and two vice presidents. In connection with WellCare’s reporting of its expenditures for behavioral healthcare services to the state Medicaid program administered by the Florida Agency for Health Care Administration (“AHCA”), they are charged with multiple felonies, but no violations of the FDCA. Specifically, each defendant is charged with conspiracy, four counts of making false statements, and four counts of healthcare fraud.

Mandatory Exclusion
InterMune CEO: Mandatory Exclusion Under Section 1320a–7(a)(3) (Appeals Pending)

In 2009, Dr. Scott Harkonen, the CEO of InterMune from 1998 to 2003, was convicted of felony wire fraud in connection with his approval of a press release about InterMune’s product Actimmune. The press release in question had touted the drug’s use for idiopathic pulmonary fibrosis, which was an unapproved use. He was acquitted of introducing a misbranded drug into interstate commerce in violation of the FDCA.

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Recent Enforcement Actions

Among numerous recent cases implicating the RCO doctrine, some have led to mandatory exclusion and others to permissive exclusion or attempted permissive exclusion. As the following examples illustrate, mandatory exclusion is typically based on a felony conviction, so in most such cases the defendant has acknowledged or been convicted of knowing of and/or participating in the misconduct. On the other hand, in cases of permissive intent, knowledge or intent may be entirely absent.

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The indictment alleges that the executives each personally engaged in fraudulent activities intended to reduce WellCare’s premium refund obligations to the Florida Medicaid program, such as providing inaccurate information to AHCA; including expenditures for services other than behavioral healthcare services in the reporting worksheets it submitted; using a wholly-owned subsidiary, Harmony Behavioral Health, Inc., to conceal WellCare’s actual costs for behavioral healthcare services provided; and failing to accurately respond to AHCA’s requests for a detailed justification of the difference between the medical loss ratios WellCare used and the medical loss ratio calculated by AHCA. Due to the volume of discovery in the case, the defendants requested, and received, a continuance of the trial, which has not yet occurred.

GlaxoSmithKline Associate General Counsel: Potential Mandatory Exclusion Under Section 1320a–7(a) (Twice Dismissed)

In 2010, Lauren C. Stevens, former associate general counsel for GlaxoSmithKline (“GSK”), was indicted on one count of obstruction of an official proceeding; one count of falsification and concealment of documents with the intent to obstruct and influence a federal investigation; and four counts of making false statements to the FDA. The charges related to the FDA’s investigation into whether GSK engaged in off-label promotion of Wellbutrin as a weight-loss and obesity treatment. In response, Stevens asserted an advice of counsel defense.

According to the indictment, the FDA sent GSK a letter in 2002 (“Request”), requesting GSK “to provide materials related to W-Drug [Wellbutrin] promotional programs, including copies of all slides, videos, handouts, and other materials presented or distributed at any GSK program or activity related to” Wellbutrin. The indictment alleged that Stevens withheld documents that were responsive to the FDA’s Request, falsely represented to the FDA that GSK’s response to its Request was complete, and sent a series of correspondence to the FDA in which she concealed incriminating evidence of the company’s off-label promotion of Wellbutrin and represented that GSK’s activities were consistent with FDA requirements.

Stevens sought disclosure of the grand jury transcripts to determine whether the government properly instructed the grand jury on her advice of counsel defense. In support, Stevens described her reliance on the advice of outside counsel, stating that:

- GSK had engaged an experienced law firm to participate in preparing GSK’s response to the FDA’s inquiry;
- Outside counsel was intimately involved in the investigation of underlying facts and collection of relevant documents;
- Outside counsel concluded that GSK did not have a corporate strategy to promote Wellbutrin for off-label use;
- Outside counsel drafted, edited, and reviewed each of six substantive letters that Stevens, on behalf of GSK, sent to the FDA in response to its inquiry, and the letters were sent to the FDA only after consensus was reached among the in-house and outside counsel;
- In-house and outside counsel reached a consensus not to immediately produce certain documents responsive to the FDA’s inquiry, but rather to seek a meeting with the FDA at which GSK would present and discuss the materials; and
- Despite Stevens’ multiple attempts to schedule such a meeting, the FDA did not respond to Stevens’ calls, and outside counsel did not advise GSK that its failure to produce the materials was unlawful.

Partial disclosure of the transcripts revealed that a grand juror questioned the relevance of the advice of counsel defense, and that the government responded to the question by instructing the grand jury that the advice of counsel defense “is a defense that a defendant can raise, once the defendant has been charged” and “can be relevant at trial.”

The U.S. District Court for the District of Maryland found “little doubt” that the government’s instruction to the grand jury regarding Stevens’ advice of counsel defense was erroneous and dismissed the indictment without prejudice on March 23, 2011. The court stated that a proper instruction “would have informed the grand jurors that if Stevens relied in good faith on the advice of counsel, after fully disclosing to counsel all relevant facts, then she would lack the wrongful intent to violate the law and could not be indicted for the crimes charged in the proposed indictment.”

Stevens was indicted again on the same charges and her trial commenced less than two months later, in May 2011. Following presentation of the government’s case, however, the same judge who had dismissed the indictment in March granted Stevens’ Rule 29 motion for judgment of acquittal. The judge ruled that no reasonable jury could convict her on the basis of the evidence presented. He further noted that the attorney-client privileged documents to which the government had been granted access on the basis of the crime fraud exception actually established that the defendant had acted reasonably in her responses to the FDA. The judge underscored the deleterious implications for the legal profession and the
enormous potential for abuse of allowing lawyers to be prosecuted for doing their jobs, i.e., providing legal guidance.\textsuperscript{71}

**Permissive Exclusion**

*Purdue Frederick Company Executives: Permissive Exclusion Under Sections 1320a–7(b)(1) and (b)(3) (Appeal Pending)*

In 2007, three Purdue Frederick Company senior executives – its former president and chief executive officer, general counsel, and chief scientific officer – pled guilty as responsible corporate officers to introducing a misbranded drug into interstate commerce in violation of 21 U.S.C. Sections 331(a) and 333(a)(1). They maintained that had not personally participated in any misconduct, but agreed to plead guilty on the grounds that they had responsibility and authority either to prevent or to promptly correct the company’s conduct that constituted misbranding and did not do so. According to the government’s allegations, Purdue supervisors and employees marketed and promoted OxyContin as less addictive, less subject to abuse, and less likely to cause tolerance and withdrawal than other pain medications, statements that were not supported by the drug’s FDA-approved application.\textsuperscript{72}

Shortly after the defendants pled guilty, in March 2008, OIG advised them that they would be excluded from program participation for 20 years pursuant to 42 U.S.C. Section 1320a–7(b)(1) (permissive exclusion for misdemeanor convictions relating to fraud) and Section 1320a–7(b)(3) (permissive exclusion for misdemeanor convictions relating to controlled substances). Arguing that their guilty pleas had been based on RCO liability and therefore reflected no personal wrongdoing or intent to defraud, the executives appealed the exclusion determination to the HHSC Departmental Appeals Board (“Board”).\textsuperscript{73}

The Board rejected this argument and the contention that exclusion in the absence of personal misconduct or intent to defraud is inconsistent with the text and purpose of 42 U.S.C. Section 1320a–7(b).\textsuperscript{74} Instead, the Board found that culpability existed by virtue of the fact that the defendants “had, but failed to exercise, the duty and responsibility, and the power and authority, to learn about and curtail the fraudulent activities of Purdue employees.”\textsuperscript{75} The Board, however, found insufficient evidence that the executives’ conduct had a significant, adverse physical or mental impact on program beneficiaries. Accordingly, it reduced the exclusions to 12 years (from 15 years, following a previously reduction by OIG from 20 to 15 years due to the executives’ cooperation with law enforcement).\textsuperscript{76}

The executives lost their appeal of the Board’s decision when the U.S. District Court for the District of Columbia upheld the exclusions, construing the phrase “relating to fraud” in Section 1320a–7(b)(1) to mean “having a connection with or reference to fraud.”\textsuperscript{77} The court found that the phrase does not require that an individual personally commit fraud and that, even it were ambiguous, the government’s interpretation was reasonable.\textsuperscript{78} The defendants’ appeal of the district court decision remains pending, following oral argument in the D.C. Circuit on December 6, 2011.\textsuperscript{79}

*Synthes, Inc. Executives: Permissive Exclusion Under Sections 1320a–7(b)(1) and (b)(3)*

The government indicted four former Synthes, Inc. executives as responsible corporate officers, charging them with a single count of introducing two misbranded devices, Norian XR and Norian SRS, into interstate commerce.\textsuperscript{80} The government alleged that Norian Corp. conspired with Synthes, Inc., its parent company, and the four Synthes executives to conduct unauthorized clinical trials of two bone cements for an unapproved use, marketed the products without first conducting clinical trials required by FDA, continued to market the products until three patients died during surgeries in which the products were used, and did not recall the products from the market because such an action would have required them to notify the FDA.

The executives entered guilty pleas in 2009 and in late 2011 each was sentenced to a term of imprisonment between five and nine months. They face potential exclusion by OIG. Synthes and Norian also pled guilty and agreed to pay $23.2 million in fines. In addition, OIG forced Synthes to divest Norian or risk permissive exclusion. Norian, which was bought by Kensey Nash Corp., was subject to mandatory exclusion. Synthes has agreed to be acquired next year by Johnson & Johnson for about $21 billion.\textsuperscript{81}

*KV Pharmaceutical CEO: Permissive Exclusion Under Sections 1320a–7(b)(1) and (b)(3)*

The government charged Marc Hermelin, the former chief executive officer and a director of KV Pharmaceutical as a responsible corporate officer, with two counts of introducing a misbranded drug into interstate commerce. He pled guilty in March 2011, was sentenced to 30 days in jail, and ordered to pay $1.9 million in fines and forfeitures.\textsuperscript{82} OIG excluded Hermelin from participation in federal healthcare programs retroactive to November 18, 2010.\textsuperscript{83}

The government alleged that KV and its subsidiary Ethex Corp. distributed pharmaceutical tablets of the wrong size and potency due to Hermelin’s and the KV management team’s decision to use several tablet presses that had fewer safety and automation features than more modern tablet presses available. The government further alleged that “[b]y virtue of his role at KV and Ethex, Hermelin had the power, authority, continued on page 10
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and responsibility to prevent drug manufacturing problems in the first instance and promptly correct any drug manufacturing problems that did occur. Moreover, after KV began investigating customer complaints regarding oversized tablets, the government alleged that Hermelin: (1) instructed employees to minimize written communications and limit distribution and discussion of any documents referencing the problems, given the “business risk” created by written materials; (2) stated that Quality Assurance employees should be out of the “information flow,” and (3) offered his views on what the root cause finding of the investigation should be.

According to a KV press release, the company, Hermelin and OIG entered into a settlement agreement pursuant to which Hermelin surrendered his KV stock and resigned to avoid permissive exclusion of KV. KV has been operating under a civil consent decree limiting its ability to manufacture drugs since 2009. KV also agreed to dissolve Ethex, which pled guilty to two felony counts of failing to file field alerts with the FDA and was ordered to pay fines, restitution, and forfeitures totaling over $27 million.

Forest Pharmaceuticals CEO: Permissive Exclusion Sought Under Section 1320a–7(a) (Withdrawn)

On September 15, 2010, Forest Laboratories, Inc. and its subsidiary Forest Pharmaceuticals, Inc. entered into an agreement to resolve criminal charges and three qui tam actions under the False Claims Act arising out of its distribution and marketing of Lexapro, Celexa, and Levothroid. Forest Laboratories paid $313 million and entered into a CIA, while Forest Pharmaceuticals pled guilty to felony obstruction of an agency proceeding, distributing a misbranded drug, and distributing an unapproved drug.

Howard Solomon, Forest Laboratories’ chairman, CEO, and president, was never charged. Nevertheless, in 2011, OIG advised him of its intent to exclude him based on his association with a sanctioned entity. Several months later, after widespread outcry, OIG advised Solomon that it would not proceed with exclusion. No reason for the change in course was provided.

Best Practices for Avoiding RCO Liability

Based on the factors outlined in OIG’s latest guidance on permissive exclusion and the fact patterns underlying recent RCO prosecutions, the following practical pointers are offered for minimizing RCO liability of companies and their executives, officers, and in-house counsel. As noted above, these factors fall within four broad categories: the circumstances and seriousness of the misconduct; the individual’s role in the organization; the individual’s response to the misconduct; and the nature and history of the organization.

The good news for attorneys and others potentially subject to RCO prosecution is that they are well-situated to directly influence two of the classes of factors, namely those focused on the individual’s role in and response to any misconduct. And while less can be done with respect to factors relating to the organization itself, such as past violations, an effective compliance program can significantly shape the circumstances and seriousness of any misconduct.

First, as part of a comprehensive risk management and mitigation program, high-risk policies, practices, and business lines should be identified and a multi-pronged mitigation approach to particular risk exposure should be considered. This should include the development and implementation – or revision and redeployment – of policies and procedures addressed to each identified risk. Such policies and procedures should, inter alia, specify that legal and compliance personnel do not have the ability or authority to control the conduct of employees beyond their departments, but are limited to offering advice and recommendations.

The policies should include procedures for creating a comprehensive record of corrective actions taken in response to compliance incidents and which senior personnel and functions (e.g. Line v. Compliance v. Legal) were involved. And, in anticipation of the inevitable future compliance failure, the procedures developed should establish a rapid response team to immediately assess and contain such incidents, as well as to escalate, resolve, and self-report those failures as warranted. The team should be staffed with representatives of relevant functions and provide it with a framework and formal guidance to govern its work. When compliance failures have been identified and remedial measures established, a business-line supervisor should be designated (and the designation documented) to monitor implementation and provide periodic reports to the legal/compliance function.

In tandem with the foregoing, a system of periodic audits should be included to identify variations of company practices from policies and procedures and, based on audit findings, the sufficiency of such policies and procedures should be re-assessed and personnel should be re-trained for compliance as necessary. Lastly, relevant employees, officers, and executives should be required to annually re-certify their understanding of and compliance with the relevant policies and procedures. Potential RCO targets in healthcare organizations are well-advised to heed the recurrent reminders that federal prosecutors remain committed to “disprov[ing] the ill-advised
notion that health care fraud enforcement is simply the cost of doing business” and to that end will bring “prosecutions against individuals, including misdemeanor prosecutions under the Park doctrine.” Already the marketplace has heard the warnings and responded to this risk exposure by offering new RCO insurance policies to mitigate the economic loss of an RCO prosecution or debarment. Thus, in addition to adopting some or all of the suggestions above, a prudent response to this risk may entail consideration of such coverage for at-risk executives and owners.

Conclusion

The fact that healthcare executives, including officers, managers, and in-house counsel increasingly are now in the government’s crosshairs, is the new reality. In the new world of healthcare fraud and abuse enforcement, healthcare companies and their executives face the prospect of derivative criminal prosecution and exclusion from federal health programs for the actions or omissions of others within their companies, despite a lack of personal involvement in or even awareness of the alleged misconduct. Robust compliance initiatives, based on the factors outlined in OIG’s latest guidance on permissive exclusion and the fact patterns underlying recent RCO prosecutions, must be developed and/or enhanced and the practical pointers addressed herein must be followed scrupulously to minimize RCO liability of companies and their executives, officers, and in-house counsel.

Brian Castro is a Washington, D.C.-based attorney who specializes in litigation, regulatory, and enforcement matters in highly regulated sectors. A former federal district court law clerk, he has successfully resolved cases before administrative agencies and in federal courts throughout the United States. As counsel to financial institutions, healthcare companies, federal officials, whistleblowers, and manufacturers, Mr. Castro guides clients through regulatory mandates and complex litigation involving securities, banking, government contracting, antitrust, and healthcare. He is a former economic and regulatory policy advisor to U.S. Senator Chris Coons and senior counsel to the Department of Enforcement of the Financial Industry Regulatory Authority (“FINRA”).

Mr. Castro’s civic work includes advising non-profit organizations on regulatory matters, advocating on behalf of political and social justice causes, and serving on various federal and national boards, including the ABA’s Presidential Commission on Hispanic Legal Rights and Responsibilities Advisory Committee; the D.C. Circuit Judicial Conference’s Standing Committee on Pro Bono Legal Services; the National LGBT Bar Association Board of Directors; and the Freedom to Work Board of Directors. He also is a member of the ABA Business Law Section Committees on Federal Securities Regulation and International Law.

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Endnotes

3. See e.g. United States v. Iverson, 162 F.3d 1015 (9th Cir. 1998) (applying the RCO doctrine and affirming the conviction of a chemical products company president for violations of the federal Clean Water Act); United States v. Hanousek, 176 F.3d 116 (9th Cir. 1999) (construing the Clean Water Act to allow conviction of a misdemeanor offense without a showing of mens rea).
4. 320 U.S. 277 (1943).
5. 320 U.S. at 286.
6. Id. at 285.
7. Id. at 284.
8. Id. at 285.
9. Id. at 284-285.
10. Id. at 285.
11. Id. at 286.
13. Id. at 672-673.
14. Id. at 672.
15. See, e.g., United States v. Starr, 535 F.2d 512 (9th Cir. 1976) (upholding conviction of continued on page 12
company’s secretary-treasurer who was responsible for sanitation problems and had actual knowledge of such problems).


19 Id.


21 The federal sentencing guidelines provide non-binding standards to assist judges in imposing uniform sentences on defendants convicted in federal court.

22 635 F.3d 196 (5th Cir. 2011).

23 Id. at 203.

24 Id.

25 316 F.3d 495 (4th Cir. 2003).


27 2-level increase in the offense level for any defendant convicted of a federal healthcare offense relating to a Government healthcare program which involves a loss of more than $1 million; 3-level increase in the offense level for any defendant convicted of a federal healthcare offense relating to a Government healthcare program which involves a loss of more than $7 million; 4-level increase in the offense level for any defendant convicted of a federal healthcare offense relating to a Government healthcare program which involves a loss of more than $20 million. Id. at § 2B1.1(b)(8).

28 Id. at § 3B1.2, Application Note 3(A) (emphasis added).


30 42 U.S.C. § 401, et seq.


32 Id. at § 1320a–7(a)(2).

33 Id. at § 1320a–7(a)(3).

34 Id. at § 1320a–7(a)(4).


37 42 U.S.C. § 1320a–7(b)(3).


39 42 U.S.C. § 1320a–7(b)(5).

40 42 U.S.C. § 1320a–7(b)(6).

41 42 U.S.C. § 1320a–7(b)(7).

42 42 U.S.C. § 1320a–7(b)(11).


47 A “sanctioned entity” is defined as an entity that has been: (a) convicted of any offense under 1320a–7(a) (i.e., offenses that require mandatory exclusion); (b) convicted of an offense described in 1320a–7(b)(1), (2), or (3) (i.e., the first three offenses that can lead to permissive exclusion listed above); or (c) excluded from participation under a Medicare program or a state healthcare program. 42 U.S.C. § 1320a–7(b)(15)(B).

48 An individual “should know” of information or conduct when the individual acts in deliberate ignorance or reckless disregard of the truth or falsity of the information; no proof of specific intent to defraud is required. 42 U.S.C. § 1320a–7a(h)(6).

49 A “managing employee” is an individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity. 42 U.S.C. § 1320a–5(b).


52 Id. at 1.

53 See infra, at sections IV. B.3 and B.4.


56 “Overpayment” is defined as any funds received or retained under the Medicare and Medicaid programs to which the person or entity, after applicable reconciliation, is not entitled. See 42 U.S.C. § 1320a–7a(d)(4).

57 See supra.


60 Id.

61 United States v. Harkonen, No. 3:08-cr-00164-MHP-1 (N.D. Cal.).

62 United States v. Harkonen, No. 11-10210 (9th Cir.); No. 11-10224 (9th Cir.) (cross-appeal of the United States).


64 United States v. Lauren Stevens, No. RWT-10-CR0694, Indictment at 1-2 (D. Md.) (Nov. 8, 2010).

65 Id. at 3-10.


67 Id. at 16-19.

68 Id. at 17.

69 United States v. Lauren Stevens, No. RWT-10-CR0694, Transcript, at 3-11 (D. Md.) (May 10, 2011). Federal Rule of Civil Procedure 29 authorizes the court, on a defendant’s motion or the court’s own motion, to enter judgment of acquittal for “any offense for which the evidence is insufficient to sustain a conviction.”

70 Id. at 5.

71 Id. at 3-4, 10.

72 United States v. The Purdue Frederick Co., Inc., et al., No. 07-cr-00029 (JPJ) (W.D. Va.).

73 The HHS Departmental Appeals Board provides administrative review of disputed departmental decisions; Board rulings may be appealed to federal court.


75 Id.

76 Id. at 104-105.

77 Id. at 107-108.

78 Id. at 108-110.

79 Friedman, et al. v. Kathleen Sebelius, et al., No. 11-5028 (D.C. Cir.).


81 No. 2:09-cr-00403-LDD (E.D. Pa.).


89 Friedman, et al. v. Kathleen Sebelius, et al., No. 12-3905 (D.C. Cir.).

