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EXECUTIVES SHOULD THINK TWICE BEFORE ACCEPTING PLEAS ‘RELATING TO FRAUD’: THE EXPANSION OF EXCLUSION UNDER THE PARK DOCTRINE

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Introduction

Over the last three years, the Health Care Fraud Prevention and Enforcement Action Team (“HEAT”) has recovered over \$10.2 billion in healthcare fraud settlements, many involving pharmaceutical companies charged with the “off-label promotion”¹ of drugs to healthcare providers.² As an effort to change corporate culture, each of these settlements has included a corporate integrity agreement (“CIA”) with the Office of Inspector General (“OIG”) for the Department of Health and Human Services (“HHS”). The deterrent effect of CIAs, however, is uncertain,³ and even the OIG has acknowledged that billion dollar settlements are not a sufficient deterrent to change corporate culture in pharmaceutical companies.⁴ Moreover, some companies view paying these fines as merely the “cost of doing business.”⁵

One reason for the lack of deterrence may be that pharmaceutical companies believe they are “too big”⁶ to be excluded by the OIG because of the risk it would pose to the welfare of government healthcare beneficiaries.⁷ Another reason may be due to the failure of the laws governing “directors’ exercise of their fiduciary duties to impel boards to pursue their company’s strict adherence to the law”⁸ and fully embrace “compliance as good business.” While some alternatives have been offered,⁹ the OIG has responded by indicating its intent to exclude corporate executives in the life sciences industry from federal healthcare programs “under a broader range of circumstances,”¹⁰ including the Responsible Corporate Officer (“RCO”) doctrine.¹¹ For example, HHS Deputy Inspector General Gerald T. Roy testified to Congress that the OIG would operate “with a presumption in favor of exclusion” when there is “evidence that an executive knew or should have known of the underlying criminal misconduct of the organization.”¹² By excluding corporate officers, the OIG believes it can better “influence

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corporate behavior without putting patient access to care at risk” and “alter the cost-benefit calculus of the corporate executives who run these companies.”¹³

Holding true to its promise, the OIG excluded three former Purdue Frederick Company (“Purdue”) executives in 2007 for their misdemeanor misbranding convictions under the RCO doctrine. On July 27, 2012, the U.S. Court of Appeals for the District of Columbia Circuit upheld their exclusions in *Friedman v. Sebelius* because the executives’ misdemeanor convictions were factually related to fraud. The Court remanded the case back to the District Court regarding the 12-year exclusion length because the OIG failed to explain why the penalty was three times longer than penalties imposed in comparable cases in the past¹⁴ and four times longer than the presumptive baseline in the statute.¹⁵ The D.C. Circuit Court denied a petition for rehearing en banc by the executives on Nov. 29, 2012.¹⁶ The Court mandated the case back to the District Court, which remanded the case to the OIG on December 12, 2012.¹⁷

Consequently, lawyers and healthcare stakeholders must closely examine this decision because the OIG may “expand its use of [permissive] exclusion against individuals”¹⁸ and the decision may encourage more RCO prosecutions. As a result, these exclusions may have the unintended consequence of deterring “talented, qualified, and ethical individuals from working in senior or leadership positions”¹⁹ in the life sciences industry for fear of being excluded when they engaged in no wrongful conduct.

Case Background

In May 2007, Purdue pled guilty to felony misbranding, in violation of 21 U.S.C. § 331(a) and § 333(a)(2) of the Food, Drug and Cosmetic Act

(“FDCA”), because some of Purdue’s employees made misrepresentations to healthcare providers that the pain-killer OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.²⁰ Purdue was placed on probation for five years, fined \$500,000, and subjected to other monetary sanctions totaling approximately \$600 million, of which approximately \$160 million was earmarked for restitution to federal and state healthcare agencies.²¹ At the same time, the three executives²² each pled guilty to a single count of misdemeanor misbranding as “responsible corporate officers,” in violation of 21 U.S.C. § 331(a) and § 333(a)(1), for their admitted failure to prevent Purdue’s fraudulent marketing of OxyContin.

The RCO Doctrine

The RCO doctrine has its roots in two Supreme Court cases: *U.S. v. Dotterweich*²³ and *U.S. v. Park*.²⁴ In *Dotterweich*, prosecutors obtained a misdemeanor conviction of the general manager of a store that sold repackaged drugs when, without his knowledge or involvement, a shipment was made to a physician that contained less potent drugs than indicated on the label. In a 5-4 decision, the U.S. Supreme Court upheld the conviction, finding that the general manager bore “a responsible share in the furtherance of the transaction which the statute outlaws.”²⁵ The Court declined to explain the meaning of “responsible share.”²⁶

The Supreme Court elaborated on the *Dotterweich* holding in *Park*, where the president and chief executive officer (“CEO”) of a national grocery chain with 900 stores was charged with a misdemeanor for selling adulterated food. Although Park claimed that he was not “personally concerned” with the violations,²⁷ the government presented testimony that “[the Food and Drug Administration

(“FDA”)] informed him, by letter, of unsanitary conditions in the store’s Baltimore warehouse.”²⁸ The Supreme Court instructed that:

the government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.²⁹

As a result, the Court held that a “corporate agent, through whose act, default, or omission the corporation committed a crime” in violation of the FDCA may be held criminally liable for the wrongdoing of the corporation or lower-level corporate employees, “whether or not the crime required ‘consciousness of wrongdoing’” by the agent.³⁰ In other words, criminal liability for an FDCA violation does not require “awareness of some wrongdoing” or “conscious fraud.”³¹

In addition, criminal liability under the RCO doctrine extends “not only to those corporate agents who themselves committed the criminal act, but also to those who by virtue of their managerial positions or other similar relation to the actor could be deemed responsible for its commission.”³² A corporate officer may therefore be guilty of misdemeanor misbranding without “knowledge of, or personal participation in,” the underlying fraudulent conduct.³³ Thus, the word “responsible” in the doctrine’s name does not mean that the individual is responsible for the misconduct, but...for the corporation.³⁴ As a result, the Court in *Park* imposed the “highest standard of care” on corporate executives, thereby permitting conviction of such “responsible corporate officials who, in light of this standard of care, have the power to prevent or

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correct violations of its provisions.”³⁵ The Court recognized that this high standard imposed on responsible corporate agents was “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 well-being of the public that supports them.”³⁶

The Court in *Park* did create a defense that corporate officers are not expected to prevent or remedy wrongdoing by doing the “objectively impossible.”³⁷ As the Washington Legal Foundation³⁸ noted in its *Friedman* amicus brief, however, “[t]his defense is surely more useful to mid-level executives than to senior level executives.”³⁹ Even if the most “thorough and assiduous supervision produced no evidence of a problem, it would always be objectively possible for a CEO, who has authority over a company, to have prevented wrongdoing.”⁴⁰

After *Park*, the RCO doctrine 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.”⁴¹ In fact, the government’s brief in *Park* acknowledged that the FDA would not “ordinarily recommend prosecution unless that official, after becoming aware of possible violations...has failed to correct them or to change his managerial system so as to prevent further violations.”⁴² In addition, FDA officials did not use the doctrine because the agency was focused on felony cases.⁴³

In 2010, however, FDA Commissioner Margaret Hamburg, PhD, sent a letter to Senator Charles Grassley (R-IA) explaining that the agency had decided to “increase the appropriate use of misdemeanor prosecutions [as] a valuable enforcement tool to hold responsible officials accountable.”⁴⁴ The FDA subsequently updated its Regulatory Procedures Manual to add a new

section on *Park* Doctrine prosecutions.⁴⁵ In addition, former FDA Deputy Chief for Litigation Eric Blumberg noted that FDA would target “pharmaceutical executives whose companies promoted off-label uses of their products” for misdemeanor prosecutions and urged federal prosecutors to “show[] more resolve to criminally charge individuals at all levels in the company.”⁴⁶ The Washington Legal Foundation responded to Blumberg with a letter, calling his comments “irresponsible” and urging the FDA not to pursue *Park* prosecutions where “the individual in question did not participate in or have knowledge of the alleged violations.”⁴⁷

In *Friedman*, the D.C. Circuit reasoned that because the executives, as part of their plea agreements, admitted having “responsibility and authority either to prevent in the first instance or to promptly correct” the misbranding, the executives admitted being guilty of misdemeanor misbranding under the RCO doctrine.⁴⁸ However, both the presiding judge who accepted the corporate and executive plea agreements and the prosecuting U.S. Attorney recognized the absence of any proof that the executives had any personal knowledge of the misbranding or any personal intent to defraud.⁴⁹

Consequently, the District Court’s holding established an unfamiliar precedent under the RCO doctrine. Previously, the Supreme Court only recognized narrow exceptions for the *mens rea* requirement in the case of misdemeanor charges under the FDCA’s RCO doctrine because the penalties were “relatively small”⁵⁰ and conviction did no “grave damage” to the person’s reputation.⁵¹ The executives in *Friedman*, however, had to disgorge approximately \$34.5 million⁵² in compensation and faced what amounted to a lifetime ban from the pharmaceutical industry.⁵³ It is practically impossible for an

excluded individual to be employed in the healthcare industry, since most pharmaceutical companies rely on revenue from federal healthcare programs.

The OIG’s Exclusion Authority and Relation to Corporate Executives

Four months after the executives were sentenced, the OIG informed them of its intent to exclude them from participating in any federal healthcare program for 20 years, pursuant to 42 U.S.C. § 1320a-7(b)(1). Exclusions, often referred to in the industry as the “economic death penalty,” are “remedial in nature, not punitive.”⁵⁴ They are a payment-related sanction, and if excluded, the government may not make any payment for any items or services billed to a federal healthcare program by the excluded individual or entity. The OIG has mandatory and permissive exclusion authority. Under the mandatory authority, the OIG *must* exclude any individual from participation in any federal healthcare program who is convicted of: (1) a program-related crime;⁵⁵ (2) an offense relating to patient abuse;⁵⁶ (3) a felony relating to healthcare fraud;⁵⁷ or (4) a felony relating to controlled substances.⁵⁸

Under the OIG’s permissive exclusion authority, the agency *may* exclude an individual “based on a host of lesser offenses and even affiliations with sanctioned entities.”⁵⁹ In the *Friedman* case, the OIG pursued permissive exclusion under Section (b)(1), which allows the OIG to exclude an individual convicted of a “misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.”⁶⁰ The OIG may also permissively exclude any individual “who has a direct or indirect ownership or control interest in a sanctioned entity⁶¹ and who knows or should know of the action constituting the basis for the [sanction]; or who is an officer or managing employee of such an entity.”⁶²

Although the OIG has relied upon this paragraph only approximately 30 times since 1996, mostly against individuals who controlled small businesses,⁶³ the OIG issued guidance⁶⁴ in October 2010 on its permissive exclusion authority under Section 1320a-7(b)(15), “which encourages greater consideration and use of this power”⁶⁵ to exclude executives. The OIG released the guidance while the Purdue executives’ case was pending.

The guidance explains that the OIG will exercise a presumption in favor of exclusion under section (b) (15) where there is evidence that an owner, officer, or managing employee⁶⁶ knew or should have known of the conduct leading to the exclusion or conviction of the entity, unless “significant factors” weigh against exclusion. In the absence of such evidence, the “OIG will apply the enumerated nonbinding factors in determining whether to exclude an officer or managing employee.”⁶⁷

First, the OIG will consider the “circumstances of the misconduct and seriousness of the offense,” which includes (a) the nature and scope of the misconduct and any related misconduct; (b) the level within the entity at which the misconduct occurred;⁶⁸ (c) the nature and scope of criminal and civil sanctions imposed on the entity; (d) whether the misconduct resulted in actual or potential harm to beneficiaries or financial harm to any persons or programs; and (e) whether the misconduct was an isolated incident or part of larger pattern of wrongdoing. Second, the OIG will consider the “individual’s role in 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.⁶⁹

Third, the OIG will consider the “individual’s action in response to the misconduct.”⁷⁰ This includes 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; and whether the individual disclosed the misconduct to the appropriate authorities and cooperated with investigators and prosecutors. If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, the OIG may consider this as a factor weighing against exclusion. Finally, the OIG will consider “information about the entity,” including any previous sanctions or convictions by any federal or state government; and the size and corporate structure of the company.⁷¹ Despite these criteria, the OIG may still exclude officers and managing employees “based solely on their position within the entity.”⁷²

The FDA’s updated Regulatory Procedures Manual outlined the use of similar criteria. For example, the Manual provides that when considering prosecution against a corporate official, the FDA should 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.”⁷³ The FDA clarified that “[k]nowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant.”⁷⁴ The Manual also added a non-exhaustive list of other considerations, many relating to the nature of the violation.⁷⁵ Consequently, federal healthcare enforcement authorities have used the OIG’s permissive exclusion guidance and the FDA’s recently updated Manual to prosecute several corporate officers in the last few years.

Examples of the OIG’s Exclusion Efforts Against Corporate Executives

Shortly after issuing its guidance, the OIG expressed its intent to expand the application of section

(b)(15) to exclude executives of large complex organizations such as a drug or device manufacturer. One reason for the OIG’s decision to expand (b)(15)’s application to executives was because the agency was “concerned about criminal conduct” and maintained that its remedy in civil cases – CIAs – was “not sufficient to protect programs going forward and provide a deterrent.”⁷⁶

Demonstrating its intent, the OIG first used (b)(15) to exclude Marc Hermelin,⁷⁷ former Chairman of the Board and Chief Executive Officer of KV Pharmaceutical Co., on November 18, 2010.⁷⁸ On December 7, 2010, Gregory Demske, Assistant Inspector General, characterized this exclusion as a “preview of things to come.”⁷⁹

Interestingly, Hermelin was not charged or convicted at the time of his exclusion. Instead, the OIG pursued his exclusion because Hermelin “was identified in the information in the criminal conviction;” there was evidence that he “was involved in what the company pled guilty to;” and there was evidence that Hermelin had made certain determinations about what to report and what not to report to the FDA.⁸⁰ Hermelin eventually pled guilty in March 2011 to two counts of misdemeanor misbranding as a responsible corporate officer, was sentenced to 30 days in jail, and ordered to pay \$1.9 million in fines and forfeitures.⁸¹ Like the Purdue executives, however, the government did not charge Hermelin with personal knowledge or intent.⁸² KV itself could have faced mandatory exclusion as well for being controlled and owned in majority by Hermelin; however, the OIG did not seek exclusion of KV once Hermelin divested himself.⁸³

The OIG also proposed excluding Howard Solomon⁸⁴ of Forest Pharmaceuticals⁸⁵ under Section (b)(15). Unlike the executives in the *Friedman* case who had admitted to misdemeanor criminal conduct pursuant to the RCO doctrine, Solomon had not admitted to any criminal intent or

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failures and was never charged. Thus, the OIG’s proposed exclusion was based solely on Solomon’s position as a “responsible corporate officer” and that he was “associated with” Forest.⁸⁶ The *Wall Street Journal* reported that the attempt was “raising alarms in that industry and beyond about a potential expansion of federal involvement in the business world.”⁸⁷ The OIG, however, dropped the exclusion action against Solomon without any explanation.⁸⁸ Interestingly, the OIG also contemplated excluding seven other top executives of Forest and informed the company of this possibility in September 2010.⁸⁹

The OIG also has not yet pursued the exclusion of Gary Osborn, owner of Apothécure Inc., a compounding pharmacy.⁹⁰ Osborn pleaded guilty under the RCO doctrine to two counts of misbranding and was sentenced to one year of probation, which included 90 days of home detention, and a \$100,000 fine.⁹¹ The criminal conduct involved the death of three patients in 2007 who died because of a colchicine⁹² overdose, which Apothécure compounded. Osborn admitted that as owner, he was “responsible for the procedures and equipment” and for ensuring that drugs were compounded properly. However, neither the criminal information nor agreed-upon facts presented to the court mention that “Osborn was aware of any discrepancies with respect to the manufacture” of the drug or aware “of specific issues related to inadequate procedures or deficient equipment in the intravenous lab (IV lab).”⁹³ The OIG did exclude Michael Dinkel, owner and president of Drew Medical, Inc., a diagnostic imaging services provider in Orlando, Florida, for improper billing and false claims.⁹⁴ Interestingly, the OIG excluded Dinkel under section 1320-a7(b)(7) without a criminal conviction⁹⁵ and “[p]rior to the civil settlement, OIG notified Dinkel that OIG intended to exclude him.”⁹⁶

Additionally, the OIG imposed a five-year exclusion on the former CEO of InterMune, W. Scott Harkonen, M.D., in August 2011, after he was sentenced for wire fraud for the creation and dissemination of a press release to the public that contained false and misleading information about the efficacy of Actimmune (Interferon gamma-1b) as a treatment for idiopathic pulmonary fibrosis (“IPF”).⁹⁷ Although the clinical trial had failed, InterMune’s press release falsely stated that the results of the clinical trial established that Actimmune helped IPF patients live longer.⁹⁸

Harkonen was convicted in a September 2009 trial and sentenced in April 2011 to three years probation, six months of home confinement, a \$20,000 fine, and 200 hours of community service. Federal prosecutors, however, had urged ten years’ imprisonment and a \$1 million fine, maintaining in their sentencing memorandum that “executive suites and board rooms of drug companies across the U.S.” would recognize a “substantial sentence,” which would “deter current and future officers of drug companies.”⁹⁹ Consequently, the U.S. Court of Appeals for the Ninth Circuit recently upheld Harkonen’s conviction for wire fraud, rejecting his argument that the press release “expressed a scientific view” that is protected by the First Amendment.¹⁰⁰ Harkonen’s attorneys indicated that he will seek en banc review of his case.¹⁰¹

As a result of the conviction, Harkonen’s exclusion was mandatory under section 1128(a)(3) because he was convicted of a felony “related to fraud...in connection with the delivery of a health care item or service.”¹⁰² Harkonen, however, challenged his exclusion to the HHS Departmental Appeals Board (“DAB”), arguing that his wire fraud conviction did not have a connection to *delivery* of a healthcare item or service. Specifically, Harkonen argued that the OIG

could not show that the statements in the press release “affected a single physician’s decision to prescribe Actimmune.”¹⁰³ He maintained that the Administrative Law Judge (“ALJ”) erroneously found a connection by relying on a “purely hypothetical ‘potential impact’”¹⁰⁴ and speculating that the charged statements *could* have caused a physician to prescribe Actimmune, despite the lack of evidence that any physicians wrote prescriptions based on the statements.¹⁰⁵ Harkonen explained how the “potential impact” could only materialize if “multiple contingencies occurred,” the possibility of which was “highly speculative.”¹⁰⁶

Harkonen further argued that the ALJ’s factual findings of a potential or *intended* impact on delivery lacked evidentiary support because (1) the jury acquitted him of the misbranding charge; (2) the district court found that the government had failed to prove that the wire fraud offense caused or was intended to cause a physician to write a single prescription of Actimmune; and (3) the ALJ misconstrued the press release.¹⁰⁷ Accordingly, Harkonen asserted that because the statements did not have any impact on patients or insurers,¹⁰⁸ the requisite connection to delivery of healthcare services or items was missing, and therefore exclusion was improper.¹⁰⁹ Harkonen also asserted that his exclusion violates the Fifth Amendment’s Double Jeopardy Clause¹¹⁰ and the Eighth Amendment’s protections against cruel and unusual punishment.

The OIG responded that because such statements were made “in an attempt to increase the sale” of Actimmune and in fact resulted in a “dramatic increase in sales” the year the press release was issued, the statements for which Harkonen was convicted of had a connection with the delivery of a healthcare item or service.¹¹¹ The OIG maintained that the “exclusion statute does not require a direct connection between

the conviction and the delivery of a specific health care item or service, but instead requires a ‘nexus’ or ‘common sense analysis’ of whether the offense had a connection with the delivery of a health care item or service.”¹¹² Accordingly, the OIG asserted that because the press release “was intended to encourage physicians to prescribe, and patients to take, Actimmune,”¹¹³ such a nexus existed. The OIG argued that the DAB interprets the phrase “in connection with” to have the same meaning as “related to” and construes both terms broadly, relying on the D.C. Circuit’s broad interpretation of such terms in *Friedman*.¹¹⁴ Specifically, the OIG argued that such broad construction “does not require that the offense result in a delivery and therefore does not require an actual delivery of an item or service.”¹¹⁵

The DAB rejected Harkonen’s arguments and sustained his exclusion.¹¹⁶ The DAB maintained that “the conduct underlying the criminal offense does not necessarily have to involve [the] *actual delivery*...of a health care item or service to the patient or beneficiary” for the OIG to exclude an individual under section 1128(a)(3).¹¹⁷ The DAB reasoned that while “financial misconduct generally is not part of the actual delivery of the item or service...it is related to payment for...an item or service... that was *intended* to be delivered.”¹¹⁸

Further, the regulations interpreting section 1128(a)(3) recognize that exclusion is proper “even if the individual’s offense does not involve his/her personally delivering an item or service as an element of the offense.”¹¹⁹ Thus, as long as the fraud is “linked in a rational way to the delivery of a health care item or service,” that offense falls under the exclusion statute.¹²⁰ The DAB also concluded that the exclusion did not violate the “Double Jeopardy Clause or the prohibition against cruel and unusual punishment” because exclusions are “remedial in nature” and

necessary to “protect federal health care programs and their beneficiaries from individuals who have been shown to be untrustworthy.”¹²¹ The DAB upheld his exclusion because the evidence showed that Harkonen was “untrustworthy in representations he made or *caused to be made*” about Actimmune.¹²² Harkonen has filed suit in the U.S. District Court for the Northern District of California seeking to overturn the exclusion.¹²³

Moreover, the OIG excluded four former Synthes, Inc. executives under section (b)(1) on October 18, 2012. The exclusions came almost a year after the four executives were sentenced to prison¹²⁴ for their misdemeanor pleas as “responsible corporate officers” for introducing two misbranded devices – Norian XR and Norian SRS, bone cement products – into interstate commerce.¹²⁵ The company and the executives pled guilty in 2009. The government alleged that the four Synthes executives conducted “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.”¹²⁶

The government introduced evidence of the executives’ “false,” “fraudulent,” “deceptive,” and “intentionally deceiving” conduct, convincing the judge that there was an “unparalleled” “pattern of deception.”¹²⁷ The court characterized the scale of the executives’ deception as “extreme” and recognized that “[n]o similar set of facts [could] be located in the universe of *Park* doctrine cases,”¹²⁸ which in turn contributed to his sentencing three of the defendants to prison terms above the federal sentencing guidelines.¹²⁹ Thus, unlike the Purdue executives and unlike the “standard *Park*-doctrine behavior, in

which an unaware corporate official is held strictly liable for the conduct of his subordinates,” the conduct here involved the “direct, knowing, intelligent and intentional choices” made by the executives.¹³⁰

Two other incidents involving potential FDCA violations are also worth examining because of the potential implications they may have on future prosecutions of corporate executives. First, in 2010 the government indicted Lauren C. Stevens, former associate general counsel for GlaxoSmithKline (“GSK”) on several counts regarding her involvement in various interactions and exchanges with the FDA regarding drugs the agency was investigating for off-label promotion.¹³¹ Stevens raised an advice of counsel defense¹³² and while her investigation was pending, sought disclosure of “grand jury transcripts to determine whether the government properly instructed the grand jury” on this defense.¹³³ Although this indictment was dismissed, the government indicted her again on the same charges shortly after.¹³⁴

At trial, the judge acquitted her, asserting that the case “should never have been prosecuted” and that it raised “serious implications for the practice of law.”¹³⁵ Importantly for in-house and outside counsel of pharmaceutical companies, the court recognized the “enormous potential for abuse in allowing prosecution of an attorney for the giving of legal advice.”¹³⁶ As a result, the decision called “into question the wisdom, in a complex regulatory setting, of using non-administrative tools – and particularly criminal process – to secure individual compliance.”¹³⁷

The second incident, in 2012, involved the government’s failed prosecution of Stryker Biotech Corporation and several of the company’s national sales directors and regional managers for off-label promotion and concealment of adverse events.¹³⁸ The government alleged that Stryker had deliberately misled surgeons and put

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patients at risk through off-label promotion, and claimed to have evidence that the individuals knew doctors were being misled.¹³⁹ Despite strong claims from the government, defense counsel for Stryker revealed that federal prosecutors “had failed to speak with any of the surgeons...or victims.”¹⁴⁰ Instead, defense counsel spoke with the surgeons who were willing to testify that no fraud or deceit had occurred; in fact, the first witness testified that “doctors mixed the two products in question, because that is consistent with medical practice, not because they had been influenced by Stryker Biotech sales reps.”¹⁴¹ As a result, the government dismissed all charges against the individuals, including Mark Philip, who was president from 2004 to 2008, and settled the case against the company with a single misdemeanor count of misbranding a medical device.¹⁴² U.S. Attorney Carmen Ortiz explained that “doing justice meant dismissing the charges, rather than subjecting these individuals to a protracted trial where the government could not put its most effective case before the jury.”¹⁴³

On the Horizon: The OIG’s Next Steps

Pharmaceutical executives may face even greater risk of exclusion in the future, particularly because the Department of Justice (“DOJ”) has expressed increased interest in pursuing “individuals responsible for illegal conduct just as vigorously” as the agency pursues corporations.¹⁴⁴ In fact, Nathaniel Yeager, Health Care Fraud Chief of the U.S. Attorney’s Office in Boston, “said that he was in regular dialogue with HHS OIG on... issues of exclusion.”¹⁴⁵ Initially, the OIG excluded Hermelin before he was convicted due to evidence tying him to the illegal conduct KV pled guilty to. The OIG next excluded the Purdue executives after they accepted misdemeanor pleas under the RCO doctrine for misbranding under the

FDCA. The OIG most recently excluded the Synthes executives after their convictions under the RCO doctrine.

The “next logical step” beyond KV and Forest, according to current Chief Counsel to the Inspector General Gregory Demske, is to “exclude someone based on the fact [that] they had been in a position of responsibility at a corporation when a crime occurred, without...admission [that] the individual was involved.”¹⁴⁶ The OIG essentially attempted this approach with Forest and Solomon, but the facts of that case may not have been strong enough to pursue under Demske’s new proposal, which may explain why the agency backed down.

Nevertheless, Demske indicated that the OIG was presently considering cases to determine when excluding an executive would be appropriate, and said the agency would use its permissive exclusion guidance¹⁴⁷ in determining whether to proceed. Moreover, in its Top Management Concerns, the OIG asserted that it would consider “cases in which excluding responsible corporate officers of sanctioned providers and suppliers is appropriate” and will monitor “the effect of such an exclusion on recidivism.”¹⁴⁸ The OIG, however, said it would not go back in time to previously settled cases and would only pursue this option with “respect to companies that were on notice before they entered a plea or settlement.”¹⁴⁹ Despite the potentially increased risk to executives of exclusion, the OIG likely will face difficulty bringing such actions without new exclusion authority because sanctioned entities typically have a new CEO and executive suite by the time the entity settles with a criminal conviction.

Specifically, the OIG can “only pursue [exclusion of] a person who is in office of a convicted entity.”¹⁵⁰ The agency cannot “reach the former

CEO”¹⁵¹ because under section 1320 a-7(b)(15), the OIG may only permissively exclude an individual “who has a direct or indirect ownership or control interest in a sanctioned entity...or who is an officer or managing employee of such an entity.”¹⁵² Thus, the OIG cannot permissively exclude a corporate executive or officer under section (b) (15) who no longer has a direct or indirect ownership or control interest in the sanctioned entity or is no longer an officer or manager of the sanctioned entity. As a result, the universe of potential executives subject to exclusion is limited, despite Senator Grassley’s attempt to expand the OIG’s permissive exclusion authority to individuals with past ownership or control interests in sanctioned entities or who were past officers or managing employees.¹⁵³ The court in *Friedman*, however, expanded the potential reach of exclusion for corporate executives, which may have the effect of changing and improving how executives manage and oversee pharmaceutical companies.

Finally, corporate executives may face new threats of exclusion by the OIG under the recently finalized regulations implementing the Physician Payment Sunshine Act – section 6002 of the Patient Protection and Affordable Care Act (“PPACA”).¹⁵⁴ In general, the “Sunshine Act” requires applicable manufacturers of drugs, devices, biologicals, or medical supplies (“AMs”) covered under Medicare, Medicaid or the Children’s Health Insurance Plan (“CHIP”) to report annually to the Centers for Medicare & Medicaid Services (“CMS”), in an electronic format, certain payments or other transfers of value (e.g., travel or meals) to covered recipients – physicians and teaching hospitals.¹⁵⁵ CMS or the OIG may penalize AMs that fail to report payments timely, accurately or completely.¹⁵⁶ To ensure compliance, the Sunshine Act requires specified corporate

executives to attest to the accuracy and completeness of the reported payment information.¹⁵⁷ Due to the tremendous amount of payments that companies will have to track and report, errors, inaccuracies, and omissions are inevitable and the OIG may impute these to the attesting officer.¹⁵⁸

For example, the OIG may take a broad interpretation of a knowing failure to report or correct a payment as a program-related crime that requires mandatory exclusion, given that CMS is implementing the Sunshine Act, coupled with the broad definition of “related to the delivery of a healthcare item or service” and the Act’s legislative history and purpose to protect the integrity of payments made by CMS.¹⁵⁹ Thus, an officer attesting to or an employee contributing to such inaccurate reporting could have committed a program-related crime, which could result in a mandatory exclusion under 42 U.S.C. § 1327a-7(a)(1). Alternatively, the OIG could consider a reporting violation as a failure to supply payment information,¹⁶⁰ a failure to disclose required information regarding ownership,¹⁶¹ or an offense “relating to fraud...or other financial misconduct,”¹⁶² which could result in a permissive exclusion. If an entity is sanctioned for non-compliance with the Sunshine Act, the OIG may also use section 1327a-7(b)(15) to exclude a certifying officer who submitted the inaccurate payment reports and should have known that such reports had errors or omissions.

Friedman’s Expansion of Exclusion Under the RCO Doctrine

The three Purdue executives appealed the OIG’s 20-year exclusion determination to an ALJ. While on appeal, the OIG reduced the exclusion to 15 years because the executives had assisted law enforcement authorities to “combat abuse of OxyContin.”¹⁶³ The ALJ affirmed the 15-year exclusion as

being within a “reasonable range.”¹⁶⁴ The executives appealed this decision to the DAB, which affirmed the exclusion, only reducing its length to 12 years because there was no substantial evidence that the misbranded Oxycontin had any adverse effect on program beneficiaries and others.¹⁶⁵ The Purdue executives then sought review in the U.S. District Court for the District of Columbia, which also upheld the exclusion.¹⁶⁶ On appeal to the D.C. Circuit, the *Friedman* case presented the question of whether the phrase “misdemeanor relating to fraud” in section 1320a-7(b)(1)(A) refers to a (1) generic criminal offense – the categorical approach – or (2) to the facts underlying the particular defendant’s conviction – the circumstance-specific approach.¹⁶⁷

The categorical approach “prohibits the later court from delving into particular facts disclosed by the record of conviction” and directs that court to “look only to the fact of conviction and the statutory definition of the prior offense,” including the elements of that offense.¹⁶⁸ Under the “circumstance-specific” approach, by contrast, the statutory term refers to the particular conduct giving rise to the conviction, so the court “must look to the facts and circumstances underlying an offender’s conviction” to determine whether that conviction is covered by the statute.¹⁶⁹ The Appellate Court reasoned that the text, structure, and purpose of the exclusion statute indicated that the Secretary’s circumstance-specific approach was proper. The Court, however, noted a “split in authority on the question whether to defer to an agency’s interpretation of a term drawn from criminal law but used in a statute the agency administers.”¹⁷⁰

The key phrase in the exclusion statute the Court used to uphold the executives’ exclusions was “relating to,” which the court broadly defined as “stand[ing] in some relation; to have bearing or concern; to pertain; refer; to bring

into association with or connection with.”¹⁷¹ Using this definition, the Court reasoned that “relating to” includes any criminal conduct that has a factual “connection with or reference to” fraud.¹⁷² The Court explained that “relating to fraud” modifies “misdemeanor” and that a “conviction” meant a particular event on a particular occasion and “so refers to a set of facts, and not to a generic crime.”¹⁷³ Consequently, the Court explained that “[m]isdemeanor misbranding does not necessarily require a culpable mental state” like generic misdemeanors “because a conviction for the offense may be, and in this case was, predicated upon the responsible corporate officer doctrine, which entails strict liability.”¹⁷⁴

Pointing to the “broad scope” of section 1320a-7(b)(1)(A), the Court used three examples to support its position. First, the Court maintained that exclusion for a misdemeanor relating to “other financial misconduct” “expressly refers to a type of ‘conduct,’ not to a genus of criminal offense.”¹⁷⁵ Therefore, the term “misdemeanor” refers to the “particular circumstances of an individual’s conviction, and ‘relating to’ must denote a factual relationship between the conduct underlying the misdemeanor and the conduct underlying a ‘fraud.’”¹⁷⁶

Second, the Court reasoned that the limiting clause in section 1320a-7(b)(1)(B) “does not pick out a generic class of offenses because there is no generic crime of defrauding a program other than a healthcare program financed in whole or in part by a government agency.”¹⁷⁷ As a result, the Court explained that the “criminal offense” must “relate to fraud” because it has a factual relationship to conduct involving a program financed by a government agency, committed on a particular occasion.

Third, the Court explained that the phrase “the use of funds” in section 1320a-7(b)(2)(ii) does not refer to a generic offense and therefore

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must refer to specific facts on a particular occasion. As a result, the Court maintained that “related to” in this provision denotes a factual connection between an “investigation or audit” and “the use of funds.” Accordingly, the Court asserted that “[t]he only reasonable interpretation is that in all three provisions the phrases refer to a factual relationship.”¹⁷⁸ The Court also reasoned that the heading of section 1320a-7(b)(1) (“Conviction relating to fraud”) further supports this reading of the provision.

The Court then evaluated the three aggravating factors that the OIG relied on to exclude the executives for 12 years: (1) the conduct underlying the convictions lasting more than one year, (2) the amount of the financial loss, and (3) the significant adverse physical or mental impact upon program beneficiaries. First, the Court rejected the executives’ argument that there was no financial loss because Purdue paid \$160 million in “restitution,” which the executives admitted responsibility for and because Purdue generated almost \$3 billion in revenues from OxyContin during the time it misbranded the drug, much of which came from federal and state healthcare programs that would not have been paid for but for the misbranding.¹⁷⁹

Second, while the executives’ violations consisted solely of omissions, rather than “acts,” the Court concluded that HHS’ interpretation equating the two terms when only “acts” are proscribed was a permissible one.¹⁸⁰ Third, the Court rejected the executives’ argument that HHS gave insufficient weight to their cooperation with law enforcement agencies because the executives did not show that the Secretary had abused her discretion.¹⁸¹

The Court however, agreed with the executives that there was substantial

evidence that HHS did not take into account the executives’ lack of “conscious wrongdoing” as a mitigating factor.¹⁸² The Court also found that the length of the executives’ exclusion was arbitrary and capricious because (1) every case cited by HHS involved a mandatory exclusion with a presumptive baseline of five years, not a discretionary exclusion with a presumptive baseline of three years; (2) every case cited involved either a felony or Medicare fraud conviction for which the defendant was incarcerated, which was not present in this case; and (3) “none of the cases cited even concerned an exclusion under section 1320a-7(b)(1),” and HHS “had never excluded anyone for more than ten years” based upon a misdemeanor; the longest was four years.¹⁸³ The Court explained that “simply pointing to prior cases with the same bottom line but arising under a different law and involving *materially different* facts does not provide a reasoned explanation for the agency’s apparent departure from precedent.”¹⁸⁴

Subsequently, the Purdue executives argued that a rehearing en banc was justified because the “splintered panel” adopted a circumstance-specific approach that ignored the decisions of three circuits,¹⁸⁵ which all held that “‘offense relating to [specified misconduct]’ in another exclusion statute requires a ‘categorical’ analysis – *i.e.*, the elements [not the facts] of the conviction...must ‘relate to’ the specified misconduct.”¹⁸⁶ Specifically, the executives argued that “exclusion is authorized for an *offense* consisting of a misdemeanor relating to fraud,” and that the “offense,” not the factual basis for a conviction, must “relate to” fraud.¹⁸⁷ Further, the executives asserted that the majority’s rationale adopted an expansive “nexus” test with “no meaningful limit” that will have “sweeping implications for individual liberty interests” and conflicts “with Supreme Court Precedent.”¹⁸⁸

The executives also argued that “by sustaining HHS’ application of its ‘financial loss’ aggravating factor¹⁸⁹... the majority” failed to explain or identify any methodology HHS used to determine how the executives’ omissions caused more than \$5,000 in financial losses or how such losses justify a 12-year exclusion.¹⁹⁰ The executives argued that the company-negotiated restitution had “no connection to actual losses”¹⁹¹ and Purdue’s revenues for OxyContin sales could not “substitute for a finding of losses under a rational methodology... since most sales did not result from misbranding, which had no adverse effect on beneficiaries.”¹⁹² Because the record contained “no evidence of what the losses were” and HHS “did not articulate any comprehensible method to estimate the losses,” the executives argued that such “‘whimsical...reasoning’ be rejected.”¹⁹³ Finally, the panel erred in not giving the terms “acts” and “omissions” “distinct meanings” when the “exclusion statute and HHS regulations repeatedly distinguish” such terms.¹⁹⁴ Accordingly, these aggravating factors were inapplicable because the executives “were convicted only for omissions,” and thus, any equation of these two terms was unwarranted because repeated distinctions make the language of the regulation unambiguous.¹⁹⁵

In response, the government replied that the use of a categorical approach for “different provisions in wholly unrelated statutes does not warrant further review.”¹⁹⁶ The government maintained that section 1320a-7(b)(1) expressly considers “conduct, reflecting that Congress cared about what Federal health care program participants have *done* rather than the elements of the crime with which they were charged.”¹⁹⁷ In fact, section (b)(1) “contains no reference to the elements of an offense.”¹⁹⁸ Moreover, the government argued that “no generic crime of ‘financial misconduct’” exists and that the use

of “offense” and “crime” in the statute “encompass the underlying acts, context and circumstances,” allowing courts to look at “the facts and circumstances underlying the offender’s conviction to determine if the offense is within the scope of the statute.”¹⁹⁹ Further, the government maintained that a “circumstance-specific approach ensures that the Secretary can deter and redress” financial misconduct and breaches of fiduciary responsibility that bear on “professional competence [and] performance, or financial integrity,” which raise questions about “trustworthiness and reliability.”²⁰⁰

The government also asserted that while the three circuit courts used a categorical approach for an immigration statute, “those cases do not govern every statute that includes the phrase ‘related to’” and thus, there is no circuit split.²⁰¹ In addition, the government argued that the panel properly interpreted “relating to” as meaning “[to] have a connection with or reference to” which allows courts to examine the facts and conduct underlying the conviction. The government asserted further that the financial loss-aggravating factor only required a “reasonable *expectation* that the conduct would cause losses over \$5,000,” which was demonstrated by the \$159 million settlement and executive bonus disgorgement.²⁰² Finally, the government maintained that exclusions based on “culpable omissions” was consistent with “binding precedent” and was a proper interpretation of the exclusion statute for the “regulatory purpose of predicting future trustworthiness based largely on the extent and effects” of the executives’ criminal behavior.²⁰³ Consequently, the D.C. Circuit denied the executives’ petition for rehearing en banc without an opinion.²⁰⁴

Recommendations for the Industry

The *Friedman* case, coupled with the OIG’s recent trend of excluding

executives, will have significant repercussions for those in the health-care industry for several reasons. First, the decision likely will deter corporate healthcare executives from agreeing to pleas under the RCO doctrine because doing so could lead to exclusion, which would effectively end their careers even where the exclusionary period is significantly less than 12 years. As a result, it may be more difficult for the government and corporate defendants to resolve these types of cases through pleas, which may lead to increased litigation and related costs. Executives, however, may still be forced to accept a misdemeanor plea because prosecutors may threaten them with indictments under a felony charge, which could result in jail time as well as *mandatory* exclusion.²⁰⁵ They may also face pressure from corporate boards or shareholders to “take one for the team.”²⁰⁶

Second, a plausible defense under the RCO doctrine is extremely difficult. The government need only prove that the executive had supervisory authority at the time the underlying violations took place to convict senior executives of an RCO offense. This would be easy for prosecutors “once the underlying violations have been proven or admitted to by the corporation.”²⁰⁷ Moreover, although *Park* created the defense of objective impossibility,²⁰⁸ such a defense is impractical.²⁰⁹ As a result, executives faced with this situation may want to “obtain advice from counsel separate from the company’s counsel.”²¹⁰

Third, “before an organization pleads guilty, all counsel should scrutinize language in the statement of the offense to reduce the quantity as well as the quality of admissions that could be used against an executive” not only at sentencing, but also in a debarment or exclusion proceeding.²¹¹ Companies that want to protect their executives from exclusion may want to refuse to agree to plea facts “suggesting false, misleading or deceptive

promotional practices by the company.”²¹² This is particularly important because a guilty plea may have collateral consequences related to “sentencing, business decision making, shareholder derivative actions, and Directors and Officers (“D&O”) insurance policies.”²¹³ For example, U.S. Sentencing Guidelines provide for multiple level enhancements for healthcare fraud offenses involving losses exceeding \$1 million.²¹⁴

Additionally, counsel must investigate and advise clients about how a criminal charge may affect the status of a medical license.²¹⁵ State law and the rules of the applicable professional licensing board govern licensure matters, and under such laws, offenses associated with healthcare fraud may raise issues of “moral turpitude.”²¹⁶ Accordingly, counsel should advocate during settlement negotiations for “the particular offense that best promotes the defendant’s chances for avoiding loss of licensure.”²¹⁷

Fourth, publicly traded pharmaceutical companies must implement a comprehensive strategy for dealing with shareholders, particularly those with significant holdings, due to the potential challenges such shareholders may bring if corporate executives are implicated in criminal charges that may lead to exclusion. For example, in the case of the OIG’s proposed exclusion of Forest CEO Howard Solomon, business magnate Carl Icahn – who had acquired about seven percent of Forest stock – nominated four directors to the Forest board.²¹⁸ In addition, the union giant AFL-CIO, which also controls a significant number of shares in Forest Labs,²¹⁹ called for Solomon’s resignation and urged shareholders to “withhold” their vote for him.²²⁰ Accordingly, companies should have in place clear and transparent policies and procedures for dealing with the potential suspension or removal of board members or executives facing charges or exclusion to avoid further disruption from shareholders and uncertainty from investors.

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Fifth, executives may be less likely to plead to misdemeanors without assurances from the OIG as to exclusion. As a result, defense counsel should focus on achieving a global resolution early in negotiations by engaging all government agencies involved, and if possible, to negotiate a waiver of exclusion/debarment.²²¹ Accordingly, counsel should request a decision from the OIG about exclusion before any individual or organization pleads guilty, similar to how corporate defendants negotiate the terms of their CIAs before entering criminal pleas or civil settlements. “This request should be made even when an investigation is closed without a guilty plea because the OIG’s authority to seek permissive exclusion does not require a criminal conviction.”²²² The OIG likely will “resist the request for an advance decision about exclusion by claiming that it cannot exercise its discretion until after the resolution of criminal and civil matters.”²²³

This argument, however, is problematic because the OIG makes decisions about exclusions for companies before such cases are resolved by knowing enough about the investigation to accept the terms of the CIA. Moreover, the case of Michael Dinkel is precedent that the OIG will make a decision about exclusion before accepting a settlement.²²⁴ Additionally, defense counsel may “argue that a timely decision about exclusion is a matter of due process because the parties need to evaluate the true impact of a proposed agreement with the government.”²²⁵ If the OIG continues to refuse, defense counsel should negotiate a way to limit “the number of individuals or the types of positions that might be considered for permissive exclusion,” and should ask the OIG to render exclusion decisions “within a certain period of time so that the organization and the individuals can plan their futures accordingly.”²²⁶

Sixth, individuals and companies must proactively avoid debarment by the FDA, which requires the agency to refuse accepting any drug applications from the individual or entity.²²⁷ For the most part, an FDA debarment has effects similar to exclusion in that a debarred individual cannot assist or provide services (either indirectly or through employment) “in any capacity”²²⁸ for a company that has an approved or pending drug application with the FDA.²²⁹ The mandatory provisions direct the FDA to debar an individual who has received a felony conviction for misconduct relating to the development, approval, or regulation of a drug.²³⁰ The regulations also give the FDA the discretion to permissively debar an individual for up to five years for receiving a federal misdemeanor or state felony conviction for conduct relating to the development, approval, or regulation of drug products, or if such individual has been convicted of a felony unrelated to regulation of drugs that involves certain crimes.²³¹ The FDA may consider several factors in determining debarment length.²³² As there may be increased risk for debarment given the FDA’s recent reforms that have improved the “quantity, efficiency, and transparency of its debarment actions,”²³³ counsel should negotiate to avoid such actions.

Seventh, Lauren Stevens’ experience offers several important factors for in-house and outside counsel and drug companies to consider moving forward given the increased potential use of the RCO doctrine. Specifically, companies and counsel should (1) work closely with a multi-disciplinary team of attorneys who understand the government entity with which they are dealing; (2) encourage company counsel to carefully consider whether outside counsel should sign any submissions to government agencies; (3) keep dialogue and tone with

government civil; (4) draft any written product – particularly those being submitted to the government – with an eye toward how a criminal investigator would interpret the writing with full benefit of hindsight;²³⁴ (5) engage outside counsel early on in an investigation to take advantage of the attorney-client privilege and advice of counsel defense; (6) make clear to government officials from the outset that the company will be relying on advice of outside counsel; (7) create a paper trail that documents the investigation process followed by in-house counsel at the advice of or in coordination with outside counsel;²³⁵ and (8) “thoroughly document not only identified problems, but also the responses to those problems.”²³⁶

Additionally, although it may be difficult for other companies to apply the Stryker Biotech case to their own situation because of the unique factual circumstances, several problems the government faced in that case may be useful for counsel to consider. To the extent facts or evidence allow such arguments, counsel should look for opportunities to (1) emphasize the highly technical nature or skilled training requirements of a product that make a company’s influence over an individual difficult to prove; (2) demonstrate the safety of a product through adverse event reporting and detailed analysis of whether such reports are minor; (3) show that relationships between sales representatives and physicians are long-term; and (4) point to market competition and undermine notions of maximizing short-term sales.²³⁷

Finally, to determine particular risk exposure, companies should identify high-risk policies, practices, and business lines as part of a comprehensive risk management and mitigation program – requirements that many CIAs already include. There should

also be a procedure to “establish a rapid response team to immediately assess and contain any compliance failure, as well as to escalate, resolve, and self-report those failures as warranted.”²³⁸ When such failure has 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.”²³⁹ Moreover, companies should establish policies and procedures for “creating a comprehensive record of corrective actions taken in response to compliance incidents and which senior personnel” take such actions.²⁴⁰

Companies should also establish a system for periodic audits to identify variations from company policies and procedures and to determine, based on audit findings, when such policies and procedures “should be re-assessed and personnel should be re-trained for compliance.”²⁴¹ Further, companies should consider requiring relevant employees, officers, and executives to “annually re-certify their understanding of and compliance with the relevant policies and procedures.”²⁴² This is particularly important given that OIG Chief Counsel Gregory Demske recently emphasized that effective healthcare boards are “active,” “raise questions,” “stay informed on risk areas,” “learn of *all* significant compliance issues,” and “attend compliance training and speak to staff about compliance.”²⁴³ Companies may even want to pursue RCO insurance policies to “mitigate the economic loss of an RCO prosecution or debarment.”²⁴⁴ Finally, executives and employees responsible for transparency and payment reporting must exercise due diligence and establish explicit checks and balances at every level of data collection to reduce potential individual liability.²⁴⁵

Conclusion

Ultimately, the *Friedman* case underscores “the government’s

expectation that upper management be actively involved in ensuring corporate compliance with federal healthcare laws and regulations.”²⁴⁶ Two factors in the OIG’s guidance on permissive exclusion – the individual’s role and response to the misconduct – demand that corporate executives become integrally involved in their company’s compliance efforts to ensure that affirmative steps are being taken to minimize the risk of misconduct. Moreover, the recently amended Federal Sentencing Guidelines for Organizations emphasize the use of corporate compliance programs to facilitate corporate transformation.²⁴⁷ Six pharmaceutical companies have already developed a “set of principles on the recoupment of executive incentive compensation in the event of corporate compliance or other violations.”²⁴⁸

Now that the OIG has strong precedent in both federal and administrative court upholding executives’ exclusions, coupled with the FDA, the DOJ, and the OIG’s recent emphasis on changing corporate behavior through the RCO doctrine, healthcare executives face new and real challenges. The *Friedman* and other RCO cases demonstrate that a guilty plea could potentially result in exclusion, despite a lack of personal involvement in or even awareness of the alleged misconduct, if there is a factual connection relating to fraud.

Accordingly, healthcare stakeholders will need “to work proactively with the OIG prior to accepting a guilty plea to better assess whether an exclusion proceeding may occur subsequent to conviction.”²⁴⁹ Additionally, companies will need to design, develop, enhance, and implement robust compliance initiatives based on the factors outlined in the OIG’s latest guidance on permissive exclusion, and the fact patterns underlying recent RCO prosecutions, to minimize RCO liability of companies and their executives, officers, and in-house counsel.



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