Clients&FriendsMemo

The Responsible Corporate Officer Doctrine in the Wake of *DeCoster*

May 3, 2017

Executive Summary: The most important *Park* doctrine case in over forty years may be heading to the Supreme Court – but not if the federal government has its way. The Responsible Corporate Officer doctrine ("RCO doctrine"), commonly referred to as the *Park* doctrine, permits the government to prosecute employees for corporate misconduct when they are in a "position of authority" and fail to prevent or correct a violation of the Food, Drug and Cosmetic Act ("FDCA").[1] Not only is it a strict liability offense, it is a vicarious liability offense and is rarely used by the Department of Justice ("DOJ") to seek prison time for supervisory employees.[2] However, an important *Park* doctrine case, *United States v. DeCoster*, is pending potential review by the U.S. Supreme Court and might provide long-sought-after guidance for corporate executives in the food and drug industries.

DeCoster is notable because the company's owner and chief operating officer argue they should not be sentenced to prison since they did not have "actual knowledge" that their egg distribution company sold eggs contaminated with salmonella.[3] In their Petition for Writ of Certiorari, the DeCosters argue that the Eighth Circuit's holding, affirming the conviction and sentencing of both executives to three months imprisonment, gravely expands the RCO doctrine and an innocent supervisor convicted of vicarious criminal liability should not face imprisonment.[4]

As evidence that the DOJ will continue to focus on prosecuting individuals for corporate misconduct, the Fraud Section recently released its Evaluation of Corporate Compliance Programs ("the Evaluation Program"). The 11 topics and list of questions provide insight into how the Department intends to judge compliance programs. Importantly, a company should use the Evaluation Program to strengthen its compliance program so the company and its supervisory employees stay out of the crosshairs of government enforcement actions.

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1 *United States v. Park*, 421 U.S. 658 (1975); *see also* Jose P. Sierra, *The Park Doctrine: All Bark and No Bite*, pharmarisc (Apr. 6, 2012), http://www.pharmarisc.com/2012/04/the-park-doctrine-all-bark-and-no-bite/.

2 21 U.S.C. § 301 et seq.

3 *United States v. DeCoster*, 828 F.3d 626, 629, 631 (8th Cir. 2016).

4 Petition for a Writ of Certiorari, DeCoster v. United States (filed Jan. 10, 2016).

I. Introduction – Strict Liability Under the FDCA

The RCO doctrine targets employees for their company's misconduct. In our increasingly regulated world, the RCO doctrine is a powerful tool for prosecutors to use as a basis for civil and criminal convictions in their quest for individual accountability. Accordingly, health care companies and their executives must be cognizant that misconduct at any level might result in jarring penalties.

United States v. Park and subsequent case law created an attractive mechanism for prosecutors to rein in companies' misconduct because these cases define a "responsible corporate officer" in broad strokes. To punish an employee for their company's bad acts, the government only has to prove that the defendant is within the chain of command and has the authority and responsibility for the business unit in which the violation occurred.[5]

At the same time, prosecutors do not have free rein to indict individuals for their company's illegal conduct. Because *Park* doctrine cases have "nationwide implications," the United States Attorneys' Manual states that United States Attorney Offices "must notify and consult with" the Consumer Protection Branch of the Civil Division ("CPB") before pursuing a *Park* doctrine investigation.[6] Main Justice asserts centralized control over the *Park* doctrine to ensure consistency in cases that do not require personal knowledge to secure convictions.

If the CPB permits prosecutors to use the *Park* doctrine, prosecutors have a fairly easy road to convict executives.[7] On the other hand, a corporate officer might avoid liability where he or she is "powerless to prevent or correct the violation."[8] However, executives who are not aware of or turn a blind eye to wrongdoing are unlikely to skirt liability given the government's low bar for a proper conviction.

II. The FDCA and Strict Liability – the Framework of 21 U.S.C. § 331

The FDCA prohibits someone from "causing" the adulteration or misbranding of any drug in interstate commerce, or "causing" the introduction or delivery for introduction into interstate commerce an adulterated or misbranded drug.[9] Any person who causes the actions in section 331

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5 Brent J. Gurney et al., *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA*, WilmerHale, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwib1qGDg8zRAhWFMyYKHdjWBJ0QFggcMAA&url=http%3A%2F%2Fwww.wilmerhale.com%2FuploadedFiles%2FWilmerHale_Shared_Content%2FFiles%2FEditorial%2FPublication%2FThe_Crime_of_Doing_Nothing.pdf&usg=AFQjCNHJbTLNIeieLVLFta3rIxId5ruQzA&cad=rja [hereinafter *The Crime of Doing Nothing*].

6 4-8.200 - Federal Food, Drug, and Cosmetic Act Litigation, https://www.justice.gov/usam/usam-4-8000-consumer-protection#4-8.200 (last visited Apr. 28, 2017).

7 *United States v. Iverson*, 162 F.3d 1015, 1025 (9th Cir. 1998) ("[A] person is a 'responsible corporate officer' if the person has authority to exercise control over the corporation's activity that is causing the [violation].").

8 *Park*, 421 U.S. at 673.

9 21 U.S.C. § 331(a), (b), (k) (2016).

is guilty of a misdemeanor.[10] Where the government can prove the "intent to defraud or mislead" (or if that person had already been convicted under section 331) the person is guilty of a felony.[11]

A. Strict Liability Under the FDCA

Under the FDCA, the government can secure a conviction when (1) "a prohibited act took place somewhere within the company," and (2) "the defendant's position within the company was one that gave him or her responsibility and authority either to prevent the violation or to correct it" and the defendant failed to do so.[12] In this regard, section 333(a)(1) of the FDCA creates essentially a strict liability offense. The crime requires only a prohibited act,[13] which need not be intentional or reckless, and the defendant can be convicted without having personal knowledge of the prohibited act.[14]

III. The RCO Doctrine's Origins

The RCO doctrine is unique because its roots are in strict and vicarious liability. Thus, courts can hold executives accountable separate from and in addition to charges against their corporation, and penalties can include imprisonment, fines, and disqualification from the company.[15]

The bedrock cases establishing the RCO doctrine are *Dotterweich* and *Park*.

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[10] 21 U.S.C. § 333(a)(1) (2015).

[11] 21 U.S.C. § 333(a)(2).

[12] *Id.*

[13] Section 331 of the FDCA lays out dozens of prohibited acts, including (1) introducing or delivering into interstate commerce an adulterated or misbranded drug or device, (2) making or dispensing counterfeit drugs, (3) altering or removing any food or drug label, if the product is for sale and removing the label results in the product being adulterated or misbranded, (4) operating a food processing or holding facility with foreseeable hazards, or the owner fails to implement and monitor preventative controls.

[14] *See United States v. Park*, 421 U.S. 658 (1975) (finding the CEO of a national grocery store chain liable for food safety violations at a company warehouse, even though the CEO was generally unaware of the violations); *United States v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (holding that three executives who were not personally aware of Purdue's misbranding of OxyContin pleaded guilty to violating the FDCA). *See also The Crime of Doing Nothing*, *supra* note 5. *But see Lady J. Lingerie, Inc. v. City of Jacksonville*, 176 F.3d 1358 (11th Cir. 1999) (striking down the validity of a Jacksonville, Florida ordinance "at least to [the] extent" the government sought imprisonment for a *Park* doctrine offense, because "criminal liability based on respondeat superior is acceptable if the defendant is in a 'responsible relation' to the unlawful conduct or omission, but only if the penalty does not involve imprisonment.").

[15] *Meyer v. Holley*, 537 U.S. 280, 287 (2003) (noting that *Dotterweich* and the responsible corporate officer doctrine was "intended" to cover vicarious liability).

A. *United States v. Dotterweich*[16]

In *Dotterweich*, the Buffalo Pharmacal Company and Joseph Dotterweich, its President and General Manager who controlled the company's daily operations, were charged with violating the FDCA after they placed a misbranded and adulterated drug into interstate commerce.[17]

Importantly, Mr. Dotterweich had no knowledge that the drugs had been shipped.[18] While the trial court acquitted the corporation for charges brought under the FDCA, it found Mr. Dotterweich vicariously liable under the same statute.[19] Following the Second Circuit's reversal, the Supreme Court reinstated the trial court's holding and found Mr. Dotterweich guilty, fining him $500 and sentencing him to 60 days' probation.[20]

In so holding, the Court wrote the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[21]

B. *United States v. Park*[22]

John Park was the President of Acme Markets–a national food store chain–and the government alleged the FDA had repeatedly notified Mr. Park and the company of food safety violations at the company's warehouses.[23] On that basis (detailed below), he was found guilty of violating the FDCA for failing to correct food safety issues at the warehouses and shipping food from those facilities.

As President and CEO of a nationwide retail food chain with over 35,000 employees, almost 900 stores, and 16 warehouses, Mr. Park was generally unaware of the food safety violations. [24] He and Acme, however, received two letters in relation to rodent-infested warehouses.[25] Mr. Park argued that he appropriately handled the problematic conditions: "[h]e identified those individuals responsible for sanitation...[and] he had conferred with the vice president for legal affairs, who

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16 *United States v. Dotterweich*, 320 U.S. 277 (1943).

17 *Id.* at 278.

18 *Id.* at 286 (Murphy, J., dissenting).

19 *Id.* at 278.

20 *Id.* at 285; Stephen Crane & Paige Bennett, *Jail Time for Not Knowing: Strict Liability for Executives Under the Park Doctrine*, Corporate Compliance Insights (July 18, 2016), http://www.corporatecomplianceinsights.com/jail-time-not-knowing-strict-liability-executives-park-doctrine/ [hereinafter *Jail Time for Not Knowing*].

21 *United States v. Dotterweich*, 320 U.S. 277, 280-81 (1943).

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

23 *Id.* at 658.

24 *Id.* at 661, 663.

25 *Id.*

informed him that the Baltimore division vice president 'was investigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter.' [Mr. Park] stated that he did not 'believe there was anything (he) could have done more constructively than what (he) found was being done.'"[26]

Relying on *Dotterweich*, the Court fined Mr. Park $250 for FDCA violations because he had the "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."[27] In other words, Mr. Park was liable because he had at least some control over Acme's misconduct.

IV. Recent *Park* Decisions

Following *Dotterweich* and *Park*, any tension between prosecuting blameless employees for corporate misconduct and the pressure to hold individuals liable for their company's misconduct did not completely deter prosecutions against corporate executives under the RCO doctrine. Summarized below are *Park* doctrine convictions where defendants did not have knowledge of their company's misconduct:

A. *United States v. Purdue Frederick Co., Inc.*[28]

In 2007, the government alleged that the Purdue Frederick Company, the distributor of OxyContin and other drugs, and its supervisors and employees defrauded and misled the public through its marketing and promotion of OxyContin.[29]

In part, the government presented evidence that Purdue trained sales representatives and sponsored trainings to disseminate false messages to encourage OxyContin use.[30] Purdue pleaded guilty to charges of misbranding a drug because it falsely marketed OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.[31]

Meanwhile, the government also charged several Purdue executives–including its CEO–under the FDCA for Purdue's misconduct. Although the government could not show the executives were

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26 *Id.* at 663-64.

27 *Id.* at 674; *Jail Time for Not Knowing*, *supra* note 20.

28 *United States v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569 (W.D. Va. 2007).

29 *Id.* at 570-71.

30 *Id.* at 571.

31 *Id.* at 570.

involved in or knew about the improprieties, the executives were charged and pleaded guilty "based on the fact that they were responsible corporate officials at the time" of the misconduct.[32]

B. *United States v. Hermelin*[33]

In 2011, Marc Hermelin, the former Chairman of the Board and CEO of KV Pharmaceutical Company pleaded guilty to KV Pharmaceutical having violated the FDCA. In 2007 through 2008, KV Pharmaceutical introduced oversized morphine sulfate tablets, a pain relief drug, into interstate commerce.[34] The drugs contained more active ingredients than their labels indicated, making them "misbranded" under the FDCA.[35]

According to the government, KV Pharmaceutical knew but did not inform the FDA that its pill manufacturing machines could randomly produce the oversized tablets.[36] Although Hermelin did not know about the misconduct or intend to violate the FDCA, the government charged Hermelin as a responsible corporate officer because he had the "authority and responsibility to prevent and correct FDCA violations."[37]

Hermelin pleaded guilty to misdemeanor misbranding charges, and he was sentenced to 30 days' imprisonment and ordered to pay a $1.9 million fine.[38] In addition, Hermelin was prohibited from doing business with federal health care programs.

C. *United States v. Osborn*[39]

In 2012, Apothécure, Inc. and Gary Osborn, the company's Owner, President, and chief pharmacist, were charged with distributing misbranded drugs, and violating the FDCA, after the company sold super- and sub-potent vials of colchicine, a drug commonly prescribed to treat

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32 Brent J. Gurney et al., *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA*, Andrews Litigation Reporter (Dec. 2007), https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwiNv8y3razTAhUKKyYKHbgeDqUQFggzMAI&url=http%3A%2F%2Fwww.wilmerhale.com%2FuploadedFiles%2FWilmerHale_Shared_Content%2FFiles%2FEditorial%2FPublication%2FThe%2520Crime%2520of%2520Doing%2520Nothing.pdf&usg=AFQjCNGOCW0ZSVyjOd1ihAFdwSBHaYOokA&cad=rja.

33 *United States v. Hermelin*, No. 4:11-CR-00085-ERW (E.D. Mo. 2011).

34 Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case, Dep't of Justice (Mar. 10, 2011), https://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case [hereinafter *Hermelin DOJ Press Release*].

35 Information at 7, *United States v. Hermelin*, No. 4:11-CR-00085-ERW (E.D. Mo. Mar. 10, 2011), ECF No. 1.

36 *Id.* at 3, 6.

37 *Id.* at 1-2.

38 *Hermelin DOJ Press Release*, *supra* note 34.

39 *United States v. Osborn*, No. 3:12-cr-00047-M (N.D. Tex. 2012).

arthritis and neck and back pain, to a Portland, Oregon hospital.[40] The hospital administered the drugs on three patients, and the patients died.[41]

Osborn was responsible for Apothécure's employee training and product quality control, but there was no evidence Osborn engaged in illegal conduct.[42] Indeed, the Information did not allege that Osborn knew the drugs were illegal.

Despite having no personal knowledge of the company's misconduct, Osborn, as the person with "the responsibility and authority to prevent the misbranding," pleaded guilty to two counts of adulteration and misbranding of drugs.[43] He was sentenced to in-home confinement for 90 days and one year of probation, and ordered to pay up to $100,000 in fines.[44]

D. *United States v. Facteau*[45]

In July 2016, William Facteau, the former CEO, and Patrick Fabian, the former Vice President of Sales of Acclarent, a medical device company, were convicted of "introducing adulterated and misbranded medical devices into interstate commerce," even though the government could not show criminal intent.[46]

The government alleged that both executives, through trainings to sales representatives, promoted the off-label use of a product known as "Stratus" for use as a steroid delivery device, when the FDA had approved Stratus only as a device to treat sinus infections.[47] However, the executives contended they told the FDA about using Stratus as a delivery device, and, at the same time, they did not promote off-label use to employees.[48]

While the Court did not agree with the government's use of the *Park* doctrine, the jury convicted the defendants on misdemeanor counts of misbranding under the FDCA. Judge Burroughs told

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40 Information, *United States v. Osborn*, No. 3:12-cr-00047-M (N.D. Tex. Feb. 10, 2012), ECF No. 1

41 *Id.* at 3.

42 *Id.* at 1.

43 Dallas Compounding Pharmacy Owner Pleads Guilty in Connection with Misbranded Drug Shipment, Dep't of Justice (Apr. 24, 2012), https://www.justice.gov/opa/pr/dallas-compounding-pharmacy-owner-pleads-guilty-connection-misbranded-drug-shipment.

44 *Id.*

45 *United States v. Facteau et al.*, No. 1:15-CR-10076-ADB (D. Mass. 2016).

46 *Former Acclarent, Inc. Executives Convicted of Crimes Related to the Sale of Medical Devices*, Dep't of Justice (July 20, 2016), https://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-convicted-crimes-related-sale-medical-devices.

47 Indictment at 9, *United States v. Facteau*, No. 1:15-CR-10076-ADB (D. Mass. Apr. 8, 2015), ECF No. 1.

48 Brandon Lowrey, *Minor Convictions In Acclarent Trial Raise Major Questions*, Law 360 (July 22, 2016, 11:29 PM), https://www.law360.com/articles/820531/minor-convictions-in-acclarent-trial-raise-major-questions/.

counsel, "I share your distaste for *Park*, but there's nothing I can do" because Supreme Court precedent required her to give a jury instruction that dispensed with defendants' knowledge of wrongdoing to find the executives guilty as responsible corporate officers under the FDCA.[49]

Defendants have not been sentenced, and they filed their motion for judgment of acquittal or, alternatively, a new trial. The post-trial motions are pending the Court's review.

V. *DeCoster* May Test the *Park* Doctrine's Limits

Against this backdrop of RCO doctrine precedents comes the DeCosters' FDCA prosecution. Austin "Jack" DeCoster owned Quality Egg, and his son Peter DeCoster served as its Chief Operating Officer.[50] Quality Egg operated six farms with 73 barns that had five million hens.[51] They also owned 24 other barns with young chickens, and processing plants for cleaning, packing, and shipping the eggs.[52]

After an August 2010 salmonella outbreak was traced to Quality Egg, the company recalled "hundreds of millions of shell eggs produced at Quality Egg's facilities."[53] The company pleaded guilty to several FDCA violations, and the government charged the DeCosters as responsible corporate officers under section 303(a)(1) of the FDCA for introducing the contaminated eggs into interstate commerce, despite their having no "actual knowledge" that Quality Eggs sold contaminated eggs.[54] They were each fined $100,000 and sentenced to three-month prison terms.[55]

The DeCosters appealed their prison sentences to the Eighth Circuit. Characterizing the DeCosters as "mere unaware corporate executive[s]," the Eighth Circuit cited several reasons why the charges were appropriate: (1) Quality Egg's "egregious" safety and sanitation procedures; (2) ignoring earlier positive salmonella results and failing to later test the eggs; and (3) Quality Egg employees deceived and bribed USDA officials.[56] The Court emphasized this case did not center on vicarious liability. Rather it "imported" blame directly to the DeCosters for their failure to "prevent

49 Joseph F. Savage, Jr. & Kate E. MacLeman, *The Responsible Corporate Officer Doctrine*, Law Journal Newsletters (Dec. 2016), http://www.lawjournalnewsletters.com/sites/lawjournalnewsletters/2016/12/01/the-responsible-corporate-officer-doctrine-2/?slreturn=20170318090824.

50 *United States v. DeCoster*, 828 F.3d 626, 629 (8th Cir. 2016).

51 *Id.*

52 *Id.* at 629-30.

53 *Id.* at 642.

54 *Id.* at 629, 631.

55 *Id.* at 631.

56 *Id.*

or remedy the conditions which gave rise to the charges against [them]."[57] Ultimately, the Eighth Circuit found the DeCosters strictly liable for introducing the adulterated eggs into interstate commerce, and affirmed their prison terms.[58]

A. The DeCosters' Petition for Writ of Certiorari

On January 10, 2017, the DeCosters filed their Petition for Writ of Certiorari with the Supreme Court, asking the high court to review whether a corporate executive can be sentenced to prison for a *Park* doctrine conviction. The DeCosters contend their convictions as responsible corporate officers are based on vicarious liability, because they did not have "actual knowledge" that their egg distribution company sold contaminated eggs.[59] Therefore, they argue, federal precedent dictates that imprisonment violates due process.[60]

Anticipating the government's argument that the DeCosters' own negligence as responsible corporate officers is the source of their liability, the DeCosters state that *Park* doctrine liability has historically not been based on negligence by the responsible corporate officer.[61] Rather, the argument continues, the *Park* doctrine is a strict liability offense based on the corporate officer's position of authority and the presumption that the officer is in a position to prevent violations of the FDCA. A sentence of imprisonment for a strict liability violation, they maintain, violates due process.[62] Accordingly, the DeCosters argue that the Eighth Circuit's holding, affirming the conviction and sentencing of both executives to three months' imprisonment, gravely expands the RCO doctrine and an "innocent" supervisor convicted of vicarious criminal liability should not face imprisonment.[63]

Secondarily, the DeCosters ask the Supreme Court to overrule the *Park* doctrine because its "arbitrary and selective enforcement" invites liability where there is none.[64] In fact, the DeCosters characterize the *Park* doctrine as "boundless" because "anyone in the chain of command of a company, large or small, with at least nominal responsibility for a given activity" is a potential defendant.[65]

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[57] *Id.* at 633.

[58] *Id.* at 639.

[59] *Id.* at 629, 631.

[60] Petition for a Writ of Certiorari at *12-16, *DeCoster v. United States* (filed Jan. 10, 2016).

[61] *Id.* at *17.

[62] *Id.* at *23-26.

[63] *Id.* at *30.

[64] *Id.* at *27.

[65] *Id.* at *32.

On April 12, 2016, the Acting Solicitor General of the United States filed his brief in opposition to the U.S. Supreme Court's potential review of *DeCoster*. The Acting Solicitor General opposes the Supreme Court's review and contends the DeCosters' prison terms were based on their acts and omissions, not vicarious liability.[66] The government cites *United States v. Park* to explain the prison terms are appropriate because the FDCA "imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."[67]

If the Supreme Court reviews *DeCoster*, it will part with decades of precedence that relied on "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries" to guide the *Park* doctrine.[68] Its review and subsequent decision will be a breath of fresh air for industry advocates who have longed for a precise guide to ensure corporate executives are not at the mercy of prosecutors and juries.

VI. The DOJ's New Era of Evaluating Corporate Compliance Programs

In February 2017, the DOJ's Fraud Section released its "Evaluation of Corporate Compliance Programs" ("the Evaluation Program").[69] The DOJ draws from existing guidance to evaluate safeguards against corporate misconduct and identifies 11 criteria to determine the effectiveness of compliance programs. Accordingly, the DOJ evaluates whether the company has mechanisms in place to identify misconduct as early as possible, analyzes if the company devotes enough resources to develop and sustain a qualified compliance program, and reviews the company's efforts to continuously improve areas of weakness.[70]

Although an evaluation of Quality Egg's compliance program is outside the scope of the Supreme Court's potential review of *DeCoster*, Quality Egg can look to the DOJ's new guidance to tighten its compliance controls. Fundamentally, Quality Egg, along with all companies wishing to prevent corporate misconduct, should use the DOJ's new guidance to assess their current compliance program and to determine if the program has an adequate early detection system in place to identify misconduct and prevent future bad acts.

The DOJ does not outline the perfect "one size fits all" compliance program. However, the Evaluation Program constructs its review model around 11 key areas and asks nuanced questions to guide companies within each topic.

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66 Brief for the United States in Opposition, *DeCoster v. United States*, at *10 (filed Apr. 12, 2017).

67 *Id.*

68 *United States v. Dotterweich*, 320 U.S. 277, 285 (1943).

69 *U.S. Department of Justice Criminal Division Fraud Section Evaluation of Corporate Compliance Programs* (2017), https://www.justice.gov/criminal-fraud/page/file/937501/download.

70 *Id.*

1) Analysis and Remediation of Underlying Misconduct

The DOJ aims to identify the root cause of the misconduct. Consequently, an airtight compliance program detects potential misconduct and alerts appropriate personnel.

2) Senior and Middle Management

The Fraud Section expects best practices to begin with management. Accordingly, senior leaders and business departments responsible for best practices should commit equally to building and maintaining an environment that promotes good behavior. Importantly, the Department's new guidance highlights the need for having policies and procedures that discourage misconduct, as well as ensuring that a company's compliance program can adequately monitor senior management's behavior.

3) Autonomy and Resources

The freedom of the company's compliance department to investigate misconduct is a pillar of any effective compliance program. Thus, the company's compliance department must have autonomy to monitor behavior and regularly meet with management to review performance. Of course, the company should provide the resources necessary to monitor corporate behavior.

4) Policies and Procedures

The DOJ attacks policies and procedures on two fronts: design and accessibility, and operational integration.

- Design and Accessibility: The company should employ a flexible approach when evaluating its compliance program–it must understand its current policies, identify the missing processes required by the current and future business environments, and implement procedures to mitigate risk. Also, "gatekeepers" should have the training to control misconduct, and employees should understand how the company expects them to act.
- Operational Integration: The DOJ expects companies to integrate new or amended policies into its existing framework. This means identifying who is responsible for rolling out policies and ensuring that those responsible understand how to remedy control failures and misconduct.

5) Risk Assessment

Here, inquiries ask how the company identifies and addresses risks, the types of information the company collects to enhance its compliance program, and whether the company's current "risk assessment process" contributed to misconduct.

6) Training and Communications

Effective employee training programs fuel a bulletproof compliance system. Thus, the Fraud Section focuses on specific training for "high-risk and control employees" where misconduct might occur, the availability of training programs, and management conveying to employees that it will not tolerate bad acts.

7) Confidential Reporting and Investigation

This area evaluates the company's appetite and tolerance for misconduct. The DOJ asks what information the company collects to investigate misconduct, its measures to certify the breadth and scope of investigations, and the system's ability to detect wrongdoing.

8) Incentive and Disciplinary Measures

The Fraud Section asks that a company's compliance program promote a level playing field. This means holding employees at all levels accountable for misconduct and crafting an incentive-based system that rewards good behavior and punishes bad acts.

9) Continuous Improvement, Periodic Testing and Review

A static compliance program is ineffective because business environments change often and rapidly. The model program uses audits, testing, and monitoring to evaluate risk and mobilize change. In turn, the company's program will implement the modifications necessary to thwart internal and external risks.

10) Third Party Management

Business environments in which most companies work are complex and require third-party assistance. Therefore, the company should understand when to use third parties and which third parties to hire. Once the company engages a third party, the company must manage and monitor the third party to mitigate risks by certifying it complies with the company's compliance standards.

11) Mergers and Acquisitions

Issues arise in mergers and acquisitions because compliance systems oftentimes cannot detect the acquired company's misconduct. Thus, the acquiring company should identify risks during the due diligence phase and incorporate the more sound policies into the newly formed entity.

VII. Conclusion

Following the Yates Memo,[71] the RCO doctrine takes on heightened importance because there is greater tension between, on the one hand, the policy of encouraging a corporation's executive staff

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[71] On September 9, 2015 the DOJ issued a memorandum titled, Individual Accountability for Corporate Wrongdoing, which is commonly referred to as the "Yates Memo." *See New DOJ Policy Regarding Individual Accountability for Corporate Wrongdoing*, Cadwalader (Sept. 10, 2015), http://www.cadwalader.com/resources/clients-friends-memos/new-doj-policy-regarding-individual-accountability-for-corporate-wrongdoing.

to identify and report the actual corporate wrongdoers to the government, and, on the other hand, the risk of imprisonment to the same staff for the reported misconduct simply because it occurs under their watch. The latter outcome might be viewed as a disincentive for the kind of cooperation the DOJ is expecting of corporations, including pharmaceutical and medical device manufacturers, if it could result in vicarious, individual criminal liability under the FDCA. The Yates Memo highlights this point because, if corporate officers come clean and identify the bad actors, the government can immediately find the officer liable by virtue of an officer being a supervisory employee. Concomitantly, perhaps the Supreme Court's review of *DeCoster* will limit liability by prohibiting the government from seeking imprisonment for employees who have no knowledge of their company's illegal conduct. In the interim, corporate compliance departments should proactively use the Fraud Section's new guidance to implement stronger compliance programs so that companies and supervisory employees stay out of the crosshairs of government enforcement actions.

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