Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine

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Over the past several years, prosecutors have used and threatened more use of the responsible corporate officer (RCO) doctrine under the Federal Food, Drug, and Cosmetic Act (FDCA) in ways not envisioned by the Congress that enacted the legislation, in a manner inconsistent with assurances offered by the U.S. Department of Justice (DOJ) when the doctrine was argued before the Supreme Court and with consequences at odds with fundamental notions of our criminal justice system. This article will examine recent developments in the application of the RCO doctrine, consider how its use has moved well beyond its properly limited scope when it was created decades ago, and analyze how the potential for imprisonment, massive fines and collateral sanctions result in its use becoming untethered from the intellectual foundation on which it was initially built. The article concludes with a call for DOJ to issue guidelines for RCO prosecutions to ensure that this most unusual form of criminal liability is imposed fairly and consistently.

I. FUNDAMENTALS OF THE RCO DOCTRINE1

The RCO doctrine provides for the prosecution of corporate officers for public welfare offenses committed by a company. The government may make a prima facie case by showing that the individual had, by reason of his or her position in the corporation, responsibility and authority to prevent in the first instance, or promptly to correct, the wrongdoing and that he or she failed to do so.2 The “requirements of foresight and vigilance” imposed on RCOs are “beyond question demanding, and perhaps onerous,” and many commentators view the RCO doctrine as permitting the imposition of strict criminal liability.3

The Supreme Court originally applied the RCO doctrine to prosecute misdemeanors under the FDCA in United States v. Dotterweich in 1943.4 After decades of near-dormancy, the next major update of the doctrine was in 1975’s United States v. Park.5 A handful of district and circuit courts grappled with the implications of Park in the late 1970s and early-to-mid-1980s. Since that time, however, DOJ has

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3 Id. at 672.

4 320 U.S. 277 (1943).

5 421 U.S. 658.
not used the RCO doctrine to prosecute individuals for FDCA offenses, and only in recent years has the doctrine emerged as a basis for misdemeanor guilty pleas.

A. Origins of the Doctrine: Dotterweich and Park

In Dotterweich, the Supreme Court upheld the conviction of a drug company's president and general manager for the company's shipping of misbranded and adulterated drugs in interstate commerce. There was no evidence that the individual defendant, Joseph H. Dotterweich, participated in the misbranding or that he even knew of the misbranding. But he did "share[] responsibility in the business process" resulting in the misbranding, according to the Court, and this "responsible relation" provided the Court with enough justification to uphold his conviction.

The Court in Dotterweich declined to define which types of employees possessed the "responsible relation" that would result in criminal liability. It did say that reading the FDCA to provide for the prosecution of "any person however remotely entangled" would be too harsh. It also acknowledged the "hardship" created by penalizing individuals even "though consciousness of wrongdoing be totally wanting." However, the Court found that in "dispens[ing] with the conventional requirement for criminal conduct—awareness of some wrongdoing," Congress chose to visit hardship on the responsible officer rather than "the innocent public who are wholly helpless."

A few cases applied the RCO doctrine in the immediate aftermath of Dotterweich, but a circuit split led the Court to revisit the issue of RCO liability 32 years later in Park. John R. Park was the president of a national food store chain whose warehouses were besieged by rats. Park was responsible for warehouse sanitation, albeit only in the sense that providing sanitary conditions for his company's foods was something that he was "responsible for in the entire operation of the company." He was convicted of an FDCA misdemeanor under Dotterweich; the question on appeal was whether the trial court should have required the jury to find "wrongful action" by Park to sustain his conviction.

In upholding Park's conviction and rejecting the necessity of the "wrongful action" instruction, the Court expounded upon the RCO doctrine introduced in Dotterweich. The Government may make out a prima facie case against a corporate officer by showing that the officer had "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." However, the Court in Park interpreted the FDCA as providing for a defense that officers are not expected to prevent or remedy wrongdoing by doing the "objectively impossible."
B. After Park

The few post-Park cases that primarily focused on the RCO doctrine in FDCA cases tended to explore the contours of the “objective impossibility” defense to RCO liability. For example, in *United States v. Y. Hata & Co.*, company president Minoru Hata was convicted of an FDCA misdemeanor.\(^{18}\) Birds had repeatedly entered the company’s food warehouse, perched on overhead sprinkler pipes and on bags of rice, eaten from rice bags, and excreted on bags.\(^{19}\) Although the jury was instructed that the government need not prove knowledge or intent to violate the statute, the appellate court noted from Hata’s repeated attempts to control the birds that he was aware of the problems.\(^{20}\) Hata nevertheless claimed he was entitled to an instruction on the Park “objective impossibility” defense because, even exercising the utmost foresight, it would have been objectively impossible for him to conceive of the barrier against the birds before he, in fact, did so. The Ninth Circuit disagreed with Hata’s interpretation of the “objective impossibility” defense, saying, “One maintaining far less than the requisite ‘highest standard of foresight and vigilance’ would have recognized as early as August 1971 that implementation of a wire cage system would substantially, if not completely, prevent access by thieving and untidy birds.”\(^{21}\)

In *United States v. Starr*, the Ninth Circuit again focused on the “objective impossibility” defense.\(^{22}\) The court affirmed the FDCA conviction of a food company’s secretary-treasurer under the RCO doctrine. As in *Park*, warehouses were found to be rodent-infested; unlike in *Park*, the company’s secretary-treasurer was specifically responsible for handling sanitation problems and had actual knowledge of the infestation.\(^{23}\) The defendant argued that he was entitled to a jury instruction\(^{24}\) on the “objective impossibility” defense for two reasons: First, he argued it was impossible for him to avoid the mouse infestation because the infestation resulted from the “natural phenomenon” of plowing a nearby field. The court rejected this on the basis that someone with a mere “minimum of foresight” would recognize that rodents and insects would flee from freshly plowed fields.\(^{25}\) Second, Starr said it was objectively impossible for him to avoid the infestation because he instructed the warehouse janitor to fix the problem, but the janitor did not do so. The court again disagreed, noting that after providing this admonishment to the janitor, Starr did not follow up to ensure compliance and did not learn of the janitor’s noncompliance until a second inspection a month later.\(^{26}\) It is objectively possible, said the court, for RCOs to anticipate subordinates’ shortcomings and counteract them.\(^{27}\)

Following these explorations of the “objective impossibility” defense in the late 1970s and early 1980s, the RCO doctrine fell into disuse as applied to the FDCA. Only in recent years has the doctrine begun to make a comeback. Within the last three years, seven executives at two major pharmaceutical and device companies have pled guilty to FDCA misdemeanors under the RCO doctrine. Government officials have indicated an intention to pursue individuals in appropriate circumstances. In comments made to a health care industry audience in the fall of 2009, DOJ Civil Division Head Tony West made clear that healthcare fraud enforcement “[w]ill not

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\(^{18}\) 535 F.2d 508 (9th Cir. 1976).
\(^{19}\) Id. at 509.
\(^{20}\) Id. at 510, 511.
\(^{21}\) Id. at 511 (quoting Park, 421 U.S. at 673).
\(^{22}\) 535 F.2d 512 (9th Cir. 1976).
\(^{23}\) Id. at 514.
\(^{24}\) Had his case gone to a jury, which it did not. Id. at 515.
\(^{25}\) Id.
\(^{26}\) Id. at 515-16.
\(^{27}\) Id. at 516.
be limited to corporate actors. In those cases where the facts and law allow [DOJ] to pursue criminal cases against individuals responsible for illegal conduct, [DOJ] will do so.28 Similarly, the Food and Drug Administration (FDA) recently announced its intention to increase the number of RCO prosecution recommendations.29

II. THE QUESTION OF MENTAL STATE

The mental state that must be proven to justify an RCO conviction, if any, has been the subject of much commentary and consternation. It remains unclear whether the RCO doctrine alters the mens rea of the underlying crime—i.e., the FDCA or some other public welfare statute—or leaves it unchanged.30 Under the former reading, the mental state of the statute would be unnecessary for the RCO’s conviction because “the willfulness or negligence of the [actual] actor [as required where the underlying statute required willfulness or negligence] would be imputed to [the RCO] by virtue of [the RCO’s] position of responsibility.”31 Under the latter reading, whatever mental state is required to be shown per the underlying statute would likewise be required to be shown to result in an RCO doctrine conviction.

This question was primarily discussed in the environmental context for two reasons: First, the RCO doctrine took flight in the environmental context in the 1990s while it went dormant in the FDCA context. Second, many of the environmental laws that underlied RCO cases required some mens rea. Various provisions of the FDCA, by contrast, are silent on mental state and have been interpreted as strict liability offenses.32 Therefore, regardless of whether the RCO doctrine assumes a mental state by virtue of a position of responsibility or refers to the mental state requirement of the underlying crime, some courts33 and com-

28 DOJ Officials Outline Enforcement, Prevention Initiatives to Tackle Fraud, HEALTH CARE DAILY REP. (BNA) (Nov. 16, 2009) (comments attributed to Tony West).


30 Commentators differ even on whether there is a lack of clarity on this issue. See Joseph E. Cole, Environmental Criminal Liability: What Federal Officials Know Can Hurt Them - Or Should Know, 54 AM. FOREC L. REV. 1, 26 (treating courts’ approaches to mens rea as alternatives and noting, “There have been a number of different decisions applying the RCO doctrine to environmental statutes, and almost as many methods of application.”); but see Aagaard, 96 J. CRIM. L. & CRIMINOLOGY at 1265 (recognizing the continued disagreement among commentators but stating that “courts essentially had reached consensus by the mid-1990s that the responsible corporate officer doctrine did not alter statutory mental state requirements”).

31 Brittain, 931 F.2d at 1419.

32 Most relevant: “Any person who violates a provision of [21 U.S.C. § 331, i.e., misbranding and related and other crimes] shall be imprisoned for not more than one year or fined not more than $1,000, or both.” 21 U.S.C. § 333(a)(1).

33 United States v. Cordoba-Hincapie, 825 F. Supp. 485, 508 (E.D.N.Y. 1993) (“It is, in effect, a prima facie strict liability standard because the defendant officer’s negligence is presumed.”); United States v. Poulin, 926 F. Supp. 246, 253 (D. Mass. 1996) (“[A] corporate officer can be held personally liable for violations of law, where there is strict liability, because he is the person who had ‘authority with respect to the conditions that formed the basis of the alleged violations’… [citing Park].”); United States v. O’Mara, 963 F.2d 1288, 1295 (9th Cir. 1992) (“[T]he two cases where the Court interpreted silence to allow strict and vicarious liability involved misdemeanors… [citing Park] and Dotterweich.”); Stepniowski v. Gagnon, 732 F.2d 567, 573 (7th Cir. 1984) (“In United States v. Dotterweich…, for example, the Court recognized the reasonableness of imposing strict liability under the [FDCA],…”); Allied Prods. Co. v. Fed. Mine Safety & Health Review Comm’n, 666 F.2d 890, 893 (3d Cir. 1982) (“[I]t is a common regulatory practice to impose a kind of strict liability on the employer as an incentive… [citing Park].”); Ft. Worth & Denver Ry. Co. v. Goldschmidt, 518 F. Supp. 121, 130 (N.D. Tex. 1981) (“Plaintiffs claim that whenever the courts have upheld a standard of strict liability, they always have done so on the basis of a clearly expressed legislative intent to impose such liability… [citing Park].”), rev’d on other grounds, Ft. Worth & Denver Ry. Co. v. Lewis, 693 F.2d 432 (5th Cir. 1982).
mentators\textsuperscript{34} argue, the RCO \textit{mens rea} standard under the relevant portions of the FDCA is strict liability.

The reality is more complicated. It is unusual enough—given that some courts require an “express” indication that Congress intended to create a strict liability crime\textsuperscript{35} and others, at least, prefer such an expression\textsuperscript{36}—that Congress apparently sought to create a strict liability crime in the FDCA through mere implication. But, moreover, it does not appear that Congress intended to create a strict \textit{and vicarious} liability crime, in which an individual can be guilty through the acts of others and with \textit{no mens rea}. Second, in describing the RCO doctrine, \textit{Park} used the language of negligence. If the FDCA indeed creates strict liability crimes, it is arguable that the Supreme Court in \textit{Park} ruled that an RCO case based on the FDCA requires a showing of negligence or, at minimum, “strict liability plus.” Third, in the limited number of FDCA cases that have employed the doctrine since \textit{Park}, the defendant has nearly always been alleged to have either had knowledge of the underlying violation, participated to some extent in the wrongdoing, or both.

A. \textit{Strict and Vicarious Criminal Liability}

Strict and vicarious criminal liability is a rare and disfavored species in American law. In the absence of clear Congressional intent, it is a heavy lift to interpret the RCO doctrine as imposing such liability with respect to the FDCA. A bedrock rule of criminal jurisprudence is that, with very few exceptions, society does not impose criminal sanctions on an individual who lacks a \textit{mens rea}:

In our jurisprudence guilt is personal. Thus, we must construe a criminal statute in light of the fundamental principle that a person is not criminally responsible unless an evil-meaning mind accompanies an evil-doing hand. In other words, unless Congress expressly communicates its intent to dispense with a \textit{mens rea} requirement and create strict criminal liability, the notion of personal guilt requires some culpable intent before criminal liability attaches.\textsuperscript{37}

\textsuperscript{34} Nicholas Frietag, \textit{Federal Food and Drug Act Violations}, 41 AM. CRIM. L. REV. 647, 653 (2004) ("In \textit{United States v. Dotterweich}, the Supreme Court established a standard of strict liability for violations of the FDCA....") (footnote omitted); Amiad Kushner, \textit{Applying the Responsible Corporate Officer Doctrine Outside the Public Welfare Context}, 93 J. CRIM. L. & CRIMINOLOGY 681, 692-93 (2003) (Dotterweich’s conviction [was] premised on a strict liability theory [and] \textit{Park} not only reaffirmed the imposition of strict liability in principle, but applied it to a large corporation."); Joel M. Androphy et al., \textit{General Corporate Criminal Liability}, 60 TEX. B. J. 121, 126 (1997) ("In both [\textit{Park} and \textit{Dotterweich}], the Court held that a corporate officer could be liable for the criminal acts of the corporation, despite the officer never having been aware of the criminal conduct at issue (i.e., despite the officer having no guilty mind, or in other words, no \textit{mens rea}.")

\textsuperscript{35} See \textit{Humanitarian Law Project v. Mukasey}, 552 F.3d 916, 925 (9th Cir.), cert. granted, 130 S. Ct. 48 (2009).

\textsuperscript{36} See \textit{Ft. Worth & Denver Ry. Co.}, 518 F. Supp. at 130.

\textsuperscript{37} \textit{Mukasey}, 552 F.3d at 925 (citing \textit{Brown v. United States}, 334 F.2d 488, 495 (9th Cir. 1964); \textit{United States v. Nguyen}, 73 F.3d 887, 890 (9th Cir. 1995) (citing \textit{Morissette v. United States}, 342 U.S. 246, 251 (1952))) (internal quotes omitted).
Commentators have likewise criticized such strict liability crimes as being ineffective and unjust.\(^\text{38}\) Strict and vicarious liability, even in the civil context, is viewed warily because “[t]he reach of strict vicarious liability is potentially endless.”\(^\text{39}\) Strict and vicarious criminal liability is an ugly hybrid that knows few analogues, as the problems with both strict criminal liability and strict vicarious liability are exacerbated in the combination.

Consider the following scenario: A pharmaceutical maker’s portfolio includes a product with substantial off-label use. The company’s CEO implements a comprehensive compliance program. The CEO “walks the walk” on compliance issues, receives periodic reports on auditing and investigative efforts, and has supported tough but fair disciplinary actions against errant employees. The program is well resourced. Nevertheless, a government investigation later finds that a group of sales reps and their manager frequently provided off-label information to physicians. The investigation also finds that several medical science liaisons assigned to monitor the development of clinical guidelines by an important physician’s group stray into ghostwriting portions of the assessment supporting new guidelines that support off-label use of the company’s product. Under a strict and vicarious liability standard, the hypothetical CEO could be jailed, subject to substantial fines, and excluded from participating in federal health care programs.

Given the general resistance to strict and vicarious criminal liability, it is appropriate to question whether Congress intended for the FDCA to create such liability, whether courts have misinterpreted the statute, or whether commentators have misinterpreted the courts. The third possibility seems most likely. The FDCA is silent on mens rea with respect to some offenses, which may, at least, permit the possibility of inferring simple strict liability. But adding the wrinkle of vicarious liability is a serious problem, as the legislative history of the FDCA reveals that language prescribing vicarious liability was included in initial iterations of the bill but ultimately deleted from the final act.\(^\text{40}\) Said the four dissenters in *Dotterweich* of this deletion, “It is thus unreasonable to assume that the omission of such language was due to a belief that the Act as it now stands was sufficient to impose liability on corporate officers. Such deliberate deletion is consistent only with an intent to allow such officers to remain free from criminal liability.”\(^\text{41}\)

Courts are obligated to give effect to the penal sanctions established by Congress, so long as they are constitutional.\(^\text{42}\) Although the “harshness” of a “true construction” “is no concern of the courts,” a statute should not be “given an absurd or utterly unreasonable interpretation, leading to hardship and injustice, if any other interpretation is reasonably possible.”\(^\text{43}\) Courts “should not enlarge the reach of

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\(^{38}\) See, e.g., Assaf Hamdani, *Mens Rea and the Cost of Ignorance*, 93 Va. L. Rev. 415, 416-17 (2007) (“For decades, criminal law scholars have argued that this doctrine punishes innocent actors and is thus unjust, unconstitutional, and ineffective. But despite nearly unanimous vilification, strict liability continues to occupy an important place in modern criminal law.”).

\(^{39}\) Scott v. Ross, 151 F.3d 1247, 1250 (9th Cir. 1998) (Kozinski, J., dissenting).

\(^{40}\) The language read: “[W]henever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation.” *Dotterweich*, 320 U.S. at 291 (Murphy, J., dissenting) (citing S. 1944, 73d Cong. § 18(b) (1st Sess. 1933); S. 2000, 73d Cong. § 18(b) (2d Sess. 1934); S. 2800, 73d Cong. § 18(b) (2d Sess. 1934); S. 2800, 74th Cong. § 709(b) (1st Sess. 1935); S. 5, 74th Cong. § 709(b) (1st Sess. 1935)).

\(^{41}\) Dotterweich, 320 U.S. at 292.

\(^{42}\) Park, 421 U.S. at 673.

enacted crimes by constituting them from anything less than the incriminating components contemplated by the words used in the statute.”44 As will be shown in the next subsection, however, the case on which the foundation of the RCO doctrine rests, Park, did not use the language of strict liability in interpreting Congress’s intent. Rather, in Park, the Supreme Court used the language of negligence.

B. The Language of Negligence

The Court in Park used the language of negligence in describing the standard for proving an FDCA violation under the RCO doctrine, finding that Congress had imposed on RCOs 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.”45 It also created a defense that RCOs are not expected to do that which is “objectively impossible.”46 The court never referred to “strict liability,” nor did it provide the explanation that an extraordinary strict and vicarious liability criminal standard would seem to require. Perhaps the strongest endorsement of a negligence reading of Park comes from Justices Stewart, Marshall, and Powell in their Park dissent, in which Justice Stewart describes the majority opinion as follows:

As I understand the Court’s opinion, it holds that in order to sustain a conviction under § 301(k) of the Federal Food, Drug, and Cosmetic Act, the prosecution must at least show that, by reason of an individual’s corporate position and responsibilities, he had a duty to use care to maintain the physical integrity of the corporation’s food products. A jury may then draw the inference that when the food is found to be in such condition as to violate the statute’s prohibitions, that condition was “caused” by a breach of the standard of care imposed upon the responsible official. This is the language of negligence, and I agree with it.47

C. Cases Show More than Strict Liability

Even if the RCO doctrine permits strict liability, the reality of its application post-Park is that nearly every case featured misconduct by the defendant that met the standard of negligence and, further, evidenced the individual’s knowledge of the company’s misconduct. To begin with Park itself, the individual defendant was far from blameless for his company’s FDCA violation, given his knowledge of conditions that led to the violation. He personally received at least one notice of a failed inspection, then personally conferred with a vice president about the failed inspection and the company’s response.48 Also, the Court found that evidence was properly admitted at trial to demonstrate that Park “was on notice that he could not rely on his system of delegation to subordinates to prevent or correct unsanitary conditions at [Acme Markets, Inc.’s] warehouses, and that he must have been aware of the deficiencies of this system before the Baltimore violations were discovered.”49

44 Morissette, 342 U.S. at 263.
45 Park, 421 U.S. at 672.
46 Id. at 673.
47 Id. at 678-79 (Stewart, J., dissenting).
48 Id. at 663-64.
49 Id. at 678.
The three FDCA RCO cases that immediately followed Park in the late 1970s all likewise showed that the individual defendant was not only negligent, but had knowledge about the condition on which the FDCA claim was predicated. In United States v. Acri Wholesale Grocery Co., one of the two individual defendants acknowledged awareness of a rodent problem in a food warehouse.\(^\text{50}\) He accompanied inspectors on tour where they saw excrement, received receipts of inspection samples and copies of the reports, and even asked inspectors for advice in controlling rodents.\(^\text{51}\) In Y. Hata, the Ninth Circuit noted from individual defendant Hata’s repeated attempts to control the birds that were soiling his warehouse that he was aware of problems at least nine months before the inspection at issue.\(^\text{52}\) And in United States v. Starr, the individual defendant was aware of infestation problems for at least a month before the same problems were found in a repeat inspection: “Starr, as the one charged with handling sanitation problems, knew of the problem and took some corrective measures.”\(^\text{53}\)

After these cases, in which the RCO doctrine was the main focus, a series of cases touched on RCO issues while remaining primarily oriented toward discussing other issues. Because RCO issues were secondary, the lack of details about the negligence and/or knowledge of wrongdoing in the opinions should not necessarily be taken as evidence of an absence of negligence and/or knowledge on the individuals’ part. Given the nature of the defendants and companies in these cases—all of the companies were very closely held and the individual defendant was shown to have day-to-day involvement with the manufacturing process in each case—it is reasonable to surmise the presence of negligence and/or knowledge rather than the absence of it. Indeed, in some of the cases, the court explicitly discusses the individual defendants’ negligence and/or knowledge.

In United States v. New England Grocers, another food adulteration case, prosecutors charged a company’s president, a vice president, and the vice president/general manager of the facility in question under the RCO doctrine.\(^\text{54}\) The third defendant was “in complete control” of the facility in question, making it reasonable to infer his knowledge or, at least, negligence with respect to the adulteration of the food in his facility.\(^\text{55}\) The first defendant “had been consulted with respect to the condition at the warehouse and [was] in direct contact with” the third defendant.\(^\text{56}\) The lack of explicit language in the opinion indicating the second defendant’s negligence or knowledge, again, should be taken more as a reflection of the peripheral nature of the RCO standard in this case rather than evidence that he was necessarily convicted despite no negligence or knowledge whatsoever. The same goes for the three defendants in United States v. Treffiletti & Sons, in which the opinion lacks explicit language showing the defendants were negligent or had prior knowledge with respect to the alleged wrongdoing but nonetheless finds them guilty under the RCO doctrine.\(^\text{57}\)

\(^{50}\) 409 F. Supp. 529, 532 (S.D. Iowa 1976). With respect to the other defendant, there is insufficient information in the opinion to conclude that he was negligent or possessed knowledge of the misconduct.

\(^{51}\) Id. at 531-32.

\(^{52}\) 535 F.2d at 511.

\(^{53}\) 535 F.2d at 514.


\(^{55}\) Id. at 234.

\(^{56}\) Id.

\(^{57}\) 496 F. Supp. 53 (N.D.N.Y. 1980).
In United States v. Torigian Laboratories, Inc., the individual defendant, who was president and controlling owner, had been “faced with clear warnings” of the problem.58 He was aware that two lots had an extraordinarily high number of rejected product, but he never inquired into the source of the problem nor directed tests.59 In United States v. Gel Spice Co., the president, who also owned part of the company, knew of failed inspections.60

United States v. General Nutrition, Inc., is perhaps the most recent FDCA RCO doctrine case, and in many ways it is an outlier from the others.61 It involved a large company rather than a closely held small company, focused on an allegedly misbranded drug and not adulterated food, does not discuss liability standard issues in any detail whatsoever and was not a final opinion. Although the sales-level employees ostensibly had first-hand awareness of the misconduct at issue in General Nutrition, is difficult to know whether the executive-level defendants were negligent or had knowledge of the wrongdoing.

III. CHANGING CIRCUMSTANCES CREATE NEW RISKS

The circumstances surrounding application of the RCO doctrine as applied to the FDCA have changed dramatically from the days of Dotterweich and Park to the present day. Among the changes are increased penalties attached to an RCO conviction, a less centralized case selection process and attendant effects, and an increased inclination by parties and the government to settle FDCA cases before trial.

A. Increased Penalties

Potential penalties for an FDCA conviction under the RCO doctrine have increased dramatically since the halcyon days of Dotterweich and Park. In Dotterweich, the defendant was obliged to pay a $500 fine and serve 60 days probation.62 Even after accounting for inflation, this fine would be a mere $6,300 in today’s dollars.63 In Park, the penalty was even smaller: $250, or just $1,000 in today’s dollars.64 Neither conviction entailed jail time. Exclusion from federal health care programs was not imposed or even contemplated, since that collateral punishment—a routine consequence of criminal convictions in the health care field today—did not exist at the time of Park or Dotterweich. Today, by contrast, a plea to an RCO misdemeanor often has dire consequences including tens of millions in fines, exclusion and jail time. Three executives paid a combined $34.5 million and were excluded for 12 years each on the basis of RCO pleas.

It is worthwhile to contemplate whether the Supreme Court would have reached the same conclusion on the RCO doctrine if it came up anew today. For those who subscribe to the notion that the RCO doctrine imposes strict liability, the size of the penalties clashes with the justification for allowing strict liability crimes to exist.

59 Id.
60 773 F.2d 427 (2d Cir. 1985).
64 Park, 421 U.S. at 666; Inflation Calculator.
an exception to the general disfavor with which courts view strict criminal liability, the Supreme Court has stated that such liability may be appropriate when penalties “are relatively small, and conviction does no grave damage to an offender’s reputation.”65 Naturally, as penalties increase, that justification loses sway.

Furthermore, Dotterweich itself notably prescribed that a check on the doctrine should be prosecutorial discretion, which implies that DOJ should not bring RCO prosecutions in high-penalty cases.66 In addition, in briefing Park before the Supreme Court, DOJ acknowledged that FDA had a policy limiting criminal enforcement to situations involving “continuing violations, violations of an obvious or flagrant nature, and intentionally false or fraudulent violations” and that “even if investigation discloses the elements of liability, and indicates that an official bears a responsible relationship to them, the agency will not ordinarily recommend prosecution unless that official, after becoming aware of possible violations, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.”67 If prosecutors are to exercise discretion, as Dotterweich assumes and DOJ acknowledges, then deciding whether to prosecute individuals in high-stakes, high-volume health care cases involving heavy penalties should be an easy call: no. “[E]xercising discretion” should be read to indicate that RCO prosecutions should be used sparingly and generally in cases where penalties are not overwhelming.68 The decision in Dotterweich hinged on prosecutors exercising discretion in such cases and the viability of Dotterweich depends on prosecutorial discretion remaining a top priority.

Thus, it is no stretch to imagine that today’s RCO doctrine would not pass muster before the Supreme Court, whether before the bench of 1943, 1975, or 2010. Dotterweich and Park were both narrow majorities—5-4 and 6-3, respectively—with strong dissents. Most recently, the Court’s unanimous willingness to trim honest services fraud—and the desire of three justices, including Justice Kennedy, to invalidate the provision altogether—shows the Court’s focus on a showing of clear Congressional intent.69 If the Court knew at the time of Dotterweich and Park that much higher penalties would be sought for RCO convictions, it may not have endorsed the doctrine; if a RCO case reached the Court today, it might not stand.

B. Case Selection

The process by which U.S. Attorney’s Offices consider FDCA cases with RCO implications and elect to pursue them has changed since Park as well. Formerly, an important referral path for FDCA criminal cases was through FDA. FDA opened investigations over the companies that it regulated and referred them to U.S. Attorney’s Offices as appropriate. FDA’s criminal referral decisions were guided by a subchapter of the FDA Regulatory Procedures Manual (RPM), a substantial volume that made criminal investigations of individuals part of a coherent overall enforcement strategy. Criminal referral was based on “all of the facts,”70 required that each summary and recommendation “present the evidence of each element of the offense to be charged”71 and required the concurrence of a variety of offices within FDA. There is little doubt that the FDA’s referral system sought and largely

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65 Morissette, 342 U.S. at 256; see also United States v. Freed, 189 Fed. App’x 888, 891-92 (11th Cir. 2006); O’Mara, 963 F.2d at 1295.
66 Dotterweich, 320 U.S. at 292.
68 Dotterweich, 320 U.S. at 292.
69 No. 08-1394, slip op. (June 24, 2010).
71 Id. at § 6-5-3. For cases when the FDA referred an indictment or an information.
achieved the sort of prosecutorial discretion demanded by the Supreme Court in *Dotterweich*.

At the outset of the section dealing with prosecution referrals, the RPM states:

> With the exception of prosecution recommendations involving gross, flagrant, or intentional violations, fraud, or danger to health, each recommendation should ordinarily contain proposed criminal charges that show a continuous or repeated course of violative conduct. This may consist of counts from two or more inspections, or counts from separate violative shipments at different points in time. This is because the agency ordinarily exercises its prosecutorial discretion to seek criminal sanctions against a person only when a prior warning or other type of notice can be shown. Establishing a background of warning or other type of notice will demonstrate to the U.S. Attorney, the judge, and the jury that there has been a continuous course of violative conduct and a failure to effect correction in the past.

Furthermore, as mandated by federal law, any FDA criminal referral had to be preceded by “appropriate notice” to the potential defendant and “an opportunity to present his [or her] views, either orally or in writing, with regard to such contemplated proceeding.” This requirement has been essentially vitiated by a subsequent regulation carving numerous exceptions to the law and court decisions endorsing the exceptions. Like the FDA criminal referral process generally, the notice requirement remains on the books as a dusty codification of a process that has fallen out of favor.

Today, supplementing the FDA referral process are matters brought to the attention of prosecutors by Relators (whistleblowers). Typically, a Relator files a *qui tam* lawsuit under the Federal False Claims Act (FCA), a U.S. Attorney’s Office investigates pursuant to its statutory mandate, criminal charges are sometimes brought, individuals are sometimes charged under the RCO doctrine and the company settles for tens or hundreds of millions of dollars. The Relator nets a percentage of this windfall, which is generally in the millions of dollars as well.

It is difficult to dispute that Relators have assumed a central role in determining what matters are investigated by prosecutors. For example, Florida pharmacy Ven-A-Care has become a successful “professional whistleblower” and it is joined by a growing industry of professional whistleblowers and support entities like law firms. The system for determining which matters should be investigated is quite different from the one that prevailed in the *Park* era.

**C. Settling Before Trial**

*Dotterweich* and *Park* were decided at a time when more cases went to trial. By contrast, the modern era of health care enforcement is characterized by settle-
ments and plea agreements. DOJ and defendants alike have some interests that are served by settling, but in the context of FDCA prosecutions under the RCO doctrine, distortions of justice can result.

The interests of companies and their officers converge but do not mirror each other. Thus, when justice is dispensed by a three-way negotiation—in which one party, DOJ, holds a dramatic leverage advantage—the result for the two weaker parties, the corporation and the individual, may depend more on their relative power and less on the just result. In most instances, the more powerful of the two weaker parties is the corporation. A high-profile recent example of a corporation “holding the cards” at the expense of individuals was United States v. Stein, in which it was suggested that federal prosecutors pressured KPMG to withhold attorneys’ fees for individual officers who were also under investigation.

This analysis presumes convictions of corporations and individuals are equally valuable, but this may not always be true. Particularly in a publicly salient case, convictions of individuals can be more impactful than convictions of corporations. Moreover, a view exists that in a technical sense, companies do not do wrong, only individuals do wrong and that supervising officers “set the tone” for a company and are guilty even when, as under the RCO doctrine, they are personally accused of no specific wrongdoing. On the other hand, the collective intent doctrine makes it much easier to marshall sufficient proof against companies. Companies are also better positioned to pay the substantial financial penalties associated with contemporary FDCA convictions, a powerful countervailing consideration.

IV. Fashioning a Remedy

The risks of the improper use of the RCO doctrine are real, and now is the time—before such prosecutions become more common—for DOJ to put in place procedures to ensure the doctrine is used sparingly and only in the most egregious circumstances, if at all.

A. The Case for Guidelines

Since the doctrine was premised on the sound exercise of prosecutorial discretion, guidelines would facilitate the prosecutorial reticence that was expressly relied upon by the Supreme Court in establishing the RCO doctrine. In Dotterweich, the Supreme Court stated:

In such matters [determining which persons should be prosecuted under the RCO doctrine], the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on conscience and circumspection in prosecuting officers....

Indeed, prosecutorial conscience and circumspection have largely prevailed with respect to the RCO doctrine. However, given today’s overburdened federal prosecutorial apparatus and the higher stakes involved in cases, it is increasingly un-
realistic to expect prosecutorial discretion without some kind of guidance. Even
the best-intentioned prosecutors may overlook what was once—and should always
remain—a core limiting principle of the RCO doctrine. This principle needs to be
reaffirmed through express statements from DOJ.

Guidelines are an appropriate way to alleviate these and other problems. They
have been used successfully in analogous contexts to keep the government’s ap-
proach consistent and fair. For example, in June 1999, then-Deputy Attorney
General Eric Holder unveiled the Principles of Federal Prosecution of Business
Organizations, which aimed to standardize government charging decisions against
corporate defendants.81 Just a year earlier, in response to widespread concerns
about DOJ’s health care fraud enforcement efforts,82 Holder issued guidelines
on the use of the civil FCA in health care fraud cases.83 Prosecutorial guidelines have
gained popularity among DOJ84 states,85 municipalities,86 other countries,87 and
nongovernmental organizations.88

Moreover, as discussed supra, the FDA itself has a standard for referring cases
to DOJ that, when employed, serves as the functional guideline for its referrals.89

80 Id.
81 Memorandum from Deputy Attorney General Eric Holder to All Component Heads and
reports/1999/charging-corps.pdf.
82 See U.S. General Accounting Office, Applications of the False Claims Act to Hospital Billing
Practices (GAO/HEHS-98-195, July 1998), 18 (pointing to “legitimate concerns” about pre-guidelines
prosecutions)
83 Memorandum from Deputy Attorney General Eric Holder to All United States Attorneys et
84 See Memorandum from Deputy Attorney General David W. Ogden to Selected United States
(guidelines for prosecuting drug crimes in states that have enacted laws authorizing the use of marijuana
for medical purposes); see also Restrictions on the Possession of Firearms by Individuals Convicted of
a Misdemeanor Crime of Domestic Violence, available at http://www.jacobshklaw.com/OntheLaw/Li-
brary/Lautenberg%20Amt%20Prosecution%20Guidelines.pdf (guidelines for prosecuting possession
of firearms by individuals convicted of a misdemeanor crime of domestic violence).
tax.state.ny.us/pdf/enforcement/siu_guidelines.pdf; Prosecution of Shoplifting Offenses (New Jersey),
available at www.state.nj.us/oag/ldcj/agguide/shoplift.pdf.
86 See, e.g., Humboldt County District Attorney’s Health & Safety Code §§ 11357-11360. Prosecu-
tion Guidelines (Humboldt County, California), available at www.safeaccessnow.net/pdf/humboldt-
uk/publications/docs/code2010english.pdf.
89 See section III, supra.
Back when FDA had more responsibility for identifying and referring cases to DOJ, FDA functioned as an important check on cases that were referred for investigation by DOJ. The decision about whether to refer a case for prosecution was thoughtful, orderly, consistent, and based on principles of justice included in FDA's RPM. Since Relators have supplemented FDA as an important source of cases that are brought to DOJ for investigation, however, the pool of cases that are investigated have become increasingly divorced from FDA's guidelines. A useful aspect of potential guidelines would be to provide for additional collaboration between DOJ and FDA, similar to that which formerly existed under the FDA criminal referral process. Coordination between these agencies is desirable since FDA is the primary day-to-day regulatory body and RCO prosecutions undoubtedly have a wide-ranging impact. The coordination could take place via post-approval notice from DOJ to FDA about the former's intent to prosecute an individual under the RCO doctrine. Bringing FDA back into the decision-making process in a meaningful way would serve the interests of the government, potentially affected parties and the public generally.

B. What the Guidelines Should Look Like

The most important aspect of a new guidelines regime would clarify the mental state required for an RCO conviction. The minimum \textit{mens rea} for an RCO prosecution under the proposed guidelines should be aggravated negligence. This would reflect the fact that Congress never provided for strict and vicarious criminal liability under the FDCA and account for the extraordinary nature of presuming such liability on the basis of mere silence.

Second, the guidelines should provide a list of aggravating and mitigating factors to guide prosecutors in seeking the appropriate level of enforcement. Among the aggravating factors should be the \textit{mens rea}—if the defendant is alleged to have intent or knowledge, for example, the enforcement may be more aggressive—the presence of negative safety issues arising from the individual's alleged conduct, and the repeated or sustained nature of the individual's misconduct. These aggravating factors, of course, derive substantially from and reframe the RPM factors. The RPM makes DOJ criminal referral contingent on the presence of one of a higher \textit{mens rea} ("gross, flagrant, or intentional violations" or "fraud"), negative safety issues ("danger to health") or repeated or sustained misconduct ("a continuous or repeated course of violative conduct").\footnote{FDA, Reg. Procs. Manual § 6-5-1.} The proposed DOJ guidelines would actually grant prosecutors more discretion than does the FDA system. Unlike the FDA system, the proposed guidelines would also permit variations in the intensity of enforcement given the presence of two or all three of the aggravating factors, rather than treating the presence of one or more of the factors as a monolithic trigger.

The presence of mitigating factors, by contrast, should cause a prosecutor to seek less aggressive enforcement solutions or bypass criminal prosecution under the RCO doctrine altogether. Among the mitigating factors should be the existence of specific compliance steps taken by the corporate officer either before or after the alleged misconduct at issue and, separately, the existence of a generally robust compliance program at the company. If a corporate officer is deemed responsible for poor conduct at a company, he or she should be likewise deemed responsible for salutary conduct.