

## The Responsible Corporate Officer Doctrine: Defending Individuals in FDCA Cases

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To the extent intended by Congress and permitted by the Constitution, courts may impose criminal sanctions on individual corporate officers who were in positions of authority to have prevented or corrected wrongdoing within a corporation but failed to do so. That concept, which has come to be known as the responsible corporate officer (RCO) doctrine, was first developed under the Food, Drug & Cosmetic Act of 1938 (FDCA). See *United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Park*, 421 U.S. 658 (1975); 21 U.S.C. §§ 331(a), 333(a)(1), 352. Under the RCO doctrine, the government is not required to prove that an officer participated in wrongdoing or even knew about it. The RCO concept also exists outside of the FDCA context – principally under environmental laws. See, e.g., *United States v. Hanousek*, 176 F.3d 116 (9th Cir. 1999) (construing the Clean Water Act to allow conviction of a misdemeanor offense punishable by a prison term not exceeding one year without a showing of *mens rea*).

Sometimes characterized as imposing a form of strict vicarious liability, and sometimes characterized as requiring a showing of negligence, the RCO doctrine under the FDCA is a powerful weapon for federal prosecutors and (at least indirectly) the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). The potential criminal consequences of a FDCA conviction under the RCO doctrine include a term of imprisonment up to 12 months and at least a six-figure fine. The potential collateral consequences of such a conviction include, as a practical matter, exclusion by HHS from participation in the medical device and pharmaceutical industries. Given the lack of a *mens rea* requirement and the potential sanctions involved, the RCO doctrine provides profound leverage to federal prosecutors to resolve cases through plea agreements, stipulated facts, and uncontested proceedings. As a result, it gives great leverage to other federal enforcement agencies, especially HHS in the exercise of its exclusion authority, and stands as a tool for efficiently advancing the broader regulatory goals of the FDA. Whether that approach to law enforcement is fair or appropriate in any given case is another question.

Prominent agency officials have announced intentions to exercise their authority more aggressively than ever in cases that may implicate the RCO doctrine. See, e.g., March 4, 2010 Letter from FDA Comm’r Margaret A. Hamburg, M.D. to Sen. Charles E. Grassley (at 2) (<http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf>) (citing a committee recommendation to “increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable”) (site last visited April 3, 2011); Testimony of Lewis Morris, Chief Counsel to the HHS IG, House Committee on Ways and Means, Subcomm. on Oversight, March 2, 2011 (available at [http://oig.hhs.gov/testimony/docs/2011/morris\\_testimony\\_03022011.pdf](http://oig.hhs.gov/testimony/docs/2011/morris_testimony_03022011.pdf)) (“We intend to use [exclusion authority] in a broader range of circumstances”) (site last visited April 3, 2011); see HHS Guidance for Implementing Permissive Exclusion Authority (available at

[http://www.oig.hhs.gov/fraud/exclusions/files/permissive\\_excl\\_under\\_1128b15\\_10192010.pdf](http://www.oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf)) (October 2010) (site last visited April 3, 2011); FDA Guidance for *Park* Doctrine Prosecutions (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3>) (January 26, 2011) (site last visited April 3, 2011).

Anyone defending an individual in an investigation implicating the FDCA must be acutely sensitive to the potential risks and consequences for individual officers in advising the client and recommending potential courses of action. Counsel for an individual should make every effort to understand (1) the meaning and scope of the RCO doctrine and whether the Department of Justice may use it in the investigation at issue; (2) the relationships among the various enforcement agencies and the agency goals with respect to a particular investigation; (3) the company's position with respect to the investigation; and (4) the individual client's theoretical and practical exposure to criminal and civil sanctions. The ultimate goal of defense counsel for an individual must be to protect the client in every possible respect and limit his or her direct and indirect exposure as much as possible.

#### I. Development of the RCO Doctrine Under the FDCA.

The roots of the RCO doctrine lie in *Dotterweich*, 320 U.S. 277. In *Dotterweich*, the president and general manager of a pharmaceutical company, along with the company itself, was charged with shipping misbranded and adulterated drugs in interstate commerce in violation of a misdemeanor provision of the FDCA, which was passed five years earlier, in 1938. *Id.* at 278. The individual defendant was convicted “solely on the basis of his authority and responsibility as president and general manager of the corporation.” *Id.* at 286 (Murphy, J., dissenting). He was sentenced to a \$500.00 fine on each count “with payment suspended on the second and third counts, and probation for 60 days on each count to run concurrently.” *United States v. Buffalo Pharmacal Co.*, 131 F.2d 500, 501 (2d Cir. 1942).

In a 5-4 decision, the Court upheld the conviction, stating that the FDCA “dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing.” 320 U.S. at 281. The Court stated that “[i]n the interest of the larger good [the FDCA] puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.” *Id.* The Court declined to “define or even to indicate by way of illustration the class of employees which stands in such a responsible relation” and stated that such an inquiry is fact-dependent. *Id.* at 285.

The Supreme Court next addressed the RCO doctrine in *United States v. Park*, 421 U.S. 658 (1975). In *Park*, a company and its chief executive officer were charged with five misdemeanor violations of the FDCA. *Id.* at 660. Each count alleged that the defendants exposed food in warehouses to rodent contamination and thus allowed the food to become adulterated. *Id.* The company pleaded guilty; the CEO was tried before a jury. *Id.* at 661. The evidence at trial established that the FDA had advised the company (including the CEO in at least one instance) of unsanitary conditions at company warehouses on numerous occasions over several years. *Id.* at 661-62. The CEO testified at trial, among other things, that “as [the company's] chief executive officer he was responsible for ‘any result which occurs in our company.’” *Id.* at 663-64. The jury returned guilty verdicts on all five counts. *Id.* at 666. The court sentenced the CEO to a \$50.00 fine per count. *Id.*

The individual defendant in *Park* challenged the conviction by arguing that the jury instructions failed to define the requisite “responsible relationship” properly under *Dotterweich* and that his conviction wrongly rested on nothing more than his status as CEO. *Id.* at 665. In affirming the conviction, the Court held that it is enough for the government to show that a “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 the “jury could not have failed to be aware that the main issue for determination was not respondent’s position in the corporate hierarchy, but rather his accountability, because of the responsibility and authority of his position, for the conditions which gave rise to the charges against him.” *Id.* at 675. The Court identified only one possible defense under the RCO doctrine, stating that a defendant may present evidence at trial that he was “‘powerless’ to prevent or correct the violation” – in other words, an affirmative defense of “objective[] impossib[ility].” *Id.* at 673.

## II. Constitutional Limitations on the RCO Doctrine.

For criminal responsibility to exist, “a *mens rea* is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence.” *United States v. United States Gypsum Co.*, 438 U.S. 422, 436 (1978); accord *Morrisette v. United States*, 342 U.S. 246, 250 (1952) (“The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil”). The RCO offense under the FDCA, which dispenses with the *mens rea* requirement, falls within a category of “public welfare offenses [that] have been created by Congress, and recognized by [the Supreme] Court, in ‘limited circumstances.’” *Staples v. United States*, 511 U.S. 600, 607 (1994). The Court has “assumed that in such cases Congress intended to place the burden on the defendant to ‘ascertain at his peril whether [his conduct] comes within the inhibition of the statute.’” *Id.* (quoting *United States v. Balint*, 258 U.S. 250, 254 (1922)). Such offenses are tolerable under the Due Process Clause *only* because “penalties commonly are relatively small, and conviction does no grave damage to an offender’s reputation.” *Morrisette*, 342 U.S. at 256; accord *Staples*, 511 U.S. at 617-18. That limitation is crucial because it implicates legal developments and other concerns, as discussed below, that did not exist even when *Park* was decided in 1975.

## III. An Application of the RCO Doctrine: Purdue Frederick.

The Purdue Frederick case, in which three executives of a pharmaceutical company were convicted of RCO misdemeanors as a result of plea agreements, and then excluded by HHS from participation in all federal health care program for 12 years, is an especially prominent example of the RCO doctrine’s force. See *United States v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (accepting plea agreements); *Friedman v. Sibelius*, 2010 WL 5079937 (D.D.C. 2010) (affirming HHS exclusion). In 2007, the Purdue Frederick Company, Inc. “pleaded guilty to misbranding OxyContin, a prescription opioid pain medication, with the intent to defraud or mislead, a felony under the [FDCA.]” 495 F. Supp. 2d at 570. In its plea agreement, the company stipulated that the criminal conduct involved the false and misleading marketing of OxyContin by company personnel for a period exceeding five years. *Id.* at 571.

The company's former president and CEO, former executive vice president and chief legal officer, and former chief scientific officer pleaded guilty to a misdemeanor misbranding charge solely under the RCO doctrine. *Id.* at 570-71. None of the individuals was "charged with personal knowledge of the misbranding or with any personal intent to defraud." *Id.* The individual defendants and the government agreed to a specific sentence under Fed. R. Crim. P. 11(c)(1)(C) in the plea agreements that provided for, among other things, payment of \$34.5 million to a state fund and no term of incarceration. 495 F. Supp. 2d at 571. (Under Rule 11(c)(1)(C), a district court is bound to accept the stipulated sentence or allow a defendant to withdraw the plea and go to trial.) The district court accepted the plea agreements. *Id.* at 576-77.

After the resolution of the criminal case, HHS notified the three individual defendants that they were subject to permissive exclusion under 42 U.S.C. § 1320a-7(b) from participation in federal health care programs. *Friedman v. Sibelius*, 2010 WL 5079937, \*3. (Permissive exclusion involves the exercise of agency discretion. Mandatory exclusion, required under 42 U.S.C. § 1320a-7(a) for certain conduct, was not at issue with respect to the individuals in the Purdue case.) Several months later, HHS informed the individuals that the period of exclusion would be increased from "three years to twenty years based on its consideration of certain aggravating factors." *Id.* (citing 42 U.S.C. § 1320a-7(c)(3)(D)). After further administrative proceedings, the period of exclusion was reduced from 20 to 15 years. 2010 WL 5079937, \*3. That sanction was affirmed by an administrative law judge. *Id.* \*4. The sanction then was reduced from 15 to 12 years in an administrative appeal. *Id.*

The individuals filed a complaint in federal district court in October 2009 alleging that the HHS exclusion violated the Administrative Procedure Act, 5 U.S.C. § 706 *et seq.* 2010 WL 5079937, \*4. They argued that HHS lacks exclusion authority based on a conviction under the RCO doctrine in the absence of evidence of personal wrongdoing and also attacked the administrative decision on various other grounds. *Id.* The district court held that the statutory language – granting permissive exclusion authority for "a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service[.]" 42 U.S.C. § 1320a-7(b)(1)(A)(i) – plainly includes RCO misdemeanors. 2010 WL 5079937, \*6. The court held in the alternative that HHS reasonably may interpret the language to encompass RCO misdemeanors. *Id.*

The district court further held that the individuals inaccurately characterized the scope of the RCO doctrine. According to the district court, the individuals' claim that they were being sanctioned simply because of their officer status was nothing more than a collateral attack on their convictions and an effort to assert the limited affirmative defense, recognized under *Park*, that they were "powerless" to stop the underlying illegal conduct. *Id.* \*10. The court stated: "The time for raising such a defense has, of course, long passed." *Id.* at n.19. The court rejected the balance of the individuals' attacks, which were largely fact-based, on the agency decision. *Id.* \*11-15. The court also specifically noted that the individuals did not attack the exclusion on constitutional grounds. *Id.* n. 20. The individuals filed a notice of appeal in the D.C. Circuit on February 8, 2011. The court of appeals has not yet issued a briefing schedule.

#### IV. Legal and Practical Considerations in Defending Individuals in FDCA Matters.

As the *Purdue* case shows, an individual officer in a senior position at a pharmaceutical or medical device company, whether publicly traded or privately held, may face difficult choices in an investigation. For business and other reasons, a company facing criminal exposure is unlikely to challenge the government's allegations at trial and incur the associated risks. Instead, the company may reach an agreed-upon resolution in which the company and the government stipulate that the government could prove various facts if the case had proceeded to trial. The company may agree to cooperate with the government in the criminal investigation. And the company is likely to want to reach agreements with administrative agencies as part of a global resolution (along with an eye toward resolving any private civil litigation). Even if a company and individual officer have the best possible relationship, the company's likely approach toward resolution in such circumstances tends to have the effect of making the position of individual officers more difficult.

Regardless of the company's choices, individual officers who are subjects or targets of a criminal investigation may be faced in some circumstances with a highly undesirable choice: to plead guilty to a RCO misdemeanor or face an indictment alleging a conspiracy along with variety of substantive FDCA felony violations. Even if the government's evidence as to *mens rea* is very weak, the risks associated with trying a given federal criminal case in all likelihood are going to be substantial. And the government may add a RCO misdemeanor to a felony indictment in any event (although that involves tactical issues with respect to a jury). Given the difficulty in defending a charge under the RCO doctrine (as evidenced by *Purdue*, *Park*, and *Dotterweich*), an individual thus could incur the time, expense, risk, and potential anguish involved in a federal criminal trial, prevail on all of the felony charges, and still end up with an extraordinarily high likelihood of a conviction on a RCO misdemeanor. A conviction at trial in those circumstances would put the individual in a position almost certainly no better (and probably worse) than if he or she had pleaded guilty to the RCO misdemeanor. In such an event, would a rational individual tend to invite an indictment and go to trial? Or would a rational individual tend to concede that he or she is a responsible corporate officer and agree not to contest that the government could prove that underlying substantive violations were committed by someone else if the case had proceeded to trial?

The RCO doctrine, practically speaking, also gives enormous leverage to civil enforcement agencies. For instance, HHS generally is likely to wait until an underlying criminal case is resolved before exercising its exclusion authority, as in *Purdue*, although that is not invariably the case. See *United States v. Hermelin*, No. 4:11-cr-00085-ERW (E.D. Mo.) (guilty plea and sentencing on March 10, 2011 of former CEO of KV Pharmaceuticals on two RCO misdemeanor counts); Morris Testimony at 6 (noting 20-year exclusion); <https://exclusions.oig.hhs.gov/Verification.aspx> (noting that exclusion was effective November 18, 2010). But HHS generally can exercise its exclusion authority more efficiently in a contested agency proceeding if an individual will be precluded from raising at least some defenses as a result of an underlying negotiated criminal resolution. And the agency may not need to worry about a constitutional attack on the RCO doctrine in the administrative proceeding because the individual may have foregone that argument as a result of the criminal resolution.

There is room for a constitutional challenge to the RCO doctrine. The pressure for negotiated resolutions faced by individuals in FDCA criminal investigations, and the tremendous

leverage that the government exercises in driving such resolutions, were foreign to *Dotterweich* and *Park*. Both of those cases arose from jury trials in which the government was subject to the burden of proof beyond a reasonable doubt. Both of those cases were decided before HHS started exercising the far-reaching exclusion authority that it now holds. Both of those cases were decided when the maximum fine for a misdemeanor offense in a criminal case brought under the applicable provision of the FDCA was \$1,000. The maximum fine is now \$100,000 (and potentially more) under 18 U.S.C. § 3571(b)(5) as a result of the Sentencing Reform Act of 1984 (P.L. No. 98-473, 98 Stat. 1987). Adverse publicity resulting from RCO offenses – in the media, before Congress, and elsewhere – is now widespread. In short, the changed circumstances in the landscape since *Park* show that penalties associated with a RCO offense are no longer “relatively small” and that a RCO conviction does indeed do “grave damage to an offender’s reputation.” *Morissette*, 342 U.S. at 256; see *Staples*, 511 U.S. at 617-18.

Especially given the leverage afforded to the government by the RCO doctrine, it is unlikely that the Department of Justice will expose itself to constitutional litigation over the RCO doctrine in federal court against a well-represented corporate executive before a jury subject to a burden of proof beyond a reasonable doubt under the Federal Rules of Evidence. For one thing, the government has faced substantial difficulties in trying criminal cases relating to the health care industry, and the ability to achieve enforcement goals in uncontested proceedings (putting to one side the policy questions involving fairness and the proper exercise of prosecutorial discretion) may be too attractive for the government to resist. By using its leverage to resolve cases through guilty pleas to RCO offenses with stipulated facts, the Department of Justice avoids the obstacles raised by contested proceedings and greatly eases the burden for HHS – as shown by *Friedman v. Sebelius* – in exercising its follow-on exclusion authority.

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Counsel for an individual officer embroiled in a FDCA investigation must be vigilant at all times. The individual’s lawyer should be certain to understand the criminal and civil landscape, the regulatory frameworks involved, and the potential adverse consequences in each context. For example, an exclusion sanction imposed by HHS may be worse for the individual than the criminal resolution itself. Counsel involved in a criminal investigation must be certain to keep the potential collateral consequences closely in mind. *Cf. Padilla v. Kentucky*, 130 S. Ct. 1473 (2010) (holding that defense counsel’s failure to advise defendant of potential deportation consequences of a guilty plea constitutes deficient performance under the Sixth Amendment’s right to the effective assistance of counsel).

Securing reliable and timely information, understanding the broader context, and learning the facts as they relate to the client are essential to making the most effective judgments possible. Counsel for an individual should make every effort to maximize effective communication with counsel for the company and counsel for other individuals who are involved in an investigation. Counsel for an individual should also attempt to identify the enforcement agencies involved, the persons at each agency who are involved, the relationships among the agencies, and the potential agency goals and motives involved. For example, the FDA, HHS, a U.S. Attorney’s Office, and the Office of Consumer Litigation in the Department of Justice may be involved simultaneously in a matter. Investigating agents from other agencies, such as the FBI, may be involved as well. Depending on the circumstances, direct contact with agency personnel may be appropriate even at an early stage (for instance, when the individual client is clearly at the heart of the

investigation). In other cases, it may be advisable to attempt to gather information more quietly and indirectly as matters develop. By pursuing all of these goals in a professional manner, and by acting credibly and reliably at all times, counsel for an individual officer can help ensure the best possible outcome for his or her client in a complex and difficult regulatory environment.