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Health Care Fraud Enforcement, Strict Criminal Liability, and Responsible Corporate Officials

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Any responsible corporate official (RCO) in an industry subject to the federal Food, Drug, and Cosmetic Act (FDCA) and related regulations can be ensnared in a criminal investigation of manufacturing safety practices, mislabeling, misbranding, adulteration, or advertising and promotion of products, and convicted of related crimes based solely on strict liability grounds.[1] As a result, it is no longer sufficient for an RCO to rely on what is generally considered an effective compliance program that may on occasion fail; an RCO is an insurer of corporate compliance and must make sure that corporate operations are nearly perfect on almost all occasions. Once convicted of a strict liability crime, an RCO could receive a career death sentence by being excluded from federal and state health care programs for up to twenty years.[2]

Strict Criminal Liability and the RCO Doctrine

In 1943, the Supreme Court interpreted the FDCA to impose strict criminal liability. In 1975, with reluctance, the Court upheld the application of strict criminal liability, this time in the food industry. Significantly, however, neither case presented a constitutional challenge to strict criminal liability

The Dotterweich Case

The president of a corporation that bought and distributed drugs after repacking them was convicted of having shipped "misbranded" and "adulterated" drugs, a misdemeanor. Dotterweich, the corporation's president, and the corporation were indicted in *United States v. Dotterweich* based on two separate shipments alleged to have violated the FDCA, which granted immunity from penalties if the distributor had a guaranty from the manufacturer that the drugs sold were not adulterated or misbranded. In this case, no guaranty was obtained. The jury acquitted the corporation but Dotterweich was convicted of all three counts, fined $500 and given 60 days probation.[3]

On appeal, the Second Circuit found the evidence sufficient to establish that the drugs were adulterated and misbranded, but reversed Dotterweich's conviction on the ground that, absent unusual circumstances, only the corporation was subject to prosecution.[4] In reversing Dotterweich's conviction, the court accepted his argument that the statute was "aimed only at punishment of the principal and not at punishment of an innocent agent who in good faith and in ignorance of the misbranding or adulteration takes part in an interstate shipment of food or drugs."

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Supreme Court Upholds Corporate President's Conviction

In a 5-4 opinion, the Supreme Court reversed and reinstated Dotterweich's conviction. In the Court's view, Congress's purpose in passing the FDCA was to exercise its "power to keep impure and adulterated food and drugs out of the channels of commerce" in order to protect "the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection."[5] The FDCA, Justice Frankfurter pointed out, is concerned with distribution of the drugs, and only the individual agents of the company can accomplish that objective. "But simply because if there had been a guaranty it would have been received by the proprietor, whether corporate or individual, as a safeguard for the enterprise, the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by [the relevant section of the Act]."[6] Accordingly, a liberal construction of the "central purpose of the Act," rather than "liberality" in construing the exception of the guaranty provision, "casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor."[7]

Justice Frankfurter dismissed the Second Circuit's concern that the interpretation adopted by the Court "might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment."[8] Without defining the class of potentially liable persons, Justice Frankfurter conceded that it would include "all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs." To be sure, Justice Frankfurter conceded that "there doubtless may be [hardship] under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting." According to Justice Frankfurter, Congress, after balancing the equities, chose to place the hardships on those who have the opportunity to ensure the existence of compliance with the safe conditions for the protection of consumers.

Justice Murphy's Dissent

In his dissent, Justice Murphy contended that the president of a company is a "corporate officer" who is both a "person" as defined in the FDCA and an "individual." According to Justice Murphy, the FDCA does not expressly place strict liability on "corporate officers." Justice Murphy found support for his position in the legislative history of the 1906 and 1938 Acts. He pointed out that the Senate version of the bill that became the 1906 Act contained clear language making corporate officers strictly liable. However, this language was not included in the final bill, and was replaced with language making the acts or omissions of corporate officers the acts or omissions of the corporation. In enacting the 1938 Act, Justice Murphy stated that Congress was aware of this deficiency in the 1906 Act and the framers of the later Act included language in the bill to make corporate officers strictly liable. Again, Justice Murphy stated that the law enacted by Congress did not contain such language. He therefore concluded that Congress did not intend to subject corporate officers liable under the 1938 Act.[9]

Strict Criminal Liability Affirmed

Thirty-two years after *Dotterweich*, the Court reaffirmed the strict criminal liability doctrine in a case involving rodent-contaminated food deemed to be adulterated within the meaning of the FDCA.

> Once convicted of a strict liability crime, an RCO could receive a career death sentence by being excluded from federal and state health care programs for up to twenty years.

The president of a national retail chain was charged with violating the FDCA after a rodent infestation was discovered at one of his company's warehouses. At trial, the company's chief legal officer, called by the government, testified that under the corporate by-laws the president had "normal operating duties" and that he exercised his responsibilities by retaining "certain things, which are the big, broad, principles of the operation of the company" and had the responsibility of "seeing that they all work together." The president testified that he delegated authority for sanitary conditions, although he was responsible ultimately for that part of the company's operations. The president was convicted, and fined $50 on each of five counts.[10]

The Court of Appeals reversed the conviction on the ground that the trial court's jury instruction did not require the jury to find some "wrongful action" in order to convict. The Supreme Court reversed and affirmed the lower court's jury instruction and the president's conviction. In upholding the company president's conviction, the Court pointed out that the sole limiting principle established by *Dotterweich* was that a charged person must have "a responsible share in the furtherance of the transaction which the statute outlaws."[11] Significantly, the Court noted that the jury instruction, read as a whole, informed the jury that to find the defendant guilty it must conclude that he had "a responsible relation to the situation [presumably the rodent infestation]."[12] Accordingly, the Court concluded that guilt could not have been "predicated solely on respondent's corporate position." While disagreeing with the majority's interpretation of the jury instruction as a whole, the dissent read the Court's opinion to hold that conviction under the FDCA required at least negligence. The dissent disagreed with the Court's application of that standard to uphold the trial court's jury charge. Nevertheless, the Court's rationale apparently supports the position that mere

corporate status, which confers formal authority to stop or rectify wrongdoing within the corporate hierarchy, is insufficient to establish criminal conduct.

Constitutionality of Strict Liability Crime

Despite broadly worded statements by some enforcement officials, the government has not charged an RCO merely because of his or her corporate status and authority to stop wrongful conduct.[13] If and when such a case is brought, and a conviction obtained, the Supreme Court would not be likely to uphold the conviction.[14]

In *Liparota v. United States*, the owner of a restaurant was convicted for fraud based on his purchases from an undercover agent of food stamps at what was, according to the Court, substantially less than face value. The Court reversed the conviction because of an improper jury instruction on mens rea. The Court read into the statutory text an element of mens rea and conceded that the "legislative history of the statute contains nothing that would clarify the congressional purpose on this point."[15] "Criminal offenses," noted the Court, "requiring no *mens rea* have a 'generally disfavored status.'"[16] The Court distinguished *Dotterweich,* among other cases, as construing a "public welfare" law rendering criminal "a type of conduct that a reasonable person should know is subject to stringent public regulation and may seriously threaten the community's health or safety."[17]

Despite broadly worded statements by some enforcement officials, the government has not charged an RCO merely because of his or her corporate status and authority to stop wrongful conduct

Defending the Criminal Investigation and OIG Exclusion

Those individuals responsible for certain tasks within a company should be clearly identified and their precise legal authority (consistent with corporate law and the company's bylaws) should be delineated in writing. In addition, de facto authority should also be captured in writing to the extent possible. Both formal legal authority and the company's "operational culture" should be captured in writing. These preliminary steps will help to defend a criminal charge if an investigation goes that far.

The most plausible defense in a *Park* doctrine prosecution is that the defendant lacked de facto or legal authority to stop the conduct that the government alleges is a violation.[18] At trial, the defense should request a jury instruction "that the government was required to prove beyond a reasonable doubt that [the defendant] was not without the power or capacity to affect the conditions which founded the charges."[19]

In the health care industry, defense counsel must focus early in an investigation on the exclusion authority of the Office of Inspector General of the U.S. Department of Health and Human Services (OIG). Counsel should insist that any plea agreement be accompanied by an agreement with the regulators about the exclusionary consequences of the plea. Since the charge under consideration is a misdemeanor, the OIG would only have permissive exclusion authority, although with broad discretion with respect to the length of an exclusion.

Challenging Exclusion as Excessive Punishment

The OIG's permissive exclusion authority has been interpreted by HHS as favoring presumptive exclusion.[20] As a result, the only issue effectively open to challenge in an OIG administrative exclusion proceeding following a conviction is the length of the exclusion, which can be as long as 20 years, depending on mitigating and aggravating circumstances. While all relevant evidence bearing on the administrative exercise of discretion should be presented to minimize the exclusion period, in some cases, the exclusionary period can be disproportionate punishment in violation of the Eighth Amendment to the U.S. Constitution, or at least so harsh as to be an abuse of discretion.

The Eighth Amendment bars imposition of excessive fines and cruel and unusual punishments that are grossly disproportional to the offense. [21] In the context of permissive exclusion for a misdemeanor offense requiring no mens rea, an exclusionary period from all federal and state health care programs beyond a certain length of time can effectively be a career death sentence that should be open to an Eighth Amendment challenge. This would be especially so where the excluded individual had no personal notice as to the conduct giving rise to the violation and was convicted merely because his or her corporate status granted legal authority to put a stop to the violation found by the government.

The parallel developments in the OIG's exclusionary authority and health care fraud prosecutions threaten extremely severe career-ending punishment for admittedly serious violations on those who lack any knowledge or notice of, or culpable responsibility for, such violations. Congress granted OIG the exclusion authority, in part, because prosecutors lacked interest in bringing criminal cases in this area.[22] Since then, prosecutors have been extremely active in enforcing criminal health care statutes, while the regulators have developed the exclusion authority on a parallel track. The criminal cases were brought to enforce traditional criminal statutes that required knowing

and willful conduct. On the regulatory side, the regulators were willing to bargain away their exclusionary authority in return for a corporate integrity agreement.

Prosecutors and regulators have joined forces to combine strict liability, the most troubling of criminal theories, with permissive exclusion, the most discretionary form of presumptive exclusionary authority. It is no exaggeration to say that Congress probably did not contemplate this enforcement development, however much it supports vigorous health care fraud enforcement. Nor did the Supreme Court have any reason to foresee that strict liability would be used together with exclusionary authority in health care enforcement, because the power to exclude did not exist in that field when the Court upheld the *Park* conviction and reaffirmed the *Dotterweich* doctrine.[23] In appropriate future cases, challenges to both the use of strict criminal liability separately and in combination with permissive exclusion should serve to clarify the legal standard necessary to prove criminal liability under the FDCA misdemeanor statute and the scope of discretionary exclusion.

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[1] Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. The Supreme Court has upheld application of strict criminal liability under the misdemeanor section of that statute in *United States v. Dotterweich*, 320 U.S. 277 (1943) and *United States v. Park*, 421 U.S. 658 (1975). *Dotterweich* decided who is subject to liability under the FDCA misdemeanor statute. *Park* addressed the sufficient proof required for conviction.

[2] *Friedman v. Sebelius,* 755 F. Supp. 2d 98, 2010 BL 295672 (D.D.C. Dec. 13, 2010). The initial exclusion by the Administrative Law Judge (ALJ) had been for twenty (20) years, reduced at first to fifteen (15) years due to the individuals' cooperation in the criminal investigation, and ultimately reduced by the Department Appeals Board (DAB) in the HHS Secretary's final decision to twelve (12) years. The 12-year exclusion was recently upheld by the district court as a valid exercise of the Secretary's statutory discretion. Two of the individuals in the *Friedman* case are over 60 years old. The company's former general counsel has appealed the district court's ruling to the District of Columbia Court of Appeals.

[3] *United States v. Buffalo Pharmacal Co*., 131 F.2d 500, 501 (2d Cir. 1942), *rev'd sub nom. United States v. Dotterweich*, 320 U.S. 277 (1943).

[4] *Id.*

[5] *United States v. Dotterweich* at 281.

[6] *Id.* at 284 (emphasis added).

[7] *Id.* at 284.

[8] *Id.*

[9] *United States v. Dotterweich*, 320 U.S. at 292. Justice Frankfurter had interpreted this legislative history differently. In his view, the language included in the 1906 Act was needed to make clear that a corporation is liable. But by 1938 the evolution of the law in this area had clearly accepted corporate liability, and thus Congress had merely deleted mere surplusage from the statute without intending any substantive effect. *Id.* at 282.

[10] The company had pleaded guilty.

[11] *United States v. Park*, 421 U.S. at 669 (quoting *United States v. Dotterweich*, 320 U.S. at 284).

[12] *Id.* at 674.

[13] *See* Daniel R. Levinson, Inspector General of the Department of Health and Human Services, "Highlights of the Keynote Address," Health Care Compliance Association Annual Compliance Institute, April 19, 2010, at 5-6.

[14] *Liparota v. United States*, 471 U.S. 419 (1985).

[15] *Id.* at 424.

[16] *Id.* at 425.

[17] *Id.* at 433.

[18] This is the so-called "objective impossibility" defense. *United States v. Gel Spice Company, Inc*., 773 F.2d 427 (2d Cir. 1985); *United States v. Y. Hata & Company*, 535 F.2d 508 (9th Cir. 1976).

[19] *United States v. Park*, 421 U.S. at 676. Such an instruction, as the Court noted, was not requested in *Park*.

[20] 42 U.S.C. § 1320a-7(b) (permissive exclusion authority); Sue Reisinger, "Government Vows Expanded Use of Fraud-Fighting Tool," *New York L. J.*, March 7, 2011, p. 2 (quoting counsel to OIG-HHS as saying "when there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization, [we] will operate with a presumption in favor of exclusion of that executive.").

[21] *See United States v. Bajakalian*, 524 U.S. 321 (1998).

[22] *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995); *Anderson v. Thompson*, 311 F. Supp 1121, 1126 (D. Kan. 2004)("The legislative history of section 1320a-7(b)(7) [permissive exclusion] indicates it was enacted as an alternative to criminal prosecution or where a program-related conviction does *not* exist.") (Emphasis in original.)

[23] There was no exclusion authority in the food industry to exclude Mr. Park from the business.