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EXECUTIVE SUMMARY

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Alerting the "C-Suite":
The Responsible Corporate Officer Doctrine

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Health lawyers should note a controversial trend in criminal enforcement seeking to hold corporate leadership responsible for organizational non-compliance—even if the officer or director had no involvement with or knowledge of the challenged conduct. The Responsible Corporate Officer Doctrine (RCOD) is a strict liability-based theory that is increasingly being threatened in government investigations involving health industry companies. The RCOD's use reflects government interest in "following the conduct" to identify individuals who can be held responsible—whether they are "in the field," executive suite, or the board room.

RCOD-associated risk should not be understated by corporate counsel and compliance officers. The U.S. Department of Justice (DOJ) interprets the RCOD as permitting (in certain circumstances) the prosecution of officers and directors for misdemeanor criminal offenses— without the need to establish their intent, knowledge, or involvement in the alleged illegal conduct. It is in essence an efficient (albeit controversial) prosecution tool from the government's perspective. Indeed, in two separate, recent prosecutions, health industry executives (including a general counsel) were charged and subsequently pled guilty to certain RCOD-based misdemeanors, with serious personal penalties.

To date, healthcare application of the RCOD has been limited to allegations under the federal Food, Drug, and Cosmetic Act (FDCA).[1] Evidence of illegal intent remains an essential element of most key healthcare antifraud criminal statutes. However, the concern is whether DOJ may seek to expand use of the RCOD to other healthcare-related, strict liability contexts (e.g., Stark). This concern is sharpened by the fundamental vagaries of the doctrine, and the amorphous and ambiguous nature of possible defenses.

RCOD Foundations

The RCOD is based upon two U.S. Supreme Court decisions (decided thirty-two years apart) with severe fact patterns that disturb the conscience. In each case, the Supreme Court upheld the conviction of corporate officers for public welfare-based crimes without evidence that they had any knowledge of or participation in the core criminal activity. Both *United States v. Dotterweich*[2] and *United States v. Park*[3] involved FDCA violations. *Dotterweich* addressed the conviction of a pharmaceutical company executive charged with interstate shipment of misbranded drugs. While there was no evidence that the executive was aware that the shipments were indeed misbranded or adulterated, the Supreme Court upheld his conviction. In doing so, it held that criminal liability for violation of a public welfare-based statute (e.g., FDCA) could be established where the officer possessed the authority to prevent the violation, and failed to take action to do so.[4] Critical to the court's conclusion was the extent to which violations of public welfare statutes (the risk of endangering public health) supports an exception to the traditional rules of liability.[5]

The *Park* court, which involved the same FDCA misdemeanor provisions, clarified the RCOD by articulating a standard under which criminal liability could be attributed to a

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[1] Now codified at 21 U.S.C. §§ 301 *et seq.* This statute contains a strict liability provision for misdemeanor misbranding and adulteration violations.
[2] *United States v. Dotterweich*, 320 U.S. 277 (1943).
[3] *United States v. Park*, 421 U.S. 658 (1975).
[4] *See Dotterweich*, 320 U.S. at 285-86 (Murphy, J., dissenting) (stating that there was no evidence Mr. Dotterweich "ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed to [Mr. Dotterweich] solely on the basis of his authority and responsibility as president and general manager of the corporation.")
[5] *See Park*, 421 U.S. at 670-71 (stating the interpretation of the FDCA as applied in *Dotterweich* is that those who fail to exercise the authority and supervising responsibility reposed in them by the company, resulting in the charged violation, are to be held criminally responsible.)

corporate officer for the actions of subordinates in the absence of knowledge or involvement in such actions:

- By virtue of his position in the corporation, the officer both:
  - Had "the responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of"; and
  - Failed to prevent or correct the violation.[6]

It should be noted that prosecutors have, with judicial approval, successfully applied RCOD-type theories to several different types of state and federal statutes, including but not limited to criminal violations of the Sherman Act, the federal securities laws, and state/federal environmental laws. A common thread is that the statute under which liability is sought to be imposed is a public welfare statute.[7]

Recent Health Sector Application

The RCOD is relevant to health lawyers because of: (1) its recent application to obtain guilty pleas from healthcare corporate officers in two separate criminal prosecutions; (2) a series of recent public speeches by DOJ officials promoting the RCOD's use in the healthcare sector; and (3) the strict liability aspects of the Stark Law that at least superficially may make it vulnerable to an attempt to apply the RCOD.

Guilty Pleas

In two recent instances, DOJ prosecutions of medical companies for FDCA violations[8] have led to misdemeanor guilty pleas (and significant penalties) by corporate officers under the RCOD.

Over the summer of 2009, four executives of Synthes Inc. and its Spine Division pled guilty to misdemeanor charges associated with shipping adulterated and misbranded medical devices in interstate commerce. The pleas related to a ninety-seven-count

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[6] *See Park,* 421 U.S. at 673-74. Mr. Park was the president of a retail food company who had no meaningful oversight over company practices at the core of the FDCA violation (rodent infestation).

[7] Blue Sky § 9:117.5 (SEC BLUE § 9:117.5); Berman and Donath, *When No Knowledge Can Still Be a Dangerous Thing: The Potential Criminal Liability of Officers and Directors of Healthcare Companies for the Acts of Their Subordinates*, American Health Lawyers Association Business Law and Governance Practice Group, *Business Law and Governance*, Vol. 1, Issue 1, Dec. 2008.

[8] 21 U.S.C. § 331(a) prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug.

indictment of the executives, Synthes, and its Norian subsidiary, alleging the promotion of unauthorized clinical trials of bone cement for off-label use. In their guilty pleas, the executives stipulated that they were "responsible corporate officers" at the time the clinical trials were conducted.[9]

Earlier, in 2007, Purdue Frederick Company and three of its senior executives pled guilty to violations of the FDCA associated with the misbranding of the drug OxyContin. The executives included the chief executive officer *and* the general counsel. DOJ did not allege that the three officers participated in or were even aware of the misbranding. Rather, DOJ alleged simply that they were responsible corporate officers during the time period the misbranding occurred. As with Synthes, the guilty pleas of the executives contained a statement acknowledging that they were responsible corporate officers at the time the conduct occurred. As part of their pleas, the executives agreed to disgorge a total of $34.5 million in personal funds but avoided incarceration.

DOJ Speeches

The vitality of the RCOD is highlighted by a series of speeches in the fall of 2009 by separate, high-ranking DOJ officials to medical device and pharmaceutical industry audiences. In their comments, the officials indicated that healthcare fraud enforcement "[w]ill not 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."[10] More particularly, "[H]olding individuals accountable, either through direct proof of their knowledge of noncompliant practices or through strict liability under the responsible corporate officer doctrine, is currently a trend in government civil and criminal investigations."[11] Attributing responsibility for non-compliant behavior to "the highest corporate levels should do more to ensure compliance" with applicable federal

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[9] The Synthes executives have yet to be sentenced because of a dispute with DOJ about the plea agreements' scope.

[10] *DOJ Officials Outline Enforcement, Prevention Initiatives to Tackle Fraud*, HEALTH CARE DAILY REP. (BNA) (Nov. 16, 2009) (Comments attributed to Tony West, head of Civil Division, DOJ).

[11] *Government Attorneys Discuss Conduct That Gives Rise to Fraud Investigations*, HEALTH CARE DAILY REP. (BNA) (Nov. 12, 2009) (Comments attributed to Gerald Sullivan, of the U.S. Attorney's Office for the Eastern District of Pennsylvania).

law, and "could also lead to more prosecutions under the responsible corporate officer doctrine."[12]

Application to Providers

As noted above, DOJ has normally applied the RCOD in the healthcare sector to impose criminal liability on executives for violations of the FDCA misdemeanor provisions.[13] This makes application of the RCOD an awkward fit with most of the principal antifraud statutes applicable to hospitals and other providers. Neither the Anti-Kickback laws nor the False Claims Act are "strict liability" laws, but require proof of intent as an element of a violation.

The Stark Law, by contrast, is a strict liability law,[14] prohibiting certain healthcare providers from submitting claims to Medicare when the referring physician has a noncompliant financial relationship with the provider and subjecting them to civil money penalties for presenting a prohibited claim, regardless of the parties' intent in entering into the underlying financial relationship.

Although the Stark Law has no intent requirement, penalties arise only if the provider has knowledge, of or acted in reckless disregard or deliberate ignorance of an improper referral.[15] However, it is certainly possible that a prosecutor could try to apply the RCOD to a corporate officer who should have ensured that only proper claims were filed. Therefore, it would not be surprising if prosecutors attempted to expand the FDCA theory to an arguably analogous setting—Stark—even though it would seem not warranted by current law. This risk is enhanced if DOJ perceives Stark as a "public welfare"-type statute (often a fundamental requirement for consideration of RCOD liability).[16]

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[12] *More than Compliance Needed to Avoid Enforcement, Attorneys Tell Meeting*, HEALTH CARE DAILY REP. (BNA) (Sept. 28, 2009), (Comments attributed to Sara M. Bloom, Assistant U.S. Attorney for the District of Massachusetts in Boston).

[13] Health lawyers are aware that the Internal Revenue Service has recently successfully applied RCOD-type arguments to affix liability on hospital officers and directors for the organization's failure to withhold and/or pay over to the government payroll taxes.

[14] 42 U.S.C. § 1393nn; 42 C.F.R. § 411.351 *et seq*.

[15] A provider is not prohibited from filing a claim and need not refund Medicare reimbursement if it did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of the identity of the physician who made the referral. 42 C.F.R. § 411.353(e).

[16] SEC BLUE § 9.117.5; Berman and Donath, *supra* note 7.

What to Do

The RCOD is a controversial and aggressive theory of criminal liability. It imposes liability on corporate officers, and in certain instances directors, by virtue of their organizational authority, without regard to "guilty knowledge" or willful conduct. DOJ officials have referenced its application in a series of recent public presentations to medical device and pharma audiences. Whether the RCOD may be successfully applied to hospital executives or board members in the context of traditional provider-based, antifraud provisions is uncertain. Nevertheless, it is a development that healthcare executives—and boards—should take seriously.

RCOD risk is exacerbated by the absence of any clearly articulated guideposts from which officers and directors may appropriately structure their conduct. *Park* and several other courts have recognized an "impossibility defense" to FDCA violations, raised when the defendant introduces evidence that he had exercised "extraordinary care" yet was powerless to prevent FDCA violations.[17] However, the availability of such an "impossibility defense" is elusive to the point of frustration. There simply is no reliable definition of conduct constituting "extraordinary care" or "the utmost care." None of the courts, administrative proceedings, or DOJ has provided useful guidance on how the elements of this defense can be satisfied.

In the absence of such guidance, efforts by officers and directors to adopt a comprehensive, "state of the art" compliance program may prove helpful in the broadest sense. In particular, the following types of compliance plan enhancements as mandated by executive leadership, general counsel, and the board, may be generally responsive to RCOD risk:

- Materially increased compliance education and training;
- Enhanced reporting mechanisms that provide executive leadership with a more accurate awareness of the organization's compliance profile;

[17] *Park*, 421 U.S. at 673; *United States v. Wisenfeld Warehouse Co.*, 376 U.S. 86, 84 S.Ct. 559, II L. Ed. 2d 536 (1964); s*ee also Goldenheim, et al. v. Inspector General*, Dec. No. 2268 (Departmental App. Bd. Appellate Dir. Aug. 28, 2009) (Final Review of Administrative Law Judge's Decisions) ("[I]f indeed the fraud occurred despite the [defendants] having exercised the 'utmost care' and having taken 'extraordinary measures' to ensure that the company behaved lawfully . . . then at trial they could have mounted the affirmative defense that they were powerless to stop [the fraud]."

- Emphasis on close monitoring of potential compliance risk areas;
- Significant increase in employee and vendor accessibility to confidential reporting mechanisms and in organizational response to individual reports;
- Effective “upstream” reporting relationships (with futility bypass) for the chief compliance officer, general counsel, and outside counsel;
- Evidence of material board attentiveness to compliance-related comments in the “management letter” from the independent auditor;
- Periodic review of compliance plan effectiveness by advisors with federal law enforcement (e.g., ex Assistant U.S. Attorney or Office of the Inspector General) background; and
- Financial incentives for conduct consistent with the compliance plan, and harsh remediation of conduct inconsistent with the compliance plan.

However, there can be no assurance that such enhancements or similar efforts will constitute a successful defense to RCOD-based allegations. Furthermore, the absence of such efforts should not be interpreted as proof of less-than-utmost care (or anything else, for that matter). Nevertheless, the more that corporate officers and directors are made aware of RCOD risks, the more likely they are to support efforts to assure that the organization maintains a state of the art compliance program. This ultimately may be the best available defense to RCOD liability.

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