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There are many reasons for companies in the health care and life sciences industries to develop and maintain a strong compliance program. For executives at health care and life sciences companies, the Responsible Corporate Officer ("RCO") doctrine is an especially compelling reason. The RCO doctrine is key tool being utilized in government investigations and prosecutions of health care and life sciences companies. It is a strict liability theory which provides that responsible corporate officers face potential criminal liability for violations of the Food, Drug, and Cosmetic Act ("FDCA"), and possibly other health care laws, even if they did not participate in these violations and had no actual knowledge of the wrongdoing. The FDCA provides that, for their failure to prevent or correct such wrongdoing, corporate officers may face fines of up to $100,000 per violation and up to one year of imprisonment[1], as well as Food and Drug Administration ("FDA") debarment from the pharmaceutical industry[2] and permissive exclusion from federal and state health care programs such as Medicare and Medicaid.[3]

In a 1975 United States Supreme Court case, *U.S. v. Acme Markets, Inc. and John R. Park, President*[4], a large food chain corporation pleaded guilty to shipping contaminated food across state lines in violation of the FDCA. The president of the company pleaded not guilty and moved for a judgment of acquittal because he had delegated responsibility for addressing unsanitary conditions at company warehouses and "[was] not personally concerned in this Food and Drug violation."[5] In *Park,* the Court held that the corporation's president could be criminally liable because his position of authority and his supervisory responsibility created duties to seek out, implement preventive measures against, and remedy FDCA violations.[6] Put another way, the FDCA is essentially a strict liability statute[7], and prosecutors were not required to prove the corporation president's knowledge, intent, negligence, or participation in these FDCA violations. The Supreme Court's reasoning in this case became known alternatively as the *Park* doctrine or the RCO doctrine.

The RCO doctrine continues to threaten responsible corporate officers, and that threat may be increasing given recent enforcement trends. Although the government often declined to bring RCO doctrine cases during the previous two decades, the RCO doctrine appears to be poised for resurgence. In two recent cases from 2007 and 2009, executives from Purdue Frederick Company and Synthes Inc. pleaded guilty to misbranding violations that occurred while they were admittedly responsible corporate officers. Since 2009, the FDA and U.S. Department of Justice ("DOJ") officials have publically told Congress and warned industry officials that RCO doctrine prosecutions will increase. The government's recent interest in the RCO doctrine could potentially lead to expanded application of the doctrine to violations of a broader range of health care fraud and abuse laws, such as the Criminal and Civil False Claims Acts[8] and the Federal Anti-Kickback Statute[9]. In particular, the federal physician self-referral law (commonly known as the "Stark Law") is a strict liability statute like the FDCA, which may make it the most natural context for expansion of the RCO doctrine.[10]

The implications of the RCO doctrine are evident for corporate officers of companies, including health care and life sciences companies, whose activities are subject to the FDCA and possibly other health care laws—and the RCO doctrine could potentially extend to private equity companies that own portfolio health care or life sciences companies. Supplemental insurance coverage for RCO doctrine liability is available, but even insured responsible corporate officers have a duty to act as watchdogs of their own company. In practice, this likely includes implementing a robust compliance program with, among other things, training programs, reporting mechanisms, internal controls, auditing and monitoring, and disciplinary responses, as well as documentation of all such initiatives to prevent or address violations. Given that delegation is not a defense, responsible corporate officers will want to hire trusted employees, run background checks, and potentially require certifications that employees are following compliant business practices.

Finally, responsible corporate officers will want to take special care to avoid FDCA violations that fall within the scope of the government's recent prosecutorial priories, which may include off-label promotion, health scares in the public eye, and industry practices under scrutiny. The FDA's Regulatory Procedures Manual **Section 6-5-3 "Special Procedures and Considerations for Park Doctrine Prosecutions"** lists general factors meant to guide FDA personnel on whether to recommend a misdemeanor prosecution against a corporate official:

When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.

Other factors to consider include but are not limited to:

1. Whether the violation involves actual or potential harm to the public;
2. Whether the violation is obvious;
3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
4. Whether the violation is widespread;
5. Whether the violation is serious;
6. The quality of the legal and factual support for the proposed prosecution; and
7. Whether the proposed prosecution is a prudent use of agency resources.[11]

Should the government decide to bring a RCO doctrine prosecution, defenses include that a responsible corporate officer was "powerless" to prevent or correct a violation or that prevention or correction was objectively impossible.[12] Because such defenses can be difficult to define and because it may help build a case for such an impossibility defense, a comprehensive and diligently managed compliance program remains essential.

For questions about the implications of the RCO doctrine for your organization or for assistance in developing an appropriate regulatory compliance program, please contact one of the attorneys listed above.

**NOTES**

1 21 U.S.C. § 333(a) and 18 U.S.C. § 3571.

2 21 U.S.C. § 335a.

3 42 U.S.C. § 1320A-7(b) and 42 CFR 1001.201.

4 421 U.S. 658 (1975).

5 421 U.S. at 663.

6 *Id.* at 671-672.

7 The FDCA prohibits "[t]he adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce" without regard to the violator's intent. See 21 U.S.C. § 331(b).

8 18 U.S.C. § 287 and 31 U.S.C. § 3729.

9 42 U.S.C. §1320a-7b.

10 In brief, the Stark Law prohibits physicians from making a referral, without regard to their intent, for certain health services reimbursable by Medicare to a health care provider with which they, personally or through a family member, have ownership or investment interests or compensation arrangements. See 42 U.S.C. § 1395nn(a).

11 **Food and Drug Administration, Regulatory Procedures Manual**, Section 6-5-3 "Special Procedures and Considerations for Park Doctrine Prosecutions."

12 421 U.S. at 673 (citing *U.S. v. Wiesenfeld Warehouse Co.,* 376 U.S. 86, 91 (1964).