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Pharmaceutical Industry Executives Face Enforcement Risks Under The Responsible Corporate Officer Doctrine

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The recent decision of the D.C. Circuit in Friedman v. Sebelius, No. 11-5028 (D.C. Cir. July 27, 2012), demonstrates the enforcement risk to pharmaceutical and medical device industry executives under the "responsible corporate officer" (RCO) doctrine. Under the RCO doctrine, officers, managers and in-house counsel employed by life sciences companies could face misdemeanor criminal liability and exclusion from Medicare and other federal health programs, even if they were not personally involved in wrongdoing. Indeed, an executive can be liable under the RCO doctrine even if they did not know that their organization had engaged in wrongdoing, so long as the executive should have known of the organization misconduct by virtue of the executive's position within the organization.

The RCO doctrine originated in United States v. Dotterweich, 320 U.S. 277 (1943), in which the Supreme Court upheld the misdemeanor conviction of the president of a drug company that had shipped adulterated drugs in violation of the Food, Drug and Cometic Act (FDCA). That statute imposes misdemeanor liability on one who introduces or delivers an adulterated drug into interstate commerce. The president had no prior knowledge of the unlawful conduct, but was found guilty "solely on the basis of his authority and responsibility as president and general manager of the corporation." Id. at 280. Upholding the conviction of the company president, the Court stated that the FDCA "dispenses with the conventional requirement for criminal conduct — awareness of some wrongdoing." Id. at 281. Furthermore, according to the Court, "[i]n the interest of the larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." Id.

Thereafter, in United States v. Park, 421 U.S. 658 (1975), the Supreme Court upheld the misdemeanor conviction of the president of a national supermarket chain. The supermarket chain and its president were charged with running a rat-infested warehouse in Baltimore in violation of the FDCA. The president was convicted, even though responsibility for warehouse operations had been delegated to others, and the president had no prior knowledge of the infestation of the Baltimore facility. According to the Supreme Court, the FDCA imposed on executives of FDCA-regulated businesses "not only 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." Id. at 672. The Court stated further that "[t]he requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more

stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and wellbeing of the public that supports them." Id. (The RCO doctrine is often referred to as the "Park doctrine" due to the Court's decision in this case.)

The FDA has announced that it intends to increasingly refer executives to the Department of Justice (DOJ) for misdemeanor prosecutions under the RCO doctrine. In February 2011, the FDA revised its Regulatory Procedures Manual to describe circumstances under which the FDA will make criminal referrals to the DOJ under the RCO doctrine. Among other things, the FDA intends to 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." Furthermore, according to the FDA, "[k]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."

In addition to misdemeanor criminal liability, Congress also enacted legislation that expressly permits the OIG to exclude executives from Medicare and other federal health programs where the executive fails to prevent organizational wrongdoing about which the executive should have known.

First, the exclusion statute authorizes the OIG to exclude any individual "who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know of the action constituting the basis for the [sanction]; or who is an officer or managing employee of such an entity." 42 U.S.C. § 1320a-7(b)(15). A "sanctioned entity" is one that has been convicted or pled guilty to a healthcare-related crime. In Friedman, the D.C. Circuit held that a misdemeanor conviction or guilty plea to misbranding under the FDCA is an example of such a crime. Thus, if a pharmaceutical or device company pleads guilty to a misdemeanor misbranding violation, executives who should have known of the organization's wrongdoing could be subject to an OIG effort to exclude. And, the OIG has announced its intent to exclude in precisely those circumstances. HHS Deputy Inspector General Gerald Roy testified in April 2011 to a House of Representatives Committee that "[w]hen there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization, OIG will operate with a presumption in favor of exclusion of that executive." The OIG, however, would have the burden of proving before an HHS Administrative Law Judge that the executive should have known of the misconduct; the mere guilty plea of the organization alone is insufficient.

Alternatively, the OIG is authorized to exclude an individual who has pled guilty to a healthcare-related crime. Under this exclusion mechanism, the OIG does not need to prove the individual's guilt; the fact of the individual's conviction or guilty plea is sufficient. In Friedman, the OIG sought to exclude three former senior executives of Purdue Pharma, the company's former President, General Counsel and Vice President of Worldwide Medical Affairs. As part of a global settlement in 2007, Purdue Pharma paid $600 million to resolve allegations that it had fraudulently misbranded OxyContin as less addictive and less subject to abuse than other pain medications. As part of the settlement, Purdue pled guilty to a felony misbranding charge. The three executives also pled guilty to misdemeanor misbranding under the responsible corporate office doctrine; they did not admit that they knew of misconduct, but only that they were responsible corporate officers and that the misbranding did occur. After their guilt plea, the OIG sought to exclude the three officers, and HHS subsequently excluded them for 12 years. The executives then appealed to federal court. In Friedman, the D.C. Circuit ruled that the misbranding misdemeanor guilty pleas under the responsible corporate officer doctrine provided sufficient grounds for exclusion (although the Court did remand the matter back to the agency to better justify the length of time for the exclusion).

As the government continues to ramp up its enforcement of FDCA violations against pharmaceutical and device companies, executives also face an enhanced enforcement risk – even executives who did not personally engage in any misconduct. The FDA and OIG have expressed interest in bringing misdemeanor prosecutions and exclusion actions against “responsible corporate officers,” and the Supreme Court – and now the D.C. Circuit – have issued opinions supporting the government’s enforcement theories. Executives can reduce their enforcement risks by ensuring that their organizations have effective compliance programs.

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