

FDA Announces New Push to Prosecute Corporate Officers and Executives for No-Intent Crimes

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Agency Action Follows Stepped-Up DOJ Enforcement Actions

The Food and Drug Administration (FDA) has called for more frequent prosecutions of “responsible corporate officers” under the federal Food, Drug and Cosmetic Act (FDCA). Under the responsible corporate officer (RCO) doctrine, also known as the *Park* doctrine, senior individuals in FDA-regulated companies can be charged with strict-liability misdemeanor offenses even when the individual did not participate in, or even know about, the underlying misconduct. The FDA’s announcement is consistent with the Department of Justice’s increased use of RCO prosecutions of pharmaceutical and medical device executives. Individuals convicted of strict-liability misdemeanor offenses face imprisonment, substantial criminal fines, debarment and, potentially, lengthy exclusions from federal health programs that have the practical effect of barring the individuals from working in the health care industry. The management of FDA-regulated companies should understand the RCO doctrine and the risks it poses to individuals at many levels of the company, and should implement rigorous corporate ethics and compliance programs.

The FDA’s Announcement

The FDA’s announcement, in the form of a March 4 letter from FDA Commissioner Margaret Hamburg to Congress,¹ is based on the recommendation of an internal FDA committee charged with “examin[ing] opportunities and develop[ing] recommendations” for the agency’s Office of Criminal Investigations (OCI). The commissioner described the committee’s recommendation as follows:

A third recommendation from the committee was to increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable. Criteria now have been developed for consideration in selection of misdemeanor prosecution cases and will be incorporated into the revised policies and procedures that cover appropriate use of misdemeanor prosecutions.

The commissioner sent her letter on the same day that the Government Accounting Office (GAO) released a report criticizing the FDA for its lack of oversight over the OCI.² The commissioner referenced the GAO report in her letter and expressed agreement with the GAO’s finding.

Early development of the RCO doctrine

The Supreme Court first authorized RCO prosecutions in *Dotterweich v. United States*.³ In *Dotterweich*, the Court upheld the conviction of a drug company’s president and general manager for the company’s shipping of misbranded and adulterated drugs in interstate commerce. According to the dissent, “There is no proof or claim that [Dotterweich] ever

1 Letter from Margaret Hamburg, FDA commissioner, to The Honorable Chuck Grassley, ranking member of the Senate Finance Committee (Mar. 4, 2010) (on file with author).

2 U.S. Gen. Accounting Office, Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations (Mar. 4, 2010), available at <http://www.gao.gov/new.items/d10221.pdf>.

3 320 U.S. 277, 279 (1943).

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 [Dotterweich] solely on the basis of his authority and responsibility as president and general manager of the corporation.”⁴ The majority acknowledged the hardship of imposing liability on someone whose “consciousness of wrongdoing be totally wanting” but preferred that to exposing the “innocent public” to the hazard of misbranded and adulterated drugs.⁵

The next major case applying the RCO doctrine was *United States v. Park*.⁶ Here, the Court upheld the conviction of a president of a national food chain whose warehouses had become infested by rats. The Court described the standard imposed on RCOs under the FDCA:

The [FDCA] imposes 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 occur. The 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 well-being of the public that supports them.⁷

Despite the fact that Park had delegated warehouse operations and had no personal knowledge of unsanitary conditions, the Court reaffirmed that RCO doctrine liability did not turn on the RCO’s awareness of wrongdoing. The Court did acknowledge that the doctrine did not require RCOs to do that which is “objectively impossible,” but this caveat did not save Park from conviction.⁸

Modern RCO Case Law

Since *Park*, only a handful of FDCA cases have been brought against corporate officers based on their responsible relation to the misconduct. Almost all of the cases brought against executives under the misdemeanor provision have been based on the individual’s conduct, not just her/his position. For example, in *United States v. Starr*, the Ninth Circuit affirmed the FDCA conviction of a food company’s secretary-treasurer.⁹ As in *Park*, a warehouse was found to be mouse-infested; unlike in *Park*, the secretary-treasurer was specifically responsible for handling sanitation problems and, most importantly, knew of the infestation.¹⁰ Most other post-*Park* FDCA cases have fit this mold. The reason does not appear to be a lack of cases where an RCO could have been charged; rather, prosecutors have exercised “circumspection” in charging RCOs with strict-liability misdemeanors, as the Supreme Court urged in establishing the doctrine.¹¹

However, there has been a recent uptick in prosecutors using the RCO doctrine for *Park*-style prosecutions of pharmaceutical or medical device executives. Purdue Pharma’s former president and CEO, executive vice president and chief medical officer, and executive vice president and chief legal

4 *Id.* at 286 (J. Murphy, dissenting).

5 *Id.* at 284.

6 421 U.S. 658 (1975).

7 *Id.* at 672.

8 *Id.* at 673.

9 535 F.2d 512 (9th Cir. 1976)

10 *Id.*

11 *Dotterweich*, 320 U.S. at 279.

counsel each pleaded guilty to an RCO misdemeanor in 2007. Four former executives of Synthes, a device maker, also pleaded guilty to misdemeanors under the RCO doctrine in 2009. Numerous senior government enforcement officials have said prosecutors are focusing more investigative attention on individual corporate officials under RCO and more traditional FDCA and criminal fraud theories.

Changing Consequences

When the RCO doctrine was created, only small penalties were attached. In *Dotterweich*, the defendant received a \$500 fine and 60 days probation.¹² In *Park*, the defendant received a \$250 fine.¹³ The executives were not subsequently excluded from federal health care programs in either of these cases, since the Department of Health and Human Services (HHS) only began its exclusion program in 1977.

Today's dramatically different landscape is underscored by the *Purdue* case. The three executives who accepted a strict-liability RCO misdemeanor plea paid a combined \$34.5 million in criminal fines. Furthermore, following the executives' guilty pleas, the HHS Office of the Inspector General (OIG) moved to exclude them from federal healthcare programs for 20 years under the agency's permissive exclusion authorities.¹⁴ The OIG's exclusion decision was upheld by the HHS Departmental Appeals Board, although the period was reduced to 12 years. The executives are now seeking review of the exclusion order in the U.S. District Court for the District of Columbia.

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¹² *United States v. Buffalo Pharmacal Co., Inc.*, 131 F.2d 500, 501 (2d Cir. 1942), *rev'd*, *Dotterweich*, 320 U.S. 277.

¹³ *Park*, 421 U.S. at 666.

¹⁴ 42 U.S.C. § 1320a-7(b).