
FDA Plans to Increase Strict Liability Criminal Prosecutions of Corporate Executives

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The Food and Drug Administration (FDA) has announced that it plans to increase criminal prosecutions of individual corporate executives under the strict liability misdemeanor provision of the Food, Drug, and Cosmetic Act (FDCA). The announcement is consistent with recent cases in which the FDA and the Department of Justice have brought misdemeanor criminal charges against high-level executives who historically would not have been prosecuted because they neither participated in nor knew of illegal conduct.

In a March 4, 2010 letter to Sen. Charles E. Grassley, FDA Commissioner Margaret Hamburg said that an internal FDA committee had recommended that the agency's Office of Criminal Investigations (OCI) "increase the appropriate use of misdemeanor prosecutions . . . to hold responsible corporate officials accountable."¹ Commissioner Hamburg further announced that the agency had developed criteria for selection of misdemeanor prosecution cases, which would be incorporated into "revised policies and procedures that cover appropriate use of misdemeanor prosecutions." The Commissioner did not disclose these new criteria.

The FDCA allows the criminal prosecution of anyone who "causes" any condition that violates the Act, such as mislabeled drugs or adulterated food.² Unintentional violations are punishable as misdemeanors, with up to a year in prison,³ plus fines and forfeitures. In addition, individuals convicted are potentially vulnerable to administrative exclusion from federal health care programs, which in practice can rule out future employment in the health care industry.

The Supreme Court has held that the FDCA's misdemeanor provision is sufficiently broad to encompass individual executives who neither participated in nor knew of a violation, but whose position put them in a "responsible relation" to it.⁴ This has become known as the "responsible corporate officer" doctrine – or "*Park* liability," after one of the Supreme Court's decisions. Historically, the government has been conservative in its use of the responsible corporate officer doctrine, primarily reserving criminal prosecution for individuals who were personally involved in the violation, or who had notice of it and failed to correct it.⁵ However, recent prosecutions have suggested a more aggressive view, which may reflect the increasing role of the Department of

Justice in initiating and controlling prosecutions related to health care. In 2007, the government insisted on misdemeanor charges against three senior executives of the drug maker Purdue Pharma L.P. The government did so even though – by its own accounts – it lacked evidence that the executives had any knowledge of any illegal conduct.⁶ Each executive received three years of probation and disgorged millions of dollars. In addition, the Department of Health and Human Services excluded the three senior executives from participating in federal health care programs for 12 years, a decision that is under appeal. (WilmerHale represented Purdue Pharma L.P. in this case.)

The FDA's recent statement that it intends to "increase the appropriate use of misdemeanor prosecutions" places executives in regulated industries at significant risk if it coincides, as the Purdue case suggests, with a broadening of the government's view of what is "appropriate use of misdemeanor prosecutions." WilmerHale will stay abreast of developments in this area.

¹Letter from Margaret A. Hamburg, Commissioner of Food and Drugs, to Sen. Charles E. Grassley (March 4, 2010).

² 21 U.S.C. § 331.

³ *Id.* § 333(a)(1).

⁴ *United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277 (1943).

⁵ See B. Gurney, H. Shapiro & R. Mays, *The Crime of Doing Nothing*, 22:3 WHITE COLLAR CRIME REP. 3-4 (Dec. 2007). In briefing the Supreme Court in the *Park* case, the government represented that the FDA "will not ordinarily recommend prosecution unless [the responsible corporate officer], after becoming aware of possible violations, often (as with *Park*) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations." Brief for the United States, *United States v. Park*, No. 74-215, at 31-32 (U.S. 1975).

⁶ See Gurney et al., *supra* note 5, at 4-5.

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