

FDA Recommends Increased Criminal Prosecutions of Responsible Corporate Officials; Important Questions Left Unanswered

The Food and Drug Administration (FDA) has announced its intention to push for an increase in the use of criminal misdemeanor prosecutions of individual “responsible corporate officials.” This change in enforcement policy suggests that executives or managers in the pharmaceutical, medical device, and other FDA-regulated industries may be targeted for criminal charges under the Food, Drug, and Cosmetic Act (FDCA) even if they played no role in the alleged misconduct.

Under two landmark U.S. Supreme Court cases, *United States v. Dotterweich* and *United States v. Park*, a corporate official can be convicted of a misdemeanor violation of the FDCA without personally engaging in wrongdoing, or even knowing about another person’s violation of the statute, provided the official had the responsibility or authority to prevent or correct the FDCA violation, but failed to do so. This doctrine departs from standard principles of criminal law by imposing strict, vicarious criminal liability on a person who has neither engaged in misconduct nor exhibited criminal intent. In recent years, misdemeanor FDCA prosecutions of executives based solely on an executive’s relationship of responsibility over others in the company have been rare, although notable exceptions exist. Executives convicted of misdemeanor violations of the FDCA can face imprisonment, substantial fines, and exclusion from participation in federal health care programs.

The potential for increased prosecution of responsible corporate officials for violations of the FDCA is one of several developments touted by Commissioner of Food and Drugs, Margaret A. Hamburg, in a letter to Senator Charles Grassley released on March 4, 2010—the same day that the Government Accountability Office (GAO) released a report criticizing FDA’s monitoring and oversight of FDA’s Office of Criminal Investigations (OCI). According to the letter, an FDA committee made up of senior leadership has recommended that the agency “increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable.” The letter also reveals that “[c]riteria 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.”

FDA’s new announcement regarding the criminal prosecution of executives raises a number of important questions, including:

- What are the new “criteria” that FDA has adopted to drive the selection of misdemeanor FDCA prosecutions? Will these criteria be made available to the public, and will the public have an opportunity to comment on these criteria before they are incorporated into FDA’s official policies and procedures?
- Was the Department of Justice (DOJ) involved in developing FDA’s new criteria? Recent prosecutions of executives under the FDCA have been driven primarily by DOJ, and DOJ will continue to decide whether to initiate criminal charges following an FDA referral. What effect will FDA’s initiative regarding responsible corporate officials have on DOJ’s charging practices going forward?

- Under FDA's new policies, will misdemeanor prosecutions of executives under the responsible corporate officer doctrine continue to be limited to the most serious cases (such as those involving patient deaths), or will executives face criminal charges in cases without such aggravating conditions? If the latter approach is taken, how will FDA draw the line between cases that are pursued using the FDCA's civil enforcement tools and cases enforced through a criminal prosecution?
- Will FDA adhere to its "prior notice" policy, under which the agency "ordinarily exercises its prosecutorial discretion to seek criminal sanctions against a person only when a prior warning or other type of notice can be shown?"
- Will the FDA afford executives who are targeted in strict liability misdemeanor prosecutions an opportunity to be heard prior to referring matters to DOJ's Office of Consumer Litigation or U.S. Attorneys for criminal prosecution under the FDCA?
- Does FDA's new announcement signal the agency's intention to re-assert its authority to decide which FDCA violations merit criminal prosecution?

Ropes & Gray will continue to follow developments relating to the policies and practices surrounding the criminal enforcement of the FDCA. For more information on the current and future enforcement environment, contact your regular Ropes & Gray lawyer.