Life Sciences Alert

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Mintz Levin Cohn Ferris Glovsky and Popeo PC

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FDA Releases Criteria for Responsible Officer Prosecutions

BY LINDA D. BENTLEY

After almost a year of making clear its intention to target more individual executives when their companies allegedly violate the Federal Food, Drug, and Cosmetic Act (FDCA), the U.S. Food and Drug Administration (FDA) recently added a new chapter to its *Regulatory Procedures Manual*, outlining the criteria that it will consider in determining whether to target those individuals.

The FDA has had authority to prosecute responsible corporate officers since at least 1975 when the U.S. Supreme Court decided *United States v. Park*.[1] Under the so-called Park Doctrine, a responsible corporate official can be convicted of a misdemeanor based on his or her position of responsibility and authority to prevent and correct violations of the FDCA. Evidence that the individual participated in the alleged violations or even had knowledge of them is not necessary.

Some of the factors—in addition to 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—that will be considered in the FDA's decision to refer a matter for a misdemeanor prosecution are as follows:

- Whether the violation involves actual or potential harm to the public;
- Whether the violation is obvious;
- Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- Whether the violation is widespread;
- Whether the violation is serious;
- The quality of the legal and factual support for the proposed prosecution; and
- Whether the proposed prosecution is a prudent use of agency resources.

While these factors are not new and are similar to those already considered in other types of prosecutions, the FDA's decision to publish these nonbinding criteria at this time suggests that it intends to follow through on its previously stated intention to target individual executives. The penalties for violations can be steep, and may include, among other things, potentially career-ending exclusions from federal health care programs.

Consequently, this is a good time for FDA-regulated companies to review their compliance programs. The existence of a compliance program will not necessarily prevent prosecution, but to the extent that such prosecutions are intended in part to serve as a broader enforcement tool, a robust compliance program may play a role in the prosecutorial decision.

View the "Prosecution" section of the *Regulatory Procedures Manual*, including new section 6-5-3.

If you have any questions about this alert, please do not hesitate to contact the author or the Mintz Levin attorneys with whom you usually work. We will continue to follow developments in this area.

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Endnotes

1 421 U.S. 658 (1975)

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