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Litigation Advisory

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FDA Publishes New Standards for Misdemeanor Prosecutions

The Food and Drug Administration ("FDA") published a new section of its Regulatory Procedures Manual, outlining criteria for recommending "*Park* doctrine" prosecutions of responsible corporate officers. Under the *Park* doctrine, a corporate officer can be held "strictly liable" for misdemeanor violations of the Food, Drug, and Cosmetic Act (the "Act"). In other words, corporate officers can be held liable for a first time misdemeanor under the Act without proof that the corporate official acted with intent or even negligence, and even if the corporate official did not have any actual knowledge of or participation in the offense. The FDA last year announced its plans to step up misdemeanor *Park* doctrine prosecutions, but until now had not made its criteria for recommending prosecution public.

Under the new "Special Procedures and Consideration for *Park* Doctrine Prosecutions," the FDA confirmed that while knowledge of and participation in a violation of the Act are factors to be considered in recommending a misdemeanor charge, they are not a prerequisite to prosecution. The Regulatory Procedures Manual also provides that consideration of the individual's position in the company and relationship to the violation, as well as whether the official had the authority to correct or prevent the violation, will be considered. **www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm**

Other factors include the following:

1. whether the violation involves actual or potential harm to the public;

2. whether the violation is obvious;

3. whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;

4. whether the violation is widespread;

5. whether the violation is serious;

6. the quality of the legal and factual support for the proposed prosecution; and

7. whether the proposed prosecution is a prudent use of agency resources.

Park doctrine prosecutions are particularly troubling given that the collateral consequences of conviction are often far worse than the conviction itself. For example, if convicted, an executive can face debarment from dealing with federal health plans like Medicaid and Medicare. Moreover, once an individual is convicted of a misdemeanor under the Act, any subsequent violation of the Act is a felony, even without proof that the defendant acted with the intent to defraud or mislead. In one of the few recent cases involving corporate officers of a major medical manufacturer, three executives at Purdue Pharma who had pleaded guilty to a Park doctrine misdemeanor under the Act were barred for twelve years. The three executives also paid a combined $34.5 million in fines. A federal district court judge subsequently upheld the disbarments, rejecting arguments that disbarment was not warranted because the executives' convictions resulted simply from their status as senior corporate officers, rather than from their conduct.

Executives and counsel need to be aware of the FDA's increased emphasis on *Park* prosecutions. Liability stems not only from personal or corporate involvement in wrongdoing under the Act, but can be found based merely on an individual's executive position.