Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Brian D. Eyink

Date: February 15, 2011

Re: **Re-emergence of FDA *Park* Doctrine Prosecutions**

The Food and Drug Administration ("FDA") has recently revised portions of Section 6 of its *Regulatory Procedures Manual*, which, among other things, outlines internal agency procedures regarding *Park* Doctrine prosecutions. After years of dormancy, these procedures reflect the agency's renewed interest in using the longstanding *Park* doctrine as part of its enforcement regime. After providing some background information, this memorandum summarizes FDA's current approach to *Park* prosecutions.

Background on *Park* Prosecutions

Under the *Park* Doctrine, a corporate official can be held criminally liable for violations of the Federal Food, Drug, and Cosmetic Act ("FFDCA") in areas of the company under the official's control, even if the official did not intend for the violations to occur or was not aware of the violations. The first such violation is a misdemeanor, punishable by up to a $1,000 fine and up to six months in prison. A subsequent violation is a felony punishable by up to a $10,000 fine and up to three years in prison.

The *Park* Doctrine, named for the 1975 Supreme Court case *United States v. Park*,1/ actually originated with the 1943 Supreme Court decision in *United States v. Dotterweich*,2/ in which the Supreme Court upheld the conviction of the president of a company that was repackaging misbranded drugs. The Supreme Court in *Park* reaffirmed that strict criminal liability applied to corporate officials whose failure to exercise authority led to a violation of the FFDCA. In *Park*, the government prosecuted Acme Markets, a national food retailer, and Park, its CEO, for violating the FFDCA by allowing food to be stored in rodent-infested warehouses. Even though Park claimed he relied on a subordinate to remedy the problem, the Supreme Court noted that, as CEO,

---

1/ *United States v. Park*, 421 U.S. 658 (1975).
2/ *United States v. Dotterweich*, 320 U.S. 277 (1943).

Park was ultimately responsible under the corporation's by-laws for overseeing sanitation. The Court, relying on *Dotterweich*, therefore held that Park could be criminally liable for the FFDCA violations because he had the final responsibility for ensuring compliance with the FFDCA and failed to do so.

Although FDA had shifted away from pursuing *Park* prosecutions over the past two decades, the agency has signaled renewed interest over the past year in using the *Park* Doctrine. In a letter to Senator Grassley dated March 4, 2010, Commissioner Hamburg explained that an internal FDA review committee recommended "increas[ing] the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable." In response, she reported, the agency was incorporating into its prosecution policies and procedures criteria for selecting misdemeanor cases. 3/ Since then, FDA Deputy Chief Counsel for Litigation Eric Blumberg has made public comments about the agency's renewed interest in the *Park* doctrine as an enforcement tool. 4/

Park* Doctrine in the *Regulatory Procedures Manual

The *Regulatory Procedures Manual* (RPM) is an internal policy guide for FDA field personnel. Although it is not binding, it provides insight into how FDA has instructed its field personnel to handle enforcement matters.

Role of *Park* Prosecutions

The agency is once again viewing *Park* prosecutions as part of its general enforcement toolbox. The agency considers misdemeanor prosecutions to be "a valuable enforcement tool" and advises its personnel that "[m]isdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities."

Factors that Influence the Initiation of a *Park* Prosecution

The RPM lists several factors that FDA officials should consider before initiating a *Park* prosecution:

3/ A copy of the letter is available on Senator Grassley's website at http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf.

4/ *See, e.g.*, Anna Edney, *Drugmaker CEOs May Be Targets for U.S. FDA in Off-Label Cases, Lawyer Says*, Bloomberg.com, October 14, 2010, http://www.bloomberg.com/news/2010-10-14/drugmaker-executives-may-become-targets-of-fda-for-off-label-promotions.html (speaking about *Park* prosecutions against drugmakers). Blumberg spoke about *Park* prosecutions in the food context at the Food and Drug Law Institute's Annual Conference in October. *See* Enforcement and Litigation Conference: FDA Enforcement—More Individuals, More Often, http://www.fdli.org/conf/highlights/enforcement2010.html.

- The corporate official's position in the company and relationship to the violation;
- Whether the official had the authority to correct or prevent the violation;
- The official's knowledge of and actual participation in the violation (although the RPM notes that these are not prerequisites to a misdemeanor prosecution);
- 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;
- The seriousness of the violation;
- The quality of the legal and factual support for the proposed prosecution; and
- Whether the proposed prosecution is a prudent use of agency resources.

FDA's Internal Process

FDA district offices considering initiating a *Park* prosecution must first consult with the appropriate center in the agency to determine whether the proposed prosecution aligns with agency priorities. District offices are also encouraged to consult with FDA's Office of Chief Counsel, Office of Criminal Investigations, and Investigative Operations Division early in the process.

Notice to the Corporate Official

Section 305 of the FFDCA requires FDA to give a person notice and an opportunity to respond before referring a case to the United States Attorney for criminal prosecution. These have long been referred to as "305 hearings". Notice is not required if FDA believes it will lead to evidence destruction or will cause the person to flee.

* * *

Based on the increased agency rhetoric, we should anticipate *Park* prosecutions may once again play a role in FDA enforcement. Companies should continue to evaluate the effectiveness of their internal compliance policies.

* * * *

We will continue to monitor FDA's use of the *Park* Doctrine and other enforcement mechanisms. Please do not hesitate to contact us with any questions.