Prosecuted For Being In Charge of the Company? Yes, Says FDA Enforcement

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The Food and Drug Administration (FDA) has announced that it will target and seek prosecution of corporate employees for company violations of the federal Food, Drug and Cosmetic Act (FDCA) – *and it will do so even in the absence of proof that the employees participated in or even knew about the violations at the company.*

Can the FDA do this? It can, has, and apparently plans to continue doing so under the *Park* criminal liability doctrine. Under this rather obscure doctrine (also known as the responsible corporate officer doctrine), the government may seek criminal misdemeanor convictions and penalties against company officials for violation of the FDCA, even if the officials had no knowledge of the violation, as long as the officials were in a position of authority to prevent or correct the violation. In other words, corporate executives and managers can be held strictly criminally liable for their company's FDA violations.

Where did this doctrine come from? The *Park* doctrine is named after the 1975 U.S. Supreme Court case, *United States v. Park*, 421 U.S. 658 (1975). In the 1970s, John Park was the president and CEO of Acme Markets, a national food chain with more than 36,000 employees, 874 retail outlets and numerous warehouses. In 1970, the company received a letter from the FDA advising the company of insanitary conditions — evidence of rodent infestation — at one of its Philadelphia warehouses. In 1971, the FDA notified the company of similar conditions at a Baltimore warehouse. At that time, Mr. Park confirmed with his staff that the manager in charge of the Baltimore warehouse was investigating and taking proper remedial action. During re-inspection in 1972, the FDA noted improvement in the conditions at the Baltimore warehouse but still found some evidence of rodent activity in the building. The government then charged Acme and CEO Park with misdemeanors under the FDCA for causing food to become adulterated while stored in Acme warehouses. The company pleaded guilty and was fined for the violations. Mr. Park pleaded not guilty, proceeded to trial and was convicted and fined $250 ($50 per count).

Mr. Park appealed his conviction arguing that he was not personally involved in committing the FDA violation, that he relied on company protocol whereby he delegated responsibilities for sanitation, and he had no reason to suspect that his employees were failing to ensure compliance with the FDCA. While the appeals court vacated Park's conviction, the U.S. Supreme Court ordered the conviction to be reinstated. In doing so, the Court ruled that managerial employees may be criminally liable for company FDA violations, regardless of their knowledge of or personal participation in the violation — as long as the manager had the power, by virtue of the relationship to the corporation, to prevent the violation. The Court opined: "The [company executive], if he does not will the violation, usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his

responsibilities." The Court further reasoned: "The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."

Why haven't you heard of this doctrine before? Throughout the 1970s and 1980s, the FDA frequently used the *Park* doctrine to bring misdemeanor prosecutions against executives for company violations of the FDCA. Usually, these cases involved insanitary conditions at food companies and generally ended in convictions with relatively small fines like those issued in the *Park* case. By the late 1980s, however, the *Park* doctrine was rarely used. Instead, the FDA and federal prosecutors focused on higher profile felony prosecutions where potential penalties were much higher. In the last 20 years, pure *Park*-type strict liability prosecutions have been almost non-existent.

But in the last year, the new FDA administration and federal law enforcement have promised to revive the doctrine. On March 4, 2010, in a letter to U.S. Senator Charles Grassley, FDA Commissioner Margaret Hamburg stated that the FDA will "increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable." On October 13, 2010, FDA Deputy Chief-in-Charge of Litigation Eric Blumberg stated that monetary settlements with drug companies were "not getting the job done" to deter illegal off-label promotion of drugs, and urged federal prosecutors to "criminally charge individuals at all levels of the company." Even more recently, on November 9, 2010, in connection with charges brought against a former in-house lawyer for a major pharmaceutical company, federal law enforcement officials emphasized their intent to prosecute individuals: "[W]e will investigate those responsible for unlawful acts done on a company's behalf. When individual employees are identified, they will be held accountable for their illegal activity."

So, what kind of conduct can trigger *Park* liability? The *Park* doctrine can be applied to any FDA-regulated entity, and can theoretically be applied to any violation of the FDCA. This, of course, is a scary proposition because nearly all FDA inspections yield at least one technical violation of the FDCA. For now, FDA enforcement officials have indicated that they will focus efforts and *Park* prosecutions on cases involving:

- Off-label promotion of drugs
- Distribution of unapproved drugs
- Failure to report adverse events
- Safety related violations, including conditions that would necessitate product recall

Ok, but it's only a misdemeanor so that's not so bad, right? Wrong. The days of the $50 fine and proverbial slap on the wrist are long gone; the potential penalties for misdemeanor convictions under the FDCA are now quite severe. In addition to imprisonment for up to one year, penalties may include:

- **Fines:** Since *Park* was decided, fines for misdemeanor FDCA violations have been increased to a maximum of $100,000 per criminal count.

- **FDA Debarment:** The FDA has discretion to order up to 5 years of debarment of individuals convicted of misdemeanors relating to the development, approval or regulation of drugs. Anyone debarred by the FDA is prohibited from providing services in any capacity to a company that has an approved or pending drug product application with the FDA. Thus, a debarred executive may be prohibited from working for any pharmaceutical company, *in any capacity*, for up to 5 years.
- **Exclusion from federal health care programs:** Exclusion is an enforcement tool used by the Office of the Inspector General (OIG) of the Department of Health and Human Services to prohibit individuals convicted of crimes from participating in federal health care programs. Upon conviction of a misdemeanor relating to fraud, theft, embezzlement or breach of fiduciary responsibility, OIG may exclude an individual for a minimum of 3 years. During the period of exclusion, no payment will be made by any federal health care program, including Medicare and Medicaid, for any items or services furnished, ordered or prescribed by an excluded individual, *or by anyone who employs or contracts with the excluded person*.

The FDA's new enforcement approach is draconian and inconsistent with the agency's prior longstanding enforcement policy. More than that, use of this approach in situations where an executive had no prior knowledge of a violation may be unconstitutional. Nevertheless, the FDA is clearly no longer content to just levy fines against corporate violators. And the agency has made it personal — attempting to hit companies and executives where it hurts. As a result, now more than ever, companies involved in the food, drug, cosmetic and nutritional supplement industries (and their executives) should take proactive measures to ensure FDA compliance. CEOs and company managers should implement effective and up-to-date FDA compliance and safety procedures, and confirm that they are followed. Complaints about violations or safety issues must be taken seriously, thoroughly investigated and fully documented. When dealing with the FDA, companies are prudent to involve legal counsel sooner rather than later. And all communications with the FDA must be carefully prepared and reviewed — because what you say today may be used against you later in a *Park* prosecution.