Criminal Liability for Corporate Officers—The Resurrection of the Park Doctrine in Food & Drug Cases

By Robert J. Becerra (Devine Goodman Rasco Watts-FitzGerald & Wells) and Jennifer Diaz (Becker & Poliakoff)

The Food & Drug Administration ("FDA") recently made clear that criminal enforcement against individuals for strict liability violations of the Food, Drug & Cosmetic Act ("FDCA") is now a priority for the agency. Although criminal charges against corporate officials for violations of the FDCA were enacted in 1938, the FDA and the Department of Justice ("DOJ") have directed their activities against individual corporate executives with renewed vigor through the use of the "Responsible Corporate Officer Doctrine" ("RCO"), better known as the "Park Doctrine". The Doctrine is limited to misdemeanors for regulatory or public safety crimes that do not require the defendant to possess criminal knowledge or intent.

The Park Doctrine is named after the Supreme Court case of *United States v. Park*, 421 U.S. 658 (1975) which held that the president of a company could be held personally criminally liable under the FDCA for contaminated food shipments. In that case, the Supreme Court stated that corporate executives have an affirmative duty under the FDCA to ensure the safety of their companies' food products. Based on this decision, a corporate executive may be criminally prosecuted under the FDCA if he or she, by reason of his/her position, fails to carry out his/her responsibility or authority to either prevent the violation or promptly correct it.

This Doctrine does not even require the executive to be aware of wrongdoing within the corporation; the government is only required to prove that the violation of the FDCA occurred, and that the executive had the authority to prevent or correct it. The Supreme Court stated that this is so because an executive has a "positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." This offense is also known as a "strict liability misdemeanor". The only defense recognized in the Park case to this Doctrine would be proof that the corporate officer was "powerless" to prevent or correct the violation. Importantly, if an executive is convicted of a FDCA strict liability misdemeanor under the Park Doctrine, any subsequent violations of the FDCA by that executive are treated as felony violations of the FDCA under 21 U.S.C. Sec. 333, and do not require proof of an intent to defraud or mislead.

Park Doctrine misdemeanor convictions under the FDCA are punishable by up to a $100,000 fine for individuals and up to a $250,000 fine if a death resulted from the violation. Fines can be increased up to twice the defendant's gain or the victim's loss from the offense. Offenders can receive sentences of up to one year incarceration, along with probation.

This "strict liability" criminal liability exists because these "public welfare" crimes can have widespread, and perhaps catastrophic, consequences. The idea is that prosecuting individual executives, instead of just the companies that employ them, encourages greater individual supervision over the companies' activities, which should deter violations in the first place. In this manner, the reasoning follows, the public is protected and benefits from higher levels of safety.

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FDA's Commissioner, Margaret Hamburg, stated to a senate committee that the FDA recommends increasing "the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable." To further highlight its emphasis on utilizing the Park Doctrine to pursue criminal convictions of executives, the FDA released written "criteria" for consideration of which types of cases are appropriate for Park Doctrine prosecution. That "criteria" includes, besides the individual's position within the company, and whether he or she had authority to prevent or correct violations, the following factors:

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

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2. Whether the violation is obvious;
3. Whether the violation reflects a pattern of illegal behavior, or a failure to heed 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.

The FDA expressly stated that it will seek to increase prosecution of individual executives under the Park Doctrine for its strong deterrent effect on potential violators and to show FDA is getting "tough" on individuals running companies in regulated industries. In addition, criminal convictions under the Park Doctrine can result in serious collateral consequences, such as debarments or exclusions from participation in federal programs.

The risks presented to corporate executives and their employers from the FDA's renewed emphasis on utilizing the Park Doctrine to obtain criminal convictions resulted in the creation of an RCO insurance policy by leading insurers. These policies provide coverage for control group executives for the costs of defending a criminal investigation or Park Doctrine prosecution including resulting losses from debarment or exclusion from federal programs as a result of a conviction. Normally, Directors and Officers policies ("D&O") exclude coverage for criminal liability. These new RCO insurance policies permit executives being investigated or charged with Park Doctrine offenses to adequately fund their defenses without facing financial ruin. The policies however, contain exclusions for offenses providing for proof of criminal or fraudulent intent.

The devastating consequences of a conviction under the Park Doctrine were exhibited recently in the case of *United States v. Purdue Frederick*. In 2007, the Purdue Frederick Company pleaded guilty to misbranding the drug Oxycontin with intent to defraud, a felony. Its former president and chief executive officer, former vice-president and chief legal officer, and former chief scientific officer all plead guilty to misbranding under the Park Doctrine, a criminal misdemeanor. The executives were not charged with having knowledge of the misbranding or intent to defraud. The prosecution and the defendants agreed to a sentence of no incarceration and a monetary payment. After the sentencing, the Department of Health & Human Services, ("HHS") informed the executives that they were subject to exclusion for up to 20 years from participating in federal health programs. After administrative appeals, the exclusion period was reduced to 12 years. The executives then sued the HHS stating that it lacked the authority to exclude an executive where the evidence showed no personal wrongdoing. The court ruled against the executives, finding that the HHS had the authority to debar or exclude based on RCO, Park Doctrine misdemeanor convictions. This finding, that the exclusion was legal, essentially ended the executives' careers. Ultimately the D.C. Circuit Court of Appeals affirmed the authority of the HHS to exclude the executives for a Park Doctrine conviction, but remanded to the lower court for another hearing on the length of the exclusions because the HHS did not explain the basis of its decision to exclude the executives for 12 years.

In addition to the Purdue Frederick case, the Park Doctrine was also recently implicated in cases involving the importation of pet food ingredients from China, such as *United States v. Chemnutra, Sally Miller and Stephen Miller*, where the defendants plead guilty to strict liability violations of the FDCA for importing ingredients from China tainted with Melamine, although it was stipulated at the plea and sentencing that the Millers had no knowledge the ingredients were tainted when they were imported. The Park Doctrine was also used in *United States v. Synthes* to secure guilty pleas from executives for shipping adulterated and misbranded product that included the off-label promotion of a bone void filler. In *Synthes*, the guilty pleas to the strict liability misdemeanors under the Park Doctrine resulted in the executives receiving prison sentences.

Especially in the food industry, importers and distributors are wide open to criminal liability under the Park Doctrine if they import or purchase food items that turn out to be adulterated or misbranded. Given that a Park Doctrine criminal conviction does not require any proof that the defendant even knew that the food product was tainted or mislabeled in any fashion, importers and distributors are criminally liable even if their suppliers defrauded them without their knowledge by shipping them tainted food or by falsely mislabeling the food container. Recent statistics show that anywhere from 33 to over 75 percent of seafood sold in the U.S., depending on location and market, is mislabeled as one species when it is in fact another, the potential pool of individual criminal defendants is huge.

Given the exposure to incarceration and exclusion/debarment that the Park Doctrine brings, what does an executive in an FDA regulated industry do to try to avoid being the target of the

FDA's emphasis on strict liability misdemeanor prosecutions? Heightened due diligence and adherence to written compliance policies and procedures is a must. At a minimum, executives in these industries should:

1. Assure senior management is on board and proactive in regards to regulatory compliance, not reactive.
2. Have a written corporate compliance program that is followed, constantly revised to reflect current conditions, and is regularly audited to ensure employees are obeying its dictates.
3. Institute a program of recurrent training for employees and make sure it is accomplished.
4. Encourage employees to report violations to senior management and assure no retaliatory action is taken when they do.
5. Make sure that the corporate culture of the company, from the top down, is one of adherence to the law and that employees should not cut corners that may result in violations, even if it helps the bottom line.
6. Consult experienced legal counsel and follow his/her advice.

Conclusion

Given the FDA's emphasis on bringing the heavy hand of criminal enforcement down on individual executives under the Park Doctrine, corporate officers must be proactive in ensuring employees adhere to the corporation's compliance program. Since corporate officers can be held criminally liable for violations that occurred without their knowledge or intent, heightened due diligence may be the difference between liberty and incarceration, coupled with exclusion from federal programs. ❑

Robert J. Becerra (rbecerra@devinegoodman.com) is an international trade criminal lawyer with Devine Goodman Rasco Watts-FitzGerald & Wells practicing in Miami, Florida. Jennifer Diaz (jdiaz@becker-poliakoff.com) is a Board Certified International Attorney who is considered an expert in international law by the Florida Bar. She leads Becker & Poliakoff's Customs and International Trade Department in Miami, Florida assisting clients with a focus on federal regulatory issues impacting importers and exporters. She is a thought leader, publishing a weekly article on the Becker and Poliakoff Customs and International Trade Law Blog at www.customsandinternationaltradelaw.com.