

Don't Mistake FDA's Peanut Prosecution As Setting The Bar

Law360, New York (April 02, 2013, 5:23 PM ET) -- The unsealing of a 76-count indictment of several officials of the Peanut Corporation of America ("PCA") on Feb. 21 understandably received a great deal of attention in the press. The indictment charged the PCA's owner and president, vice president, operations manager, and a plant operations manager with substantive counts of introduction of adulterated and misbranded peanut products into interstate commerce with intent to defraud or mislead, wire and mail fraud, and related conspiracies. The indictment also charged the president, operations manager and quality assurance manager with several counts of obstruction of justice.

Underlying these charges were sensational allegations of a pattern of knowing, deliberate and coordinated food safety process violations and regular misrepresentations to customers about food safety. According to the indictment, this pattern culminated in a nationwide salmonella outbreak. Finally, the government alleges that the PCA and several defendants lied to federal investigators and otherwise obstructed their investigation in the wake of the outbreak.

Prosecutors and regulators highlighted the egregiousness of the alleged conduct in their statements about the case. For example, the head of the U.S. Department of Justice's Civil Division, Stuart F. Delery, stated that the DOJ would "not hesitate to pursue" those who "cut corners," and "put all of us at risk." [1] U.S. Food and Drug Administration Commissioner Margaret A. Hamburg, M.D., added that the FDA would hold accountable individuals who "violate[] food safety rules or conceal[] relevant information," adding that, "[t]he health of our families and the safety of our food system is too important to be thwarted by the criminal acts of any individual or group." [2]

But corporate officials should keep in mind that far less than the conduct alleged in the PCA indictment can lead to criminal charges. Indeed, the FDA is in the midst of a push to pursue criminal charges against individual corporate officials even where they have not engaged in or been aware of any wrongful activity or negligence within their companies.

The PCA defendants were all charged with introducing adulterated and misbranded food into interstate commerce with intent to defraud or mislead, but the Federal Food, Drug and Cosmetic Act authorizes misdemeanor criminal charges absent any wrongdoing at all, absent any negligence, and absent knowledge of either wrongdoing or negligence. Specifically, although the act only authorizes felony charges against those who violate the act "with the intent to defraud or mislead," the act states that "[a]ny person who violates" certain provisions shall be convicted of a misdemeanor. [3]

Pursuant to the so-called Park doctrine, originating in a 1975 U.S. Supreme Court case, *United States v. Park*, 431 U.S. 658 (1975), this provision applies to individuals as well as companies who violate the law, and specifically to any corporate agent who had the authority to prevent a company's violation — a "responsible corporate official" — even if he had no knowledge of and was not complicit in the violation. [4]

This departure from usual criminal responsibility law is based on the rationale that “the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.”[5] The end result, as the court put it, is that the law imposes on corporate officials of FDA-regulated companies “not only 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.” [6]

Application of this doctrine by the FDA had fallen off, but Congress has recently pressured the FDA to use its criminal enforcement tools more aggressively, and Commissioner Hamburg has pledged to revive use of the doctrine and misdemeanor charges. In this climate, and as FDA rolls out new rules implementing the 2011 Food Safety and Modernization Act imposing even greater regulatory burdens on food manufacturers and distributors, corporate officials at responsible companies should be careful not to mistakenly conclude that the PCA allegations are the only type of conduct the FDA is likely to pursue criminally.

Of course, the fact that the FDA can pursue criminal charges against an individual who did not knowingly or negligently participate in a violation does not mean the agency always will do so. The FDA’s Regulatory Procedures Manual outlines several nonexclusive factors FDA officials must consider before recommending a “Park doctrine prosecution” to the FDA’s Office of Criminal Investigations, including, among other things, whether the official in question actually did know of or participate in the violation, and the seriousness of the violation.

One factor not listed in the manual that FDA officials nevertheless undoubtedly consider when making prosecution recommendations is the extent to which a potential target for prosecution cooperates in — or obstructs — an FDA inspection or investigation. How a company or individual reacts to an inspection or investigation can have a dramatic impact on the discretion to recommend or charge a misdemeanor. And given that false statement and obstruction charges are typically felonies, even if avoiding obstruction cannot prevent a misdemeanor Park doctrine prosecution, it can mean the difference between a misdemeanor and a felony prosecution.

The PCA case serves as a useful reminder of the damage an individual or company can self-inflict by lying to investigators and obstructing investigations. Even if the government had no evidence that the officials charged in that case had acted with intent to defraud or mislead — that is, only had evidence sufficient to charge a misdemeanor — the officials’ obstructive conduct still would likely have led to eight felony counts of obstruction.

In short, officials working for companies regulated by FDA must recognize that even if they are not knowingly engaged in violations of the law or other outrageous conduct of the type alleged in the PCA indictment, they could face criminal charges if they fail to satisfy their “duty to implement measures that will insure that violations will not occur.” And as the old adage says, the cover-up is often worse than the underlying crime — at least in the eyes of dismayed regulators. Companies and individuals must guard against exacerbating any potential violation by making false statements to or obstructing FDA inspections or investigations.

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[1] Former Officials and Broker of Peanut Corporation of America Indicted Related to Salmonella-Tainted Peanut Butter, Feb. 21, 2013 Press Release, available at <http://www.justice.gov/opa/pr/2013/February/13-civ-220.html>.

[2] Press Release, Department of Justice, "Former Officials and Broker of Peanut Corporation of America Indicted Related to Salmonella-Tainted Peanut Products" (Feb. 21, 2013), available at <http://www.justice.gov/opa/pr/2013/February/13-civ-220.html>.

[3] Compare 21 U.S.C. § 333(a)(2) (describing felony violation) to 21 U.S.C. § 333(a)(1) ("Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000 or both.").

[4] *United States v. Park*, 421 U.S. 658, 672-77 (1975).

[5] *Id.* (quoting *Smith v. California*, 361 U.S. 147, 152 (1959)).

[6] *Id.* at 672.

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