



Far-reaching PCA Criminal Indictments: A Harbinger for Things to Come Under FSMA?

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Last week, the Department of Justice brought a [sweeping indictment](#) against several former Peanut Corporation of America (PCA) executives alleging egregious, and intentional, violations of food safety laws that caused the salmonella peanut outbreak of 2008. The indictment alleges that the individuals perpetrated a scheme from as early as 2003 where they sold peanut products to food manufacturers that the individuals allegedly knew were contaminated with salmonella and other pathogens. The indictment further alleges that the individuals routinely falsified Certificates of Analyses (COAs) accompanying the product shipments to state that the shipped product had been tested and met the customers' respective specifications for microbiological testing when, in fact, microbiological testing of that product showed that the product was contaminated with salmonella and other pathogens. In other instances, the individuals sent falsified COAs with product that PCA had never tested. The individuals also covered up their alleged fraud by lying to their customers directly about salmonella contamination as well as lying to the FDA when it was investigating the 2008 peanut outbreak.

The government charged four individuals who allegedly directed the scheme in an indictment that contains 76 counts of conspiracy, wire fraud, mail fraud, violations of federal food and drug laws, and obstruction of justice: Stewart Parnell (owner and President of PCA); Michael Parnell (a food broker for PCA), Samuel Lightsey (Operations Manager for PCA's Blakely plant during the relevant time period); and Mary Wilkerson (Quality Assurance Manager at the Blakely plant). It appears that a fifth defendant, Daniel Kilgore, a former PCA plant Operations Manager, is cooperating with the government as a witness as he was separately charged in an Information and already pleaded guilty to 29 counts. Mr. Kilgore's plea agreement does not appear to be publicly available at present.

The facts alleged, if proven to be true, are particularly egregious. It has been settled law since the Supreme Court's decision in *United States v. Park*, 421 U.S. 658 (1975) that executives of FDA-regulated companies can be held strictly liable and criminally responsible for the actions of the companies they run for violations of food and drug laws, regardless of whether the executives knew of the offending actions. Historically, the government has sought criminal sanctions against senior executives in cases involving food safety violations on a fairly infrequent basis. Usually, the government seeks enforcement remedies that are aimed primarily at protecting the public from exposure to unsafe products and preventing violations from reoccurring. Ordinarily, the government begins with administrative enforcement measures (e.g., warning letters, import detentions), progressing to product seizures or injunctive remedies (e.g., consent decree) when deemed necessary to achieve reasonable legal compliance. Typically, the government seeks criminal sanctions in cases in which the violations alleged are considered to be more egregious and result

from willful misconduct involving fraud or deception.

In view of the historical enforcement policies that have been applied in food safety cases and the facts alleged in the PCA case, the government's decision to seek criminal sanctions is hardly surprising. What is more significant is the reach of the alleged violations and the number and management positions that were held by the former PCA employees that have been indicted in the case. The government is casting a wide net in an effort to hold a number of individuals accountable for the role they played in enabling the alleged PCA violations. The breadth of the indictments in the case raises the question of whether the PCA case represents an enforcement policy outlier due to the particularly egregious facts alleged in the indictment, or is it a harbinger of FDA and DOJ enforcement policies to come with the enactment of the Food Safety Modernization Act (FSMA) amendments to the Federal Food, Drug & Cosmetic Act (FDCA) in 2011. Several features of the PCA case may well signal the government's increased readiness to use criminal prosecutions to police violations of the nation's food safety laws.

- First, presumably as part of his plea agreement, Mr. Kilgore pleaded guilty to 29 counts. Typically, cooperating witnesses plead to only a few counts. This indicates that the government may be taking a tough stance against those who endanger the lives of consumers through their gross negligence related to the safety of food products.
- Second, the government has cast an unusually wide net for offenders in this case. In *Park*-related prosecutions, the government typically has targeted the chief executives who had the authority, by virtue of their position within the organization, to prevent the food safety violations from occurring. According to the *Park* Court, "the [FDC] Act imposes [on individuals] not only the 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."¹ Importantly, the *Park* Court noted that "[t]he Act does not...make criminal liability turn on awareness of some wrongdoing or conscious fraud."² Here, while there are several unindicted co-conspirators and the charges allege "conscious fraud", other than PCA owner and President, Stewart Parnell, the indicted individuals appear to have held middle management positions at PCA. Indeed, one of the defendants, Mary Wilkerson, started at PCA as a receptionist and was the Quality Assurance Manager. While the government alleges that each of these individuals were part of an unlawful scheme and contributed to the alleged PCA violations by falsifying documents and causing contaminated peanut products to be shipped, the evidence in the case ultimately may show that some or all of these individuals were simply following Mr. Parnell's orders and directions. Notably, the indictments include references to and quotations from communications allegedly issued by Mr. Parnell to PCA company employees which emphasize the business costs to PCA in failing to ship peanut products that are implicated in the case.³
- Third, it is worth noting the wide range of violations that the government has alleged. The government did not limit the counts in the indictments to alleged violations of food safety laws. Rather, the government included a number of conspiracy and fraud counts to the indictment. The addition of these counts has significant implications with respect to the criminal penalties the indicted individuals could face if convicted of these crimes. For example, penalties for each food safety violation are limited to 1 to 3 years of imprisonment⁴ whereas each fraud count carries a maximum penalty of 20 years.⁵

Finally, the 2008 peanut salmonella scare has contributed to both regulatory and legal changes designed to hold company executives criminally more responsible for the actions of their company.

In a letter to Senator Charles Grassley in March 2010, FDA Commissioner, Dr. Margaret Hamburg, reported that an internal FDA evaluation committee had recommended "increas[ing] the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable."⁶ Consistent with this recommendation, subsequently, in January 2011, FDA revised the agency's internal regulatory procedures guiding the agency's determination to seek criminal sanctions against individuals.⁷ The use of criminal prosecutions for violations of the nation's food and drug laws is a matter of ongoing debate as policymakers grapple with the question of how to ensure that the enforcement of statutes and regulations promote compliance and discourage executives of regulated companies from management strategies that mistake fines or other enforcement remedies for food and drug law violations as mere costs of doing business.

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[1] *Park*, 421 U.S. at 672.

[2] *Id.* at 672–73.

[3] See Parnell Indictment at 34 ("On or about March 21, 2007, upon being told that salmonella testing results were not yet available and that shipment of a portion of a customer's product would therefore be delayed, **STEWART PARNELL** stated, via email: '...just ship it. I cannot afford to lose [sic] another customer;' In referring to 1374 pounds of peanuts set aside as waste, Mr. Parnell stated via email: "I am not sure anyone down there quite understands how SERIOUS this is ...these are not peanuts you are throwing away every day...**IT IS MONEY.....IT IS MONEY.....IT IS GOD DAMN MONEY THAT WE DO NOT HAVE BECAUSE OF HOW LONG I HAVE ALLOWED you, your crew and everyone down there to let THIS GO ON.**" (Emphases in the indictment)).

[4] 18 U.S.C. § 333(a).

[5] 18 U.S.C. §§ 1341, 1343.

[6] Letter from Letter from Margaret A. Hamburg, Commissioner of Food and Drugs, to Sen. Charles E. Grassley (March 4, 2010), *available at* <http://www.grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf>.

[7] US Food and Drug Admin., Regulatory Procedures Manual *available at* <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm>.