# THE PARK DOCTRINE AND PROSECUTION OF MISDEMEANOR VIOLATIONS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (OR...FARMER BILL GOES TO JAIL)

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### THE PARK DOCTRINE AND PROSECUTION OF MISDEMEANOR VIOLATIONS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (OR...FARMER BILL GOES TO JAIL)

#### INTRODCUTION

The Park Doctrine, also called the "Responsible Corporate Officer" Doctrine, is a doctrine under which potentially unassuming corporate officers whose companies engage in unlawful activities under the Federal Food, Drug & Cosmetic Act ("FDCA") may be held strictly liable for unintentional violations of the FDCA. As such, the government can seek to obtain misdemeanor convictions of a company official for alleged violations of the FDCA – even if the corporate official was unaware of the violation – if the official was in a position of authority to prevent or correct the violation and did not do so.

The Park Doctrine draws its name from a 1975 Supreme Court decision: *United States v. Park*, 421 U.S. 658 (1975). John Park was the president of a large national food chain that operated several warehouses that the FDA determined to be infested with rodents. Park was convicted of a misdemeanor violation of the FDCA for having held for sale "adulterated" or "misbranded" food. A federal appeals court overturned the conviction, finding that it was "predicated solely upon a showing that the defendant, Park, was the President of the offending corporation." Concluding that as "a general proposition, some act of commission or omission is an essential element of every crime," the appeals court held that due process barred Park's conviction in the absence of a finding that he had engaged in some "wrongful action."

The Supreme Court reinstated the conviction, recognizing that while Park was unlikely to be in a position to directly supervise all of the company's 30,000 employees and to ensure that all acted in compliance with the FDCA, § 331 of the FDCA imposes on senior corporate executives an unwavering "duty to implement measures that will insure that violations will not occur." The Court explained that the imposition of this duty was justified by the strong "public interest in the purity of its food."

#### PROHIBITED ACTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The basic prohibitions of the FDCA are contained at 21 U.S.C. § 331. The FDCA prohibits the following acts and the causing thereof:

- (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
- **(b)** The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.
- (c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

21 USCS § 331.

Typically, every crime has two elements—a bad act and a culpable state of mind (mens rea, which generally means intent or recklessness). Section 333(a)(1) of the FDCA, the misdemeanor provision, is noteworthy because it creates one of the few true strict liability crimes in federal criminal law. That is, the government does not need to prove a state of mind in order to obtain a conviction. If a food product is misbranded or adulterated, or if a misbranded or adulterated drug is distributed into the channels of interstate commerce, a crime has been committed.

That the perpetrator of the crime had neither knowledge nor intent and still could be convicted is troubling, especially since jail time is a possibility. A violation of 21 USCS § 331 is punishable by imprisonment for not more than one year or a fine of not more than \$1,000.00, or both. Additionally, if any person violates § 331 with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.

#### REEMERGENCE OF THE PARK DOCTRINE

There were few prosecutions under the Park Doctrine between 1975 and 2010. That changed on March 4, 2010, when FDA Commissioner Margaret Hamburg wrote Sen. Charles Grassley (R-IA) to say that the agency was developing "criteria" to be used in the selection of misdemeanor prosecution cases. In her letter, Hamburg said that the FDA intended to consider "the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable." The criteria published by the FDA includes a list of broad factors that could support the prosecution of even relatively minor violations of the FDCA.

According to the FDA's criteria, when considering whether to criminally prosecute a misdemeanor violation against a corporate official, the FDA recommends that prosecutors consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution, but are factors that may be relevant when deciding whether to recommend prosecution of a misdemeanor violation.

Other factors that may be considered include, but are not limited to:

- 1. Whether the violation involves actual or potential harm to the public;
- 2. Whether the violation is obvious:
- 3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior 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 factors the FDA lists are concerning as they are (a) highly subjective and (b) give prosecutors broad discretion in determining whether to prosecute an FDCA violation. Importantly, it is apparent from the factors set out by the FDA that there is a low threshold for prosecution, if a prosecutor intends to make an example of a prospective case.

#### RECENT CASES

Three recent cases illustrate the federal government's new policy to spend resources towards the prosecution of FDCA violations.

#### Jensen Farms

Brothers Eric and Ryan Jensen were the principals in a family farming operation known as Jensen Farms in Granada, Colorado. Jensen Farms supplied cantaloupe to major grocery chains such as Walmart and Kroger. Jensen Farms operated a conveyor system in its shed that cleaned the cantaloupe upon arrival from the farm. Around May 2011, Jensen Farms revamped the conveyor system. The revamped conveyor system was thought to improve food safety. Nevertheless, Jensen Farms unknowingly began shipping cantaloupes contaminated with listeria in late Summer 2011. The government alleged that the contaminated cantaloupes caused the deaths of at least 33 individuals and caused illnesses in at least 147 people. Even though Eric and Ryan Jensen did not know that their products were contaminated and did not know that their revamped conveyor system could lead to an increased risk of contamination, federal prosecutors still brought criminal charges and argued that the Jensens failed to take appropriate steps to reduce listeria contamination in their facility.

The prosecution of the Jensens is significant because there was absolutely no evidence that they knew the cantaloupe was adulterated before it was sent out into commerce. Instead, the prosecutors only could prove that the Jensens should have been aware that the cantaloupes could be contaminated because of the manner in which there were cleaned and packed. Eric and Ryan Jensen pled guilty to misdemeanors and were sentenced to five year probation terms with six months home detention.

#### **Quality Egg**

Quality Egg, LLC ("Quality Egg") was identified by the federal government as the source of a major Salmonella outbreak in August 2010 that left thousands of people sickened across the United States. Quality Egg voluntarily recalled hundreds of millions of eggs from the market. Despite this recall, the government pressed charges against the company and its owners, Austin DeCoster and COO Peter DeCoster, alleging that the company and the DeCosters engaged in: (i) bribery of a public official; (ii) introduction of misbranded food into interstate commerce with intent to defraud or mislead; and (iii) introduction of adulterated food into interstate commerce. Specifically, the government alleged that the eggs produced and shipped by Quality Egg were adulterated because they were contaminated with salmonella. Despite the fact that the government acknowledged that the DeCosters did not have knowledge that the eggs sold by Quality Egg were contaminated, both DeCosters, as a result of their responsibilities as Quality Egg executives, were charged under FDCA section 333(a)(1).

Both DeCosters pled guilty to the two FDCA misdemeanor offenses. On April 13, 2015, the District Court sentenced father and son to three months imprisonment. The DeCosters argued at the sentencing hearing that imprisonment for a strict liability offense was unconstitutional on due process grounds. The District Court rejected this argument and held that imprisonment for a strict liability misdemeanor offense does not violate the Eighth Amendment's prohibition against cruel and unusual punishment. The Court cited *United States v. Park* and recognized the Supreme Court's repeated determinations that FDCA convictions can lead to imposition of criminal penalties, even absent proof of intent. In weighing the three month sentence, the court acknowledged that the punishment could serve to deter the marketing of unsafe foods and widespread harm to public health by similarly situated corporate officials and other executives in the industry.

#### **Peanut Corporation of America**

The most high-profile foodborne illness related criminal prosecutions under the Park Doctrine concluded on Sept. 19, 2014, and resulted in the convictions of three former executives of the Peanut Corporation of America (PCA), including owner Stewart Parnell, food broker Michael Parnell, and quality control manager Mary Wilkerson. The prosecution is significant because it is one of the first times that food processors have been prosecuted criminally in a federal food-poisoning case. The case also is significant because of the resources that the government devoted to this prosecution and how aggressively it prosecuted the case. The prosecution called 45 witnesses, and its case in chief lasted 26 days.

This trial involved allegations that the PCA executives knowingly shipped contaminated peanut butter and peanut paste to customers and faked lab tests intended to screen for salmonella, resulting in one of the largest food recalls in U.S. history.

The government presented evidence that the defendants misled customers about the presence of salmonella in their products. For example, the Parnells allegedly fabricated certificates of analysis (COAs) accompanying various shipments of peanut products, including test results concerning the presence or absence of pathogens in food. According to the evidence, the Parnells participated in a scheme to fabricate COAs that stated that the food at issue was free of pathogens when in fact (a) there had been no testing of the food or (b) tests had revealed the presence of pathogens.

The government also presented evidence that when the FDA officials inspected PCA's plant to investigate the outbreak, Stewart Parnell and Mary Wilkerson gave untrue or misleading answers to questions posed by those officials.

The jury found Stewart Parnell guilty of 67 federal felony counts, including conspiracy, wire fraud and obstruction of justice. He was sentenced to 28 years in prison. Michael Parnell was convicted of 30 counts related to falsification of lab results and was sentenced to 20 years in prison. Mary Wilkerson received a 5 year sentence for obstruction of justice.

In a press release after the sentencing, Principal Deputy Assistant Attorney General Benjamin C. Mizer touted the conviction as "a powerful message to officials in the food industry that they stand in a special position of trust with the American consumer, and those who put profit above the welfare of their customers and knowingly sell contaminated food will face serious consequences. The Department of Justice will continue to work aggressively with its partners to ensure that the American people are protected from food that is adulterated or misbranded within the meaning of the Food, Drug, and Cosmetic Act and pursue any person who fails to abide by the vital food safety protections in the law. We are dedicated to using all the tools that we have at our disposal to ensure that the processors and handlers of our food have the public's safety forefront in their minds."

#### **CONCLUSION**

The reemergence of the Park Doctrine subjects corporate officials to the harsh possibility of a criminal prosecution. Being charged with a criminal violation can have devastating effects, even if no conviction results. Without the burden of having to prove knowledge or intent, there is precious little to dissuade a prosecutor who is motivated to forge ahead with a misdemeanor prosecution. The cases of the Jensen brothers, the DeCosters, and the Parnells demonstrate the risks and challenges that lay ahead for executives in the food industry. These cases also evidence the federal government's policy to spend resources prosecuting FDCA cases against individuals, a policy which likely will continue to expand in the coming decade, according to officials.

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