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CRIMINAL LIABILITY**Food For Thought: Corporate Executives on Notice That DOJ Will Seek to Hold Them Criminally Liable for Contaminated Food Outbreaks and Product Failures**

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The Department of Justice's recent actions have put the food and consumer products industries on notice that the DOJ will aggressively investigate any contaminated food outbreaks or product failures that cause large numbers of illnesses, injuries or deaths and will seek to hold company executives personally liable wherever possible.

The September trial and convictions of several Peanut Corp. of America (PCA) personnel, including the company's owner and his brother, on charges related to PCA's sale of salmonella-tainted peanuts that killed nine people and sickened hundreds nationwide was a groundbreaking event.¹ Prior to the PCA indictment, the DOJ rarely brought charges in cases where companies sold contaminated food products that caused large numbers of illnesses or deaths. In the PCA case, by contrast, the indictment filed by the DOJ included a lengthy list of charges that may result in some defendants being imprisoned for decades. Notably, some of the DOJ's charges were based on an expansive theory of individual criminal liability that likely will serve as a template for prosecutors to use in future contaminated food or product defect cases, namely, that executives can be held criminally liable for wire fraud on account of mis-

statements to customers about adherence to product specifications.

A second development, which received far less publicity, may have similarly wide-ranging consequences. The DOJ responded to two recent, high-profile food contamination cases by bringing charges against executives using the "Responsible Corporate Officer" (RCO) doctrine under the Federal Food, Drug and Cosmetic Act (FDCA). Under the RCO doctrine, executives can be subject to criminal liability if they were in a position to prevent the FDCA violations—regardless of whether they were aware of the underlying violation. In one case, the defendants pleaded guilty as RCOs even though the DOJ agreed that they had no knowledge that their company was selling contaminated products in what appears to be the first instance of using the RCO doctrine against a defendant who had no knowledge of the underlying FDCA violation. The DOJ has thus put the food industry on notice that should companies sell contaminated food that causes widespread illness, their executives may be held criminally liable, even if they had no knowledge that contaminated food was being sold.

The DOJ's efforts to prosecute food-industry executives coincide with its heightened focus on investigating and prosecuting individuals. On Sept. 17, Attorney General Eric Holder and two other senior DOJ officials gave speeches in which they highlighted the importance to the DOJ of holding executives personally responsible

¹ 09 WCR 660 (10/3/14).

for their company's wrongdoing.² Although the focus of their remarks was the financial-services and health-care industries, their pronouncements—in combination with the recent food industry convictions and plea agreements—suggest that if something goes horribly wrong, the DOJ will have corporate executives directly in its crosshairs.

What can food and consumer products companies do to minimize the risks of being targeted by the DOJ? As discussed in detail below, there are no foolproof solutions, but there are a number of steps that prudent food companies and consumer product manufacturers can take to minimize the risk of exposure to criminal prosecution, including:

(1) ensuring that the company has the infrastructure, systems and policies in place to maximize the likelihood of compliance with applicable regulations and to proactively remedy any compliance and safety problems; and

(2) carefully monitoring all statements about product specifications, safety or performance—particularly during times of crisis—to ensure their accuracy.

Past History of Prosecutions

Prior to 2013, there appear to have been only three DOJ indictments arising out of cases in which companies sold contaminated food products that resulted in deaths or serious injuries:

- In July 1998, Odwalla pleaded guilty to allegations that it shipped an adulterated food product after its

² 09 WCR 631 (9/19/14).

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bacteria-tainted apple juice killed one person and sickened dozens more; the agreement included a \$1.5 million fine.³

- In December 1998, the DOJ indicted Hudson Foods and two employees on charges related to the sale of contaminated hamburgers that sickened 16 people, resulting in what was then the largest meat recall in U.S. history.⁴ The indictment alleged that the company and its employees misled the Department of Agriculture as to the scope of the infected beef; the company and its employees were subsequently acquitted.⁵

- In June 2001, the Sara Lee Corp. pleaded guilty to violations relating to the production and distribution of tainted meat that led to 15 deaths and made many more sick.⁶

Despite the numerous deaths and injuries that were reportedly caused by the contaminated food sold by these three companies, the only indictments that were brought in the Hudson Foods matter resulted not from the sale of contaminated food but rather from misleading government inspectors about the contamination. In other high-profile contamination cases, including hamburgers sold at Jack in the Box in 1993 that led to four deaths and 600 illnesses, and the 2006 sale of Dole spinach that caused one death and 94 illnesses, prosecutions were not instituted.

The PCA Prosecution

PCA marked a turning point. In that case, the DOJ acted aggressively in the aftermath of the revelation that the company had sold salmonella-tainted peanuts that caused large numbers of deaths and injuries.⁷

After a lengthy investigation, the DOJ indicted four individuals:

- Stuart Parnell, the owner and President of PCA;
 - Michael Parnell (Stuart's brother), the vice president of PCA and a food broker for PCA;
 - Samuel Lightsey, a PCA operations manager⁸; and
 - Mary Wilkerson, a quality-assurance manager.
- The DOJ did not indict PCA, presumably only because it had gone bankrupt.

The indictment contained 76 counts that relied on a variety of legal theories. Some of the counts included charges from the prosecutors' traditional "toolbox" for

³ *Juice Maker Fined Record \$1.5 Million for Sales of Contaminated Apple Juice*, PRODUCT SAFETY & LIABILITY REPORTER, July 31, 1998.

⁴ Pam Belluck, *U.S. Indicts Producer of Contaminated Beef*, N.Y. TIMES, Dec. 17, 1998.

⁵ *Contaminated Beef Case Ends in Acquittals*, L.A. TIMES, Dec. 4, 1999.

⁶ *Sara Lee Admits Guilt in Criminal Case on Meat Recall*, BLOOMBERG, June 22, 2001.

⁷ *Multistate Outbreak of Salmonella Typhimurium Infections Linked to Peanut Butter, 2008–2009 (Final Update)* (May 11, 2010), <http://www.cdc.gov/salmonella/typhimurium/update.html>.

⁸ Lightsey entered into a plea agreement with the DOJ in May in which he agreed to cooperate in return for a reduced sentence. Additionally, another PCA manager, Daniel Kilgore, agreed to plead guilty before the indictment against the other four individuals was issued.

a contaminated food case: FDCA violations related to the sale of contaminated foods, and obstruction of justice related to interference with the Food and Drug Administration's investigation. Other charges, however, involved an innovative theory that PCA personnel committed wire fraud and conspiracy to commit wire fraud, based on misstatements they made to customers about the product that PCA was selling.

The wire fraud statute makes it illegal to use the interstate wires (which include all forms of electronic communications) to devise "any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses."⁹ Traditionally, the statute has been used to prosecute what would be commonly thought of as a "scam" to unlawfully obtain money from someone else—with fraud charges often predicated upon violation of an underlying statute or regulation.

The PCA-related indictment, however, included charges of fraud and conspiracy to commit fraud that were predicated on the fact that PCA falsely represented to customers that the peanuts they were purchasing satisfied the customers' specifications when the peanuts did not.

For example, the DOJ charged that PCA falsely told customers that the peanuts were grown in the U.S., as specified by the customer, when they had in fact been grown in Mexico, and that PCA was selling a product that had been processed at a plant specified by the customer, when in fact the processing was done at another plant. This conduct related solely to private contractual specifications and did not relate to the sale of products that was prohibited by law. Such conduct historically would have been remedied through state law breach of contract or deceptive business practice statutes—civil actions that likely would have resulted in PCA being ordered to pay damages to its customers or fines to the state. By successfully charging this conduct as fraud committed by company executives, the DOJ is now subjecting PCA's owner and his brother to lengthy prison sentences and large fines that they personally will be required to pay.

The DOJ's willingness to charge misstatements to customers as fraud likely will have broad consequences beyond the food industry, extending to all marketers of consumer products. Prosecutors seeking to bring fraud charges related to the sale of contaminated foods or defective products have faced the challenge of proving that someone knowingly authorized the sale of a contaminated food or defective product. This hurdle is particularly great in the case of consumer products, where the question of what is considered as a defect within the applicable regulatory regime often requires subjective judgment regarding how the product is expected to perform under different circumstances and what constitutes an unacceptable risk; it is often difficult for prosecutors to demonstrate beyond a reasonable doubt that a corporate executive authorized the sale of a product knowing it was defective.

The PCA indictment template, by contrast, enables prosecutors to circumvent these thorny issues simply by alleging that corporate executives knowingly misrepresented characteristics of their food or products to their customers. If the DOJ can successfully prove fraud charges, it potentially can subject defendants to signifi-

cant jail time and large fines. The DOJ's success against PCA executives at trial is likely to embolden prosecutors to bring charges based on similar theories in the future.

DOJ's Use of the RCO Doctrine To Prosecute Contaminated Food Cases

Section 333 of the FDCA criminalizes the distribution of adulterated or misbranded food, drugs and medical devices in interstate commerce.¹⁰ A misdemeanor violation under Section 333(a)(1) requires no evidence of intent to defraud or mislead, and a conviction can result in a prison sentence of up to one year and significant fines. In the seminal case of *United States v. Park*, the U.S. Supreme Court held that the government need demonstrate only that the defendant, by virtue of his position, had the "authority and responsibility" as a RCO to prevent or correct the FDCA violation to prove liability under Section 333(a)(1).¹¹ A defendant could be held liable even if he or she were not aware of the underlying wrongdoing; the only defense recognized by the Supreme Court was that the defendant was "powerless to prevent or correct the violation."¹² It is noteworthy, however, that the defendant in *Park* was notified by the FDA of the underlying FDCA violation, the storage of food under squalid conditions, and the brief for the U.S. government before the Supreme Court explicitly stated that the FDA "will not ordinarily recommend prosecution unless [the RCO], after becoming aware of possible violations . . . has failed to correct them or to change his managerial system so as to prevent further violations."¹³

From the 1960s through the 1980s, misdemeanor RCO prosecutions were pursued with some frequency, primarily in cases such as *Park* in which food was stored under squalid conditions.¹⁴ Consistent with the position the U.S. articulated in the *Park* case, the defendants in these cases typically had some knowledge of the underlying activities or conditions.

The DOJ has recently begun using the RCO doctrine in prosecuting executives at companies that sold contaminated food products that caused large numbers of illnesses or deaths. In September 2013, the DOJ filed a criminal information against Eric Jensen and Ryan Jensen, owners of Jensen Farms, arising from the sale of cantaloupes tainted with listeria that killed at least 33 people and hospitalized 147.¹⁵ The information charged them as RCOs with a misdemeanor violation of the FDCA as a result of Jensen Farms selling adulterated cantaloupes.¹⁶ The defendants subsequently pleaded guilty and admitted that they failed to use a chlorine spray, which, if used, would have reduced the risk of

¹⁰ 21 U.S.C. § 333.

¹¹ 421 U.S. 658, 671 (1975).

¹² *Id.* at 672-73.

¹³ *Id.* at 664; *United States v. Park*, government brief at 32.

¹⁴ John R. Fleder, *The Park Criminal Liability Doctrine: Is it Dead or is it Awakening?*, FDLI UPDATE (Sept./Oct. 2009), at 49.

¹⁵ *Eric and Ryan Jensen Plead Guilty to All Counts of Introducing Tainted Cantaloupe into Interstate Commerce* (Oct. 22, 2013), <http://www.justice.gov/usao/co/news/2013/oct/10-22-13.html>.

¹⁶ See *United States v. Jensen*, No. 1:13-mj-01138, criminal information at 1-3 (D. Colo. Sept. 24, 2013).

⁹ 18 U.S.C. § 1343.

contaminated fruit. Although the Jensens admitted that they never used the spray, the information did not charge—and the defendants did not admit—that they were aware that Jensen Farms was selling contaminated cantaloupes.¹⁷ The defendants were sentenced to six months of home detention, five years of probation and \$13,184 in restitution.

The DOJ again used the RCO doctrine in connection with its recent plea agreements with Peter and Austin DeCoster of Quality Egg arising out of the sale of salmonella-tainted eggs that caused illnesses to more than 1,900 people and led to a recall of 500 million eggs.¹⁸ These unprecedented plea agreements explicitly state that the government was unaware of any evidence that the defendants knew that Quality Eggs was selling contaminated eggs.¹⁹ This appears to be the first instance in the food industry where executives were charged as RCOs without any knowledge whatsoever of wrongful conduct or failure to take some precautionary measure.

The DOJ's willingness to bring charges under the RCO doctrine absent any knowledge of wrongdoing creates a significant risk for all food industry executives with ultimate supervisory authority over food sales. The DOJ has taken the position that a food product tainted with deadly bacteria such as salmonella or listeria is adulterated within the meaning of the FDCA, which defines an adulterated food as one that "bears or contains any poisonous or deleterious substance which may render it injurious to health."²⁰ There is nothing to stop the DOJ (aside from its own discretion) from responding to the next contaminated food outbreak by charging the CEO and any other executives who had the authority to stop the sale of the contaminated food as RCOs and seeking a prison sentence and large fine—compounded by the absence of meaningful defenses under the RCO doctrine.

DOJ's High-Profile Speeches Regarding Prosecuting Individual Wrongdoing

In September, Holder and two senior DOJ officials made speeches in which they stressed the DOJ's focus on prosecuting individual wrongdoing in white collar cases. Holder expressed frustration that the DOJ had not been able to hold executives in the financial services industry personally liable for the events that led to the financial crisis of 2008, and he held up the RCO doctrine as a model that Congress should consider for the financial services industry as well. Principal Deputy Assistant Attorney General for the Criminal Division Marshall L. Miller similarly stressed the importance of prosecuting individuals for corporate wrongdoing and the DOJ's view that corporations should receive credit for

cooperating with government investigations only if they identify facts and evidence that implicate individual wrongdoing.

The DOJ's words and actions demonstrate an underlying belief that if something goes wrong and causes widespread harm—whether it is financial or physical—the department will try to find a way to hold individual executives criminally liable. This view represents a meaningful departure from past high-profile crises, which were typically handled as civil or regulatory matters unless the DOJ uncovered evidence of blatant criminal conduct. As Holder noted, the RCO doctrine affords the DOJ an easy method to hold corporate executives liable in industries that are subject to the FDCA's jurisdiction. But even in industries not subject to the FDCA, aggressive prosecutorial tactics such as attempting to use any misstatements as the basis for a fraud charge can accomplish the same result.

Minimizing Risks of DOJ Investigations

What can food and consumer product companies and their executives do to reduce the odds of a DOJ investigation? Prudent executives should take actions along two tracks to minimize the risk of DOJ prosecution in the event of a contaminated food outbreak or product failure:

(1) become actively involved in developing and maintaining a robust compliance program and addressing any potential safety compliance issues that may arise; and

(2) carefully monitoring statements to customers and the public to ensure accuracy.

Regulatory Compliance and Safety. One of the keys to minimizing the risk of DOJ action is the active involvement of both the board of directors and senior management in ensuring that the company is in compliance with applicable regulations and that any potential compliance or safety issues are proactively remedied.

An effective safety and compliance program requires infrastructure and policies that promote the fluid and timely flow of information relating to safety and compliance between working-level personnel and senior management. This includes establishing a safety and compliance committee of the board of directors that is actively involved in these issues (or making safety and compliance monitoring the responsibility of an existing board committee) and interacts on a regular basis with management. Similarly, management should establish product safety committees with personnel from key units across the company including production, engineering/agriculture and marketing that meet regularly to discuss any reported problems or emerging trends that may suggest compliance or safety issues that need to be addressed. Senior management should also consider retaining experienced outside counsel to conduct compliance reviews. Most important, when senior personnel become aware of any compliance and safety issues, it is imperative that they act on those issues immediately and document what steps were taken to investigate and remedy the problem.

An effective safety and compliance program also requires a corporate culture that prioritizes compliance issues at all levels of the company. The board and senior managers must set a "tone at the top" that rein-

¹⁷ See *United States v. Jensen*, No. 1:13-mj-01138, plea agreement and statement of facts relevant to sentencing at 7 (D. Colo. Oct. 22, 2013).

¹⁸ Stephanie Strom, *U.S. Charges Egg Business and Owners*, N.Y. TIMES, May 21, 2014.

¹⁹ See *United States v. DeCoster*, No. 3:14-cr-03024, plea agreement at 6-7 (N.D. Iowa June 2, 2014).

²⁰ See *United States v. Jensen*, No. 1:13-mj-01138, plea agreement and statement of facts relevant to sentencing at 3, n. 3 (D. Colo. Oct. 22, 2013) ("A food containing a pathogenic microorganism ... is adulterated within the meaning of § 342(a)(1).").

forces that compliance and safety are top priorities that take precedence over profits and are the responsibility of everyone at the company. Employees should be encouraged to report potential compliance issues to their superiors and be rewarded when they do so. The company should similarly have a strong anti-retaliation policy in place to ensure that no one suffers adverse consequences as a result of reporting a potential problem.

Statements to Public, Customers. It is always crucial for a company to ensure that its public statements—all advertisements, press statements and statements to specific customers that relate to a product or food's specifications, safety and performance (in the case of products)—are accurate. In times of crisis, such as a contaminated food outbreak or a product failure, it becomes even more important for the company to care-

fully script everything that is said to the public (and have it reviewed by counsel) because prosecutors will carefully review such statements to determine whether there are any discrepancies between what the company knows and what it is saying to the public. To the extent there are any such discrepancies, prosecutors may seek to follow the PCA indictment template and charge that the company and its executives committed fraud by misleading the public or specific customers.

To mitigate this risk, it is important to prepare a crisis communications plan, to avoid definitive statements about the history that led to the crisis, e.g., who knew what and when, and to make sure that any statements that involve technical issues are reviewed by the relevant employees—such as the scientists or engineers—with the substantive knowledge needed to verify the accuracy of the statements.