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# A Little Knowledge Goes a Long Way: Prosecuting Food Companies and Their Officials for Food Safety Violations

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## **A Little Knowledge Goes A Long Way: Prosecuting Food Companies and Their Officials for Food Safety Violations**

In April 2015, Austin “Jack” DeCoster and his son Peter DeCoster were sentenced to three months’ incarceration in a federal prison following their misdemeanor guilty pleas for introducing adulterated eggs into interstate commerce. The sentences surprised many people in the food industry because incarcerating corporate executives is a rare punishment for food safety violations. This article discusses the DeCoster case and other federal criminal prosecutions of food companies and their officials for Food, Drug and Cosmetic Act violations, outlining the factual scenarios that have lead the Justice Department to charge members of the food industry with a variety of federal felony and misdemeanor crimes. The article also explores the “responsible corporate officer” doctrine and its legal underpinnings, *United States v. Dotterweich*<sup>1</sup> and *United States v. Park*,<sup>2</sup> otherwise known as “the *Park* doctrine.” In light of DeCoster and other recent high profile prosecutions, the article closes with some risk management considerations for corporate officials involved in significant food safety and leadership roles within their companies.

### **I. STATUTORY BASIS FOR CRIMINAL PROSECUTION OF CORPORATIONS AND CORPORATE OFFICIALS FOR FOOD SAFETY VIOLATIONS.**

The Federal Food, Drug, and Cosmetics Act (“FFDCA”)<sup>3</sup> outlines more than two dozen prohibited acts impacting food safety and public health, ranging from selling adulterated or misbranded food, to failing to establish or maintain required food safety records, to refusing to permit facility inspections. The offense most frequently cited in prosecutions of food industry corporate officials is the introduction of adulterated or misbranded food into interstate commerce, 21 U.S.C. § 331 (a).

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<sup>1</sup> 320 U.S. 277 (1943).

<sup>2</sup> 421 U.S. 658 (1975).

<sup>3</sup> 21 U.S.C. § 301, *et seq* (2012).

Depending on the nature and extent of the misconduct, a Section 331(a) violation may be charged as a misdemeanor or a felony. Under the FFDCA’s misdemeanor provisions, any person who commits a prohibited act as a first offense with no intent to defraud or mislead faces up to one year of imprisonment and a fine of not more than \$1,000.<sup>4</sup> If the defendant has a prior Section 331 conviction, or acts with the intent to defraud or mislead, the defendant faces up to three years’ imprisonment and a fine of up to \$10,000.<sup>5</sup>

In addition to the FFDCA’s criminal provisions, the general criminal fines statute<sup>6</sup> authorizes substantially increased financial penalties, even for misdemeanor violations.<sup>7</sup> For individuals, the statute increases the maximum fine for a Class A misdemeanor that does not result in death to \$100,000; for a felony or a misdemeanor resulting in death, the maximum fine increases to \$250,000.<sup>8</sup> For organizations, the maximum fine for a Class A misdemeanor that does not result in death rises to \$200,000; for a felony or a misdemeanor resulting in death, the maximum fine rises to \$500,000.<sup>9</sup> These fines can be further increased by twice the defendant’s financial gain or the victim’s financial loss, whichever is greater.<sup>10</sup>

These augmented fines, together with the increasing use of traditional white collar charges—mail fraud, wire fraud, criminal conspiracy and obstruction of justice—have slowly changed the face of federal prosecutions in the food industry and created significant exposure for a corporate official charged with food safety-related offenses. Importantly, even in a misdemeanor context, the possibility of incarceration exists. Under Section 2N2.1 of the U.S. Sentencing Guidelines, a violation of a food law such as the FFDCA carries a base offense level corresponding to a sentencing range of zero to six months of imprisonment (for an individual with no criminal history).<sup>11</sup> In the commentary following Section 2N2.1, the Sentencing Commission advises that this guideline “assumes a regulatory offense that involved knowing or reckless conduct”. Where only negligence is involved, a downward departure may be warranted.”<sup>12</sup> However, the guideline also provides for upward departures where the offense “created a substantial risk of bodily injury or death; or bodily injury, death, extreme psychological injury, property damage, or monetary

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<sup>4</sup> 21 U.S.C. § 333(a)(1).

<sup>5</sup> 21 U.S.C. § 333(a)(2).

<sup>6</sup> 18 U.S.C. § 3571 (2012).

<sup>7</sup> Pursuant to sentencing reforms enacted in 1984, sentencing judges are able to enhance the otherwise meager fine provisions of various federal laws, including the FFDCA. “[The bill] brings Federal criminal fines into the 1980’s. It authorizes substantially increased fines for all Federal offenses. This is particularly important in the areas of drug offenses and corporate and white collar crime, where the criminal often views a fine as a cost of doing business.” 130 CONG. REC. 21486, 21490 (1984) (statement of Rep. Rodino). Notably, one commentator has observed that when the sentencing reforms were put into place, the increased fines were considered not only a deterrence to profiteering from criminal conduct, but also as an alternative to incarceration. “For individuals, the goal was to set a monetary fine that would equal the monetary value of a prison term so that fines would be seen as an effective alternative to prison sentences. For corporations, the Act was intended to remove the chance of the corporation’s retaining any of the ill-gotten gains.” AMERICAN BAR ASSOCIATION, SENTENCING GUIDELINES IN ANTITRUST: A PRACTITIONER’S HANDBOOK 9 (Robert Engelbrecht Hauberg ed.) (citing Senate Judiciary Committee Report, S.R. 98-225, 98th Congr. 2d Sess).

<sup>8</sup> 18 U.S.C. § 3571(b).

<sup>9</sup> 18 U.S.C. § 3571(c).

<sup>10</sup> 18 U.S.C. § 3571(d).

<sup>11</sup> U.S. SENTENCING GUIDELINES § 2N2.1 (U.S. SENTENCING COMM’N 2014).

<sup>12</sup> *Id.* § 2N2.1 cmt. n. 1.

loss resulted from the offense.”<sup>13</sup> Consequently, even under the best of circumstances for a defendant, where no loss of life has occurred, there is no criminal history, and the underlying conduct is not deemed to be knowing or reckless, a food industry official prosecuted under the FFDCa for a federal misdemeanor food safety violation still faces the possibility of imprisonment, home detention or, at minimum, a sentence involving federal probation.

For these reasons, members of the food industry should understand how federal prosecution under the FFDCa has been interpreted in seminal Supreme Court decisions, and how a corporate official in today’s food safety climate can be found criminally liable for a food safety offense and be incarcerated even absent proof of knowledge or active misconduct.

## II. THE *PARK* DOCTRINE—WHAT IT IS AND WHAT IT IS NOT

The *Park* doctrine allows the government to seek a misdemeanor conviction of a food industry official for a food safety violation without proving that the official knew of or actively participated in the violation. The key is proving that the official was in a position of sufficient responsibility or authority to prevent or remedy the food safety concerns but failed to do so.

The origin of the *Park* doctrine traces back to *United States v. Dotterweich*,<sup>14</sup> a 1943 Supreme Court opinion establishing the contours of an FFDCa-based criminal prosecution of a corporate official. Joseph Dotterweich was the president and general manager of a company that purchased drugs from manufacturers, repacked them under the company’s label, and shipped them in interstate commerce.<sup>15</sup> Dotterweich and his company were charged with misdemeanors for shipping adulterated and misbranded products, and a jury found Dotterweich, but not the company, guilty.<sup>16</sup> Dotterweich appealed, arguing that the corporation was the only “person” subject to prosecution under the FFDCa, and further, that he was immune from prosecution under the Act’s “guaranty” provision, which allowed him to rely on the manufacturer’s representations of product wholesomeness. The Supreme Court rejected Dotterweich’s narrow interpretation of the FFDCa and affirmed his conviction, articulating a strict liability standard for the misdemeanor prosecution of corporate officials for “public welfare” safety violations and setting the stage for the later establishment of the “responsible corporate officer” doctrine.

Observing that in a modern industrial world, certain matters involving the lives and health of people are “largely beyond self-protection,” the *Dotterweich* Court instructed:

The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.”<sup>17</sup>

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<sup>13</sup> *Id.* § 2N2.1 cmt. n. 3.

<sup>14</sup> 320 U.S. 277 (1943).

<sup>15</sup> *Id.* at 278.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 280-81.

The Court acknowledged the potentially broad reach of this strict liability standard. “Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting.”<sup>18</sup> Nevertheless, the Court declined to define “responsible relation” or to delineate a class of employees who might stand in such relation to the transaction. The Court preferred to place its faith in the evidence produced at trial, and “the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries.”<sup>19</sup>

Thirty-two years later, in *United States v. Park*, the Supreme Court again upheld a misdemeanor conviction of a food industry official for a public welfare offense, but this time the Court elaborated on the concept of “responsibility” left open by the *Dotterweich* court.<sup>20</sup> John Park was the chief executive officer of Acme Markets, a national retail food chain with 36,000 employees, 847 retail outlets and sixteen warehouses. Park and Acme were charged in a five-count Information for allowing food to become contaminated with rodent filth while in storage in an Acme warehouse in Baltimore.<sup>21</sup> Park conceded at trial that he was “responsible for the entire operation of the company,” but he also testified that he assigned sanitation in his large organization to “dependable subordinates” and that his Baltimore division vice president had specifically confirmed to him that an investigation was underway into the known rodent infestation problem and corrective action was being taken in the Baltimore warehouse.<sup>22</sup> However, Park also admitted receiving a warning letter addressed to him from the FDA regarding unsanitary conditions at Acme’s Philadelphia warehouse one and a half years prior to his notice of the problems in Baltimore, and he acknowledged that the company’s system for handling sanitation “wasn’t working perfectly” since problems had now surfaced in Baltimore.<sup>23</sup> The jury found Park guilty on all five misdemeanor counts and he was sentenced to pay a fine of \$50 on each count.<sup>24</sup>

Park argued on appeal that even if his lack of awareness of wrongdoing was not a defense, the government still needed to prove he had committed some wrongful act or omission. The Court of Appeals agreed, but the Supreme Court reinstated the conviction, finding that it was enough that Park had failed to exercise his authority and supervisory responsibility, resulting in a food safety violation.<sup>25</sup>

[T]he Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.<sup>26</sup>

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<sup>18</sup> *Id.* at 284.

<sup>19</sup> *Id.* at 284-85.

<sup>20</sup> 421 U.S. 658 (1975).

<sup>21</sup> *Id.* at 660.

<sup>22</sup> *Id.* at 664.

<sup>23</sup> *Id.* at 664-65.

<sup>24</sup> *Id.* at 665.

<sup>25</sup> *Id.* at 671.

<sup>26</sup> *Id.* at 673-74.

Conscious that it was articulating a standard whereby conviction might be predicated on corporate status alone, the Court observed that an effective set of jury instructions, particularly when viewed in the context of the whole trial, could prevent this undesired outcome. The main issue for jury determination was “not respondent’s position in the corporate hierarchy, but rather his accountability, because of the responsibility and authority of his position, for the conditions which gave rise to the charges against him.”<sup>27</sup> Thus, the Court concluded:

We are satisfied that the [FFDCA] imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations its provisions.<sup>28</sup>

In his dissent, Justice Stewart lamented that the majority’s tautological definition of “responsibility” left it to the jury to not only apply the law to the facts of the case, but to determine the law itself. It was not only unconstitutional to put this much power into the jury’s hands, Justice Stewart opined, but also insupportable to apply this murky standard to criminal—and potentially felony—convictions. Foreshadowing future challenges, Justice Stewart wrote:

So the standardless conviction approved today can serve in another case tomorrow to support a felony conviction and a substantial prison sentence. However highly the Court may regard the social objectives of the Food, Drug, and Cosmetic Act, that regard cannot serve to justify a criminal conviction so wholly alien to fundamental principles of our law.<sup>29</sup>

Today, *Park* is often mistakenly used as a shorthand reference to *any* prosecution of a corporate official whose company is involved in a serious FFDCA safety violation. In fact, a “pure-*Park*” case is no more and no less than a misdemeanor prosecution of a “responsible corporate officer” under a strict liability standard, meaning the government does not have to prove that the official knew of or actively participated in the underlying wrongdoing in order to obtain a conviction. Importantly, once a prosecutor charges a corporate official with an FFDCA violation with intent to defraud or mislead, it is no longer technically a *Park* case because *mens rea* becomes an element of the government’s burden of proof. Nonetheless, the *Park* doctrine often surfaces in plea negotiations and sentencing matters, so food industry officials need to understand how the doctrine has been used since it was formally articulated in 1975.

### III. EARLY POST-PARK PROSECUTIONS OF FOOD INDUSTRY OFFICIALS

Three years after *Park*, the Supreme Court heard *United States v. U.S. Gypsum Co.*,<sup>30</sup> a Sherman Act case in which the Court reaffirmed that *Park* was consistent with and supportive of laws designed to protect the nation’s food supply. In a footnote to the *Gypsum* opinion (which conveyed a general disfavor of strict liability schemes<sup>31</sup>), the Court clarified that while *Park* had set out a strict liability standard, “antitrust laws differ in this regard from, for example, laws

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<sup>27</sup> *Id.* at 675.

<sup>28</sup> *Id.* at 676.

<sup>29</sup> *Id.* at 683 (Stewart, J., dissenting).

<sup>30</sup> 438 U.S. 422 (1978).

<sup>31</sup> *See id.* at 440–43.

designed to insure that adulterated food will not be sold to consumers. In the latter situation, excessive caution on the part of producers is entirely consistent with the legislative purpose.”<sup>32</sup>

With the Supreme Court backing the use of a strict liability standard to prosecute food company officials for misdemeanor FFDCA violations, FDA and DOJ began to collaborate on low level prosecutions. Attorney John R. Fleder, who left the Justice Department in 1993 after nearly two decades as a prosecutor in the department’s Office of Consumer Litigation, reflected:

For the first eight or so years there, almost all of the criminal cases the government brought under the FDCA were *Park* “strict liability” cases. Most often, those cases included charges against food companies and their officials alleging that they had maintained insanitary facilities at their companies. Those cases were internally referred to as “dirty warehouse” cases. In addition, the DOJ brought some drug and device cases under the *Park* doctrine.<sup>33</sup>

Fleder suggests that *Park* doctrine misdemeanor prosecutions eventually fell out of favor with federal prosecutors because the limited sanctions did not justify the significant resources necessary to investigate and prosecute these cases.<sup>34</sup>

Felony prosecutions for FFDCA violations were even less common. In the early 1990s, a federal working group convened to study and formulate sentencing recommendations for organization convictions under the FFDCA observed that in fiscal year 1993, sixteen of the twenty-two cases resolved that year were misdemeanors, while only five involved felony convictions and one case included both felony and misdemeanor counts.<sup>35</sup> Moreover, seventeen of the cases involved misbranded /diverted prescription drugs, or adulterated meat.<sup>36</sup> Felony prosecutions in the processed food industry were few and far between, but there was at least one notable exception: the felony prosecution of Beech-Nut executives for knowingly selling adulterated and misbranded juice products marketed to babies and young children.

- ***Beech-Nut (1986)***

In 1986, federal prosecutors indicted Beech-Nut, a subsidiary of Nestle S.A., for intentionally shipping adulterated and misbranded apple juice to twenty states, Puerto Rico, the Virgin Islands and five foreign countries with intent to defraud and mislead.<sup>37</sup> Also charged were Neil Hoyvald, President and Chief Executive Officer of Beech-Nut at the time of the indictment and

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<sup>32</sup> *Id.* at 441–42 n.17.

<sup>33</sup> See John R. Fleder, *The Park Criminal Liability Doctrine: Is it Dead or is it Awakening?*, FOOD & DRUG LAW INST, ENFORCEMENT CORNER 48, 49 (Sept./Oct.2009); <http://www.hpm.com/pdf/FLEDERPARK.PDF>.

<sup>34</sup> John R. Fleder, Douglas B. Farquhar & Thomas Scarlett, “FDA and the *Park* Doctrine” Webinar presented by Hyman, Phelps & McNamara, P.C. at 30 (Oct. 8, 2010) <http://www.fdalawblog.net/files/fda-and-the-park-doctrine.pdf> (last visited May 26, 2015).

<sup>35</sup> U.S. SENTENCING COMMISSION, FOOD AND DRUG WORKING GROUP FINAL REPORT (1995), available at <http://www.ussc.gov/training/organizational-guidelines/food-and-drug-working-group>.

<sup>36</sup> *Id.*

<sup>37</sup> *United States v. Beech-Nut Nutrition Corp.*, 871 F.2d 1181 (2d Cir. 1989).

John Lavery, Vice President for Operations and the person responsible for the purchasing and processing of apple juice concentrates used in Beech-Nut's apple juice and mixed juice product.<sup>38</sup>

With the corporation deeply in debt and enticed by an opportunity for significant cost savings, Beech-Nut officials signed an agreement in 1977 with a wholesaler to purchase apple juice concentrate well below market price.<sup>39</sup> R&D and plant officials immediately expressed concerns about the quality of the concentrate to Lavery, and repeated these warnings over the course of several years, particularly as it became clear that the apple juice product being marketed by Beech-Nut to children was in fact derived not from apple juice concentrate but from a concentrate manufactured from various sugar ingredients.<sup>40</sup> Ignoring pleas to change suppliers and recall the product, Lavery responded by securing a hold harmless agreement from the supplier, ordering that the concentrate be used in mixed juice products (effectively diluting the adulterated concentrate), and threatening his colleagues with dismissal for their lack of team play.<sup>41</sup> Hoyvald was also advised of these issues and his eventual response was to direct that finished product be moved into domestic and foreign markets as quickly as possible to avoid FDA seizure and recall.<sup>42</sup> In October 1982, under FDA pressure, the company finally issued a national product recall for its “pure” apple juice products but it continued to sell mixed juice products made from the contaminated inventory into spring of the following year.<sup>43</sup>

Three years later, Beech-Nut, Hoyvald and Lavery were charged with one count of conspiring with their suppliers to violate the FFDCa, twenty counts of mail fraud, and 429 counts of introducing adulterated and misbranded apple juice into interstate commerce.<sup>44</sup> Beech-Nut pleaded guilty to 215 counts charging that it shipped mislabeled juice with intent to defraud and mislead the public in violation of 21 U.S.C. Sections 331(a) and 333(b) and agreed to pay a \$2 million fine and reimburse FDA \$140,000 in investigative costs.<sup>45</sup> At the time, the Justice Department described this as the “largest fine ever paid under the Food, Drug and Cosmetic Act by at least sixfold since the act’s enactment in 1938.”<sup>46</sup> Meanwhile, Hoyvald and Lavery chose to go to trial. Lavery was convicted on 448 counts of mail fraud, conspiracy, and FFDCa violations. Hoyvald was also convicted of 350 counts of violating the FDDCA, but a mistrial was declared on the conspiracy and mail fraud charges against him because the jury was unable to reach a verdict. Based on the mail fraud and conspiracy convictions, Lavery was facing a five-year term of imprisonment; Hoyvald faced a maximum of three years in prison and a \$10,000 fine. Both pleaded for leniency, but in June 1988, they were sentenced to a year and a day in jail,

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<sup>38</sup> *Id.* at 1183. The lengthy story of the Beech-Nut prosecution is well documented in a Second Circuit opinion regarding Hoyvald and Lavery’s appeals of their initial convictions, and in a New York Times article, *Into the Mouth of Babes*. The details exceed the scope of this article; interested readers should consult these and other sources for a full picture of the conduct underlying the convictions. See James Traub, *Into the Mouth of Babes*, N.Y. TIMES, July 24, 1988, available at <http://www.nytimes.com/1988/07/24/magazine/into-the-mouths-of-babes.html>.

<sup>39</sup> *Beech-Nut Nutrition Corp.*, 871 F.2d at 1184.

<sup>40</sup> *Id.* at 1185.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 1185–86.

<sup>43</sup> *Id.* at 1186.

<sup>44</sup> *Id.* at 1187.

<sup>45</sup> *Id.*

<sup>46</sup> Leonard Buder, *Beech-Nut is Fined \$2 Million for Sale of Fake Apple Juice*, N.Y. TIMES, Nov. 14, 1987, available at <http://www.nytimes.com/1987/11/14/business/beechnut-is-fined-2-million-for-sale-of-fake-apple-juice.html>.

and required to pay \$100,000 fines. The sentencing judge, Thomas C. Platt, was described in media reports as “troubled” by the task before him.<sup>47</sup>

[H]ere was Niels Hoyvald, fifty-four years old, tall, silver-haired, immaculately dressed, standing before Judge Platt with head bowed, as his attorney, Brendan V. Sullivan Jr., described him as ‘a person we would be proud to have in our family.’ When it was Hoyvald's turn to address the judge, he spoke firmly, but then his voice cracked as he spoke of his wife and mother: ‘I can hardly bear to look at them or speak to them,’ he said. ‘I ask for them and myself, please don't send me to jail.’<sup>48</sup>

Judge Platt was clearly troubled. He spoke in a semiaudible mutter that had the crowd in the courtroom craning forward. Though it was ‘unusual for a corporate executive to do time for consumer fraud,’ he said, he had ‘no alternative’ but to sentence Hoyvald to a prison term of a year and a day, plus fines totaling \$100,000. He then meted out the same punishment to the fifty-six-year-old Lavery, who declined to speak on his own behalf. He received his sentence with no show of emotion.<sup>49</sup>

Hoyvald and Lavery appealed. The Second Circuit, ruling that the trial had been held in the wrong district, overturned all of Hoyvald’s convictions, as well as Lavery’s convictions for FFDCa violations.<sup>50</sup> The guilty verdict against Lavery for mail fraud and conspiracy, however, was allowed to stand.<sup>51</sup> A second trial against Hoyvald ended in a mistrial, but Hoyvald eventually pleaded guilty to ten felony counts of violating the FFDCa and was sentenced to five years’ probation and six consecutive months of full-time community service.<sup>52</sup> Meanwhile, the U.S. Supreme Court rejected Lavery’s appeal, allowing the mail fraud and conspiracy convictions and the sentence of imprisonment to stand.<sup>53</sup>

*Beech-Nut* is not a *Park* doctrine case and given that the decision to prosecute Hoyvald and Lavery was made thirty years ago, it does not reflect current DOJ policy. Nevertheless, the felony prosecution of these two high level food industry officials is an instructive reminder, in that it follows a classic “profit over food safety” narrative and ends with a federal judge reticently sentencing two corporate executives to prison, probation and/or community service for their knowing and active participation in food adulteration. Notably, there were no allegations of physical harm to any of the consumers, i.e., no claims that babies developed health problems linked to their consumption of the company’s fake juice products. Hoyvald tried to impress upon the jury that he had no choice but to act to protect the company, because to act otherwise would have been tantamount to shuttering the doors at Beech-Nut. The jury was unimpressed with this form of loyalty; while Beech-Nut survived, Hoyvald and Lavery’s failure to remedy the product adulteration occurring on their watch—and with their knowledge—cost them dearly. Arguably, it

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<sup>47</sup> Traub, *supra* note 38.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Beech-Nut Nutrition Corp.*, 871 F.2d at 1189.

<sup>51</sup> *Id.*

<sup>52</sup> *United States v. Beech-Nut Nutrition Corp.*, 925 F.2d 604, 606 (2d Cir. 1991).

<sup>53</sup> *Lavery v. United States*, 493 U.S. 933, 933 (1989) (denying certiorari).



was precisely their knowledge of the adulteration and their active participation in corporate fraud that led to not only to their prosecution, but also to the relatively harsh sentences for that era, including terms of incarceration. As the sentencing judge commented, however unusual it may be for a corporate executive to do time for consumer fraud, he felt as if he had “no alternative.”<sup>54</sup>

#### **IV. THE ROLE OF THE *PARK DOCTRINE* AND THE CORPORATE OFFICIAL’S KNOWLEDGE AND CONDUCT IN RECENT FOOD INDUSTRY PROSECUTIONS**

In the years following Beech-Nut, there was no shortage of food adulteration events that could have led to prosecution of corporate officials pursuant to the criminal liability provisions of the FFDCA, at least in the misdemeanor context. Between 1985 and 2006, hundreds of consumer illnesses were linked to food contaminated with bacteria such as *Listeria monocytogenes*, *E. coli* O157:H7, and *Salmonella*; many of these food safety failures resulted in consumer deaths. Significant foodborne illness outbreaks included:

- In 1985, *Listeria* contaminated Mexican-style soft cheese made by Jalisco Mexican Products, Inc., a Los Angeles food manufacturer, sickened over 100 people; many of the victims were pregnant women who later miscarried; at least forty-eight deaths were linked to the outbreak.
- Also in 1985, an outbreak of salmonellosis occurred in Illinois, Indiana, Iowa, Michigan and Wisconsin. The outbreak was traced to cartons of two percent milk sold under Jewel Food Store’s Bluebrook brand and the Hillfarm label. At least 5,770 laboratory confirmed cases were reported, and nine deaths were attributed to the outbreak.
- In 1993, after eating ground beef contaminated with *E. coli* O157:H7 at Jack in the Box restaurants in Seattle, California, Idaho, Texas and Nevada, four children died and an estimated total of 732 customers fell ill.
- In 1996, Odwalla Inc. issued a nationwide recall of juice products containing apple juice after Washington state health officials confirmed a link between Odwalla juice and an outbreak of *E. coli* O157:H7 infections. More than sixty people suffered injury, including long term kidney damage from hemolytic uremic syndrome and one sixteen-month old child died of kidney failure.
- In 1998, 15 million pounds of Ball Park hot dogs and Sara Lee deli meats were recalled after *Listeria monocytogenes* was found in the Michigan processing plant; dozens of consumers suffered illness and at least fifteen people died as a result of the outbreak.
- In 2000, sixty-four cases of *E. coli*-related illness were linked to Sizzler restaurants in Wisconsin. A three-year old girl died from complications caused by her infection.
- In 2002, sliced turkey meats from Pilgrim’s Pride were responsible for a multistate listeriosis outbreak; eight deaths were linked to the outbreak.
- In 2006, Dole spinach contaminated with *E. coli* led to hospitalizations in twenty-six states. Three people died, thirty-one suffered kidney failure, and 200 suffered illness. The contamination is suspected to have occurred when a spinach farmer grew his produce on land leased from a cattle ranch.

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<sup>54</sup> Traub, *supra* note 38.

These serious foodborne illness outbreaks led to many civil lawsuits and also spurred on enforcement actions and food safety reforms. However, only two of these outbreaks led to federal criminal prosecution.<sup>55</sup> In 1998, Odwalla Inc. pleaded guilty to federal charges of shipping adulterated food products in interstate commerce and agreed to pay a \$1.5 million fine, the largest ever associated with a foodborne illness outbreak to that date.<sup>56</sup> In 2001, Sara Lee Corporation pleaded guilty to one misdemeanor charge and agreed to pay \$4.4 million in civil and criminal penalties for producing and distributing contaminated hotdogs and deli meats, causing fifteen deaths.<sup>57</sup> After recalling contaminated meat products, Sara Lee closed some lines in its Michigan plant and spent \$25 million on renovations to a site that government inspectors said was infested with roaches and contained old meat and debris. Still, Phillip J. Green, the United States attorney in Grand Rapids, Mich., said the company was not charged with a felony because investigators found no evidence that Sara Lee intentionally produced or distributed adulterated meats, and the company had cooperated with the investigation.<sup>58</sup> “It is tragic that people died,” Green said, “but the law does not provide for a felony charge unless we can show that the company knew and intended to ship adulterated foods.”<sup>59</sup>

Most of the FDA and Justice Department’s collaborative resources for criminal prosecutions in this era appeared focused on the pharmaceutical industry.<sup>60</sup> In the food industry, other than the Odwalla and Sara Lee prosecutions, FDA more often used its authority in civil actions to enjoin companies from conducting further business until food safety violations were corrected. For

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<sup>55</sup> Jalisco Mexican Products, Inc. and its president, Gary McPherson, were charged in California state court with sixty misdemeanor violations of state agriculture, health and safety laws. Jalisco pleaded no contest to eleven of the counts, the president to ten. A company vice president, Jose Luis Medina, pleaded no contest to twelve of sixty misdemeanor counts. Scott Harris, *60 Criminal Counts Filed in Jalisco Cheese Epidemic*, L.A. TIMES, Mar. 28, 1986, available at [http://articles.latimes.com/1986-03-28/news/mn-622\\_1\\_jalisco-cheese-epidemic](http://articles.latimes.com/1986-03-28/news/mn-622_1_jalisco-cheese-epidemic). Medina and McPherson, were sentenced to sixty days and thirty days, respectively, in Los Angeles County jail and fined a total of about \$48,000. Janny Scott & Ronny L. Soble, *Final Report Traces 1985 Outbreak of Listeriosis*, L.A. TIMES, Sept. 29, 1988, available at [http://articles.latimes.com/1988-09-29/local/me-5951\\_1\\_final-report-traces](http://articles.latimes.com/1988-09-29/local/me-5951_1_final-report-traces).

<sup>56</sup> *Odwalla Pleads Guilty*, CNN MONEY (July 23, 1998, 4:41 PM),

<http://money.cnn.com/1998/07/23/companies/odwalla/>.

<sup>57</sup> David Barboza, *Sara Lee Corp. Pleads Guilty in Meat Case*, N.Y. TIMES, June 23, 2001, available at <http://www.nytimes.com/2001/06/23/us/sara-lee-corp-pleads-guilty-in-meat-case.html>.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> In 2007, following a five-year investigation, federal prosecutors determined that a pharmaceutical company, Purdue Frederick, and three of its high level employees had deviated from FDA-approved labeling by marketing the painkiller OxyContin as less addictive and less subject to abuse than other opioid medications. Under the FFDCFA, an FDA-approved drug is “misbranded” if its manufacturer makes promotional statements about the drug that deviate from the drug’s FDA-approved labeling. Purdue Frederick pleaded guilty to felony misbranding charges and paid \$600 million in criminal and civil penalties to settle the case. Meanwhile, the company’s president and CEO, general counsel, and chief medical officer pleaded guilty to *Park* misdemeanors. Expressing regret that he could not sentence the individual defendants to prison terms due to lack of evidence that the officials knew of the wrongdoing, federal judge James P. Jones sentenced each defendant to three years’ probation and 400 hours of community service. Barry Meier, *3 Executives Spared Prison in OxyContin Case*, N.Y. TIMES, July 21, 2007, available at <http://www.nytimes.com/2007/07/21/business/21pharma.html>. In 2009, four executives of Synthes, a spinal implant manufacturer, were charged as responsible corporate officers with knowing and intentional FFDCFA violations stemming from clinical trials conducted on 200 spinal surgery patients without FDA approval. Though charged with felony offenses, the executives each pleaded guilty to misdemeanor misbranding and were sentenced to prison terms ranging from five to nine months. Peter Loftus, *Former Synthes Officers Receive Prison Sentences*, WALL STREET JOURNAL, Nov. 22, 2011, available at <http://www.wsj.com/articles/SB10001424052970204443404577052173679627572>.

example, in 2001, FDA successfully argued that a fish processor lacked proper food safety protocols (cited by FDA officials as a continuing problem over the course of several years of inspections) and as a result, had processed fish under unsanitary conditions and introduced fish contaminated with *Listeria* into interstate commerce.<sup>61</sup> FDA obtained a permanent injunction restraining the defendants from further fish processing until the unsanitary conditions at the facility were corrected.<sup>62</sup>

In 2010, ongoing congressional oversight of FDA practices—and pointed congressional criticism of FDA’s management of its Office of Criminal Investigations—led FDA Commissioner Margaret Hamburg to write a much-publicized letter to Senator Charles Grassley, confirming that among the remedial measures under discussion at FDA was a plan to increase misdemeanor prosecutions of responsible corporate officers.<sup>63</sup> The following year, FDA published an updated Regulatory Procedures Manual with criteria for evaluating *Park* doctrine prosecutions for referral to the Justice Department.<sup>64</sup> Like the *Park* opinion itself, the manual does not define categories of persons subject to prosecution or provide examples to guide personnel in making a referral decision. Rather, the FDA advises:

When considering whether to recommend a misdemeanor prosecution against a corporate official, 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 facts that may be relevant when deciding whether to recommend charging a misdemeanor violation.*<sup>65</sup>

Other non-exhaustive factors to be considered are:

- (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.<sup>66</sup>

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<sup>61</sup> United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30 (E.D.N.Y. 2001).

<sup>62</sup> *Id.*

<sup>63</sup> Letter from Commissioner Margaret A. Hamburg to Senator Charles E. Grassley (Mar. 4, 2010), *available at* <http://www.fdalawblog.net/files/fda-grassley-ltr.pdf>.

<sup>64</sup> REGULATORY PROCEDURES MANUAL, U.S. FOOD & DRUG ADMIN. § 6-5-3, *available at* <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>.

<sup>65</sup> *Id.* (emphasis added).

<sup>66</sup> *Id.*

Although FDA had clearly signaled its intent to increase misdemeanor prosecutions of responsible corporate officers, it was less clear whether agency resources would continue to focus on the pharmaceutical industry or whether the new emphasis on *Park* doctrine prosecutions would be applied to the food industry. Conditions were certainly ripe for prosecutorial interest to shift to the food company officials. The year 2010 marked passage of the Food Safety Modernization Act, an indicator of strong Congressional interest in promoting and enforcing food safety. Also, the nation was recovering from a forty-six-state outbreak of salmonellosis traced to contaminated peanuts processed by Peanut Corporation of America (PCA). Congressional hearings on this high profile outbreak revealed egregious conduct on the part of PCA officials, and a case against PCA and its officials seemed inevitable. The stage was set for the government to begin actively using federal criminal law as a food safety enforcement tool.

- *Peanut Corporation of America (2013)*

The federal investigation into activity at Peanut Corporation of America (PCA) began in late 2008, as FDA collaborated with CDC and various state health officials to identify the source of a multistate salmonellosis outbreak. As of April 2009, CDC reported that 714 people across forty-six states had been infected, leading to at least nine deaths.<sup>67</sup> The outbreak strain of *Salmonella* Typhimurium was traced to a PCA peanut roasting plant in Blakely, Georgia. PCA peanut butters and peanut paste were so widely used as ingredients in food products manufactured by other companies that it led to the nation's largest recall of food products. PCA declared bankruptcy in early 2009 and the recall ultimately cost industry an estimated \$1 billion.<sup>68</sup>

In February 2013, PCA's owner, Stewart Parnell, his brother Michael Parnell, who worked as a broker, and two PCA managers were indicted on federal criminal charges. A third company official was charged by information.<sup>69</sup> Based on the apparent strength of the evidence against PCA, the government charged all five corporate defendants with multiple felony counts. Daniel Kilgore, the operations manager, and Samuel Lightsey, the plant manager, who had both worked at the Blakely plant, pleaded guilty in exchange for their testimony at trial. The Parnell brothers and Mary Wilkerson, who was PCA's quality-assurance manager at Blakely, went to trial in July 2014. After a seven-week jury trial, the Parnells were found guilty on a combined ninety-seven felony counts, including fraud, conspiracy, obstruction of justice and introducing adulterated food into interstate commerce. Some of the charges carry a maximum sentence of twenty years in prison. The jury convicted Wilkerson on a single count of federal felony obstruction of justice, which carries a maximum five-year prison term.<sup>70</sup>

Reflecting the importance of the *mens rea* element that was to be the government's burden of proof on the felony offenses, lawyers representing Stewart Parnell publically maintained from

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<sup>67</sup> *Multistate Outbreak of Salmonella Typhimurium Infections Linked to Peanut Butter, 2008–2009*, CDC (May 11, 2010), <http://www.cdc.gov/salmonella/typhimurium/update.html>.

<sup>68</sup> Jeannine Stein, *The Salmonella Outbreak of 2008, Deconstructed*, L.A. TIMES, Aug. 17, 2011, available at <http://articles.latimes.com/2011/aug/17/news/la-heb-salmonella-peanuts-20110817>.

<sup>69</sup> Press Release, Office of Public Affairs, U.S. Dep't of Justice, Former Officials and Broker of Peanut Corporation of America Indicted Related to Salmonella-Tainted Peanut Products (Feb. 21, 2013), <http://www.justice.gov/opa/pr/former-officials-and-broker-peanut-corporation-america-indicted-related-salmonella-tainted>

<sup>70</sup> Special Verdict at 57, *United States v. Parnell*, No. 1:13-CR-12-WLS (M.D. Ga. Sept. 19, 2014).

the outset that their client “never intentionally shipped or intentionally caused to be shipped any tainted products capable of harming P.C.A.’s customers.”<sup>71</sup> At trial, the government presented forty-five witnesses and voluminous documentary evidence of Stewart and Michael Parnell’s alleged acts of fraud and conspiracy, along with evidence of widespread sanitation issues at the Blakely, GA plant, and multiple instances of specific food-safety violations. The evidence included fabricated certificates of analysis, documented claims that products that had never been tested for the presence of *Salmonella* were pathogen-free, incidents where products that had tested positive for *Salmonella* were knowingly shipped into interstate commerce, and false statements made to an FDA investigator that there were no known positive *Salmonella* test results for peanut products distributed by PCA’s Blakely plant.<sup>72</sup> In one particularly damaging email, Stewart Parnell was told by an employee that peanut meal needed to fill an order was covered in dust and rat feces, to which he responded, “Clean ‘em all up and ship them . . . .”<sup>73</sup>

It is anticipated that all five defendants will be sentenced sometime in 2015, although a sentencing date has not yet been set pending the Court’s ruling on numerous sealed post-trial motions for acquittals and/or new trials.

After the jury verdicts came in against the Parnells, then-U.S. Attorney General Eric Holder pronounced, “The verdict demonstrates that the Department of Justice will never waver in our pursuit of those who break our laws and compromise the safety of America’s food supply for financial gain. All Americans must be able to rely on the safety of the food they purchase. And any individual or company that puts the health of consumers at risk by criminally selling tainted food will be caught, prosecuted, and held accountable to the fullest extent of the law.”<sup>74</sup>

- ***Jensen Farms (2013)***

In September 2013, brothers Eric Jensen, thirty seven, and Ryan Jensen, thirty three, owners of Jensen Farms in Colorado, surrendered to U.S. Marshals on federal charges of introducing adulterated food into interstate commerce. The arrests stemmed from the 2011 multistate *Listeria* outbreak linked to cantaloupe grown by Jensen Farms. The precipitating events began in May 2011, when the Jensens installed new conveyor equipment in their packing facility. The equipment featured a specially modified catch pan and chlorine sprayer for use in cleaning the cantaloupe. The Jensens did not hook up the chlorine spray system, choosing instead to wash the fruit using fresh city water that had been chlorinated for drinking. This ultimately proved ineffective in reducing the microbial contamination of the fruit.

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<sup>71</sup> Sabrina Tavernise, *Charges Filed in Peanut Salmonella Case*, N.Y. TIMES, Feb. 21, 2013, available at [http://www.nytimes.com/2013/02/22/business/us-charges-former-owner-and-employees-in-peanut-salmonella-case.html?\\_r=0](http://www.nytimes.com/2013/02/22/business/us-charges-former-owner-and-employees-in-peanut-salmonella-case.html?_r=0).

<sup>72</sup> See Indictment, *United States v. Parnell*, No. 1:13-CR-12-WLS (M.D. Ga. Feb. 15, 2013); Press Release, Office of Public Affairs, U.S. Dep’t of Justice, *Peanut Corporation of America Former Officials and Broker Convicted on Criminal Charges Related to Salmonella-Tainted Peanut Products* (Sept. 14, 2014), <http://www.justice.gov/opa/pr/peanut-corporation-america-former-officials-and-broker-convicted-criminal-charges-related>

<sup>73</sup> *Id.* at 29.

<sup>74</sup> Press Release, Office of Public Affairs, U.S. Dept. of Justice, *Peanut Corporation of America Former Officials and Broker Convicted on Criminal Charges Related to Salmonella-Tainted Peanut Products* (Sept. 19, 2014), <http://www.justice.gov/opa/pr/peanut-corporation-america-former-officials-and-broker-convicted-criminal-charges-related>.

In July 2011, a food-safety inspector subcontracted by Primus Labs was hired by the Jensens to conduct an audit of their packing facility to satisfy a distributor's food safety requirements. The facility received a "superior" score of ninety-six percent. No recommendations were made to the Jensens to connect the chlorine sprayer or otherwise modify their cleaning practices. In fact, as the brothers maintained at sentencing, they had been motivated to replace their prior processing system of washing fruit with recirculated chlorinated water because a different Primus Labs auditor had advised them a year earlier that this was a potential "hot spot."<sup>75</sup>

By September 2011, the CDC had begun tracking a major listeriosis outbreak and quickly determined that people living in twenty-eight states had all consumed contaminated cantaloupe shipped from Jensen Farms. The Jensens recalled their product within days of FDA inspection and positive product tests and environmental swabbing of their facility, but dozens of consumers nonetheless became ill or died after eating contaminated cantaloupe from Jensen Farms. Two years later, in September 2013, federal prosecutors filed a six-count Information against the Jensens, charging them with introducing adulterated cantaloupe into interstate commerce and aiding and abetting the same.<sup>76</sup> The government presented no evidence to suggest the Jensens were motivated by financial gain or had a history of engaging in criminally negligent food safety practices. Following the Jensens' guilty pleas to all six misdemeanor counts, prosecutors recommended a sentence of probation for the brothers, citing, among other factors, their lack of intent and knowledge.

The court sentenced the Jensens to five years' probation, six months of home detention and \$150,000 (\$25,000 per count) in restitution to their victims. No fine was imposed since the defendants were noted to have no ability to pay a fine.<sup>77</sup> The restitution order was later modified to reflect that the government received declarations of losses from only three individuals, totaling \$13,184.00. Other victims presumably were involved in civil litigation against Primus Labs, the auditor that had given Jensen Farms a 96% score on their operations at the same time the farm was starting to ship contaminated cantaloupes nationwide.<sup>78</sup>

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<sup>75</sup> Sentencing Memorandum at 4, *United States v. Jensen*, No. 13-mj-01138-MEH (Colo. Jan. 14, 2014).

<sup>76</sup> Aiding and abetting is typically used where the evidence shows that a crime was committed, but it is less clear that the defendant himself personally carried out the alleged offense. Under 18 U.S.C. § 2, "those who provide knowing aid to persons committing federal crimes, with the intent to facilitate the crime, are themselves committing a crime." *Central Bank of Denver, N. A. v. First Interstate Bank of Denver, N. A.*, 511 U.S. 164, 181 (1994); *see also Rosemond v. United States*, 134 S. Ct. 1240 (2014). The "intent" element necessarily requires proof of *mens rea*, making the aiding and abetting charge an interesting bedfellow for a pure-*Park* prosecution.

<sup>77</sup> Courtroom Minutes at 3, *United States v. Jensen*, No. 13-mj-01138-MEH (D. Colo. Jan. 28, 2014).

<sup>78</sup> Jensen Farms later sued Primus Labs, claiming, *inter alia*, that Primus Labs was negligent in auditing their cantaloupe fields and packing facility in July 2011. District of Colorado Case No. 13-cv-003285. The Jensens then assigned all rights in the litigation to the victims of the outbreak, represented by attorney Bill Marler. Presumably, this arrangement allowed the Jensens to compensate for their inability to pay a large fine. In February 2015, Primus Labs announced the settlement of all claims related to the Jensen Farms *Listeria* outbreak. The amount of settlement was not disclosed. *See PrimusLabs Dismissed From Jensen Farms Litigation*, PRIMUSLABS <http://www.primuslabs.com/Services/DetailEventsNews.aspx?NewID=64> (last visited May 26, 2015).

As a pure-*Park* doctrine case, the Jensen prosecution gives insight into the impact that widespread public harm may have on prosecutorial discretion. Unlike the profit-seeking storyline underlying the Beech-Nut and PCA’s prosecutions, Eric Jensen’s attorneys and supporters described him in presentence documents as a person who would never put profit over people—a thirty-seven-year old fourth generation farmer who served as a coach, church elder and school bus driver.<sup>79</sup> The Jensens acknowledged they had the responsibility and authority to maintain a clean packing facility, but as the probation officer specifically noted, no facts had been found to suggest the brothers had cut corners to save money.<sup>80</sup> In short, there was no evidence that either Eric or Ryan Jensen had acted with criminal intent or knowledge of wrongdoing.

As Assistant U.S. Attorney Jaime Pena summarized in the Government’s Sentencing Statement:

Without a doubt, any offense that results in 33-40 deaths is a serious offense which must be given careful consideration by a sentencing court. However, the seriousness of the offense is tempered in this case by the lack of willful, intentional or knowing state of mind. These defendants were at worst negligent or reckless in their acts and omissions.<sup>81</sup>

In recommending a sentence of probation, the government also highlighted that the Jensens immediately sought to recall the product upon learning of the contamination, and then offered substantial cooperation and assistance during the investigation that led to their own arrest. The brothers also spoke directly with many of the victims and their families “in an attempt to provide the victims a sense of comfort and closure.”<sup>82</sup> Given the widespread support for the Jensens as decent farmers who fully accepted responsibility for the outbreak—support that came not only from their fellow community members, but also from the probation officer and the prosecutor himself—and considering that other food safety violators in recent years had not been subject to criminal liability, why were the Jensens prosecuted? Using almost apologetic language, the government provided this simple and direct answer in its pre-sentencing papers:

[T]his prosecution can fairly be characterized as unusual under a historical retrospective view of the enforcement efforts of the relevant statutes. The government was compelled to exercise its enforcement discretion in large part because of the devastating results associated with this case.<sup>83</sup>

The Jensen Farms *Listeria* outbreak caused or contributed to 147 illnesses, thirty-three deaths and one miscarriage, making it one of the largest foodborne illness outbreaks in U.S. history. The prosecution of Eric and Ryan Jensen demonstrates that significant widespread public harm alone can serve as a sufficient basis for federal prosecutors to invoke the *Park* doctrine and prosecute corporate officials for food safety violations. This is not to say that evidence of knowledge and active wrongdoing—or lack thereof—has no relevance. For the Jensen brothers, their widely acknowledged lack of active wrongful conduct likely served to not only keep the charging decision within misdemeanor parameters, but also to keep them out of federal prison. It may

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<sup>79</sup> Sentencing Memorandum at 4, *United States v. Jensen*, No. 13-mj-01138-MEH (D. Colo. Jan. 14, 2014).

<sup>80</sup> *Id.* at 3.

<sup>81</sup> Sentencing Statement at 14, *United States v. Jensen*, No. 13-mj-01138-MEH (D. Colo. Jan. 17, 2014).

<sup>82</sup> *Id.*

<sup>83</sup> Sentencing Statement at 14, *United States v. Jensen*, No. 13-mj-01138-MEH (D. Colo. Jan. 17, 2014).

also have helped their cause that they assigned all rights to the proceeds of their lawsuit against Primus Labs to the victims of this outbreak.

The court did choose to sentence the Jensen brothers beyond the government's recommended term of probation. However, while home detention is undisputedly a restriction on personal liberty, it is not federal prison and the sentence is at least arguably consistent with the view that strict liability misdemeanor prosecutions should not be accompanied by onerous sentences, particularly terms of imprisonment.<sup>84</sup>

- *DeCoster/Quality Egg (2014)*

In July 2010, the CDC identified a sustained nationwide increase in the usual number of cases of *Salmonella* Enteritidis (SE), a strain typically associated with eggs. The increase began in May 2010 and CDC continued to receive reports of approximately 200 SE infections every week during late June and early July. Many of the infections displayed a common PFGE pattern and traceback investigations led health officials to Wright County Egg and Hillandale Farms of Iowa. Laboratory testing of nearly 600 environmental samples from these two egg operations identified the same pattern, thereby linking the outbreak to Quality Egg, an Iowa egg producer led by Austin "Jack" DeCoster (trustee of the DeCoster Revocable Trust which owned Quality Egg) and his son Peter DeCoster (the company's Chief Operating Officer).<sup>85</sup> A voluntary recall of millions of eggs began in August 13, 2010, with two expanded recall notices issued the following week. The exact number of illnesses attributed to Quality Egg products is unknown. In its final update, CDC concluded that from May 1 to November 30, 2010, based on epidemiological data, 1,939 reported illnesses were likely associated with the outbreak.<sup>86</sup> CDC estimated that for every reported case, twenty-nine other cases go unreported, leading to estimates that more than 56,000 persons in the United States may have been sickened by the SE outbreak in 2010 linked to Quality Egg.<sup>87</sup>

In 2014, Jack and Peter DeCoster were charged with shipping and selling adulterated food in interstate commerce in violation of 21 U.S.C. §§ 331 and 333(a)(1). Both men quickly pleaded guilty to this single misdemeanor charge and Quality Egg pleaded guilty to the misdemeanor sale of adulterated food as well as two felony charges: bribing a public official and selling misbranded food with intent to defraud or mislead (a felony violation pursuant to 21 U.S.C. § 333(a)(2)).

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<sup>84</sup> See, e.g., *Morisette v. United States*, 342 U.S. 246, 25 (1952); accord *Staples v. United States*, 511 U.S. 600, 616–18 (1994) (quoting 4 WILLIAM BLACKSTONE, COMMENTARIES \*21) (expressing general disfavor of strict liability offenses, but recognizing that “the small penalties attached to such offenses complemented the absence of a *mens rea* requirement: In a system that generally requires a ‘vicious will’ to establish a crime, . . . imposing severe punishments for offenses that require no *mens rea* would seem incongruous). See also Andrew Baird, *The New Park Doctrine: Missing the Mark*, 91 N.C.L. Rev. 949 (2013).

<sup>85</sup> Quality Egg operated under the names Wright County Egg, Environ and Lund/Wright Company, and also operated two egg processing facilities under an agreement with Hillandale Farms.

<sup>86</sup> *Multistate Outbreak of Human Salmonella Enteritidis Infections Associated with Shell Eggs*, CDC (Dec. 2, 2010), <http://www.cdc.gov/salmonella/enteritidis/> (last visited May 26, 2015).

<sup>87</sup> Gov't Sentencing Memorandum at 4, *United States v. Quality Egg, LLC*, No. 14-CR-3024-MWB (N.D. Iowa Apr. 6, 2015).



Based on the significant economic losses and number of victims, as well as culpability factors, Quality Egg agreed to a fine of \$6,690,000. There was some speculation early on that this large fine might keep the DeCosters out of jail.<sup>88</sup> Attorneys for the DeCosters maintained from the outset that it would be unconstitutional to sentence their clients to incarceration or confinement based on the absence of proof of criminal knowledge or intent that accompanied the strict liability offenses to which they pleaded. Indeed, the parties stipulated in the plea agreements that the government's investigation to date had not identified anyone employed by or associated with Quality Egg, including the DeCosters, who knew during the time frame from January 10 through August 12, 2010 that eggs sold by Quality Egg were contaminated with SE.<sup>89</sup> However, the defendants acknowledged in their plea agreements that the offense to which they pleaded carried a statutory maximum penalty of up to one year of imprisonment. For its part, the government agreed to leave it to the Court's discretion whether to impose a sentence of incarceration, home confinement or probation but reserved the right to oppose any motions challenging the constitutionality the sentence.<sup>90</sup>

Jack and Peter DeCoster filed motions challenging the constitutionality of a sentence of incarceration, which the government opposed. The core of defendants' contention was that a term of incarceration (including a sentence of home confinement, as the Jensen brothers had received) without proof of *mens rea* would violate their due process rights, as well as their rights under the Sixth and Eighth Amendments because they had "no knowledge of the violation and no knowledge of the conduct underlying the offense."<sup>91</sup> The government responded that defendants knew that SE was in their facilities, were aware of how to prevent SE contamination, and understood the risk of product adulteration. Moreover, the government argued, even if they didn't have this knowledge, a sentence of incarceration would not violate defendants' Fifth or Eighth Amendment rights.<sup>92</sup>

In a sixty-eight-page order, Judge Mark W. Bennett rejected defendants' constitutional challenge and sentenced each defendant to three months in federal prison.<sup>93</sup> Relying in part on those portions of the pre-sentence investigation report to which no objections had been made, Judge Bennett made particular note of the following evidence:

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<sup>88</sup> Dan Flynn, *Big Fine and Guilty Pleas Might Keep DeCosters out of Jail*, FOOD SAFETY NEWS (June 3, 2014), <http://www.foodsafetynews.com/2014/06/7-million-fine-might-keep-jack-and-peter-decoster-out-of-jail/#.VWYDn89VhBc>.

<sup>89</sup> Quality Egg Plea Agreement at 7, ¶ 9(o) United States v. Quality Egg, LLC, No. 14-CR-3024-MWB (N.D. Iowa Apr. 18, 2014); Austin DeCoster Plea Agreement at 3, ¶ 7(c) United States v. Quality Egg, LLC, No. 14-CR-3024-MWB (N.D. Iowa Apr. 18, 2014); Peter DeCoster Plea Agreement at 3, ¶ 7(c) United States v. Quality Egg, LLC, No. 14-CR-3024-MWB (N.D. Iowa Apr. 18, 2014).

<sup>90</sup> Austin DeCoster Plea Agreement at 5, ¶ 12; Peter DeCoster Plea Agreement at 5, ¶ 12.

<sup>91</sup> Memorandum in Support of Defendant Austin DeCoster's Motion that a Sentence of Incarceration or Confinement is Unconstitutional at 1-3, United States v. Quality Egg, LLC, No. 14-CR-3024-MWB (N.D. Iowa Oct. 8, 2014).

<sup>92</sup> United States' Resistance to Defendants Austin DeCoster's and Peter DeCoster's Motions that a Sentence or Confinement is Unconstitutional at 4, 6, United States v. Quality Egg, LLC, No. 14-CR-3024-MWB (N.D. Iowa Oct. 23, 2014).

<sup>93</sup> Memorandum Opinion and Order Regarding Defendant's Motions Prior to Sentencing at 68, United States v. Quality Egg, LLC, No. 14-CR-3024-MWB (N.D. Iowa Apr. 14, 2015).

- Quality Egg personnel routinely falsified documents and misrepresented information to third party auditors who inspected Quality Egg facilities between 2007 and 2010. This included fabricating documentation related to food safety and sanitation practices, creating fake maintenance reports and pest control logs, and providing false statements and records about *Salmonella* prevention strategies used at the plants;
- Quality Egg employees bribed a USDA official to release eggs that had been retained for failing to meeting minimum quality grade standards (although there was no evidence that either DeCoster knew that the bribe was going to occur);
- Quality Egg personnel regularly changed the processing dates on eggs and sold them with false dates or shipped them with no dates in order to mislead state regulators and customers about the age of the eggs (again, there was no evidence that either defendant knew of the mislabeling practices);
- FDA’s 483 Report of its August 12, 2010 and August 30, 2010 inspections of Quality Egg’s facilities documented unsanitary conditions and a complete failure to implement appropriate pest control or SE prevention measures. Among other things, FDA inspectors observed live and dead mice, frogs, beetles and flies in many areas; missing vent covers and holes in walls and baseboards; traps with either dead rodents or no bait;
- There was pervasive SE contamination throughout the Wright County Egg operations;
- Defendants were “generally aware” of positive SE results as they were received from early 2006–10, yet did not test or divert eggs from the market;
- Peter DeCoster misrepresented to major customers, including Walmart, the nature and extent of the company’s food safety practices;
- Both DeCosters had prior criminal records. In 2003, Jack DeCoster had appeared in the same court on charges of: (1) employing undocumented aliens, for which he was sentenced to five years’ probation and ordered to pay \$875,000 in restitution, and (2) conspiring to harbor undocumented aliens, for which he received five years of supervision; Peter DeCoster’s 2003 prosecution for conspiracy to harbor undocumented aliens was deferred via a pretrial diversion program.<sup>94</sup>

Judge Bennett found on this record that defendants knew that their processing plants were contaminated with SE, and also knew how to effectively address SE contamination but they took no steps to minimize the risk that their eggs would be contaminated.<sup>95</sup> The judge noted that whether or not such findings were made, it would have no impact on maximum offense penalties or the statutorily authorized sentencing range available to him -- penalties and ranges that defendants acknowledged in their plea agreements.<sup>96</sup>

The judge rejected defendants’ Eighth Amendment challenge that a sentence of incarceration would be grossly disproportionate to their offenses, observing that thousands of consumers were harmed by the outbreak, including one small boy forced to wear steel caps over teeth that had been weakened by antibiotic therapy to treat his illness. Defendants admitted they were responsible for Quality Egg’s operations, yet the record of sustained misconduct supported the inference that defendants had created a work environment where employees not only felt comfortable disregarding regulations and bribing USDA officials, but may have even felt

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<sup>94</sup> See generally Memorandum Opinion, *supra* note 93.

<sup>95</sup> Memorandum Opinion, *supra* note 93, at 41.

<sup>96</sup> *Id.*

pressure to do so. The case was thus distinguishable from one involving a “mere unaware corporate executive” who could be deterred from future misconduct by a probationary sentence.<sup>97</sup>

Judge Bennett also summarily denied defendants’ Fifth Amendment challenge to imprisonment or confinement for a strict liability offense, pointing out that Supreme Court precedent (including *Park* and *Dotterweich*) and other lower court case law imposes no constitutional limitation on the imposition of criminal punishment, including incarceration, for violations of the public welfare laws like the FFDCA absent *mens rea*. As for defendants’ contentions that penalties for FFDCA violations must be “relatively small” and that imprisonment would be incompatible with reduced culpability for misdemeanor regulatory offenses, the judge referred to other instances in which individuals convicted of strict liability offenses had been sentenced to jail terms under one year, and to the FFDCA itself, which expressly provides for a sentence of up to one year of imprisonment for misdemeanor violations.

In addition to three months’ imprisonment followed by one year of supervised release, each DeCoster was fined \$100,000. Along with Quality Egg, the DeCosters were ordered to make restitution to outbreak victims in the amount of \$83,008.19. Quality Egg was sentenced to three years’ probation and must pay a fine of \$6.79 million and forfeit \$10,000. The DeCosters have appealed their sentences and remain free pending the appeal.

In a post-sentencing press release, Kevin W. Techau, U.S. Attorney for the Northern District of Iowa, issued this clear and simple warning to food industry officials: “The message this prosecution and sentence sends is a stern one to anyone tempted to place profits over people’s welfare. Corporate officials are on notice. If you sell contaminated food you will be held responsible for your conduct. Claims of ignorance or ‘I delegated the responsibility to someone else’ will not shield them from criminal responsibility.”<sup>98</sup>

- ***ConAgra Grocery Products (2015)***

On May 19, 2015, in a move anticipated in the food industry, ConAgra Grocery Products Company, LLC pleaded guilty to a one-count Information charging the company with the introduction into interstate commerce of adulterated food, in violation of 21 U.S.C. §§ 331(a), 342(a) and 333(a)(1).<sup>99</sup> The misdemeanor violation arises out ConAgra’s sale and distribution of Peter Pan and private label peanut butter contaminated with *Salmonella* I 4,[5],12:i:- in 2006–07. The CDC identified more than 700 cases of salmonellosis linked to the outbreak strain and estimated “thousands” of additional related cases were not reported.<sup>100</sup> The CDC did not identify any deaths related to the outbreak.<sup>101</sup>

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<sup>97</sup> *Id.* at 47.

<sup>98</sup> Press Release, FDA Office of Criminal Investigations, Quality Egg, Company Owner and Top Executive Sentenced in Connection with Distribution of Adulterated Eggs (Apr. 13, 2014), *available at* <http://www.fda.gov/ICECI/CriminalInvestigations/ucm443585.htm>

<sup>99</sup> Plea Agreement, United States v. ConAgra Grocery Prods. Co., No. 1:15-cr-24 (M.D. Ga. May 19, 2015).

<sup>100</sup> *Id.* at 6.

<sup>101</sup> *Id.*

The plea agreement provides that ConAgra will pay a criminal fine of \$8 million and forfeit assets of \$3.2 million. The Justice Department identifies this as the largest fine ever paid in a food safety case.<sup>102</sup> In addition, the government agrees to not seek probation, in light of the absence of any further known food safety violations in the Sylvester, GA plant since the 2007 recall.<sup>103</sup>

As part of the plea agreement, ConAgra and the government have stipulated to a number of facts, including:

- Prior to the 2007 recall, “the food industry generally” considered peanut butter to be low risk for *Salmonella* contamination;
- ConAgra was aware of some risk of contamination, and during routine testing on two occasions in 2004, it identified the “potential presence” of *Salmonella* in finished peanut butter samples, held product pending further testing, and destroyed contaminated product in its facility;
- In 2004-05, ConAgra employees identified a number of potential contributors to the *Salmonella* problem and had begun addressing the issues. However, the conditions were not fully corrected until after the 2007 outbreak;
- ConAgra was not aware that some employees charged with conducting and analyzing finished product tests did not know how to properly interpret test results and failed to detect *Salmonella* in peanut butter;
- ConAgra immediately shut down the Sylvester plant after the recall and initiated remedial measures to fully correct the source of the problems;
- ConAgra shared learnings about the safe manufacture of peanut butter with competitors and government regulatory agencies.<sup>104</sup>

The plea agreement also includes a unique provision addressing any potential transfer of assets or business lines within the ConAgra family of companies and confirming that this record of misdemeanor conviction would also transfer under any such reorganization of corporate holdings. As a result, a second FFDCA violation would expose the assignees, successors-in-interest, or transferees to potential felony criminal liability under 21 U.S.C. § 333(a)(2).<sup>105</sup>

The agreement must still be approved by the court. In the meantime, DOJ representatives are once again alerting the food industry that criminal prosecution remains an arrow in the government’s food safety quiver. Commenting on the ConAgra misdemeanor conviction, Acting Associate Attorney General Stuart F. Delery said:

As parents, we can make sure that our kids look both ways before they cross the street and wear a helmet when they ride their bikes. But we have to rely on the companies that make their food to make sure it is safe. That’s why the

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<sup>102</sup> Press Release, Office of Public Affairs, U.S. Dep’t of Justice, ConAgra Subsidiary Agrees to Enter Guilty Plea in Connection with 2006 through 2007 Outbreak of Salmonella Poisoning Related to Peanut Butter (May 20, 2015), <http://www.justice.gov/opa/pr/conagra-subsidiary-agrees-enter-guilty-plea-connection-2006-through-2007-outbreak-salmonella> [hereinafter DOJ Press Release, May 20, 2015].

<sup>103</sup> Plea agreement, *supra* note 99, at 3.

<sup>104</sup> Plea agreement, *supra* note 99, at 4–7.

<sup>105</sup> *Id.* at 2.

Department of Justice is dedicated to using all the tools we have to ensure the processors and handlers of our food live up to their legal obligations to keep the public's safety in mind.<sup>106</sup>

Michael J. Moore, the U.S. Attorney of the Middle District of Georgia, had sharper words of warning:

We, as consumers, take for granted that the food we feed our families is safe. We count on the companies who prepare and package the things we eat to be just as concerned with the product we put in our mouths as they are with the profit they put in their pockets. The proposed criminal fine and sentence in this case should sound the alarm to food companies across the country—we are watching, and we are expecting you to hold yourselves to a standard reflective of the trust that your consumers have placed in you. No more excuses. A lot of people got very sick because of the conduct in this case and we are committed to doing all we can to make sure that does not happen again.<sup>107</sup>

**V. LESSONS LEARNED: THE *PARK* DOCTRINE AND THE ROLE OF “KNOWLEDGE” IN THE PROSECUTION OF FOOD INDUSTRY COMPANIES AND RESPONSIBLE CORPORATE OFFICIALS.**

**A. Companies today should expect that serious foodborne illness outbreaks will be investigated by federal officials for possible criminal prosecution, regardless of whether company officials knew about or played an active role in creating the conditions leading to food safety violations or the sale of adulterated food products.**

While the factual record confirms the Jensen brothers were aware of the generalized risk of product contamination if adequate sanitation practices were not in place, there was no evidence of any *Listeria* contamination on their farm or in their fruit washing equipment at the time they shipped cantaloupes for nationwide distribution. The record also showed they relied on the advice of recommended third-party food safety auditors and at the time of the outbreak were acting in good faith (albeit, in the wrong way) to remedy a potential food safety issue that an auditor had pointed out. Nevertheless, the *Listeria* outbreak associated with their cantaloupes led to an estimated thirty three to forty deaths, causing the government to bring individual criminal charges against them. Said plaintiff's counsel and food safety advocate Bill Marler when interviewed about the case: “I think if their product had not been linked with 147 people sick and 33 people dead, this would not be happening. I think it was hard for the U.S. Attorney's office to ignore the fact that 33 people died.”<sup>108</sup> Marler's views are consistent with the prosecuting attorney's later statement in presentencing documents: “The government was compelled to

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<sup>106</sup> DOJ Press Release, *supra* note 102.

<sup>107</sup> DOJ Press Release, *supra* note 102.

<sup>108</sup> Lauren Maria Alexander, *Food Safety Lawyer Offers Insight on Jensen Farms Case*, GROWING PRODUCE (Nov. 8, 2013), <http://www.growingproduce.com/vegetables/food-safety-lawyer-offers-perspective-and-takeaways-on-jensen-farms-case/>.

exercise its enforcement discretion in large part because of the devastating results associated with this case.”<sup>109</sup>

The recent ConAgra plea agreement also supports this premise, given that the CDC identified more than 700 cases of salmonellosis linked to the ConAgra peanut butter outbreak and estimated that “thousands” of additional related cases went unreported. However, it is worth noting that no deaths were linked to the outbreak, and still, the company was prosecuted.

**B. In some cases, foodborne illness outbreaks may lead to misdemeanor prosecution of only individual corporate officials; in other cases, charges may be brought against the company alone or in combination with charges against corporate officials; evidence of the official’s prior knowledge of food safety issues does not appear to be the distinguishing factor.**

The FDA’s Regulatory Practices Manual somewhat cryptically advises its employees who are evaluating a case for potential referral for misdemeanor prosecution under the *Park* doctrine to consider evidence of knowledge: “*Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are facts that may be relevant when deciding whether to recommend charging a misdemeanor violation.*”<sup>110</sup> This guideline is consistent with the *Park* doctrine, which confirms the strict liability, “no *mens rea*” standard for conviction of responsible corporate officers. But recent misdemeanor cases offer few clues as to how prior knowledge of food safety problems impacts the decision to prosecute corporate officers for misdemeanor offenses, instead of, or in addition to charging the companies they lead.

The plea agreement in the ConAgra case reflects that company officials had limited awareness of *Salmonella* in the Sylvester, GA processing facility several years prior to the outbreak and were working to address the issues, but corrective measures had not been completed. Under those facts, the government obtained a misdemeanor guilty plea from ConAgra Grocery Products Company, LLC, but did not prosecute individual corporate officers within the ConAgra system. Meanwhile, no charges were brought against Jensen Farms, but Eric and Ryan Jensen were charged with individual misdemeanor FFDCOA offenses, even where the evidence indicated they had no knowledge that *Listeria* was in their facility, let alone that adulterated produce had been shipped into interstate commerce. Quality Egg and two corporate officials were charged with criminal liability, with the DeCosters being charged with and pleading to misdemeanor counts and Quality Egg pleading to felony and misdemeanor charges. Three outbreaks, three different charging scenarios and outcomes.

Corporate size, corporate form, and corporate financial strength may explain part of the difference between the outcomes in these cases. ConAgra, a Fortune 500 publically-held corporation, like Odwalla and Sara Lee before it, was able to pay a significant criminal fine, in fact, the largest criminal penalty ever obtained from a food company following a foodborne

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<sup>109</sup> Government Sentencing Statement at 14, *United States v. Eric Jensen and Ryan Jensen*, No. 13-mj-01138-MEH (D. Colo. Jan. 17, 2014).

<sup>110</sup> *Id.* (emphasis added).

illness outbreak.<sup>111</sup> By contrast, Jensen Farms was a privately held fourth-generation farming operation that filed for Chapter 11 bankruptcy within a year of the 2011 *Listeria* outbreak. This reportedly served to free up millions of dollars in insurance and other funds for victim compensation, but there was clearly no source of funds from which to pay a hefty criminal fine.<sup>112</sup> Similarly, no fine was imposed on the Jensen brothers because, as the sentencing court observed, they were unable to pay a fine. PCA also declared bankruptcy within months of the outbreak, well before prosecutors determined to charge the Parnells with individual federal criminal liability.

**C. There are “Park-like” or “hybrid Park” cases, where corporate officials plead to misdemeanor offenses under the FFDCa, but evidence of knowledge still plays a significant role in sentencing.**

The DeCosters were charged with the misdemeanor offense of introducing adulterated product into interstate commerce, while their company, Quality Egg, was charged with felony misbranding under the FFDCa. In the DeCoster case, the individual defendants did not stipulate in their plea agreement to having knowledge of the events leading up to the outbreak, and because they pleaded to misdemeanor offenses, the government was not required to prove *mens rea*. However, when the defendants challenged the constitutionality of potential incarceration absent proof of *mens rea* beyond a reasonable doubt, the prosecutors prepared to put on evidence at the sentencing hearing of the DeCosters’ pre-outbreak knowledge. Relying in considerable part on the stipulated facts in the plea agreements and on the pre-sentence investigation reports, the sentencing judge specifically found that the DeCosters had knowledge of the increased risk of *Salmonella* in their facilities and did not address it. This finding, together with the criminal history of the defendants, may well have impacted the court’s decision to impose a sentence that included three months’ incarceration. The judge rejected the defendants’ constitutional challenge, relying on the language of the FFDCa, *Park*, and cases prosecuted under the *Park* doctrine as unequivocal authority for sentencing misdemeanor defendants to terms of imprisonment or home detention.

The DeCosters have appealed their sentences and have indicated they will continue to challenge the constitutionality of any sentence of incarceration for a strict liability misdemeanor offense, but the sentences were not outside the guideline ranges or statutorily-prescribed penalties, and evidence of the DeCosters’ pre-outbreak knowledge remains part of the record on appeal.

A variant of the hybrid-*Park* scenario that has played out with the DeCosters involves cases where corporate officials are charged with felony FFDCa offenses (i.e., introducing adulterated products into interstate commerce with intent to defraud or mislead) but ultimately plead to *Park* misdemeanors. The government’s ability to prove criminal intent in this scenario will of course depend on the strength of the evidence of the defendant’s prior knowledge of food safety issues and violations. In either scenario, the existence of facts suggesting the corporate official had some prior knowledge becomes highly relevant to the official’s ultimate fate.

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<sup>111</sup> Because the alternative fines provision of 18 U.S.C. § 3571 authorizes the assessment of significant fines based on the defendant’s financial gain or the victim’s financial loss *even for misdemeanor offenses*, some corporate defendants may be able to escape felony liability and still satisfy criminal sentencing imperatives.

<sup>112</sup> Michael Booth, *Jensen Farms Files Bankruptcy in Wake of Cantaloupe Listeria Deaths*, Denver Post (May 25, 2012, 4:46 PM), [http://www.denverpost.com/ci\\_20713035/jensen-farms-files-bankruptcy-wake-cantaloupe-deaths](http://www.denverpost.com/ci_20713035/jensen-farms-files-bankruptcy-wake-cantaloupe-deaths).

**D. Felony charges for intentional violations of the FFDCA will be used against companies and their officials where the evidence reflects purposeful disregard of food safety issues and financial self-interest.**

The PCA prosecution, like the Beech-Nut prosecution of thirty years prior, confirms that in those cases where the evidence tends to show that corporate officials knew of but ignored food safety issues and demonstrated profit-over-safety motives, the Justice Department will use its full slate of federal felony charges (including mail and wire fraud and conspiracy, as well as the introduction of adulterated food into interstate commerce with intent to defraud and mislead) to prosecute companies and their officials and secure significant fines. To a certain extent, the DeCoster case also exemplifies this type of prosecution, in light of the fact that Quality Egg was charged with and pleaded guilty to felony adulteration and will pay a \$6.8 million fine.

**VI. RISK MANAGEMENT CONSIDERATIONS FOR CORPORATIONS AND THEIR OFFICIALS**

Based on events of the past five years, there is little doubt today that if a serious foodborne illness outbreak has been traced to a company's product or facility, the company and the officials who lead it may now face federal investigation and the prospect of criminal charges, significant fines and potential incarceration. Evidence of prior knowledge of food safety concerns will continue to play an important role in the criminal prosecution of food safety violations, but every food company and high level official should understand that even where the evidence may demonstrate only a negligent failure to address food safety issues, the risk of criminal penalties is now significant. What can food industry representatives do to mitigate this risk?

1. The only sure way to protect yourself, your company and your brand is by protecting your customers. Be a company (or in the case of individuals, work for and lead a company) where the culture demands rigorous compliance with industry food safety standards and regulations, including good manufacturing practices and the soon-to-be implemented requirements of the Food Safety Modernization Act.

2. Food safety, quality and defense should be a key part of your corporate governance structure at the C-suite and board level. It must be a top responsibility of *every* employee, which means it cannot be relegated to the "Quality" department.

3. For individuals in positions of responsibility and with authority to prevent or remedy food safety issues, a little knowledge potentially has a big impact on your exposure to criminal liability. You must take notice of each and every food safety concern *personally* and promptly act to remedy the issue.

4. Create a clear food safety reporting process within your company and thoroughly document every food safety issue as you become aware of it, including the results of your investigation and any actions taken.

5. Write as if your document is a trial exhibit and if you can't give it the proper context, consider whether it needs to be written at all. Don't overlook the value of a phone call or in-person meeting, particularly as an alternative to email communications. A poorly-written communication can sidetrack the best of intentions, plans or actions.



6. Listen carefully for the sound of a whistle blowing. If a food safety issue is brought to your attention by an employee, treat the employee respectfully and fully investigate his/her concerns. Remember that the Food Safety Modernization Act protects employees against retaliation for reporting a food safety violation or giving testimony in a legal proceeding following an alleged violation.<sup>113</sup> Moreover, consider that many whistleblowers start off as loyal long-term employees trying to help their employers do the right thing. If you fail to acknowledge an employee's good faith belief and concerns, you have not only undermined your obligation to your company, the brand and the public, but you have also taken the first step toward creating a witness who can testify against you in a criminal proceeding.

7. Listen also to your suppliers, distributors, licensees, franchisees and others in your supply chain. Moreover, listen to your customers. Social media posts are sometimes an early warning signal. Look at impressions, net sentiment and other analytics.

8. Be prepared. Develop detailed recall and crisis management plans contemplating a variety of scenarios and conduct mock inspections and mock recalls.

9. Regulators and health officials are more likely to be reasonable and open to a science-based approach when you have earned their respect and trust. You cannot build respect and trust during a crisis. Get to know them and respect what they do.

10. Audits are important, but the lesson from Jensen Farms is that you cannot drive compliance simply by auditing. Audit processes, like insurance, supplier contracts with adequate indemnification and assurances, and trace back capabilities, make good food safety and business sense, but "risk transfer" is always incomplete because it's still YOUR brand.

11. If a foodborne illness outbreak should occur, retain qualified outside food safety experts, cooperate with federal investigators and issue a recall immediately upon confirmation that the outbreak strain has been traced to your product or facility. Under the Food Safety Modernization Act, FDA now has the authority to order a recall anyway, so you gain nothing by stalling or failing to rigorously evaluate your facilities and processes in the face of alleged food safety violations.

12. Publicly express your remorse, and mean it. Take appropriate action that demonstrates your concern for individuals who are impacted by an outbreak linked to your company.

13. To address potential conflicts of interest, the company and each individual employee who is subject to government investigation should immediately retain separate counsel.

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\* <sup>i</sup>The author expresses her appreciation to Paul Benson and Don Becker for their thoughtful contributions and to Kelly Fermoye, whose diligent work with an unusual set of citations brought this article across the finish line.

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<sup>113</sup> 21 U.S.C. § 399d (2012).