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Food with Integrity?: How Responsible Corporate Officer Prosecutions Under the Federal Food, Drug, and Cosmetic Act Deny Fair Warning to Corporate Officers

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Food with Integrity?: How Responsible Corporate Officer Prosecutions Under the Federal Food, Drug, and Cosmetic Act Deny Fair Warning to Corporate Officers

[W]hen it comes to food safety, we have to rely on the companies that manufacture and distribute food to ensure that the food we buy is safe. In fact, most consumers give little thought to the safety of their food. I know I don't and I bet many of you don't either. We simply don't expect to get sick from the food at our favorite restaurant, or from peanut butter or the eggs or the cantaloupes or the countless other products that we buy at the supermarket. That is why food safety is a priority for the Justice Department. Our role in protecting consumer safety is at its apex when consumers can least protect themselves.¹

From 2012 to 2015, Chipotle Mexican Grill (Chipotle) was widely regarded as the most popular restaurant in America in the fast, casual Mexican food category.² Known for its fresh ingredients and promotion of environmental justice, the fast food restaurant chain rapidly became one of the most recognized

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1. Benjamin C. Mizer, Principal Deputy Assistant Att'y Gen., Remarks at the Consumer Federation of America's 39th Annual National Food Policy Conference (Apr. 6, 2016), <https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-benjamin-c-mizer-delivers-remarks-consumer> [https://perma.cc/9UHW-Q8E3].

2. See Hadley Malcolm, *This Restaurant Just Unseated Chipotle as the Most Popular Mexican Chain*, USA TODAY (June 11, 2016, 7:06 PM), <http://www.usatoday.com/story/money/2016/06/09/moes-southwest-grill-most-popular-mexican-chain/85640598/> [https://perma.cc/5WRJ-RRW9].

and trusted food brands in America.³ However, in 2015, Chipotle's popularity plummeted nearly as quickly as its meteoric rise began.⁴ Notably, the restaurant's signature burrito bowls and urban building designs had not changed,⁵ but the public's trust in the restaurant's ability to provide "food with integrity" was shaken after fifty-five customers became severely ill.⁶ Twenty-one of these fifty-five customers had to be hospitalized during the 2015 outbreak that spanned eleven states.⁷ Unfortunately, this was not Chipotle's first major foodborne illness outbreak.⁸ In fact, this *E. coli* outbreak occurred just months after hundreds of Chipotle patrons reported severe illness from outbreaks of *Salmonella* and norovirus in the restaurant's food product.⁹

Food companies and food law commentators are awaiting to see how the United States Food and Drug Administration (FDA) holds Chipotle, a company with over 1,800 restaurant locations and a market cap of \$13.1 billion, accountable for their food safety procedures that caused repeated outbreaks and severe illness for hundreds of Americans.¹⁰ Recent FDA action

3. See Brad Tuttle, *How Chipotle Went from Industry Darling to Restaurant to Avoid*, TIME (Dec. 8, 2015), <http://time.com/money/4140531/chipotle-e-coli-outbreak-brand-reputation/> [https://perma.cc/VW4H-XG92].

4. *Id.*

5. See Malcolm, *supra* note 2.

6. See U.S. Food & Drug Admin., *FDA Investigates Multistate Outbreak of E. Coli 026 Infections Linked to Chipotle Mexican Grill Restaurants* (Feb. 1, 2016), <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm470410.htm#update> [https://perma.cc/WJ9C-9LN2].

7. *Id.*

8. See Coral Beach, *UPDATED: CDC Declares Chipotle E. Coli Outbreaks Over; Cause Unknown*, FOOD SAFETY NEWS (Feb. 1, 2016), <http://www.foodsafetynews.com/2016/02/cdc-declares-chipotle-e-coli-outbreaks-over-cause-unknown/#.WA-V0E0zV9A> [https://perma.cc/KQZ7-AQEY].

9. *Id.*

10. See *The World's Most Innovative Companies*, FORBES (May 2016), <http://www.forbes.com/companies/chipotle-mexican-grill/> [https://perma.cc/J67R-PQ6D]; Sarah N. Lynch, *Chipotle Outbreak Eyed by Justice Dept. Consumer Unit*, REUTERS (Jan. 8, 2016, 10:00 PM), <http://www.reuters.com/article/us-chipotle-mexican-u-s-justice-dept-idUSKBN0UM2GS20160109> [https://perma.cc/L5PM-TRXE]; Hayley Peterson, *The Ridiculous Reason McDonald's Sold Chipotle and Missed Out on Billions of Dollars*, BUS. INSIDER (May 22, 2015, 3:11 PM), <http://www.businessinsider.com/the-ridiculous-reason-mcdonalds-sold-chipotle-2015-5> [https://perma.cc/6W4E-SJR8].

indicates that the agency may start by establishing a criminal record for Chipotle's corporate officers.¹¹

The high-profile Chipotle foodborne illness outbreaks emerge at a critical time for federal food safety enforcement. Under the Obama administration, the Department of Justice (DOJ) has declared the enforcement of food safety standards as a high priority.¹² Furthermore, the FDA and the DOJ have elected to enforce food safety standards by imposing criminal liability created under the Federal Food, Drug, and Cosmetic Act (FDCA) on food companies "responsible corporate officers."¹³ The FDA believes the rarely-used doctrine will hold companies more accountable for their harmful food safety procedures because corporate officers have incentive to proactively avert the implementation and continuance of such procedures.¹⁴ Further, proponents of the doctrine note that corporate officers have control to implement policies and procedures that will prevent FDCA violations.¹⁵

Alarming, as an increasing number of food company corporate officers have been investigated and prosecuted under the responsible corporate officer doctrine,¹⁶ it has become difficult to identify the precise legal standards the DOJ uses to decide whether prosecution is appropriate.¹⁷ Although some corporate officers are charged and prosecuted for their company's FDCA violations, almost as many officers in

11. See Lynch, *supra* note 10.

12. See Mizer, *supra* note 1.

13. Roscoe C. Howard Jr. & Leasa Woods Anderson, *Trends in Responsible Corporate Officer Doctrine Under FDCA*, LAW360 (Dec. 14, 2015, 1:11 PM), <https://www.law360.com/articles/737403/trends-in-responsible-corporate-officer-doctrine-under-fdca> [<https://perma.cc/HV6E-RXSL>].

14. Dan Flynn, *Relief from Criminal Prosecutions May Be Ending for Food Execs*, FOOD SAFETY NEWS (May 4, 2012), <http://www.foodsafetynews.com/2012/05/criminal-prosecution-drought-may-be-ending-for-food-execs/#.WNQM1s8rKUI> [<https://perma.cc/F3QV-N75T>]. Dr. Margaret Hamburg, the top-ranking official at the FDA, suggested that the FDA and the DOJ would establish renewed prioritization of food safety enforcement through "the appropriate use of misdemeanor prosecutions" that would "hold responsible corporate officers accountable" for food safety violations by their companies. *Id.*

15. Amiad Kushner, *Applying the Responsible Corporate Officer Doctrine Outside the Public Welfare Context*, 93 J. CRIM. L. & CRIMINOLOGY 681, 693 (2003).

16. See Howard & Anderson, *supra* note 13.

17. See *infra* Part II.

comparable factual scenarios have escaped criminal prosecution.¹⁸

This Comment asserts that the current inconsistent prosecution of corporate officers for the FDCA violations of their companies demonstrates that the statute currently denies food company corporate officers their due process rights under the Fifth and Fourteenth Amendments of the Constitution because corporate officers may be convicted of a crime without “fair warning” of the conduct that makes their actions criminal.¹⁹ Accordingly, the FDCA statute should be amended to remove strict liability misdemeanor charges that allow for easy convictions and potential prison time for corporate officers’ actions that have minimal culpability.

My argument that the FDCA statute denies responsible corporate officers their due process right to fair warning is proven in three parts. Initially, this Comment provides background on the development of the Federal Food, Drug, and Cosmetic Act and its creation of misdemeanor and felony criminal charges for adulterating and distributing adulterated food into interstate commerce. Through an analysis of *Dotterweich* and *Park*, Part I exposes how the Supreme Court inappropriately strayed from the common law trend of requiring criminal prosecutors to prove *mens rea* in food adulteration cases to finding criminal liability if an individual has a responsible relation to the cause of the food adulteration.

Part I argues that the FDCA improperly subjects responsible corporate officers to strict-liability criminal conviction based on the flawed justification that the crime is a “public welfare offense.” Responsible corporate officer prosecution for food safety violations under the FDCA is not cut and dry, as demonstrated by the calculus of guidelines prosecutors consider before pursuing charges. Thus, applying strict liability to FDCA misdemeanors based on a public welfare offense justification produces unfair and unjust results.

18. *Id.*

19. *See* *Rogers v. Tennessee*, 532 U.S. 451, 457 (2001) (explaining that the United States Supreme Court has often recognized the “basic principle that a criminal statute must give fair warning of the conduct that it makes a crime”).

Different than traffic offenses, the most common public welfare offense, where violation of the statute is clear and requires the individual charged with the crime to commit the act, responsible corporate officer convictions do not require the corporate officer to violate the statute but merely be in a position of responsibility when the company's food safety procedures fail.

In response to this theoretical problem, Part II reveals that the current application of the prosecutorial guidelines promulgated by the FDA and utilized by the DOJ provide corporate officers minimal guidance regarding how their conduct leads to criminal prosecution. Part II analyzes six major food adulteration cases since 2014 and contemplates how DOJ prosecutors have practically applied prosecutorial guidelines for FDCA cases when considering whether to prosecute corporate officers under the responsible corporate officer doctrine. These case analyses demonstrate that the application of the current guidelines is wildly inconsistent. Consequently, corporate officers are unable to use recent food adulteration cases to guide their compliance procedures and policies.

Thus, Part III of this Comment recommends that Congress remove misdemeanor charges in the FDCA for food adulteration crimes. Using the Chipotle foodborne illness outbreak incident as an example, this portion of the Comment establishes that removal of misdemeanor offenses under the FDCA would have provided "fair warning" to Chipotle CEO Steve Ells as to what conduct would subject him to criminal liability as a responsible corporate officer of the company.

I. THE CREATION OF THE RESPONSIBLE CORPORATE OFFICER DOCTRINE

A. Statutory Authority to Pursue Criminal Charges Under the 1938 Federal Food, Drug, and Cosmetic Act.

Since 1938, American companies' production and shipment of food products has been regulated under the Federal Food,

Drug, and Cosmetic Act (FDCA).²⁰ One of the central reasons for the passage of the Act was to ensure the safety of the American food supply by prohibiting the production or shipment of “adulterated” food.²¹ Section 331 of the FDCA accomplishes this goal by prohibiting food companies from “adulterat[ing]” food products or introducing, delivering, or receiving “adulterated” food products in interstate commerce.²² One way the Act considers a food to be “adulterated” is if the food “bears or contains any poisonous or deleterious substance which may render it injurious to health . . . or [] if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”²³ This definition of “adulterated” encompasses food products that cause foodborne illness.²⁴ Accordingly, the FDA frequently cites this section of the FDCA when notifying food companies of their food safety violations and choosing to press charges in foodborne illness cases.²⁵

Although the FDA has authority under the FDCA to inspect company premises related to “regulated activity,”²⁶ the agency is not authorized to prosecute criminal violations of the FDCA.²⁷

20. See 21 U.S.C. § 301 (2015).

21. See *Les v. Reilly*, 968 F.2d 985, 986 (9th Cir. 1992) (“The Federal Food, Drug, and Cosmetic Act . . . is designed to ensure the safety of the food we eat by prohibiting the sale of food that is ‘adulterated.’”).

22. 21 U.S.C. § 331 (2015).

23. 21 U.S.C. § 342 (2016).

24. See Helen Bottemiller Evich, *Prosecutions Scare Food Industry*, POLITICO (Oct. 9, 2013, 5:05 AM), <http://www.politico.com/story/2013/10/prosecutions-scare-food-industry-098011> [<https://perma.cc/VL3Z-X68A>] (discussing the recent trend of the FDA filing criminal charges against business leaders in the food industry for foodborne illness outbreaks).

25. See BRENT J. GURNEY ET. AL., *THE CRIME OF DOING NOTHING: STRICT LIABILITY FOR CORPORATE OFFICERS UNDER THE FDCA*, at F-9, F-10, http://www.wilmerhale.com/uploadedFiles/WilmerHale_Shared_Content/Files/Editorial/Publication/The_Crime_of_Doing_Nothing.pdf [<https://perma.cc/JD93-J2L7>].

26. John W. Lundquist & Sandra L. Conroy, *Defending Against Food and Drug Law Prosecutions*, NAT’L ASS’N CRIM. DEF. LAW.: THE CHAMPION (July 1997), <https://www.nacdl.org/CHAMPION/ARTICLES/97jul02.htm> [<https://perma.cc/5D8V-66KD>].

27. See Patrick O’Leary, *Credible Deterrence: FDA and the Park Doctrine in the 21st Century*, 68 FOOD & DRUG L.J. 137, 139 (2013).

Rather, FDCA criminal prosecutions are tried by the DOJ.²⁸ Accordingly, criminal prosecutions under the FDCA result from FDA referral to the DOJ or by independent initiation of a federal prosecutor.²⁹ The DOJ has “absolute discretion” in civil and criminal cases to decide when it is appropriate to prosecute or enforce the statutory provisions of the FDCA.³⁰

Where the DOJ has determined that a “person” has introduced “adulterated” food into interstate commerce, the FDCA “provides for a two-tiered system of criminal sanctions, establishing a strict liability misdemeanor offense for violating any of the prohibited-acts provisions under section 301 and a more severe felony offense for second violations and violations committed with ‘intent to defraud or mislead.’”³¹ Accordingly, a person may be charged with a misdemeanor crime without knowledge of—or intent to commit—the FDCA violation.³² If a person is charged with a misdemeanor under section 333 of the FDCA, the person “shall be imprisoned for not more than one year or fined not more than \$1,000, or both.”³³ If the person is charged with a felony on the other hand, the person “shall be imprisoned for not more than three years or fined not more than \$10,000, or both.”³⁴ These penalties, however, may be increased significantly.³⁵ For example, a misdemeanor fine may be increased to a maximum of \$500,000 if the violation results in death.³⁶

B. Park Doctrine Prosecutions: Imputing Liability on a “Responsible Corporate Officer”

Strict liability offenses, such as the misdemeanor offense for adulterated food in the FDCA statute, are commonly

28. *Id.* at 140.

29. *Id.*

30. *See Heckler v. Chaney*, 470 U.S. 821, 831 (1985).

31. O’Leary, *supra* note 27.

32. *See id.* at 139.

33. 21 U.S.C. § 333 (a)(1) (2016).

34. 21 U.S.C. § 333 (a)(1).

35. 18 U.S.C. § 3571(c)(4) (2016) (outlining fines for both individuals, which can be increased to \$100,000, and organizations, which can be increased to \$500,000).

36. 18 U.S.C. § 3571(c)(4).

criticized in the criminal law context.³⁷ This is largely because crime, as developed under the common law, generally includes both an “evil-meaning mind” and an “evil-doing hand.”³⁸ However, strict liability offenses dispense with the mental culpability element and instead require only an act or omission by the actor to trigger criminal liability.³⁹ Many strict liability offenses were established because the acts or omissions in question were “public welfare offenses.”⁴⁰ Public welfare offenses in their original form were generally regulatory offenses involving potential public harm that imposed light penalties on individuals for violating the offense.⁴¹ Courts were willing to “override the interest” of innocent defendants and penalize them without proof of intent to commit the violation because the harm caused to the public was direct and widespread.⁴²

In England, the sale of adulterated food was originally a crime that required intent to commit the violation.⁴³ However, in *Regina v. Woodrow*, the Court of Exchequer diverted from the common law norm of requiring criminal intent and held that an individual that had purchased and distributed adulterated tobacco without knowledge or reason to know it was adulterated was still criminally liable.⁴⁴ The English court stated that

37. See Alan C. Michaels, *Constitutional Innocence*, 112 HARV. L. REV. 828, 830 (1999); Richard A. Wasserstrom, *Strict Liability in the Criminal Law*, 12 STAN. L. REV. 731, 731 (1960) (“The proliferation of so-called ‘strict liability’ offenses in the criminal law has occasioned the vociferous, continued, and almost unanimous criticism of analysts and philosophers of the law.”).

38. See *Morissette v. United States*, 342 U.S. 246, 251 (1952); Francis B. Sayre, *Public Welfare Offenses*, 33 COLUM. L. REV. 55, 55 (1933).

39. Sayre, *supra* note 38.

40. *Morissette*, 342 U.S. at 255. Public welfare offenses are thought to have been created around “the middle of the nineteenth century. Before this, convictions for crime without proof of a *mens rea* are to be found only occasionally, chiefly among the nuisance cases.” Sayre, *supra* note 38, at 56.

41. Sayre, *supra* note 38, at 68; see also *Staples v. United States*, 511 U.S. 600, 617-18 (1994) (“In rehearsing the characteristics of the public welfare offense, we, too, have included in our consideration the punishments imposed and have noted that ‘penalties commonly are relatively small, and conviction does no grave damage to an offender’s reputation.’”).

42. Sayre, *supra* note 38, at 68.

43. *Id.* at 57-58.

44. *Id.* at 58.

although dispensing with the criminal intent element “may produce mischief because an innocent man may suffer from his want of care in not examining the tobacco he has received, and not taking a warranty; but the public inconvenience would be much greater, if in every case the officers were obliged to prove knowledge.”⁴⁵ The doctrine of public welfare offenses is believed to have begun with food adulteration cases such as *Woodrow*.⁴⁶

This doctrine failed to catch on in America until the middle of the nineteenth century.⁴⁷ At that time, state courts began to dispense of the intent element in crimes that were the result of violations of statutory regulations.⁴⁸ In fact, the public welfare offense doctrine became “firmly established” in food adulteration cases in Massachusetts by the late nineteenth century.⁴⁹ As society became more complex and statutory regulations increased, states increasingly took the public welfare offense doctrine first developed in food adulteration cases and began to apply it broadly to offenses such as traffic violations that warranted small monetary penalties.⁵⁰

Imposing strict liability grounded in the public welfare offense theory can serve an extremely useful purpose. Look no further than traffic violations. For example, in 1933, over a third of the cases in Massachusetts courts were regarding traffic or motor vehicle violations.⁵¹ That amounted to almost 70,000 cases in that year.⁵² As Francis Sayre points out in *Public Welfare Offenses*, with a docket filled with traffic and motor vehicle violations, it would be nearly impossible to “examine the subjective intent of each defendant, even were such

45. *Id.*

46. *Id.* at 61.

47. Sayre, *supra* note 38, at 62; see also Andrew C. Hanson, *Section 309(c) of the Clean Water Act: Using the Model Penal Code to Clarify Mental State in Water Pollution Crimes*, 20 PACE ENVTL. L. REV. 731, 740 (2003).

48. Sayre, *supra* note 38, at 63.

49. *Id.* at 64.

50. *Id.* at 67; see also Hanson, *supra* note 47, at 731.

51. Sayre, *supra* note 38, at 69.

52. *Id.* at 69 n.49.

determination desirable.”⁵³ Accordingly, strict liability in the traffic offense context became a practical and effective solution.

However, when strict liability offenses impose substantial punishment on innocent actors, the criminal punishment begins to lose its sense of justice.⁵⁴ Thus, following Sayre’s approach, strict liability offenses based on the public welfare offense doctrine should only be established when (1) the ability to determine if the offense was committed can be done without evidence of guilty intent and (2) the punishment for the offense does not subject the offender to a prison sentence.⁵⁵

Present misdemeanor prosecution of corporate officers under the FDCA fails both of these standards. First, the determination of whether the responsible corporate officer violated the FDCA statute cannot be determined without evidence of guilty intent because the corporate officer may not be the actor that causes the violation of the statute.⁵⁶ In traffic offenses, the driver is the actor that has broken the speed limit or driven without their lights on. By violating the statute, intentionally or unintentionally, the driver of the car has personally put the public at risk of harm. Thus, for the safety of the public, we believe that promoting a safer community outweighs the risk of imposing a small fine on an innocent driver who violated the statute without intent.

53. *Id.* at 69.

54. Sayre, *supra* note 38, at 70. Sayre famously opines in his article that “[t]he sense of justice of the community will not tolerate the infliction of punishment which is substantial upon those innocent of intentional or negligent wrongdoing . . .” *Id.* The United States Supreme Court has echoed this sentiment stating, “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.” *Staples v. United States*, 511 U.S. 600, 616-17 (1994).

55. Sayre, *supra* note 38, at 72; *see also* *Morissette v. United States*, 342 U.S. 246, 253-57 (1952) (supporting Sayre’s public welfare offense elements by confirming that the Court’s previously recognized public welfare offenses require “no mental element but consist only of forbidden acts or omissions” and that the penalties imposed were “relatively small” in a manner that would not cause “grave damage to [the] offender’s reputation.”); *Staples*, 511 U.S. at 618.

56. *See* Kushner, *supra* note 15, at 695, 702-03 (“The primary concern of an officer liability regime should be the distribution of liability among a class of potential officer defendants, each member of which might have contributed to a corporate crime. The classical form of the public welfare doctrine is unsuited to resolve this problem . . .”).

On the other hand, in a food adulteration case—such as when a foodborne illness outbreak occurs that is traced back to a large company—a corporate officer who is unaware that the company’s products are adulterated may not personally put the public at risk of harm. In fact, in some cases, the corporate officer has no idea that the company is shipping adulterated food in interstate commerce.⁵⁷ This reasoning explains why prosecutors currently consider multiple factors that require fact-intensive inquiry and balancing considerations to find the responsible corporate officer criminally liable under the FDCA statute.⁵⁸ Consequently, to punish a corporate officer who has not personally caused the public to be at risk of harm, solely because she had control of the agent or the process that ultimately caused the public to be at risk of harm undermines the sense of justice and deterrence justifications that form the foundation of the public welfare offense doctrine.⁵⁹

One contention to this argument is that corporate executives are held liable in other contexts for the misdeeds of the corporation, so the food industry should be no different. However, in most industries, criminal actions by the corporate executive still require knowledge or willfulness as an element of the crime.⁶⁰ The FDCA is an exception to this rule.⁶¹ Further, proponents of strict liability in FDCA cases argue that if corporate executives are not held liable for their company’s violations, justice may go unserved.⁶² However, a review of the Chipotle case refutes this argument. Currently, Mr. Ells has not been subjected to criminal liability for the Chipotle FDCA

57. See Bill Marler, *If You Are a Manufacturer of Adulterated Food Can You Face Fines and Jail?*, FORBES (June 9, 2015, 7:53 PM), <https://www.forbes.com/sites/billmarler/2015/06/09/if-you-are-a-manufacturer-of-adulterated-food-can-you-face-fines-and-jail/#628b52d32047> [https://perma.cc/9AJF-BFNH].

58. See Kushner, *supra* note 15, at 694 n.88.

59. See Sayre, *supra* note 38, at 70; *Staples*, 511 U.S. at 616-17.

60. See *Morissette v. United States*, 342 U.S. 246, 254-56 (1952).

61. See *United States v. Dotterweich*, 320 U.S. 277, 281-83 (1943).

62. See Thomas Sullivan, *The Park Doctrine and FDCA Violations: Holding Corporate Executives Accountable*, POL’Y & MEDICINE (Nov. 29, 2011, 6:43 AM), <http://www.policyed.com/2011/11/the-park-doctrine-and-fdca-violations-holding-corporate-executives-accountable.html> [https://perma.cc/6RGP-FB7P].

violations.⁶³ Nevertheless, Chipotle and Mr. Ells have suffered severe consequences because of the company's extensive food safety violations.

Chiefly, profits for the company were down eighty-two percent in 2016.⁶⁴ The public corporation's shares nose-dived after the outbreak, plunging from \$750 per share in 2013 to \$495.62 in 2015.⁶⁵ Further, Mr. Ells, as of 2014, owned 339,474 shares.⁶⁶ Thus, if Mr. Ells retained his stock during the aftermath of the foodborne illness outbreak, Mr. Ells lost approximately \$86,000,000 in stock value, an enormous punishment and deterrent against future food safety failures. Accordingly, it is simply untrue to state that Chipotle or Mr. Ells "escaped" repercussions of the company's actions even if Mr. Ells is not criminally charged under the FDCA. Importantly, this result is unlikely to be cabined to Mr. Ells' circumstance, because most corporate officers now receive a majority of their compensation in stock.⁶⁷ Regardless, without proof of knowledge or wrongful intent, it is manifestly unfair to place *criminal* liability on an individual *solely* because she or he is a corporate officer in responsible relation to the incident.

63. Chipotle has not yet faced any criminal charges for its foodborne illness outbreak. See Alberto Luperon, *Now Even the Feds Are Investigating Chipotle's Virus Outbreak*, *MEDIATE* (Jan. 6, 2016, 1:57 PM), <http://www.mediaite.com/online/feds-hey-chipotle-do-you-make-people-sick/> [<https://perma.cc/EA2Q-AGFD>]. However, the company and its employees (like CEO Steve Ells) are currently under criminal investigation for the outbreak. See Kim Janssen & Robert Channick, *Feds Probing Norovirus Outbreak at Chipotle*, *CHI. TRIB.* (Jan. 6, 2016, 4:31 PM), <http://www.chicagotribune.com/business/ct-chipotle-criminal-investigation-20160106-story.html> [<https://perma.cc/BAS9-MWWB>].

64. See Jackie Wattles, *Chipotle Profits Down 82% in Wake of E. Coli Outbreaks*, *CNN MONEY* (July 22, 2016, 8:54 AM), <http://money.cnn.com/2016/07/21/investing/chipotle-earnings/> [<https://perma.cc/QS8B-JGPB>].

65. See Dan Flynn, *Chipotle Outbreak Illness Count Hits 514 as CMG Stock Dives Below \$500*, *FOOD SAFETY NEWS* (Dec. 23, 2015), <http://www.foodsafetynews.com/2015/12/chipotle-outbreak-illness-count-hits-514-as-cmg-stock-dives-below-500/#.WLMDVzsrJPY> [<https://perma.cc/74XH-Q8SY>].

66. See Brian Solomon, *Why Chipotle's Founder Isn't a Burrito Billionaire (And May Never Be)*, *FORBES* (July 22, 2014, 12:35 PM), <https://www.forbes.com/sites/briansolomon/2014/07/22/why-chipotles-founder-still-isnt-a-billionaire-and-may-never-be/#7f0f4ad01557> [<https://perma.cc/YG99-ENMG>].

67. See Martin Zimmerman, *GM and Ford Chief Executives Putting Their Salary on the Line*, *L.A. TIMES* (Dec. 3, 2008), <http://articles.latimes.com/2008/dec/03/business/fi-autopay3> [<https://perma.cc/8TQL-2FH3>].

Corporate officers will undoubtedly face severe financial and professional consequences without imposing the iron fist of the Department of Justice.

Second, even under a misdemeanor charge, the officers may be subject to a year in prison.⁶⁸ Section 333(a) of the FDCA articulates that:

(1) *Any person* who violates a provision of section 331 of this title *shall be imprisoned for not more than one year* or fined for not more than \$1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if *any person* commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person *shall be imprisoned for not more than three years* or fined not more than \$10,000, or both.⁶⁹

Thus, misdemeanor offenses under the FDCA provide potential criminal liability that is substantial. Accordingly, the current FDCA misdemeanor prosecution of responsible corporate officers dispenses with the two most important hallmarks of public welfare offenses.⁷⁰ In its noble quest to protect the public welfare, the United States Supreme Court has forgotten the interest of innocent corporate officers by sanctioning the prosecution of strict liability criminal offenses regardless of whether a corporate officer knew they were causing harm or how substantial the punishment the corporate officer may suffer.⁷¹

1. Dotterweich: *Guilty By “Reasonable Relation”*

The United States Supreme Court first demonstrated a willingness to hold corporate officers strictly liable for the FDCA violations of their corporation under the public welfare

68. See 21 U.S.C. § 333(a) (2015).

69. 21 U.S.C. § 333(a) (emphasis added).

70. See David E. Frulla et al., *Responsible Corporate Officer Doctrine: Strict Criminal Liability for Regulatory Violations*, KELLEY DRYE (Oct. 24, 2013), <http://m.kelleydrye.com/publications/articles/1771> [https://perma.cc/9LPQ-UXV4].

71. *Id.*

offense doctrine in *United States v. Dotterweich*.⁷² Buffalo Pharmacal Company, Inc. (Buffalo), a drugs “jobber,”⁷³ purchased prescription drugs from manufacturers and repackaged them using their own label, before shipping the drugs in interstate commerce.⁷⁴ The company and Joseph Dotterweich,⁷⁵ president and general manager of Buffalo, were prosecuted and convicted for shipping misbranded products and an adulterated drug in interstate commerce.⁷⁶ Mr. Dotterweich, the top corporate officer of the company was found to have “had no personal connection” with the shipments that resulted in the prosecution.⁷⁷ However, he was in “general charge” of the corporation’s business and gave “general instructions” to the company’s employees to fill the orders for the shipments.⁷⁸ At trial, the jury found that Mr. Dotterweich was guilty on all three counts.⁷⁹

On appeal before the United States Supreme Court, Dotterweich argued that he could not be held criminally liable for the FDCA violations of his company.⁸⁰ His argument followed that the FDCA’s reference to “any person” could not implicate him as an agent for the company, because the term “person” was limited to the corporation.⁸¹ Nevertheless, the Court held that “[i]n the interest of the larger good it puts the burden of acting at hazard a person otherwise innocent but standing in responsible relation to a public danger.”⁸² In signaling that the company’s FDCA violations were public welfare offenses, the *Dotterweich* Court eliminated the

72. See *United States v. Dotterweich*, 320 U.S. 277, 281-83 (1943).

73. A drug “jobber” has been defined as “one who is involved with the legitimate distribution of drugs to authorized outlets” See *State v. Boisvert*, 348 A.2d 7, 10 (Me. 1975).

74. See *United States v. Dotterweich*, 320 U.S. 277, 278 (1943).

75. See *United States v. Buffalo Pharmacal Co.*, 131 F.2d 500, 501 (2d Cir. 1942).

76. See *Dotterweich*, 320 U.S. at 278.

77. *Buffalo Pharmacal Co.*, 131 F.2d at 501.

78. *Id.*

79. *Id.* It is interesting to note, that although Mr. Dotterweich was found guilty for the counts of misbranding and adulteration of the drugs, the corporation was not found guilty. *Id.*

80. See *Dotterweich*, 320 U.S. at 281.

81. *Id.*

82. *Id.*

conventional requirement of awareness of some wrongdoing and placed the statutory liability on individuals in *responsible relation* to the act that causes a public harm.⁸³ Thus, for the first time under the FDCA, the Court affirmed that a corporate officer could be subjected personally to criminal liability for the acts of company employees that the corporate officer did not know about or approve.⁸⁴

The *Dotterweich* Court, however, chose not to define which employees within a company may be considered in “responsible relation” to public danger.⁸⁵ Lower court cases after *Dotterweich* held that the corporate official did not have to personally commit the act causing the violation, know it occurred, or be physically present when it occurred.⁸⁶ Rather, the Court left the determination of “responsible relation” to “the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries”⁸⁷ Although Mr. Dotterweich only received a \$500 fine for each count and a sixty-day probationary period,⁸⁸ the Court’s responsible relation holding opened the door wide open for the *Park* court to establish the responsible corporate officer doctrine in food adulteration cases.

2. Park: Responsible Corporate Officer Doctrine in Food Adulteration Cases

From 1934, when the *Dotterweich* decision was handed down, until 1975, food industry counsel questioned whether *Dotterweich* would apply to food adulteration cases under the FDCA.⁸⁹ However, the *Park* court dispensed with this notion when it held that John Park, CEO of Acme Markets, Inc., a national retail food chain with 874 retail locations and 36,000

83. See Daniel F. O’Keefe Jr. & Marc H. Shapiro, *Personal Criminal Liability Under the Federal Food, Drug and Cosmetic Act—The Dotterweich Doctrine*, 30 FOOD DRUG COSM. L.J. 5, 8 (1975).

84. *Id.*; *Dotterweich*, 320 U.S. at 281.

85. *Dotterweich*, 320 U.S. at 285.

86. O’Keefe & Shapiro, *supra* note 83, at 19.

87. *Dotterweich*, 320 U.S. at 285.

88. See *U.S. v. Dotterweich*, 320 U.S. 277, 281-83 (1943).

89. O’Keefe & Shapiro, *supra* note 83, at 18.

employees, could be charged with a misdemeanor for introducing adulterated food in interstate commerce.⁹⁰ The Supreme Court held that as a “responsible corporate offic[er],” Mr. Park had the “power to prevent or correct violations of [the FDCA’s] provisions.”⁹¹ Inspections at an Acme warehouse in Baltimore uncovered evidence of rodent infestation of food products.⁹² In January of 1972, the FDA notified Park by a letter received at the corporation’s headquarters in Philadelphia of the conditions in violation of the FDCA.⁹³ Mr. Park spoke with other executives of the company who assured him that the vice-president of that location would take care of the problems.⁹⁴ After a second FDA inspection in March 1972 revealed similar conditions, the DOJ filed charges against the corporation and Mr. Park under the FDCA.⁹⁵

Park argued at trial that through his responsibilities as CEO of a large company, he was not personally involved in the FDCA violation.⁹⁶ Further, Park argued that he had done all he could do to remedy the violations.⁹⁷ Nevertheless, the jury found Park guilty of all charges against him.⁹⁸ He was sentenced to pay a fine of fifty dollars on each count.⁹⁹ On appeal, the United States Supreme Court held the conviction was proper because the FDCA imposed a duty on “responsible corporate agents” “to seek out and remedy violations when they occur” and “to implement measures that will ensure that violations will not occur.”¹⁰⁰

The Court noted that an FDCA charge cannot be brought against a corporate officer simply because of the officer’s

90. S. Prakash Sethi & Robert W. Katz, *The Expanding Scope of Personal Criminal Liability of Corporate Executives—Some Implications of United States v. Park*, 32 FOOD DRUG COSM. L.J. 544, 545-47 (1977); see also *United States v. Park*, 421 U.S. 658, 676-77 (1975).

91. *Park*, 421 U.S. at 676.

92. *Id.* at 660.

93. *Id.* at 661-62.

94. O’Keefe & Shapiro, *supra* note 83, at 21.

95. See *Park*, 421 U.S. at 662.

96. *Id.* at 676 n.17.

97. *Id.* at 664.

98. *Id.* at 666.

99. *Id.*

100. *Park*, 421 U.S. at 672; *Dotterweich*, 320 U.S. at 285.

position in the company, but only if the jury finds the individual “had authority and responsibility to deal with the situation.”¹⁰¹ Thus, after *Park*, for the DOJ to get a conviction against a responsible corporate officer resulting in a *potential prison sentence* and/or *extensive fines*, the DOJ only has to prove 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”¹⁰² The Government does not have to prove “wrongful action.”¹⁰³ Notably, the punishment in *Dotterweich* and *Park* was minimal, each receiving a fine for less than \$1,000 and serving no prison time.¹⁰⁴ However, as discussed above, the stakes for criminal prosecution under the current FDCA is much higher.¹⁰⁵

During the *Park* litigation, a critical concern raised but not recognized as a crucial part of the resolution of the case was the possibility that imposing liability on responsible corporate officers would result in criminal prosecution that allowed the DOJ to enforce the statute without consistently applying guidelines or standards.¹⁰⁶ Those in opposition to the Government’s “responsible corporate officer” test argued this rule would result in unfair prosecution based simply on the title

101. *Park*, 421 U.S. at 674. The court recognized the defendant may raise a defense claiming the defendant was “powerless’ to prevent or correct the violation.” *Id.* at 673 (quoting *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964)).

102. *Id.* at 673-74.

103. *Id.* at 673.

104. *See Park*, 421 U.S. at 666; *United States v. Buffalo Pharmacal Co.*, 131 F.2d 500, 501 (2d Cir. 1942).

105. *See infra* Part II.

106. *See* Joshua D. Greenberg & Ellen C. Brotman, *Strict Vicarious Liability for Corporations and Corporate Executives: Stretching the Boundaries of Criminalization*, 51 AM. CRIM. L. REV. 79, 93 (2014) (“Because the FDA’s ‘guidance’ provides none, the agency is effectively mirroring the approach taken in *Dotterweich*, where the Supreme Court relied on ‘conscience and circumspection in prosecuting officers’ to decide when to hold company executives strictly liable under the FDCA. Prosecutors have unfettered discretion to bring *Park* doctrine cases as a result, which creates reason for substantial fear and uncertainty among corporate executives in industries regulated by the FDA.”).

of an individual's job rather than their wrongful conduct.¹⁰⁷ Nevertheless, the Court opted to follow the Government's responsible corporate officer test,¹⁰⁸ which has resulted in arbitrary and inconsistent prosecution of food adulteration cases and has denied corporate officers a "fair warning" of what guidelines the DOJ actually uses to determine when prosecution is appropriate.¹⁰⁹

Currently the FDCA statutory text is silent regarding when a "responsible corporate officer" should be prosecuted under the statute.¹¹⁰ However, the FDA has fashioned a set of guidelines prosecutors are provided to consider when deciding whether to charge the corporate officers for the FDCA violations of their company.¹¹¹ The FDA Regulatory Procedures Manual lists seven (non-exclusive) relevant factors prosecutors should consider in responsible corporate officer prosecutions under the FDCA including:

- (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.¹¹²

107. Sethi & Katz, *supra* note 90, at 559. In their amicus brief, the Grocery Manufacturers of America argued that following the responsible corporate officer test "would expose corporate officers to criminal prosecution at the bureaucratic discretion of enforcement officials without . . . 'guidelines,' 'criteria,' or 'standards,'" which would authorize "harsh and arbitrary criminal prosecutions under the Act, based on corporate status rather than individual 'wrongful action' . . ." *Id.*

108. *See Park*, 421 U.S. at 669-70.

109. *See* Sethi & Katz, *supra* note 90, at 559-60.

110. *See* U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, at 6-48 (2015), <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm> [<https://perma.cc/D6CC-FBKY>].

111. *Id.* at 6-48 to -49.

112. *Id.*

These factors, as they currently exist, are non-exclusive and provide prosecutorial discretion mandated by the Court.¹¹³ However, looking at recent foodborne illness cases, as we will do in Part II, these factors have been applied in an extremely inconsistent manner to the point that each decision by the DOJ to prosecute or not is largely unpredictable and fails to provide “fair warning” as to what actions or omissions responsible corporate officers will be charged for under the statute.¹¹⁴

II. FAIR WARNING OR JUMBLED MESS: HOW RECENT FOOD ADULTERATION CASES PROVIDE LITTLE GUIDANCE OF WHAT ACTIONS WILL BE PROSECUTED UNDER THE STATUTE

Since 2013, there have been six major foodborne illness incidents that present comparable factual scenarios. The cases include food companies Jensen Farms, Quality Egg LLC, Peanut Corporation of America, Glass Onion, Townsend Farms/Costco, and Bidart Brothers. Although the DOJ opted to prosecute “responsible corporate officers” at three of these companies for the companies’ FDCA violations, they did not pursue prosecution against the responsible corporate officers at the other three companies. Importantly, prosecutors acting under the FDCA have prosecutorial discretion to determine which cases to prosecute.¹¹⁵ However, prosecutorial discretion cannot dispense with the constitutional guarantee of “fair warning” to provide a person of ordinary intelligence with an understanding of what actions will result in criminal liability under the statute.¹¹⁶

The current FDCA language does not provide clear guidance of specific actions or omissions that if taken by a responsible corporate officer, will result in their personal criminal liability.¹¹⁷ As discussed in Part I, this is because the

113. *Id.*

114. *See infra* Part II.

115. *See Heckler v. Chaney*, 470 U.S. 821, 831 (1985).

116. *See id.* at 830-31.

117. *See supra* Section I.A.

misdeemeanor offense under the statute is a strict liability offense that only requires the commission of the criminal violation stated in the statute.¹¹⁸ Thus, responsible corporate officers only have prior foodborne illness outbreaks and FDA/DOJ actions regarding those outbreaks to provide them “fair warning” of which actions by their companies will result in subjection to criminal liability.

Unfortunately, the six cases below all involved significant violations of the FDCA.¹¹⁹ Thus, consistently applying strict liability based on the public welfare offense doctrine would dictate that responsible corporate officers in all six cases should have been prosecuted.¹²⁰ However, all six cases were not treated comparably by the DOJ.¹²¹ The case analyses below demonstrate that the executives that were prosecuted all knew or should have known of company procedures that eventually led to the foodborne illness outbreak.¹²² On the other hand, the executives who were not prosecuted had minimal knowledge, at most, of company procedures or operations that led to the eventual foodborne illness outbreak.¹²³ This practical conclusion further supports this article’s proposed solution that the FDCA strict liability standard for misdemeanor crimes should be removed and replaced with a *mens rea* requirement.

A. Executives Prosecuted

1. *Jensen Farms*

In June of 2011, Eric and Ryan Jensen, the owners of Jensen Farms in Granada, Colorado, installed and maintained a processing center for cantaloupes produced on their farm.¹²⁴ The processing center included a conveyor system that was designed

118. See *supra* Section I.A.

119. See *infra* Sections II.A-C.

120. See *infra* Sections II.A-C.

121. See *infra* Sections II.A-C.

122. See *infra* Section II.A.

123. See *infra* Section II.B.

124. Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing at 6, United States v. Jensen, No. 13-mj-01138-MEH (D. Colo. Oct. 22, 2013), <http://www.defenselitigationinsider.com/files/2015/01/US-v-Jensen-COP.pdf> [https://perma.cc/W8QV-EVM7].

to clean, cool, and package the cantaloupes for distribution throughout the country.¹²⁵ Specifically, if functioning properly, the conveyor system would sufficiently wash the fruit with antibacterial solution to prevent adulteration.¹²⁶ Jensen Farms acquired the conveyor system, originally designed for harvesting potatoes, in May 2011.¹²⁷ The company supplying the conveyor system modified the equipment to include a catch pan to support a chlorine spray function, which would have reduced the risk of microbial contamination of fruit.¹²⁸ However, the Jensen brothers chose not to set up the chlorine spray function.¹²⁹ On July 29, 2011, a retailer received pallets of cantaloupes that were adulterated with *Listeria* from a Jensen Farms packaging facility.¹³⁰ Retailers distributed the cantaloupe to stores located in twenty-eight states causing 147 foodborne illnesses, thirty-three known deaths, and ten other deaths that were likely related.¹³¹

The Colorado Department of Health and Environment (CDHE) notified the CDC and the FDA of the astronomical increase in average number of *Listeria* cases in September.¹³² The CDHE pinpointed that all patients infected with *Listeria* reported eating cantaloupe before they experienced the symptoms.¹³³ In response, the FDA sampled Jensen Farms cantaloupes and found that the fruit tested positive for the strain of *Listeria* found in all of the infected patients.¹³⁴ Further, the FDA found that multiple locations throughout the Jensen Farms packing and storage facility were positive for the strain found in the outbreak victims.¹³⁵ On September 14, 2011, the Jensen's

125. *Id.*

126. *Id.*

127. *Id.* at 7.

128. *Id.*

129. See Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing, *supra* note 124, at 7.

130. *Id.* at 7-8.

131. *Id.* at 14.

132. *Id.* at 12-13.

133. *Id.* at 13.

134. See Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing, *supra* note 124, at 13.

135. *Id.*

took action by attempting to recall shipments of cantaloupes.¹³⁶ Nevertheless, on October 18, 2011, the FDA issued a warning letter concluding that Jensen Farms had widespread contamination throughout the facility that demonstrated poor sanitary practices.¹³⁷ An FDA Senior Adviser stated that “Jensen Farms significantly deviated from industry standards by failing to use an anti-microbial . . . in the packing of their cantaloupes”¹³⁸ As a result, the U.S. Attorney’s Office brought federal charges against the Jensen brothers for Introduction of an Adulterated Food into Interstate Commerce.¹³⁹ The Jensen brothers eventually plead guilty to misdemeanor counts.¹⁴⁰ Their indictment called for penalties of up to six years in prison and \$1.5 million in fines.¹⁴¹

Applying the prosecutorial guidelines, it is clear that an FDCA violation resulted in actual harm under Section 331 of the FDCA.¹⁴² In fact, some have referred to the outbreak as one of the most severe foodborne illness outbreaks in U.S. history.¹⁴³ Second, the violation could be deemed obvious. The Jensen brothers knew that the cantaloupe needed to be cleaned properly.¹⁴⁴ However, the brothers were grossly negligent by failing to set up the chlorine wash that would have killed the bacteria that ultimately adulterated their produce.¹⁴⁵ Third, the Jensen Farms case does not reflect a pattern of illegal behavior or a failure to heed previous warnings by the Jensen brothers as

136. *Id.*

137. *Id.* at 13-14.

138. *Id.* at 14.

139. See Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing, *supra* note 124, at 3-4.

140. *Id.* at 1.

141. *Id.* at 4-5.

142. *Id.* at 3-4.

143. See Scott Bronstein & Drew Griffin, *Third-deadliest U.S. Food Outbreak Was Preventable, Experts Say*, CNN (May 3, 2012, 9:21 AM), <http://www.cnn.com/2012/05/03/health/listeria-outbreak-investigation> /<http://www.cnn.com/2012/05/03/health/listeria-outbreak-investigation/> [<https://perma.cc/VP48-H778>].

144. See Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing, *supra* note 124, at 7.

145. *Id.*

corporate officers of the company.¹⁴⁶ Rather, the criminal incidents occurred only after Jensen Farms implemented its new conveyor system.¹⁴⁷ They only received a warning letter from the FDA after many of the foodborne illnesses were reported to public health officials.¹⁴⁸ Fourth, the violation was widespread and impacted consumers in twenty-eight states.¹⁴⁹ The result of shipping adulterated food in interstate commerce was serious as thirty-three consumers died and a total of 147 individuals reported outbreak-associated illnesses.¹⁵⁰ Fifth, the factual proof of this case was strong because the Jensen brothers were aware of the need to use the chlorine wash to eradicate the cantaloupe of the harmful bacteria but knowingly failed to implement the chlorine wash procedures while continuing to sell the fruit around the country.¹⁵¹

Thus, DOJ prosecuting attorneys had a strong argument that the Jensen brothers' prosecution was a prudent use of agency resources.¹⁵² Accordingly, following the prosecutorial guidelines, this was an easy case. It involved two owners intimately involved in the operations of their farm.¹⁵³ It involved obvious procedural guards that the owners failed to implement and it involved violations that resulted in the death of thirty-three consumers.¹⁵⁴

2. *Quality Egg, LLC*

In August 2010, eggs containing *Salmonella* bacteria sickened thousands of consumers around the country.¹⁵⁵ The table eggs were traced back to Quality Egg, LLC (Quality Egg),

146. *See id.* (describing the illegal activity of the Jensen brothers, but not mentioning any previous illegal activity).

147. *Id.* at 7-12.

148. *Id.* at 13-14.

149. Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing, *supra* note 124, at 14.

150. *See id.*

151. *Id.* at 7.

152. *Id.* at 12-14.

153. *Id.* at 6-7.

154. Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing, *supra* note 124, at 14.

155. *United States v. DeCoster*, 828 F.3d 626, 630 (8th Cir. 2016).

a company run by executives Austin DeCoster and Peter DeCoster.¹⁵⁶ The trial court found that Austin DeCoster had substantial control over Quality Egg and its assets.¹⁵⁷ Peter DeCoster was found to have “some control” over the production and distribution of shell eggs by the company.¹⁵⁸ In 2010, 1,939 individuals reported illnesses and/or cases of *Salmonella* infection associated with the Quality Egg outbreak.¹⁵⁹ The DeCosters maintain that they did not have any knowledge during the time of the *Salmonella* outbreak that the eggs their company sold were contaminated.¹⁶⁰

However, investigation into the Quality Egg case revealed that the company had commissioned tests to detect *Salmonella* and the results of the test came back positive on forty-seven percent of the days tested.¹⁶¹ Furthermore, the frequency of the test results grew in the months leading up to its recall.¹⁶² Quality Egg issued a recall, the largest recall of table eggs in U.S. history.¹⁶³ After the company’s recall, the FDA conducted a follow-up inspection finding unsanitary conditions including dead insects and fecal material pervasive in the facilities.¹⁶⁴ Following its inspection, the FDA issued Quality Egg an inspectional report detailing their observations.¹⁶⁵ However, Quality Egg failed to implement and follow its written *Salmonella* prevention plan.¹⁶⁶ As a result, the DeCosters were prosecuted under Section 331 of the FDCA for shipping and selling shell eggs that contained *Salmonella* in interstate

156. United States v. Quality Egg, LLC, 99 F. Supp. 3d 920, 923 (N.D. Iowa 2015).

157. *Id.*

158. *Id.* at 925.

159. *Id.* at 926.

160. *Id.*

161. Press Release, U.S. Dep’t of Justice, Quality Egg, Company Owner, and Top Executive Sentenced in Connection with Distribution of Adulterated Eggs (Apr. 13, 2015), <https://www.justice.gov/opa/pr/quality-egg-company-owner-and-top-executive-sentenced-connection-distribution-adulterated> [https://perma.cc/B4LP-E3LP].

162. *Id.*

163. Dan Flynn, *Egg Men Get Extra Time to File for Review with Supreme Court*, FOOD SAFETY NEWS (Dec. 15, 2016), <http://www.foodsafetynews.com/2016/12/decosters-get-extra-time-to-file-for-review-with-supreme-court/#.WPaIE1KZPVo> [https://perma.cc/W67S-BBCN].

164. United States v. Quality Egg, LLC, 99 F. Supp. 3d 920, 926 (N.D. Iowa 2015).

165. *Id.* at 931.

166. *Id.*

commerce as responsible corporate officers.¹⁶⁷ The DeCosters reached a plea agreement with the DOJ to plead guilty to one strict liability misdemeanor and paid a \$100,000 fine.¹⁶⁸ The two men were each sentenced to three months in prison.¹⁶⁹

Applying the prosecutorial guidelines here, first, Quality Egg's adulteration of its table eggs resulted in serious physical harm to 1,939 individuals around the country. Second, the violation was obvious.¹⁷⁰ Not only did FDA investigations find that Quality Egg facilities in Iowa were extremely unsanitary, there was also evidence that established that Quality Egg knew that its facilities and products were testing positive for *Salmonella*.¹⁷¹ Third, Quality Egg's failure to implement its written *Salmonella* eradication plan the company proffered to the FDA after facility inspection exposed rampant *Salmonella* contamination, was just one bad act in a pattern of illegal behavior by Quality Egg and the DeCosters.¹⁷² Quality Egg was also found to have misbranded their egg products and had previously bribed USDA inspectors.¹⁷³ Furthermore, Peter DeCoster had previously been convicted of falsifying driving logs within another business.¹⁷⁴ The facts as applied to the guidelines strongly weighed against the DeCosters in the determination of their conviction. Additionally, their violation was widespread.¹⁷⁵ The adulterated eggs had injured individuals in ten different states.¹⁷⁶ Further, the USDA had investigated and allowed Quality Egg the opportunity to fix the identified sanitation issues.¹⁷⁷ However, Quality Egg failed to implement its designated correction plans.¹⁷⁸ This provided plenty of legal and factual support for the prosecution of the DeCosters. Thus,

167. *Id.* at 924.

168. *See* United States v. DeCoster, 828 F.3d 626, 631 (8th Cir. 2016).

169. *Id.*

170. *See* Press Release, U.S. Dep't of Justice, *supra* note 161.

171. *DeCoster*, 828 F.3d at 631.

172. United States v. Quality Egg, LLC, 99 F. Supp. 3d 920, 931 (N.D. Iowa 2015).

173. *Id.* at 945-46.

174. *Id.* at 943.

175. *Id.* at 932.

176. *Id.* at 923.

177. United States v. DeCoster, 828 F.3d 626, 630 (8th Cir. 2016).

178. *Id.* at 630-31.

it follows that this open and shut case was also a prudent use for agency resources.

3. *Peanut Corporation of America*

In 2009, a *Salmonella* outbreak resulted from a peanut butter paste that was manufactured by the Peanut Corporation of America.¹⁷⁹ The outbreak killed nine people and sickened another 714 consumers across forty-six states.¹⁸⁰ The outbreak was considered the deadliest *Salmonella* outbreak in recent history.¹⁸¹ The outbreak also resulted in a huge food recall that spanned from cookies to airline snacks.¹⁸² In contrast to the two cases above, in this case there was clear evidence that Stewart Parnell, the owner and president of the peanut processing company, knew that his products were adulterated and chose to distribute the products anyway.¹⁸³ After the *Salmonella* outbreak began to spread, the FDA identified that the processing company's plant was rife with "mold, roaches, dirty equipment, holes big enough to allow rodents inside and a failure to separate raw and cooked products."¹⁸⁴ The company's own *Salmonella* testing had reported contamination six times over the years.¹⁸⁵ Because Parnell knew of the adulterated product, he was charged with a felony rather than a misdemeanor under the

179. Kevin McCoy, *Peanut Exec. in Salmonella Case Gets 28 Years*, USA TODAY (Sept. 21, 2015, 5:39 AM), <http://www.usatoday.com/story/money/business/2015/09/21/peanut-executive-salmonella-sentencing/72549166> [<https://perma.cc/UW8D-EHJN>].

180. *Id.*

181. *Id.*

182. *Id.*

183. Lindsey Bever, *Former Peanut Plant Executive Faces Life Sentence for Lethal Salmonella Coverup*, WASH. POST (July 24, 2015), https://www.washingtonpost.com/news/morning-mix/wp/2015/07/24/former-peanut-plant-executive-faces-life-sentence-for-selling-salmonella-tainted-food/?utm_term=.0276f4b456df [<https://perma.cc/8C5K-YYAM>].

184. Brady Dennis, *Executive Who Shipped Tainted Peanuts Gets 28 Years; 9 Died of Salmonella*, WASH. POST (Sept. 21, 2015), https://www.washingtonpost.com/national/health-science/a-life-sentence-for-shipping-tainted-peanuts-victims-families-say-yes/2015/09/19/e844a314-5bf1-11e5-8e9e-dce8a2a2a679_story.html?utm_term=.a17939054a0f [<https://perma.cc/6FSG-THLH>].

185. Bever, *supra* note 183.

statute.¹⁸⁶ Parnell also received a twenty-eight-year prison sentence.¹⁸⁷

Applying the prosecutorial guidelines here, the violation clearly resulted in actual harm to hundreds of individuals across the country.¹⁸⁸ Additionally, the adulterated peanut paste was obvious because the company's *Salmonella* testing had produced positive results at least six times during the time frame of the outbreak.¹⁸⁹ Further, Mr. Parnell was aware of the *Salmonella* problems and chose to ship the products in interstate commerce.¹⁹⁰ Mr. Parnell's knowledge of the *Salmonella* presence and his choice to knowingly distribute the products is what makes this case extremely egregious. His statements and actions clearly reflect that he was aware of the *Salmonella* contamination and chose not to take preventative measures to protect consumers. The adulteration of the peanut paste was widespread and serious and there was plenty of factual evidence to demonstrate that Mr. Parnell knew of the food adulteration and chose to insert the product into the food supply. Thus, it is unlikely anyone could say that prosecution of Mr. Parnell would be an unwise use of agency resources. On the contrary, Mr. Parnell is precisely the type of company executive who this Comment advocates should face felony charges.¹⁹¹

186. Sindhu Sundar, *DOJ Toughens Stance on Food Execs in Peanut Corp. Case*, LAW360 (Sept. 11, 2015, 10:58 PM), <https://www.law360.com/articles/701880/doj-toughens-stance-on-food-execs-in-peanut-corp-case> [<https://perma.cc/2UPY-YF62>].

187. McCoy, *supra* note 179.

188. *Id.*

189. *Georgia Peanut Plant Manager Testifies That Company Faked Salmonella Tests*, N.Y. DAILY NEWS (Aug. 8, 2014, 6:09 PM), <http://www.nydailynews.com/news/national/georgia-peanut-plant-manager-testifies-company-faked-salmonella-tests-article-1.1897287> [<https://perma.cc/8YQT-86FP>].

190. McCoy, *supra* note 179.

191. Thus far, this Comment has presented analyses of three cases that provide factor-by-factor explanations of why the company executives should face prosecution for the food safety outbreaks of their company. Importantly, this Comment does not question why those individuals face prosecution. Rather, this Comment is more concerned with the recent cases that seemingly present comparable factual issues regarding FDCA violations and harm done, but the Department of Justice has chosen to forgo prosecution. This Comment does not question that prosecutors have discretion to bring cases; however, this Comment is concerned that a failure to consistently prosecute executives for the food safety outbreaks of their company fails to provide fair warning of when company executives will be prosecuted for the food safety violations of their company.

B. Executives Not Prosecuted

1. *Glass Onion*

In 2013, thirty-three consumers across four states contracted *E. coli* that was traced back to pre-packaged salads sold at Trader Joes.¹⁹² Nine consumers were hospitalized and two consumers developed hemolytic uremic syndrome, a potentially fatal kidney disease associated with *E. coli* infections.¹⁹³ The products were produced by Atherstone Foods Inc., which was manufacturing the products under the name Glass Onion Catering.¹⁹⁴ The California Department of Public Health investigated Glass Onion facilities but did not find any food safety violations.¹⁹⁵ Investigators also tested the procedures and took environmental samples from the location where Glass Onion sourced its romaine lettuce and did not find a genetic match of the strain that caused the outbreak.¹⁹⁶ The health inspectors were not able to locate where the *E. coli* strain in question originated.¹⁹⁷

Applying the prosecutorial guidelines here, the adulterated salads produced by Glass Onion caused actual harm to thirty-three individuals across four states.¹⁹⁸ However, the violation was not obvious.¹⁹⁹ Neither Glass Onion nor its source of romaine lettuce were found to have conclusively committed an adulteration violation under the FDCA.²⁰⁰ Further, there is no evidence that there was a pattern of illegal behavior or a failure to heed regulatory warnings.²⁰¹

On the contrary, after notice of the violation, both Glass Onion and its lettuce supplier implemented further procedures

192. CAL. DEP'T OF PUB. HEALTH, ENVIRONMENTAL INVESTIGATION OF AN ESCHERICHIA COLI O157:H7 OUTBREAK IN OCTOBER 2013 ASSOCIATED WITH PRE-PACKAGED SALADS 6 (2014).

193. *Id.*

194. *Id.* at 5, 7.

195. *Id.* at 5.

196. *Id.*

197. CAL. DEP'T OF PUB. HEALTH, *supra* note 192, at 5.

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.* at 12.

that would limit the possibility of outbreak.²⁰² However, under the misdemeanor charge, all the prosecutors would have to prove is that the adulterated product was distributed by Glass Onion.²⁰³ This seems absurd in a case such as this because Glass Onion and its produce supplier appear to be wholly innocent. Importantly, this violation is serious. Thirty-three individuals contracted illness because of the adulterated food product.²⁰⁴ Further, there is factual evidence that creates a case that Glass Onion distributed an adulterated product in interstate commerce.²⁰⁵

Admittedly, in this case it is much less clear whether prosecuting Glass Onion would be prudent. On one hand, as the protector of the American food supply, the DOJ needs to make it clear that it will not tolerate the sale of adulterated food, regardless of whether the company was aware that their procedures would result in such an outcome. On the other hand, Glass Onion has not been shown to have done anything wrong.²⁰⁶ In fact, the company appears to be squeaky clean and worked diligently to fight the outbreak.²⁰⁷ Accordingly, prosecutorial opinion may vary on whether it would be a prudent use of resources to prosecute Glass Onion.

2. Townsend Farms/Costco

In 2013, 162 consumers were confirmed to have contracted Hepatitis A after eating Townsend Farms Organic Antioxidant Blend.²⁰⁸ The cases spanned ten states touching both coasts.²⁰⁹

202. CAL. DEP'T OF PUB. HEALTH, *supra* note 192, at 12.

203. *See id.*

204. *Id.* at 5.

205. *Id.* at 6.

206. *Id.* at 5.

207. CAL. DEP'T OF PUB. HEALTH, *supra* note 192, at 12.

208. U.S. FOOD & DRUG ADMIN., FDA INVESTIGATES MULTISTATE OUTBREAK OF HEPATITIS A ILLNESS ASSOCIATED WITH POMEGRANATE SEEDS FROM TURKISH IMPORTER (2013), <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm354698.htm> [<https://perma.cc/6UJ5-35RV>].

209. CDC Updates Hepatitis A Outbreak Numbers: 159 Ill in 10 States, FOOD SAFETY NEWS (Aug. 16, 2013), <http://www.foodsafetynews.com/2013/08/cdc-updates-hepatitis-a-outbreak-numbers-159-ill-in-10-states/#.WIaH8k0zWUk> [<https://perma.cc/YAV3-92FP>].

Sixty-nine individuals had cases so severe that they were hospitalized.²¹⁰ Additionally, in a California class action, roughly 25,000 individuals alleged injury.²¹¹ Townsend Farms quickly ordered a recall of the product.²¹² Public health officials ultimately concluded that the adulterated pomegranate seeds were imported from Turkey.²¹³ There is no evidence currently that the Townsend Farm executives knew of the adulterated product.²¹⁴

Applying the prosecutorial guidelines, Townsend Farms' FDCA violation of distributing adulterated food products in interstate commerce resulted in severe and widespread harm to allegedly 25,000 individuals.²¹⁵ The evidence of injury to those individuals as a result of consuming a Townsend Farm's product is very strong.²¹⁶ On the other hand, there is little evidence that suggests that Townsend Farms had repeatedly failed to adhere to warnings or can be shown to have a pattern of misbehavior.²¹⁷ Finally, if the incident caused injury to thousands of consumers, prosecution seems like it would be a prudent way to send a message to food producers and food executives that the government will not allow them to distribute food that is adulterated.²¹⁸ However, to this point, no criminal action has been filed.²¹⁹

210. *Id.*

211. Coral Beach, *Costco Offers Vaccines, Denies Liability and Declares Dividend*, FOOD SAFETY NEWS (Apr. 22, 2016), <http://www.foodsafetynews.com/2016/04/costco-offers-hep-a-vaccines-for-current-outbreak-denies-liability-for-2013-outbreak-frozen-fruit-implicated-both-times/> [https://perma.cc/6UCG-WB2D].

212. U.S. FOOD & DRUG ADMIN., *supra* note 208.

213. *Id.*

214. *See id.*

215. *See* Beach, *supra* note 211.

216. *See Multistate Outbreak of Hepatitis A Virus Infections Linked to Pomegranate Seeds from Turkey (Final Update)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 28, 2013, 4:30 PM), <https://www.cdc.gov/hepatitis/outbreaks/2013/a1b-03-31/> [https://perma.cc/BK7F-Q5FG] (discussing number of victims and spread of infection from specific source).

217. *See id.* (stating that infection was linked to one contaminated shipment of seeds not negligence on part of Townsend).

218. *See* Flynn, *supra* note 14.

219. *See* Bill Marler, *Food "Crimes"—When to Prosecute and When to Not?*, FORBES (July 18, 2015, 10:21 PM), <https://www.forbes.com/sites/billmarler/2015/07/18/food-crimes-when-to-prosecute-and-when-to-not/#53065df61b3d> [https://perma.cc/585Q-7SRS].

3. Bidart Brothers

In 2014, thirty-five consumers reported illness from *Listeria* after eating whole caramel apples.²²⁰ The *Listeria* outbreak spanned twelve states and caused thirty-four of the thirty-five consumers to be hospitalized.²²¹ Seven of the consumers died.²²² Eleven of the illnesses were pregnancy-related and one of the illnesses resulted in fetal loss.²²³ Ultimately, the public health officials traced the *Listeria* outbreak to Bidart Brothers, an apple producer in California.²²⁴ Investigators found the *Listeria* on farm tools, packing drains, and on the automatic packing line.²²⁵ Additionally, inspectors identified that the packing equipment was constructed in a manner that prevented the equipment from being properly cleaned.²²⁶ While there is little evidence regarding how much the farm owners knew about the potential adulteration of their apples, this case sounds eerily similar to the Jensen Farms case. Nevertheless, Bidart Brothers executives have avoided prosecution thus far.²²⁷

Applying the prosecutorial guidelines here, Bidart Brothers shipping of apples that contained adulterated products resulted in a severe, widespread, and serious violation of the FDCA.²²⁸ Further, public health agencies were able to link the foodborne illness to the farm's unsanitary conditions.²²⁹ Although there was no evidence that Bidart Brothers failed to heed warnings, nor was this a step in a line of illegal actions, this case would

220. See Dan Flynn, *Inspectors Find Listeria at Bidart Bros. Cooling and Packing House*, FOOD SAFETY NEWS (May 27, 2015), <http://www.foodsafetynews.com/2015/05/bidart-bros-cooling-and-packing-house-samples-were-positive-for-listeria/#.WIaIXU0zWUk> [<https://perma.cc/V3EM-VCX2>].

221. *Id.*

222. *Id.*

223. *FDA Investigated Listeria Monocytogenes Illness Linked to Caramel Apples*, U.S. FOOD & DRUG ADMIN. (Aug. 21, 2015), <https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm427573.htm> [<https://perma.cc/ANN8-F57T>].

224. See Flynn, *supra* note 220.

225. *Id.*

226. *Id.*

227. *Id.*

228. See *supra* Section I.D.

229. Flynn, *supra* note 220.

provide another opportunity to enforce the importance of food safety through the FDCA.²³⁰ Thus, this seems as if prosecution would be a prudent use of agency resources. However, the Department of Justice has chosen not to do so.²³¹

C. Case Analyses Summary

In summary, the case analyses demonstrate that there is little distinction in evidence of food adulteration or injury result between cases where the Department of Justice has chosen to prosecute food safety executives and those cases where no criminal action has been taken.²³² The one conclusion that can be drawn from all cases where the company executives were prosecuted is that all of those cases present evidence that the executive *knew or should have known* about circumstances that could have led to the cause of the food adulteration but chose to do nothing about it.²³³ In Jensen Farms, the brothers knew they should have been using the chlorine spray but chose not to implement the practice.²³⁴ In Quality Egg, the executives knew of the unsanitary conditions reported by investigators but took no action to remedy the problems.²³⁵ In Peanut Corporation of America, Mr. Parnell knew of the failing *Salmonella* test but chose to ship the products without confirmation that the shipment was *Salmonella* free.²³⁶ Each executive knew to some degree about the eventual cause of the outbreak. Arguably each case could have been brought under a felony charge.

On the other hand, the cases that have not been prosecuted, present clear evidence that each company distributed adulterated food in interstate commerce.²³⁷ In the Bidart Brothers case, the facility investigation even showed unsanitary conditions that led to the eventual outbreak, however, no charges were filed.²³⁸ As

230. *Id.*

231. *Id.*

232. *See supra* Sections II.A-B.

233. *See Id.*

234. *See supra* Section II.A.1.

235. *See supra* Section II.A.2.

236. *See supra* Section II.A.3.

237. *See supra* Section II.B.

238. *See supra* Section II.B.3.

a result, determining when food company executives will be prosecuted under the current statute is unpredictable even with the prosecutorial guidelines.

III. HOW REMOVING THE STRICT LIABILITY MISDEMEANOR OFFENSE FOR FOOD ADULTERATION CASES WOULD SATISFY THE FAIR WARNING REQUIREMENT OF THE DUE PROCESS CLAUSE

After reviewing the cases, it is clear the prosecutorial guidelines should remain in place. However, prosecution under the statute will be more just and predictable by eliminating the strict liability misdemeanor offense for food adulteration under the FDCA. To explain how this would bring clear results, we will return to the Chipotle case one final time.

In 2015, at least sixty consumers suffered illness across fourteen states resulting from *E. coli* contamination contracted after eating at Chipotle.²³⁹ Public Health officials have not been able to trace which specific ingredient caused the *E. coli* outbreak.²⁴⁰ Some experts assert that a contributing factor in the Chipotle outbreak may have been systemic failures in food handling, food preparation, and employee hygiene.²⁴¹ Nevertheless, under the responsible corporate officer doctrine, Chipotle CEO Steve Ells may be prosecuted because his company shipped adulterated food in interstate commerce. The current statute for misdemeanor charges only requires that Mr. Ells be in a position of responsible relation to the company's foodborne illness outbreak.²⁴²

However, by eliminating the strict liability misdemeanor charge and leaving the felony charge requiring knowledge of the cause of the food adulteration, prosecutors would only be able to

239. See Beach, *supra* note 8.

240. *Id.*

241. Samantha Masunaga, *What Went Wrong at Chipotle? Food Safety Expert Trevor Suslow Breaks It Down*, L.A. TIMES (Mar. 23, 2016, 3:00 AM), <http://www.latimes.com/business/la-fi-qa-food-safety-20160317-story.html> [<https://perma.cc/LG34-SRG2>].

242. See *supra* Part I.D.

convict Mr. Ells if he knew that a company procedure or failure to implement a company procedure contributed to the company's food product becoming contaminated with *E. coli*.

This would properly punish executives for their actual wrongdoing. The deterrence rationale would serve its purpose in criminalizing Mr. Ells' actions. However, this change would also protect unknowing CEOs, who were not aware that company practice or policies were resulting in adulterated food, from criminal prosecution and destruction of their professional careers. Rest assured a foodborne illness outbreak of the type would still greatly impact the unknowing CEO. Just ask Mr. Ells; suffering an 86 million dollar loss is a substantial punishment.

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