

2012

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Recommended Citation

Kimberly Bolte, *Shot Through the Heart: The FDA Gives All Health Care Company Executives a Bad Name Under the Controversial Strict-Liability Misdemeanor Provision of the Federal Food, Drug, and Cosmetic Act*, 6 Brook. J. Corp. Fin. & Com. L. (2012).
Available at: <https://brooklynworks.brooklaw.edu/bjcfcl/vol6/iss2/7>

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SHOT THROUGH THE HEART: THE FDA GIVES ALL HEALTH CARE COMPANY EXECUTIVES A BAD NAME UNDER THE CONTROVERSIAL STRICT-LIABILITY MISDEMEANOR PROVISION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

INTRODUCTION

The government is pulling out a dusty old weapon from its arsenal to use as it embarks on a seemingly tyrannical mission against health care company executives.¹ Recently,² the Food and Drug Administration (FDA)³ and the Department of Justice (DOJ)⁴ expressed an intention to aggressively prosecute high-ranking executives of health care companies⁵ through the

1. See Barry Meier, *When Heart Devices Fail, Who Should Be Blamed?*, N.Y. TIMES, Apr. 21, 2010, at B1 [hereinafter *When Heart Devices Fail*].

[T]he Obama administration intends to push for more prosecutions of corporate officials, a move that is likely to please patient advocates but also to touch off intense debate.

John M. Taylor III, counselor to the F.D.A. commissioner, Dr. Margaret Hamburg, said that the agency would soon start training agency personnel about the reach of the Food, Drug and Cosmetic Act of 1938

Id. The Bureau of Justice Statistics reports that over a ten-year span, only 271 individuals were charged with such violations. Brent J. Gurney, Howard M. Shapiro & Robert A. Mays, *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA*, WILMERHALE F-27 n.45 (Dec. 3, 2007), available at http://www.wilmerhale.com/files/Publication/7b1c0866-a547-48c7-86d0-04d0449c03d7/Presentation/PublicationAttachment/c5eda281-2dae-4154-a0f8-13b817f25b52/The_Crime_of_Doing_Nothing.pdf.

2. Historically, the FDA and DOJ would not bring misdemeanor criminal charges against high-level executives when they neither participated in nor knew of the illegal conduct. Karen F. Green et al., *FDA Plans to Increase Strict Liability Criminal Prosecutions of Corporate Executives*, WILMERHALE (Mar. 11, 2010), available at http://www.wilmerhale.com/fda_plans_to_increase_strict_liability_criminal_prosecutions_of_corporate_executives_03-11-2010/.

3. The FDA is a constituent agency of the U.S. Department of Health & Human Services (HHS). *About FDA*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/default.htm> (last visited Feb. 4, 2012).

4. References made to the DOJ refer collectively to the U.S. Attorney's Offices for all districts across the United States. See *infra* note 26 (providing more information on how the FDA and DOJ operate to investigate and prosecute violations of the Federal Food, Drug, and Cosmetic Act).

5. Letter from Margaret A. Hamburg, M.D., Comm'r of Food and Drugs, to The Honorable Charles E. Grassley, Ranking Member, Senate Comm. on Fin. (Mar. 4, 2010), available at <http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf>. This letter explained steps taken to address the Committee's recommendation that the FDA "increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable." *Id.* It also noted that the "FDA will enhance its procedures to support the development of debarment and disqualification actions, and . . . will clarify the circumstances under which such administrative actions may proceed concurrently with pending criminal investigations and prosecutions." *Id.*

use of the controversial strict-liability misdemeanor provision⁶ of the Federal Food, Drug, and Cosmetic Act (FDCA).⁷ Without having to prove anything more than the executive's position on the corporate ladder,⁸ the government can sit back and watch guilty pleas roll in from powerless companies and their executives. The careers of many of these professional men and women will come to an undeserved and abrupt end when they are branded with a scarlet criminal record.⁹ The impetus behind this "new approach . . . reflects frustration with corporate recidivism even in the face of ramped-up fines, penalties and disgorgements."¹⁰ Yet, the proposed means are not narrowly tailored to achieve the ends. For example, when the

6. See 21 U.S.C. § 331 (2006) (detailing prohibited activities); 21 U.S.C. § 333(a) (2006) (imposing misdemeanor punishments of imprisonment for not more than one year or a fine of not more than \$1,000 or both for violations of § 331). If any such violation constitutes a second conviction or is found to have been committed "with the intent to defraud or mislead," the violation becomes a felony, carrying a maximum of three years of imprisonment and a fine of not more than \$10,000 or both. *Id.* Since the Supreme Court's endorsement, in *United States v. Park*, of the strict-liability provision in the FDCA, there have only been thirteen cases "in which the government charged a corporate executive with a misdemeanor FDCA violation based solely on the executive's 'responsible relation' to the violation." Gurney et al., *supra* note 1, at F-17, F-25 n.39. Records show that

the overall number of FDCA criminal prosecutions has been small, and misdemeanor prosecutions have been rare or nonexistent. This conservative use of the "responsible corporate officer" doctrine has also shown itself in a series of major settlements reached in criminal investigations of major [health care] companies since 2000. Each of these cases presented circumstances in which the government clearly could have charged individual executives with misdemeanor (if not felony) FDCA violations, or demanded misdemeanor pleas as part of any settlement. Yet none of these major settlements has involved *individual* criminal charges under the FDCA.

Id. at F-18 (emphasis added) (footnotes omitted).

7. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399a (2006).

8. John W. Lundquist & Sandra L. Conroy, *Defending Against Food & Drug Prosecutions*, THE CHAMPION, July 1997, at 20 ("[The FDA] does not often refer cases for criminal prosecution, but when it does, it can be a formidable adversary. Among the weapons at its disposal are a statutory scheme imposing strict liability on offenders and a doctrine of corporate responsibility that allows the FDA to target virtually any high-ranking corporate official simply by virtue of the position he or she occupies, even though the defendant performed no acts in furtherance of the alleged criminal violation.").

9. See generally Daniel R. Margolis, Mark R. Hellerer & Aaron S. Dyer, *FDA to Bring More Criminal Charges Against Executives for Companies' FDCA Violations*, PILLSBURY CLIENT ALERT (Mar. 9, 2010), <http://www.pillsburylaw.com/siteFiles/Publications/D98DF569EA917C29C8CE406316FA213C.pdf> (discussing the trend of bringing misdemeanor criminal actions against corporate executives under the FDCA). "[I]ndividuals convicted [of unintentional violations] are potentially vulnerable to administrative exclusion from federal health care programs, which in practice can rule out future employment in the health care industry." Green et al., *supra* note 2.

10. Ken Stier, *HHS Learns from SEC: Fraudster Execs Will be Barred from Drug Industry*, CNN MONEY (June 16, 2010), http://money.cnn.com/2010/06/04/news/companies/astrazeneca_pharmaceutical_fines.fortune/index.htm. Lewis Morris, chief counsel to the Inspector General, explains that the government is "going to start to use that authority in the appropriate circumstances to get high level executives out of companies, so that the company has a better shot at changing its behavior." *Id.*

failure of medical devices results in serious injury or death, using high-ranking executives as scapegoats,¹¹ rather than charging individuals who are directly responsible for the corporation's FDCA violation, will not combat recidivism¹² to achieve the ultimate goal of protecting the patients.¹³ From the government's point of view, this may be the quickest and easiest way, but it is not the most effective and fairest means to deter corporate criminal behavior.

Instead, the government should conduct focused investigations of the specific sect of the corporation responsible for the particular FDCA violation(s) to reveal the direct culprit(s), who are often in a lower echelon of the corporate hierarchy.¹⁴ To achieve this end, Congress should amend the misdemeanor provision of the FDCA, which currently allows corporate executives to be charged with crimes committed by employees or agents of their companies,¹⁵ even if they had no knowledge of the criminal activity.¹⁶ An open-ended, strict-liability criminal offense such as this could have the chilling effect of putting innocent businesspeople behind bars.¹⁷ The current policies behind investigations and prosecutions under the penalty provisions of the FDCA do not actually result in imprisoning guilty individuals.¹⁸ An amendment to this provision should require the government to prove criminal intent to some degree, depending on whether it chooses to charge under a misdemeanor or felony offense.¹⁹

11. This is not to say that all figurehead executives, CEOs, or presidents of companies are not culpable. See *United States v. Prigmore*, 243 F.3d 1, 3, 24 (1st Cir. 2001) (arguing that there was "substantial evidence" that the corporate executive defendants had in fact committed serious conspiracy "to defraud and impair the functioning of the [FDA] in connection with its oversight and regulation of [Class III] medical devices").

12. *When Heart Devices Fail*, *supra* note 1. In this note, however, I argue that this is the wrong means to achieve that end.

13. *Id.*

14. Oftentimes, managers of certain divisions of a company are directly responsible for ensuring compliance with regulations and monitoring a smaller group of employees. These individuals are likely to be more knowledgeable about violations and preventing them than the highest ranking figurehead of the corporation. See Assaf Hamdani, Essay, *Mens Rea and the Cost of Ignorance*, 93 VA. L. REV. 415, 447 (2007).

15. Gurney et al., *supra* note 1, at F-20.

16. Margolis et al., *supra* note 9, at 1.

17. Gurney et al., *supra* note 1, at F-18. This is not to say that there are not circumstances where figurehead executives may be criminally liable. In those situations, they should be held accountable.

18. In *United States v. Guidant LLC*, federal prosecutors and the executives on trial entered into plea agreements, dropping the prison sentence in exchange for higher monetary fines. *United States v. Guidant LLC*, 708 F. Supp. 2d 903, 921–22 (D. Minn. 2010).

19. In addition, the DOJ can impose administrative enforcement and civil sanctions if it finds criminal prosecution is inappropriate. These include "impos[ing] a 'clinical hold' on the drug or device, seek injunctive relief against violators, seize products and materials, debar or suspend organizations and individuals from operating in the regulated field, and impose civil monetary penalties." Lundquist & Conroy, *supra* note 8, at 21 (citing 21 C.F.R. § 312.42; 21 U.S.C. § 332(a); 21 U.S.C. § 334; 21 U.S.C. § 335(a); 21 U.S.C. §§ 333(f), 335(b), and 21 C.F.R. Part 17).

This note will focus on the criminal prosecutions under the FDCA of high-ranking executives of Class III medical device manufacturing companies.²⁰ In light of the recent announcements to aggressively prosecute executives of medical device corporations,²¹ and the prevalence of repeat violations of the FDCA by these companies,²² congressional action is necessary. Part I presents an overview of the FDA as a regulatory and enforcement agency with particular emphasis on the FDCA. Part II

20. The term medical “device” is defined within the FDCA as the following:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory which is--

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h).

There are 3 FDA regulatory classifications of medical devices: Class I, Class II and Class III. The classifications are assigned by the risk the medical device presents to the patient As the classification level increases, the risk to the patient and FDA regulatory control increase. . . .

. . . .

Class III medical devices have the most stringent regulatory controls. For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potentially unreasonable risk of illness or injury to the patient. Typically, Pre-Market Approval (PMA) submission to the FDA is required to allow marketing of a Class III medical device. . . . Examples of Class III devices that require PMA are: replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.

Gary Syring, *Overview: FDA Regulation of Medical Devices*, QUALITY & REG. ASSOCIATES (May 6, 2003), available at http://www.qrasupport.com/FDA_MED_DEVICE.html. For a critique of the FDA Class III medical device pre- and post-market approval process, see generally Michael VanBuren, Note, *Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441 (2007). The FDCA regulates several industries, and thus applies to food, pharmaceutical, medical device, and cosmetic companies; therefore, I caution the reader that my proposal to abolish the misdemeanor provision will, by default, affect all entities and individuals subject to the FDCA. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399.

21. See *supra* note 1.

22. John T. Boese, Beth C. McClain & Benjamin Hernandez-Stern, *Healthcare Behind Bars: The Use of Criminal Prosecutions in Forcing Corporate Compliance*, 3 J. HEALTH & LIFE SCI. L. 91, 94 (2009).

examines two seminal Supreme Court decisions²³ which established the controversial responsible corporate officer doctrine that enables the DOJ to prosecute the high-ranking corporate individuals.²⁴ Part III considers a recent case where a Class III medical device manufacturer—along with its top executives—was charged with violating the FDCA and the ensuing controversial plea agreement.²⁵ Part IV proposes an amendment to the FDCA that abolishes or revises the strict-liability misdemeanor provision. This will require prosecutors to prove criminal intent in the prosecution of corporate defendants. Finally, I conclude by critiquing the current prosecutorial policies and demonstrating how the revised FDCA and proposed new policies will achieve more effective and fair results.

I. INSIDE THE GOVERNING AGENCIES AND REGULATION

A. FEDERAL AGENCIES RESPONSIBLE FOR FDCA REGULATIONS AND PROSECUTION²⁶

The FDA is responsible for protecting the public health and safety by regulating industries that produce certain products, such as food, drugs, and cosmetics.²⁷ The agency investigates violations of the FDCA,²⁸ which

23. *United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Park*, 421 U.S. 658 (1975).

24. Todd S. Aagaard, *A Fresh Look at the Responsible Relation Doctrine*, 96 J. CRIM. L. & CRIMINOLOGY 1245, 1246 (2006). “Responsible corporate office doctrine” is used interchangeably with “responsible relation doctrine,” which is also commonly referred to as the “Park doctrine.”

25. *United States v. Guidant LLC*, 708 F. Supp. 2d 903, 907–08 (D. Minn. 2010).

26. White-collar criminal defense and complex civil litigation attorneys Gurney, Shapiro and Mays explain that

[m]ost criminal prosecutions [begin] with a visit from an FDA inspector, and charges rarely [are] filed without a prosecution recommendation from the agency. Today, there is a virtual constant stream of announcements of plea deals and multi-million dollar settlements between prosecutors, led by U.S. Attorneys’ Offices and the Office of Consumer Litigation, and pharmaceutical companies. These cases originate at DOJ, in the U.S. Attorneys’ Offices, with civil *qui tam* complaints, and elsewhere; probably few originate or are meaningfully steered by FDA. And it is not surprising that prosecutors who know less about how the industry in fact operates take a more favorable view of a provision that essentially puts the burden on executives to ensure perfect compliance with the FDCA throughout their companies.

At the same time, it makes much less sense today than it did in 1938 to indulge the fiction that executives—in pharmaceuticals or any other industry—can personally carry this burden. We no longer live in a world of neighborhood druggists and family-owned companies that directly supervise their own employees and operations. Modern-day pharmaceutical executives “supervise” the work of sometimes hundreds of thousands of employees and scores of corporate entities in dozens of countries.

Gurney, *supra* note 1, at F-22 (footnote omitted).

27. *About FDA*, *supra* note 3.

28. *Legislation*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last updated May 4, 2011).

regulates the manufacture and distribution of, *inter alia*, medical devices to ensure efficacy and safety.²⁹ Pursuant to the FDCA's goals as a public health law, FDCA violations are punishable by criminal penalties, as well as civil sanctions.³⁰

Within the FDA, the Office of Criminal Investigations (OCI)³¹ conducts criminal investigations of companies and individuals suspected of violating FDA regulations and "collect[s] evidence to support successful prosecutions."³² OCI agents gather information and evidence and refer the case to the DOJ—specifically, to the U.S. Attorney's Office in the appropriate jurisdiction.³³ As a constituent of the FDA, OCI plays an integral part in the corporate investigation, providing U.S. Attorney's Offices, which typically lack expertise in these medical industries, with expert information about sophisticated FDA-regulated products.³⁴ While the DOJ has the ultimate discretion to dismiss or prosecute alleged FDCA violations,³⁵ U.S. Attorney's Offices secure guilty pleas or convictions in a significant number of OCI referrals.³⁶ Those companies and individuals found guilty under the FDCA can expect to pay multi-million dollar fines

29. *What does FDA do?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> (last updated Dec. 17, 2010) [hereinafter *What does FDA do?*].

30. Carol Benjamin & Betsy J. Floman, *Federal Food and Drug Act Violations*, 31 AM. CRIM. L. REV. 629, 630 (1994); *see also* 21 U.S.C. § 333 (2006).

31. OCI was formed in 1992. From its beginning to 2009, OCI obtained 4,392 convictions that resulted in the imposition of \$9.89 billion in fines and restitution and forfeited assets worth over \$1 billion. Hamburg, *supra* note 5, at 1.

32. *Inspections, Compliance, Enforcement, and Criminal Investigations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/CriminalInvestigations/ucm123027.htm> (last updated May 29, 2009).

33. Lundquist & Conroy, *supra* note 8, at 21.

34. *FDA Criminal Unit Guards Public Health*, U.S. FOOD & DRUG ADMIN. (Jan. 2011), available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm048718.pdf> [hereinafter *FDA Criminal Unit Guards Public Health*].

35. Lundquist & Conroy, *supra* note 8, at 21. ("Despite the fact that the decision to pursue criminal prosecution is one of pure discretion, the presence of certain factors are predictive of prosecution. . . . In addition, if the violation was intentional, easily detectable, preventable, fraudulent, or life threatening, prosecution will be more likely. Violations which cause economic injury are viewed no differently than violations which cause injury to the public health." (footnotes omitted)).

36. *See FDA Criminal Unit Guards Public Health*, *supra* note 34, at 2; *FDA Law Enforcers Protect Consumers' Health Inside the Office of Criminal Investigations*, FDA (Aug. 19, 2008, 8:18 PM), http://foodconsumer.org/7777/8888/L_aws_amp_Reg_64/081908182008_FDA_Law_Enforcers_Protect_Consumers_Health_Inside_the_Office_of_Criminal_Investigations.shtml ("In a typical year, FDA's Special Agents will investigate about 1,000 criminal cases resulting in the arrests of hundreds of suspected violators of public health laws. On average, 200 criminal suspects are convicted each year as the result of OCI investigations. From 1993 to [2008], OCI has made 4,593 arrests that resulted in 3,546 convictions and more than \$5.7 billion in fines and restitutions.").

and are threatened with federal prison sentences.³⁷ The FDA has been most active in prosecuting medical device companies for FDCA violations.³⁸

Earlier this year, the U.S. Government Accountability Office (GAO) put the FDA's "hand to the fire" for inadequate oversight of OCI.³⁹ In a scathing report, GAO found that the FDA "lacks performance measures that could enhance its oversight of OCI by allowing it to assess OCI's overall success."⁴⁰ Notwithstanding its concession "that OCI's impact on protecting the public health cannot be measured solely by the number of arrests and convictions,"⁴¹ GAO insisted on the FDA implementing an adequate review process that would focus on *accountability*.⁴² Pursuant to this report, OCI announced several changes to improve its effectiveness—the most controversial of which is "increas[ing] the appropriate use of misdemeanor prosecutions . . . to hold responsible corporate officials accountable."⁴³ In addition, the office will "enhance its procedures to support the development of debarment and disqualification actions."⁴⁴ OCI hopes these changes will satisfy GAO's mandates to crack down on corporate recidivism.⁴⁵ Nevertheless, it seems as though OCI will be taking the blame out on corporate executives for its own inadequacies.

B. THE FDCA

The FDCA was originally passed by Congress and signed into law in 1938.⁴⁶ Replacing the ineffective 1906 Food and Drugs Act,⁴⁷ the FDCA was adopted in response to a public outcry that ensued following over 100 deaths caused by an adulterated pharmaceutical.⁴⁸ The drug company produced an untested "wonder drug" marketed for pediatric patients, which

37. *FDA Criminal Unit Guards Public Health*, *supra* note 34, at 1. "Criminal charges [against individual defendants] will generally not be dismissed in return for a guilty plea by a corporate defendant." Benjamin & Floman, *supra* note 30, at 641.

38. Lundquist & Conroy, *supra* note 8, at 6. FDA also actively prosecutes FDCA violations in areas of adulteration, misbranding, and clinical investigations. *Id.*

39. Shepard Mullin, *FDA Looks to Boost Criminal Prosecutions*, FDA LAW BLOG UPDATE (Mar. 11, 2010, 6:44 AM), <http://www.fdalawblog.com/2010/03/articles/legislation/fda-looks-to-boost-criminal-prosecutions/>; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-221, FOOD AND DRUG ADMINISTRATION: IMPROVED MONITORING AND DEVELOPMENT OF PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF CRIMINAL AND MISCONDUCT INVESTIGATIONS 10 (2010), [hereinafter GAO REPORT], *available at* <http://www.gao.gov/new.items/d10221.pdf>.

40. GAO REPORT, *supra* note 39, at 10.

41. *Id.* at 17.

42. *Id.* at 25.

43. Hamburg, *supra* note 5.

44. *Id.*

45. *Id.*

46. *FDA History-Part II*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> (last updated June 6, 2009).

47. *Id.*

48. *Id.*

unknowingly turned out to be highly toxic.⁴⁹ This event propelled Congress and President Roosevelt to enact a regulatory law to standardize and control the production, approval processes, and labeling of drugs, medical devices, food, and cosmetics.⁵⁰ The FDCA has been amended several times over the years, evolving into its current powerful and comprehensive form.⁵¹

Title 21 in the Code of Federal Regulations Parts 800 et seq.,⁵² promulgated by the FDA⁵³ pursuant to the FDCA (21 U.S.C. § 331 et seq.),⁵⁴ codifies specific rules and regulations applicable to certain entities, such as medical device manufacturers.⁵⁵ It sets forth guidelines ranging from the classification of medical devices⁵⁶ and pre- and post-market approval requirements,⁵⁷ including proper labeling and distribution procedures⁵⁸ to providing definitions of all relevant industry terms.⁵⁹ The FDA enforces these regulations to promote the safety and efficacy of products' intended uses.⁶⁰

Of particular importance in this note are the criminal penalty terms set forth in the FDCA.⁶¹ The misdemeanor provision (§ 333(a)(1)) provides that “[a]ny person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.”⁶² Section 333(a)(2) stipulates,

Notwithstanding the [misdemeanor provisions], 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,

49. *Id.*

50. *Id.*; *FDA History-Part IV*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055137.htm> (last updated June 18, 2009).

51. *FDA History-Part III*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055118.htm> (last updated June 18, 2009).

52. Food and Drugs, 21 C.F.R. §§ 800–1299 (2010).

53. *Code of Federal Regulations – Title 21 – Food and Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm> (last updated June 19, 2009).

54. Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301–399(a) (2006).

55. *See, e.g., Rules & Regulations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm> (last updated June 18, 2009).

56. *Device Classification*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last updated Apr. 27, 2009).

57. *See, e.g., How to Market Your Device*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm> (last updated Mar. 18, 2010) [hereinafter *How to Market Your Device*]; *Postmarket Requirements (Devices)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/default.htm> (last updated Mar. 13, 2012).

58. *How to Market Your Device*, *supra* note 57.

59. Food and Drugs, 21 C.F.R. §§ 800–1299 (2010).

60. *See, e.g., What does FDA do?*, *supra* note 29.

61. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 333(a) (2006).

62. *Id.* § 333(a)(1).

such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.⁶³

A close examination of these two provisions highlights some serious issues. First, the misdemeanor provision is a strict-liability offense, requiring no proof of any knowledge with respect to the alleged violation.⁶⁴ Second, while the felony provision requires proof of “intent to defraud or mislead” under some circumstances, it can also be applied when an individual is charged a second time under the misdemeanor provision.⁶⁵ In effect, an individual executive can be charged with a misdemeanor violation under § 333(a)(1) and several years later be charged with a second misdemeanor violation which would then constitute a felony according to § 333(a)(2).⁶⁶ This could happen even if the individual executive is named in criminal prosecutions under § 333(a) when working for different companies several years apart.⁶⁷ Although this will likely have a deterrent effect, it is an excessive punishment to impose on these individuals. Congress increased the maximum fines, requiring individuals to pay \$100,000 per count and \$250,000 if a death occurred, and corporations to pay \$200,000 to \$500,000 for each count charged.⁶⁸ Additionally, amendments made to the Sentencing Guidelines in 2008 resulted in an increased likelihood of prison time for misdemeanor convictions under the FDCA.⁶⁹ These two changes “stacked the cards” in the government’s favor even more, causing individuals charged with misdemeanor offenses to enter into plea agreements, hoping to perhaps exchange a prison sentence for an increased fine.⁷⁰ Thus, corporate executives have no other choice but to plead guilty and pay the ramped up fines to avoid a scarlet criminal record and jail time.

II. JUSTICE SERVED OR JUSTICE DENIED?

A short primer on criminal law is necessary to fully understand why the FDCA’s strict-liability penalty provision needs to be amended.

63. 21 U.S.C. § 333(a)(2) (2006).

64. *Monograph, Office of Consumer Litigation*, U.S. DEP’T JUSTICE, http://www.justice.gov/civil/docs_forms/OCPL_Monograph.pdf, 4 (last visited Apr. 15, 2012).

65. 21 U.S.C. § 333(a)(2).

66. *Id.*

67. See Gurney et al., *supra* note 1, F-17.

68. Melissa Gilmore & Brian K. Parker, *FDA Sharpens Enforcement Teeth: Pre-Warning Letter Executive Misdemeanor Charges Expected to Rise*, MCGUIREWOODS (Apr. 27, 2010), <http://www.mcguirewoods.com/news-resources/item.asp?item=4722>.

69. Margolis et al., *supra* note 9, at 2.

70. *FDA Announces New Push to Prosecute Corporate Officers and Executives for No-Intent Crimes*, SKADDEN, 3 (Mar. 5, 2010), <http://www.skadden.com/Index.cfm?contentID=51&itemID=2003> [hereinafter *FDA Announces New Push*] (noting that three Purdue Pharma executives who were charged with violations of the FDCA and accepted a strict-liability misdemeanor plea paid \$34 million in criminal fines).

A. A BACKGROUND ON CRIMINAL LAW

The principle purpose of criminal law is to prevent harm to society.⁷¹ Any criminal offense is considered to be more reprehensible than even the most outrageous civil violation.⁷² Criminals are generally viewed as menaces to society, who ought to be punished for their wrongdoing.⁷³ Therefore, our American criminal justice system strives to discourage certain conduct that does not fit within socially “normal” behavior.⁷⁴ Because of this, criminal punishment is markedly different from civil sanctions.⁷⁵ Usually, regardless of how egregious a civil liability is, the worst punishment will only be monetary.⁷⁶ Criminal conduct, however, is punished by both monetary sanctions and the threat of incarceration; in some instances, the death penalty may even be imposed. The stigma behind being accused and convicted of any crime is so offensive that even if it results in a mere “slap on the wrist” and a fine, the devastation to the individual’s integrity remains.⁷⁷

Another important distinction between civil and criminal liability is that the government is held to a higher burden of proof than parties in civil cases. The prosecutor must prove every material element of the offense beyond a reasonable doubt⁷⁸ whereas the civil burden of proof is a mere preponderance of the evidence.⁷⁹ The legal principle—“it is better that ten guilty persons escape, than that one innocent suffer”⁸⁰—coined by English jurist William Blackstone signifies the magnitude and importance of the constitutional protection of a defendant’s individual liberties and freedom.

71. JOSHUA DRESSLER, UNDERSTANDING CRIMINAL LAW 1 (Matthew Bender & Company, Inc. 5th ed. 2009) [hereinafter UNDERSTANDING CRIMINAL LAW].

72. JOSHUA DRESSLER, CASES AND MATERIALS ON CRIMINAL LAW 3 (Thompson/West, 4th ed. 2007) [hereinafter CASES AND MATERIALS ON CRIMINAL LAW].

73. *Id.* at 2.

74. *Id.* at 3.

75. UNDERSTANDING CRIMINAL LAW, *supra* note 71, at 2.

76. *See id.* Criminal law is distinguished from civil by the “societal condemnation and stigma that accompanies the conviction.” *Id.*

77. Corporate executives will suffer from the “personal and professional stain of simply being charged with a crime in the first instance.” Gurney et al., *supra* note 1, at F-17.

78. UNDERSTANDING CRIMINAL LAW, *supra* note 71, at 68.

79. “Preponderance of the evidence” is defined as

[t]he greater weight of the evidence, not necessarily established by the greater number of witnesses testifying to a fact but by evidence that has the most convincing force; superior evidentiary weight that, though not sufficient to free the mind wholly from all reasonable doubt, is still sufficient to incline a fair and impartial mind to one side of the issue rather than the other. This is the burden of proof in most civil trials, in which the jury is instructed to find for the party that, on the whole, has the stronger evidence, however slight the edge may be.

BLACK’S LAW DICTIONARY 556 (5th pocket ed. 2004).

80. 4 WILLIAM BLACKSTONE, COMMENTARIES *352.

In general, a criminal act contains two components: the *actus reus* and the *mens rea*.⁸¹ The *actus reus* (i.e., the prohibited act that causes a social harm) is required for every crime.⁸² Typically, this is defined as an affirmative action; however, albeit extremely uncommon, a person can be prosecuted for failing to act, known as a criminal act of omission.⁸³ Therefore, the *actus reus* is best understood as the prohibition of certain conduct that causes a specific result by either action or inaction.⁸⁴ Following this principle, one cannot be criminally charged with a “status offense”—that is, simply possessing some state of *being*, such as alcoholism, drug addiction, or homelessness.⁸⁵ While every offense must define a particular forbidden act,⁸⁶ not all crimes require a culpable state of mind.⁸⁷

Despite being “deeply rooted in our legal tradition as one of our first principles of law,”⁸⁸ there is much debate as to the precise understanding of what is the *mens rea*.⁸⁹ In the general sense, *mens rea* connotes a “morally blameworthy state of mind.”⁹⁰ But the *mens rea* also has a more narrowly tailored definition, which is specifically associated with each *actus reus* defined in the offense.⁹¹ Scholars call this the “elemental” definition of *mens rea*.⁹² There are four levels of culpability: purpose, knowledge, recklessness, and negligence.⁹³ The most serious offenses, which carry the greatest penalties, require the prosecutor to prove the defendant committed the act purposely or knowingly. In some instances, however, penal codes assign lower levels of mental culpability (e.g., recklessness or criminal negligence) to serious offenses where it is far too difficult to prove the defendant’s mental state, or where the act is considered so reprehensible or affects a large number of people that the legislature does not require proof of any *mens rea*.⁹⁴ In other words, it does not matter that the defendant did or did not intend to commit the offensive act; the fact that he committed the

81. UNDERSTANDING CRIMINAL LAW, *supra* note 71, at 85.

82. *Id.*

83. *Id.* at 105.

84. *Id.* at 85, 105.

85. *Id.* at 96–100.

86. *Id.* at 87.

87. *Id.* at 145.

88. *United States v. Cordoba-Hincapie*, 825 F. Supp. 485, 489 (E.D.N.Y. 1993), *discussed in* CASES AND MATERIALS ON CRIMINAL LAW, *supra* note 72, at 147.

89. CASE AND MATERIALS ON CRIMINAL LAW, *supra* note 72, at 148 (“I have always thought that most of the difficulties as to the *mens rea* was due to having no precise understanding what the *mens rea* is.”) (quoting 1 Holmes-Laski Letters 4 (M. Wolfe, ed. 1953) (letter of July 14, 1916) (Oliver Wendell Holmes)).

90. CASES AND MATERIALS ON CRIMINAL LAW, *supra* note 72, at 148.

91. *Id.*

92. *Id.*

93. AM. LAW INST., MODEL PENAL CODE AND COMMENTARIES § 2.02 cmt. (Official Draft and Explanatory Notes 1985).

94. *See generally* UNDERSTANDING CRIMINAL LAW, *supra* note 71, at 145–51.

act is enough to convict. These are called strict-liability offenses.⁹⁵ Yet, these types of offenses are rare exceptions to the rule. Strict liability is most often applied in the “public welfare” context, where penalties for violations are usually minor, such as a small monetary fine or a very short jail sentence.⁹⁶

There is a strong presumption against strict liability.⁹⁷ According to the canons of statutory interpretation, when there is no *mens rea* written in the statute of a certain offense, it is assumed that at least criminal negligence is attached and must be proven.⁹⁸

In summary, crimes generally consist of the *actus reus* and *mens rea*.⁹⁹ The *actus reus* is usually a voluntary act,¹⁰⁰ but in rare instances can also be a criminal act of omission.¹⁰¹ While strict-liability offenses may consist of just *actus reus*,¹⁰² the defendant can never be accused of just a culpable state of mind.¹⁰³ These principles are graphically summarized below and illustrate how the FDCA’s misdemeanor provision does not fall within any category of criminal offenses. Therefore, it belongs outside the ambit of criminal law, unless an amendment is made to include some level of mental culpability that will rectify its current misinterpretation and application. The following chart provides a comparison of the elements of the rape and homicide statutes to the FDCA’s misdemeanor provision.

Comparison of Elements in Common Crimes to the FDCA’s Misdemeanor Provision		
	<i>Mens rea</i> (purposely, knowingly, recklessly, or negligently)	<i>Actus reus</i> (voluntary act or legal omission causing social harm)
No crime	No <i>mens rea</i>	No act
Rape (MPC § 213.1)	No <i>mens rea</i> (strict liability)	Engages in sexual intercourse with a female by means of force, threats of bodily injury, or intoxicants or while the female is unconscious or less than ten years old.

95. See, e.g., BLACK’S LAW DICTIONARY 427 (3rd pocket ed. 2006) (defining “strict liability” as “liability that does not depend on actual negligence or intent to harm, but that is based on the breach of an absolute duty to make something safe”).

96. UNDERSTANDING CRIMINAL LAW, *supra* note 71, at 147.

97. *Id.* at 146.

98. *Id.*

99. *Id.* at 85.

100. *Id.* at 87.

101. *Id.* at 105.

102. *Id.* at 145.

103. *Id.* at 86–87.

Comparison of Elements in Common Crimes to the FDCA's Misdemeanor Provision		
	<i>Mens rea</i> (purposely, knowingly, recklessly, or negligently)	<i>Actus reus</i> (voluntary act or legal omission causing social harm)
Negligent Homicide (MPC § 210.4)	Negligently	Causes the death of another human being
Manslaughter (MPC § 210.3)	Recklessly	Causes the death of another human being
Murder (MPC § 210.2)	Purposely or knowingly	Causes the death of another human being
The FDCA's Misdemeanor Provision (21 U.S.C. § 333(a))	No <i>mens rea</i> (strict liability)	No act—executives “held accountable for criminal misdeeds simply by virtue of their position” ¹⁰⁴ (i.e., criminal omission)

While a strict-liability offense may be appropriate in the context of FDCA violations because it is a public welfare offense, the misdemeanor provision of the FDCA has not only been interpreted as strict liability, but also criminalizes an act of omission.¹⁰⁵ Nothing could be more contrary to the fundamental principles of American criminal law.¹⁰⁶ It combines the rarest form of *actus reus* with the rare strict-liability principle to form a highly controversial and unfair criminal offense. High-ranking executives of health care companies can be charged based on either their status in the corporate hierarchy, or their failure to act, and without wrongful intent or knowledge of any criminal conduct.¹⁰⁷ It could not reasonably have been Congress' intent to impose criminal penalties for merely possessing a certain position or status in one's place of employment. Nor could it reasonably have been Congress' intent to criminalize an executive's failure to monitor each employee's conduct without having to prove any intent in his failure to act. As discussed above, canons of statutory interpretation require that any criminal offense that does not expressly include a mental

104. Mark Carlisle Levy & Gregory G. Schwab, *The Responsible Corporate Officer Doctrine—The Doctrine no Longer Sleeps for Drug and Device Companies*, SAUL EWING UPDATE, 7 (July/Aug. 2010), http://www.saul.com/media/article/1018_PDF_2736.pdf.

105. See Gurney et al., *supra* note 1, at F-10; Aagaard, *supra* note 24, at 1274–85 (discussing criminal omissions and finding that the responsible relation doctrine is a form of criminal omission, which “raises more questions than it answers” because “even morally reprehensible omissions, are not punished as crimes”).

106. UNDERSTANDING CRIMINAL LAW, *supra* note 71, at 85.

107. Gurney et al., *supra* note 1, at F-9.

culpability deemed by default must impose at least criminal negligence. Therefore, the FDCA's misdemeanor provision should only be interpreted as an executive's negligent or reckless failure to monitor employees whose conduct has caused a harm.

It is also important to note that it has long been standard prosecutorial policy not to charge individuals with misdemeanor violations of the FDCA specifically because it was unfair to make a criminal out of an individual executive without proving any knowledge of the wrongdoing.¹⁰⁸ Instead, individual executives would only be prosecuted under the felony provision when there was clear intent involved.¹⁰⁹

B. THE RESPONSIBLE CORPORATE OFFICER DOCTRINE

In 1943, the Supreme Court authorized no-intent misdemeanor prosecutions in *Dotterweich v. United States*,¹¹⁰ and again in 1975 in *United States v. Park*.¹¹¹ Both cases involved violations of § 333(a)(1) of the FDCA by FDA-regulated companies and resulted in convictions of the accused high-ranking corporate executives.¹¹² The defendant in *Dotterweich*, who was the president and general manager of a pharmaceutical company, was charged and convicted for three counts of pharmaceutical misbranding

based on a single order from a single physician. One drug in the shipment included an ingredient that had been removed from the official formula listed on the "National Formulary." Another was less potent than required by the government and than indicated on the label. Dotterweich had no personal connection to the particular shipment for which he was charged; his only connection was that he was "in general charge of the corporation's business and had given general instructions to its employees to fill orders received from physicians." He was convicted, while the corporation was acquitted.¹¹³

The rationale behind the court's conclusion to "dispense[] with the conventional requirement for criminal conduct—awareness of some wrongdoing" was based on the "interest of the larger good [to put] the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."¹¹⁴

108. *When Heart Devices Fail*, *supra* note 1, at 4.

109. *Id.*

110. *See generally* *United States v. Dotterweich*, 320 U.S. 277 (1943).

111. *See generally* *United States v. Park*, 421 U.S. 658 (1975).

112. *See generally* *Dotterweich*, 320 U.S. 277; *Park*, 421 U.S. 658.

113. Gurney et al., *supra* note 1, at F-10 (quoting *United States v. Buffalo Pharmacal Co.*, 131 F.2d 500, 501 (2d Cir. 1942), *rev'd sub nom.*, *United States v. Dotterweich*, 320 U.S. 277, 278 (1943)).

114. *Dotterweich*, 320 U.S. at 281.

Over thirty years later, the Court returned to this issue and clarified *Dotterweich's* responsible relation doctrine in *Park*.¹¹⁵ In *Park*, the president of a large national food store chain was charged and convicted with five counts of violating the FDCA for causing the adulteration of food due to rat infestations in the company's warehouses.¹¹⁶ *Park* was fully aware that the system to ensure sanitary conditions was inadequate, and although he was responsible for ensuring that sanitation measures were sufficient, he failed to implement a more effective system.¹¹⁷ Notwithstanding his awareness of the violations, *Park*, like *Dotterweich*, was convicted based on his status as a "supervisor[] or manager[] who st[ood] in 'responsible relation' to the violation by virtue of [his] authority and responsibility."¹¹⁸

The responsible relation doctrine is faulty because in neither of the seminal cases does the Supreme Court's rationale "clearly explain from what authority the doctrine is derived [and] how the doctrine relates to the elements of the offense."¹¹⁹ Scholars have attempted to justify the doctrine based on the need to encourage corporate executives to avoid conduct that threatens the public health and safety, despite the recognition that this will be a "potentially onerous . . . obligation" to impose on these individuals.¹²⁰ This deterrence explanation overlooks the fact that almost every criminal offense poses an equally grave threat to public health and welfare¹²¹ (e.g., homicide statutes). Furthermore, criminal law generally does not set out to prohibit acts of omission and hold individuals liable for failing to prevent certain conduct or unwanted results from occurring.¹²²

115. *Park*, 421 U.S. 658.

116. *Id.*

117. *Id.* at 664–65.

118. Aagaard, *supra* note 24, at 1251. The FDCA has been interpreted to extend "to all those having such 'a responsible share in the furtherance of the transaction which the statute outlaws.'" Gurney et al., *supra* note 1, at F-10 (quoting *Dotterweich*, 320 U.S. at 284).

119. Aagaard, *supra* note 24, at 1251. See also the Fourth Circuit's analysis in *Park*, finding that

[t]he Government argues that the conviction may be predicated solely upon a showing that the defendant, *Park*, was the President of the offending corporation. The error here is that the Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action'; *Dotterweich* dispenses with the need to prove the first of those elements but not the second.

United States v. *Park*, 499 F.2d 839, 841 (4th Cir. 1974) (citation omitted).

120. Aagaard, *supra* note 24, at 1246.

121. See CASES AND MATERIALS ON CRIMINAL LAW, *supra* note 72, at 2 (quoting George K. Gardner, *Bailey v. Richardson and the Constitution of the United States*, 33 B.U. L. REV. 176, 196 (1953)) ("What distinguishes a criminal from a civil sanction and all that distinguishes it, it is ventured, is the judgment of community condemnation which accompanies and justifies its imposition. . . . 'It is the expression of the community's hatred, fear, or contempt for the convict which alone characterizes physical hardship as punishment.'").

122. See discussion *supra* Part II.A.

Some argue that although American law disfavors making a failure to act a criminal offense,¹²³ the responsible relation doctrine is a form of criminal omission¹²⁴ that “substitutes a breach of a duty to act for the conventional act requirement.”¹²⁵ Nonetheless, the FDCA does not delineate a wrongful act at all, but rather causes a ‘responsible officer’ to be guilty merely by his status¹²⁶ in the corporate hierarchy.¹²⁷ This raises serious constitutional issues as it violates an individual’s due process rights.¹²⁸

123. Aagaard, *supra* note 24, at 1275.

124. *Id.* at 1274. The author clarifies this point in noting that “the defendant is liable for his failure to act to prevent or correct a violation, rather than for affirmative misconduct.” *Id.*

125. *Id.* at 1269.; To further this point, a well-known law firm explained that

[c]ommission of the crime requires only an act. The act need not have been intentional or reckless, or even negligent. It is irrelevant what the defendant knew or should have known. If a drug is misbranded or adulterated, or if a misbranded or adulterated drug is distributed . . . someone . . . has committed a crime.

Gurney et al., *supra* note 1, at F-10.

126. An expert on directors’ and officers’ liability insurance issues discusses in his blog:

[T]he idea that liability can be imposed on an individual for corporate misconduct, in apparent disregard of the corporate form and without culpable involvement or even a requirement of a culpable state of mind, seems inconsistent with the most basic concepts surrounding the corporate form. The doctrine arguably imposes liability for nothing more than a person’s status. The word “responsible” in the doctrine’s name does not mean that the individual is responsible for the *misconduct*, but on that that the individual is responsible for the *corporation*.

Kevin LaCroix, *More About the Responsible Corporate Officer Doctrine*, D&O DIARY (Mar. 8, 2010, 4:24 AM), <http://www.dandodiary.com/2010/03/articles/corporate-governance/more-about-the-responsible-corporate-officer-doctrine/print.html> (emphasis in original).

127. This point is discussed in WilmerHale’s publication, stating that

[e]ven more remarkable is that for certain classes of people, even a bad act is unnecessary to secure a criminal conviction under the FDCA. In particular, the executives and managers of the companies that make, distribute, and sell pharmaceuticals can be convicted for violating the FDCA without having personally participated in the act being punished or having been an accessory to it. For these persons, it is enough to secure a conviction that (a) a prohibited act took place somewhere within the company, and (b) the defendant’s position within the company was one that gave him or her responsibility and authority either to prevent the violation or to correct it. In other words, the crime is being in the wrong position at the wrong time. It is not just strict liability; it is strict, *vicarious* liability.

Gurney et al., *supra* note 1, at F-10 (emphasis in original).

128. Aagaard, *supra* note 24, at 1269. In deciding *United States v. Park*, the Fourth Circuit stated:

It is argued by the prosecution that the requirement of such proof will make enforcement more difficult. Nevertheless, the requirements of due process are intended to favor fairness and justice over ease of enforcement. We perceive nothing harsh about requiring proof of personal wrongdoing before sanctioning the imposition of criminal penalties.

United States v. Park, 499 F.2d 839, 842 (4th Cir. 1974).

Another attempt to justify the “omission” rationale is the idea that “responsible” corporate officers “[assume] a contractual obligation to protect the general public from certain hazards.”¹²⁹ This argument also quickly loses force because basic contract, business association, and agency law all dictate that in this context the officer has established a relationship with the *corporation*, not the public.¹³⁰ For example, an officer’s violation of the FDCA would make the medical device company, not the officer, liable to the public based on the doctrine of *respondeat superior*.¹³¹

The responsible corporate officer doctrine is not only applicable to high-ranking officers.¹³² Thus, it should be used to prosecute lower-level managers and employees who have direct responsibility for the conduct that caused an FDCA violation. Any employee holding a position of authority and responsibility who is accountable for even the smallest aspect of the corporate operations should be held criminally liable under this doctrine, not just the CEO or other figurehead executive.¹³³ To further illustrate this point, imagine Acme, Inc., a medical device manufacturing company of heart defibrillators that has numerous worldwide corporate affiliations assisting with the production of its medical devices. One such affiliation is with a foreign manufacturer that produces a component of the heart device, which is incorporated into Acme’s product. Suppose Smith, a lower-level manager of that foreign corporation, fails to monitor the employees for whom he is directly responsible, and a manufacturing error results, causing some of the devices to malfunction. Several years later, perhaps even after Smith has left the corporation, the manufacturing error is discovered when patients are harmed as a result of the malfunction in Acme’s medical device. Who is to blame? According to the responsible corporate officer doctrine, all of Acme’s managers and executives who stand in ‘responsible relation’ to the manufacturing error could be held liable. But this is not how the responsible corporate officer doctrine is currently being used with the FDCA. It would make more sense if Smith were held liable since he was directly responsible for the error and should have at least informed his manager of it. In fact, this would be the only rational way to remedy and prevent similar errors from occurring in the future. Punishing only the highest-ranking corporate officer will do nothing to deter lower-level managers from committing similar violations in the future since they are not being held accountable. Some argue that the high-ranking corporate official’s job responsibility is to oversee all corporate operations and ensure

129. Aagaard, *supra* note 24, at 1281.

130. *Id.* at 1282. The Fourth Circuit explains: “It is the defendant’s relation to the criminal acts, not merely his relation to the corporation, which the jury must consider; 21 U.S.C. § 331 is concerned with criminal conduct and not proprietary relationships.” *Park*, 499 F.2d at 841.

131. See Ved P. Nanda, *Corporate Criminal Liability in the United States: Is a New Approach Warranted?*, 58 AM. J. CORP. L. 605, 607 (2010).

132. Aagaard, *supra* note 24, at 1286.

133. *Id.*

that the medical device company does not violate the FDCA and any other applicable laws.¹³⁴ Yet, it is irrational to believe that one individual can monitor and *know everything* about every aspect of the corporation and its affiliate corporations, especially since medical device manufacturers employ thousands of people and have operations spanning across the country and even around the globe.¹³⁵

Another important implication arising from prosecutions based on the responsible corporate officer doctrine is the difficulty, if not impossibility, of individual officers to successfully plead not guilty when the company chooses to plead guilty.¹³⁶ Basic principles of business associations and agency law define a corporation as an entity that can only act through its agents (i.e., individual employees). Considering this, it would be difficult for a jury to reconcile finding the officer not guilty when the corporation pled guilty to the same FDCA violation. This is further complicated by the fact that plea agreements made with the corporation typically require full disclosure of company information to assist with the prosecution of the individual executive(s). The executive is essentially stripped of his constitutional rights because he is left with no other choice than to plead guilty and face the harsh criminal penalties imposed by the FDCA. With everything “stacked in favor” of the government, he does not have a fair chance at trial. Even if the individual decides to plead not guilty to charges brought based on his status as a “responsible corporate officer,” there are very few defenses available.¹³⁷ Furthermore, the available defenses are

134. *Id.* at 1282.

135. Gurney et al., *supra* note 1, at F-22.

136. FDA-regulated companies will often find it more cost effective and beneficial for the long-term survival of the company to plead guilty. FDA guidelines and DOJ manuals indicate that they will be more lenient on companies that plead guilty and cooperate with the FDA investigation and prosecution. Cooperation often involves the company assisting the government with the prosecution of the high-ranking corporate officials, who have also been charged with the FDCA violation(s). These corporations are threatened with the possibility of being barred from having future products obtain FDA-approval, which would undoubtedly negatively impact the corporations' prosperity. Clearly, so as to not breach their fiduciary duty, the boards of directors will choose to cooperate with the government, regardless of how this will affect the individuals who are charged. It should also be recognized that no matter how comprehensive a corporation's compliance program is, other errors or violations may exist at any given time. Therefore, it is in the company's best interest to plead guilty because upon investigation, the government may find other violations, and for failing to enter into a plea agreement to the alleged charges, the government could then aggressively prosecute the company for these other violations. The company is cornered just as much as the individual corporate executives are in these situations. See generally Albert W. Alschuler, *Two Ways to Think About the Punishment of Corporations*, 46 AM. CRIM. L. REV. 1359, 1380–82 (2009); see also Nanda, *supra* note 131, at 613–14.

137. Lundquist & Conroy, *supra* note 8, at 24–25. One expert outlined the following defenses to FDCA violation allegations:

[C]riminal estoppel is based on the notion that when those responsible for enforcing the law are aware of the allegedly violative behavior, yet explicitly or implicitly condone or ignore it, justice would dictate that those same officials not be allowed to later punish that behavior.

“amorphous and ambiguous,” which raises serious fairness issues about the doctrine’s use.¹³⁸ Being charged automatically imputes guilt.¹³⁹

III. UNITED STATES V. GUIDANT

A. MAJOR MEDICAL DEVICE MANUFACTURER CHARGED WITH VIOLATIONS OF THE FDCA

On February 25, 2010, Guidant, LLC, a medical device manufacturer, and its top executives, were charged with criminal violations of the FDCA related to safety problems with some of the company’s implantable cardioverter defibrillators (ICDs).¹⁴⁰ After a four-year investigation, a criminal information was filed in the District Court for the District of Minnesota alleging that Guidant and its executives concealed information regarding catastrophic failures of some of the company’s ICDs.¹⁴¹

. . . The defendant must show that he relied on the misinformation and that reliance was reasonable.

....

Substantive defenses, of course, may be asserted in prosecutions under the FDCA. Some of these defenses may center on such issues as whether the food was, indeed, adulterated, whether the drug was mislabeled, or whether false statements were actually made.

....

Impossibility was recognized as a defense to FDCA violations in *United States v. Park*. . . . [The impossibility defense] “is raised when defendant introduces sufficient evidence of the exercise of extraordinary care to justify placing an additional burden on the government — that of proving beyond a reasonable doubt that had defendant indeed exercised such extraordinary care, he could have prevented or corrected these violations.”

Id. (emphasis in original) (citing 421 U.S. 658 (1975); *United States v. Gel Spice Co.*, 601 F. Supp. 1205, 1213 (E.D.N.Y. 1984)).

138. Michael W. Peregrine & Joshua T. Buchman, *Alerting the ‘C-Suite;’ The Responsible Corporate Officer Doctrine*, AM. HEALTH LAW. ASS’N 2 (Feb. 2010), available at http://www.mwe.com/info/pubs/AHLA_0210.pdf.

139. See generally Gurney et al., *supra* note 1.

140. *United States v. Guidant LLC*, 708 F. Supp. 2d. 903, 907 (D. Minn. 2010). ICDs are Class III

lifesaving devices used to detect and treat abnormal heart rhythms that can result in sudden cardiac death The devices, once surgically implanted, constantly monitor the electrical activity in a patient’s heart for deadly electrical rhythms and deliver an electrical shock to the heart in an effort to return the heartbeat to normal. If they fail to operate properly when needed, a person can die within minutes.

Defibrillator Maker Pleads Guilty; Penalty to Exceed \$296 Million, OCCUPATIONAL HEALTH & SAFETY (Apr. 7, 2010) [hereinafter *Defibrillator Maker Pleads Guilty*], available at <http://ohsonline.com/articles/2010/04/07/defib-maker-pleads-guilty.aspx>.

141. Press Release, Dep’t of Justice Office of Pub. Affairs, Medical Device Manufacturer Guidant Charged in Failure to Report Defibrillator Safety Problems to FDA (Feb. 25, 2010)

In 2002, Guidant became aware that one of its ICDs was prone to failure, rendering the device inoperative and unable to deliver lifesaving therapy.¹⁴² Guidant, however, neglected to alert the FDA of this information¹⁴³ as required by the applicable regulation.¹⁴⁴ Guidant subsequently changed the design to correct the problem,¹⁴⁵ but falsely submitted a “Product Update” to the FDA, stating that the changes did not affect the device’s safety or efficacy.¹⁴⁶ Yet, the design changes were specifically made to correct this flaw.¹⁴⁷ In 2004, Guidant discovered a similar problem with two more of its ICDs.¹⁴⁸ During that year, a twenty-year-old college student with one of Guidant’s malfunctioning ICDs

[hereinafter Press Release], available at <http://www.justice.gov/opa/pr/2010/February/10-civ-202.html>.

142. *Id.*

143. *Defibrillator Maker Pleads Guilty*, *supra* note 140.

144. 21 C.F.R. § 803.50(a) (2010) (“If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.”); *Id.* § 803.53 (“You must submit a 5-day report to us . . . no later than 5 work days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the ordinal written request if we determine it is in the interest of the public health.”); *Id.* § 803.3 (defining a *MDR reportable event* as “[a]n event that manufacturers . . . become aware of that reasonably suggests that one of their marketed devices: (i) May have caused or contributed to a death or serious injury, or (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur”).

145. Thomas M. Burton & Anna Wilde Matthews, *Guidant Sold Heart Device After Discovering Flaw*, WALL ST. J., June 2, 2005, at D3.

146. Press Release, *supra* note 141.

(a) Each device manufacturer . . . shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer . . . if the correction or removal was initiated:

(1) To reduce a risk to health posed by the device; or

(2) To remedy a violation of the act caused by the device which may present a risk to health

(b) The manufacturer . . . shall submit any report required by paragraph (a) of this section *within 10-working days* of initiating such correction or removal

21 C.F.R. § 806.10 (emphasis added). Section 806.1(b) outlines the several actions that are exempt from the reporting requirements, including “[a]ctions taken by device manufacturers . . . to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.” *Id.* § 806.1(b).

147. Press Release, *supra* note 141.

148. *Id.*

died when the device short-circuited and failed to shock his heart back into rhythm.¹⁴⁹ The patient's doctors notified Guidant of this event, but the company decided not to inform the FDA.¹⁵⁰ Guidant sent a "Product Update" communication to physicians, which instructed caretakers on how to monitor the device to avoid potential risks posed by the short-circuiting.¹⁵¹ Despite this, Guidant neglected to alert the FDA about this action within the required ten days.¹⁵² At least seven individuals with Guidant ICDs died as a result of the malfunctioning device.¹⁵³ Guidant executives contended that they complied with FDA regulations by reporting the "manufacturing enhancements" of the ICDs in their 2003 annual report.¹⁵⁴ According to Guidant, the changes made to the ICDs were so minor that they did not fall under the reportable medical device changes category,¹⁵⁵ as required under 21 C.F.R. § 806.10. In defense of the other charge—that they failed to notify the FDA of their awareness that a patient had suffered a serious bodily injury or death as a result of their malfunctioning medical device, as required under 21 C.F.R. § 803.53—Guidant argued that it did not believe it would be wise to startle the public and cause patients to undergo risky surgical removal of the device because it considered the occurrence of the malfunctioning to be statistically insignificant.¹⁵⁶ There were over 37,000 implanted devices¹⁵⁷ and only twenty-six known adverse events.¹⁵⁸ The figurehead Guidant executives, who were charged with the FDCA violations, may or may not have known about the defect, but perhaps other lower-level executives responsible for the engineering operations of the ICDs did know.¹⁵⁹ The government did not conduct a focused investigation of the operations to uncover the direct culprit.¹⁶⁰ Under the strict-liability misdemeanor penalty in the FDCA, it does not matter what the charged official knew or did not know.¹⁶¹ Using figureheads as scapegoats and not holding the person(s) directly responsible

149. Barry Meier, *Heart Device Sold Despite Flaw, Data Shows*, N.Y. TIMES, June 2, 2005, at C.1 [hereinafter *Heart Devices Sold Despite Flaw*].

150. See Press Release, *supra* note 141.

151. See *id.*

152. *CPB Open Cases: U.S. v. Guidant LLC*, OFFICE OF CONSUMER LITIGATION, U.S. DEP'T OF JUSTICE (Apr. 27, 2010), available at www.justice.gov/civil/cpb/cases/cases/guidant/index.html.

153. Barry Meier, *More Deaths Are Linked to Device*, N.Y. TIMES, Dec. 14, 2005, at C.1.

154. *Heart Device Sold Despite Flaw, Data Shows*, *supra* note 149.

155. *Id.*

156. *Id.*

157. Burton & Matthews, *supra* note 145.

158. *Id.*

159. Barry Meier, *Files Show Guidant Foresaw Some Risks*, N.Y. TIMES, Dec. 24, 2005, at C.1.

160. Guidant and its executives quickly entered into a plea agreement upon being charged with violations of the FDCA. *United States v. Guidant LLC*, 708 F. Supp. 2d 903, 907–08 (D. Minn. 2010).

161. Gurney et al., *supra* note 1, at F-10.

for the error liable ensures that these types of occurrences are likely to happen again.

B. CONTROVERSIAL PLEA AGREEMENT

Guidant and its executives were charged with two counts of violations of the FDCA for submitting a false and misleading report to the FDA regarding changes made to two of the company's ICDs.¹⁶² On April 5, 2010, Guidant pled guilty to the two misdemeanor charges pursuant to 21 U.S.C. § 333(a)(1).¹⁶³ After entering into negotiations with the government, the plea agreement was submitted to Judge Donovan W. Frank of the U.S. District Court for the District of Minnesota for approval.¹⁶⁴ The plea consisted of dropping the criminal charges against the individual executives and requiring Guidant to pay a criminal fine of \$253,962,251 and \$42,079,675 in criminal forfeiture fees, which only amounted to a 1 percent fine to the company.¹⁶⁵ Judge Frank rejected the parties' plea agreement, finding it not to be "in the best interests of justice and . . . not [to] serve the public's interests because [it does] not adequately address Guidant's history and the criminal conduct at issue."¹⁶⁶ This decision came after Drs. Hauser and Maron—the treating physicians of the twenty-one-year-old who died as a result of the defective device—wrote Judge Frank, urging him to reject the plea agreement.¹⁶⁷ The physicians considered the agreement unsatisfactory, as the government agreed not to prosecute the company and the individuals whose "egregious act[s]" caused patients to "die[] or suffer[] pain and mental anguish as the direct result of Guidant's illegal and unethical behavior."¹⁶⁸ As noted in the decision rejecting the agreement, the judge urged the parties to incorporate probation provisions and resubmit the plea.¹⁶⁹

162. *Guidant LLC*, 708 F. Supp. 2d at 905.

163. *Id.* at 915.

164. *Id.* at 921.

165. *Id.* at 908.

166. *Id.* at 915.

167. Letter from Robert G. Hauser, M.D. & Barry J. Maron, M.D. to The Honorable Donovan W. Frank (Apr. 12, 2010) (on file with author) [hereinafter Letter to Judge Frank].

168. *Id.*

169. *Guidant LLC*, 708 F. Supp. 2d at 918–22. The Court did not require the parties to include restitution, stating that,

For the reasons set forth below, the Court concludes that [the parties have] a right to order restitution . . . but that there are no victims directly and proximately harmed by Guidant's criminal conduct as it relates to the crimes to which Guidant has pled guilty to and to the underlying circumstances related to those crimes as admitted by Guidant.

Id. at 906.

IV. TIME FOR CHANGE—PROPOSED AMENDMENT TO FDCA

A. INCORPORATING A *MENS REA* ELEMENT INTO THE MISDEMEANOR PENALTY

The Supreme Court has interpreted § 333(a), the criminal penalty provisions of the FDCA, as holding corporations and/or individuals who violate any provision of § 331 of the Act liable without proof of criminal intent (i.e., strict liability).¹⁷⁰ In light of the recent interest in prosecuting FDCA violations made by health care industry corporations and their top executives, supported by the Court's controversial decisions,¹⁷¹ § 333(a)(1), the misdemeanor provision, should be rewritten to include a *mens rea* requirement of at least criminal negligence or reckless conduct. Subsections 333(a) and (b) of the FDCA set forth misdemeanor and felony penalties for acts in violation of Title 21 of the Federal Code of Regulations—Food and Drugs.¹⁷² As it stands, these ambiguously written criminal provisions and their interpretations strip individuals of their constitutional due process rights and run afoul of fundamental corporate law principles, as well as accepted canons of statutory interpretation. Authorizing federal prosecutors to go on a tirade against health care company executives with these vague and unfair criminal statutes has the unsettling potential to make criminals out of law-abiding businesspeople.¹⁷³ Congressional action will not only protect the innocent in the corporate world, but will also prevent future adverse effects on patients from adulterated medical devices, and achieve the FDA's ultimate goal of securing public health and safety.¹⁷⁴

Congress is currently debating whether to criminalize product liability tort law to ensure corporate accountability.¹⁷⁵ A Senate Judiciary Hearing was held on March 10, 2010, where several experts in the product-manufacturing and defective product liability law fields were questioned regarding this controversial step.¹⁷⁶ One expert in tort law, Mr. Victor E. Schwartz, testified at the hearing and raised the hotly contested issue over the current excessive punitive damage awards imposed on manufacturers.¹⁷⁷ Some experts take the stance that these high punitive penalties are

170. Kevin LaCroix, *More About the Responsible Corporate Officer Doctrine*, D&O DIARY (Mar. 8, 2010, 4:24 AM), <http://www.dandodiary.com/2010/03/articles/corporate-governance/more-about-the-responsible-corporate-officer-doctrine/print.html>.

171. See *FDA Announces New Push*, *supra* note 70 (examining the government's new push to prosecute pharmaceutical and medical device executives under the FDCA and the responsible corporate officer doctrine, and its recent impact on health care companies and executives).

172. Food and Drugs, 21 C.F.R. §§ 800–1299 (2010); 21 U.S.C. §§ 301–399 (2006).

173. Gurney et al., *supra* note 1, at F-13.

174. *What does FDA do?*, *supra* note 29.

175. *Defective Products: Will Criminal Penalties Ensure Corporate Accountability?: Hearing Before the Comm. on the Judiciary*, 109th Cong. (2006).

176. *Id.*

177. *Id.* at 14–15 (statement of Victor E. Schwartz, Shook, Hardy, and Bacon LLP).

necessary to encourage manufacturers to be more vigilant in their product safety.¹⁷⁸ It has been argued, however, that even these excessive punitive damage awards are not achieving their intended deterrent effect and, therefore, criminal penalties must be added.¹⁷⁹ Mr. Schwartz warns the committee,

[P]unitive damages have run wild in this country and people don't know when they are going to be punished or how they are going to be punished or where. It is over-heated at this point, and that is why constitutional constraints have been put on punitive damages. It is really not a wise thing right now to add yet another vague alternative and make it criminal.

....

In a nutshell, . . . [w]e don't want manufacturers to be killing people, but to put a crime based on the topic of defect [which is a vaguely defined term in tort law] is putting a crime based on a fog.¹⁸⁰

This debate over criminalizing tort product liability is highly relevant to the controversial misdemeanor provisions under the FDCA. Experts worry that imposing criminal sanctions based on vague tort law concepts will have a “chilling effect on law-abiding companies.”¹⁸¹ In the same vein, prosecuting corporate executives under the FDCA's misdemeanor provision without proof of criminal intent or any knowledge with respect to the violation will have a similar chilling effect.

There are several reasons why the misdemeanor provision must be amended. First, the Supreme Court's two controversial decisions on the interpretation of the misdemeanor provision are outdated and, thus, must be revisited.¹⁸² The health care manufacturing industry, and corporations in general, have expanded and changed significantly since those decisions were passed down.¹⁸³ In 1943, when *Dotterweich* was decided, pharmaceutical companies were more akin to “mom-and-pop” apothecaries than to today's complex, multi-faceted international manufacturing corporations, such as Guidant, LLC and Johnson & Johnson, Inc. At the time of *Dotterweich*, executives were capable of directly overseeing all day-to-day activities and could reasonably be held liable under a “knew or should have known” standard. Today, it is virtually impossible for high-ranking individuals to be aware of every manufacturing operation in the corporation. Some may argue that executives who sign their employment

178. See *id.* at 15–17 (statement of Donald L. Mays, Senior Dir., Product Safety and Consumer Sciences, Consumers Union, Yonkers, N.Y.).

179. See, e.g., *id.* at 6.

180. *Id.* at 14–15 (statement of Victor E. Schwartz, Shook, Hardy, and Bacon LLP).

181. *Id.* at 6 (statement of Barry J. Maron, M.D., Director, Hypertrophic Cardiomyopathy Center, Minneapolis Heart Institute Foundation).

182. Margolis et al., *supra* note 9, at 6.

183. See Gurney et al., *supra* note 1, at F-22.

contracts assume the responsibility of ensuring the corporation complies with every aspect of not only the FDCA but all other applicable laws and regulations as well. This, however, is a naïve assumption and an impossible onus to impose on executives in this day and age, with thousands of employees directly and indirectly associated with corporations that make hundreds of thousands of products.

Today's complex corporate structure must be considered when amending the FDCA's misdemeanor provision. There are numerous officers and managers holding positions of authority in the corporate hierarchy; therefore, it is necessary to revise the policy under the responsible corporate officer doctrine, which currently endorses the prosecution of all high-ranking officials who might have some remote responsibility, regardless of their involvement in the FDCA violation. Instead, prosecutorial policies should not center on using the figurehead executives as scapegoats, but rather should focus on conducting investigations that uncover the direct managerial culprit, as well as the individual employees who were *aware* of the conduct that caused the FDCA violation and failed to report it.

The Supreme Court's interpretation of § 333(a) as a strict-liability criminal provision is highly controversial.¹⁸⁴ According to the fundamental principles of criminal law, "[p]ublic-welfare offenses are the most common examples of . . . strict-liability offenses. . . . [H]owever, a statute that is silent regarding *mens rea* may, nonetheless, be interpreted as requiring at least some minimal level of *mens rea*."¹⁸⁵ "[I]f the penalty is light, involving a relatively small fine and not including imprisonment, then *mens rea* probably is not required."¹⁸⁶ Since FDCA violations do carry substantial fines and imprisonment sentences, it is highly unlikely that Congress intended for this to be one of the rare federal strict-liability offenses. In fact, there is no suggestion that this was Congress' intention. Constitutional due process rights also support the argument against a strict-liability interpretation. Federal prosecutors are permitted to impose imprisonment penalties on corporate executives without proving that they had any involvement in the FDCA violation. Once slapped with a criminal indictment, high-ranking executives are left with no other option than to plead guilty and pay the consequences for someone else's misconduct. With the proposed mental culpability attached to the misdemeanor provision, the prosecutor would be required to prove that the individual executive had some intent regarding the conduct. The individual will then at least be able to raise the defense that he did not have any knowledge or involvement with the violation.

184. *Id.* at F-13.

185. CASES AND MATERIALS ON CRIMINAL LAW, *supra* note 72, at 173–74.

186. *United States v. Cordoba-Hincapie*, 825 F. Supp. 485, 496 (E.D.N.Y. 1993), *discussed in* CASES AND MATERIALS ON CRIMINAL LAW, *supra* note 72, at 173.

B. PROSECUTORIAL POLICY CHANGES AND ITS IMPACT

A policy change when enforcing this provision, which includes a rebuttable presumption of innocence¹⁸⁷ with respect to the individual executives, should also be adopted.¹⁸⁸ This would be consistent with the congressional purpose to facilitate public reliance on the integrity of corporate officers, as well as constitutional and criminal procedure principles that an individual is innocent until proven guilty.¹⁸⁹ There are, however, circumstances when figurehead executives may be criminally liable for the alleged FDCA violations. This note is not concerned with such instances. Instead, this note focuses on those individuals who have absolutely no knowledge of the conduct that caused an FDCA violation and could not possibly have realized these infractions due to the complexity and vastness of modern manufacturing corporations.¹⁹⁰

Furthermore, a policy change with respect to plea agreements must be adopted. The Guidant scandal demonstrates the problems that exist under the current policy. The government entered into a plea agreement to drop charges against the individual executives in exchange for Guidant handing the government a \$296 million criminal fine.¹⁹¹ As noted in the court's decision that rejected the plea agreement, victims of the criminal conduct do not get any of the money;¹⁹² it all goes to the government. This raises several concerns. First, it limits the amount of money the victims will be able to recover in any potential class action product liability suit. In addition, these criminal fines merely come out of the pocket of the shareholders,¹⁹³ having little to no effect on the corporation or the executives who allegedly committed these offenses, and thus provides no incentive for the company or its executives to reform. It is apparent that the government's use of the no-intent misdemeanor provision against the company and the figurehead executives is nothing more than a threat to induce plea agreements that will result in exorbitant amounts of money going into the government's pocket.¹⁹⁴ The prosecutor needs to do nothing more than charge a medical device manufacturer and its executives with an FDCA offense, making this arguably a simple and cost-effective way to

187. BLACK'S LAW DICTIONARY 558–559 (3rd pocket ed. 2006) (defining “rebuttable presumption” as “[a]n inference drawn from certain facts that establish a prima facie case, which may be overcome by the introduction of contrary evidence”).

188. This would be similar to the rebuttable presumption against judicial review of duty of care claims under the business judgment rule in corporate law. The burden of proof is placed on the plaintiff to rebut the business judgment of the corporate officer or director, thus insulating those individuals from liability in carrying out their corporate duties so long as the act was made in good faith. See STEPHEN M. BAINBRIDGE, CORPORATE LAW 539–44 (Foundation Press, 2nd ed. 2009).

189. UNDERSTANDING CRIMINAL LAW, *supra* note 71, at 5.

190. See generally Gurney et al., *supra* note 1, at F-22.

191. United States v. Guidant LLC, 708 F. Supp. 2d 903, 908 (2010).

192. *Id.* at 909.

193. Letter to Judge Frank, *supra* note 167.

194. Gurney et al., *supra* note 1, at F-21.

increase the government's revenue. If the government was serious about deterring individuals who allegedly committed criminal acts under the FDCA, it would not have entered into a plea agreement for just monetary penalties, but instead would have insisted on imprisoning the guilty individuals.¹⁹⁵ But it is clearly not the government's intent to promote the goals of the FDA, which are designed to protect the public and the patient. Based on the facts given in the Guidant case, it is highly likely that the company and its executives were liable for the alleged violations, and had they gone forward with trial rather than entering into a plea agreement, they would have been found guilty under the strict-liability misdemeanor provision. Under my proposed amendment, which would require some proof of knowledge and with the new prosecutorial policies, Guidant and its executives would not have "gotten away with murder" like they did. In fact, they would perhaps have faced serious and well-deserved jail time, but at least they would have been given a fair trial.

CONCLUSION

My proposal to both amend the misdemeanor provision of the FDCA, requiring proof of some criminal intent, and adopt prosecutorial policy changes will achieve several goals. First, it will protect executives who had absolutely no knowledge of or involvement in the FDCA violation. Requiring proof of some *mens rea* will ensure that businesspeople are not forced to plead guilty because they do not have a viable defense. Second, it protects the corporation and its shareholders from having to pay exorbitant criminal fines. Third, the policy changes will ensure that those who are found guilty under the revised FDCA criminal provisions will be sent to jail rather than allowing them to enter into plea agreements, which do nothing to combat recidivism. Lastly, but most importantly, these changes will promote the ultimate goal of ensuring that these types of violations do not occur again, protecting patients' health and well-being.

*Kimberly Bolte**

195. Federal prosecutors are given broad discretion in defining white-collar infractions and deciding when to bring charges against corporate individuals, which has led to overcriminalization. J. Kelly Strader, UNDERSTANDING WHITE COLLAR CRIME 8 (Matthew Bender & Company, Inc., 2002).

*B.A., College of the Holy Cross, 2007; J.D. candidate, Brooklyn Law School, 2012. I would like to thank the members of the Journal for their assistance in preparing this note for publication. Special thanks to my loving family for their endless support and encouragement throughout law school.