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The Crime of Being in Charge: Executive Culpability and Collateral Consequences

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FEATURED ARTICLE

THE CRIME OF BEING IN CHARGE:
EXECUTIVE CULPABILITY AND COLLATERAL CONSEQUENCES

Katrice Bridges Copeland*

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I. Introduction

The pharmaceutical industry has long been an enforcement headache for the Food and Drug Administration (FDA). In particular, the FDA has struggled with enforcing the laws restricting the promotion of drugs. Off-label promotion, or the promotion of FDA-approved drugs for unapproved uses, is generally prohibited. Nevertheless, pharmaceutical manufacturers have risked the health and safety of patients by promoting their drugs for uses that have been explicitly rejected by the FDA as well as uses that were never presented to the FDA for approval. Because these illegal promotional activities were largely aimed at doctors, the FDA had difficulty detecting the violations and often relied on whistle blowers to alert the agency to the misconduct. Once the violations were detected, however, the FDA was presented with an enforcement dilemma.

The FDA pursued a strategy of cooperative enforcement with pharmaceutical companies to avoid the collateral consequences of criminal conviction. If a pharmaceutical company is convicted of a felony, it would be automatically excluded from participation in federal health care programs, such as Medicare and Medicaid, for a period of at least five years. Exclusion has been described as a “death sentence” for pharmaceutical manufacturers because it prevents the federal government from reimbursing patients for any drug produced by the

1. The dissemination of truthful off-label information through scientific journals is permitted. U.S. Dep’t of Health and Human Serv., Guidance for Industry, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, at III, V (2009), available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm. There is no specific statutory prohibition on the promotion or marketing of FDA-approved drugs for unapproved uses (off-label promotion). The FDA has interpreted the Food Drug and Cosmetic Act (FDCA), however, to prohibit such off-label promotion. Under the FDCA, a pharmaceutical manufacturer must provide scientific evidence to demonstrate that a drug is safe and effective for a particular use before the manufacturer may introduce the drug into interstate commerce. 21 U.S.C. § 355(d) (2012). The approved uses are included on the FDA-approved label. A drug is considered to be criminally misbranded under the FDCA if it does not bear adequate directions for its intended use. 21 U.S.C. §§ 331, 352(f) (2012). If a pharmaceutical manufacturer promotes a drug for off-label uses, the FDA considers that to be a misbranding violation because the off-label promotion is evidence that the manufacturer is putting forth an intended use for the drug for which there are no directions on the FDA-approved label. This theory recently ran into some difficulty in United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), where the Second Circuit narrowly interpreted the FDCA’s misbranding provision as not “criminaliz[ing] the simple promotion of a drug’s off-label use” because such an interpretation would run afoul of the First Amendment’s protection of commercial speech. Id. at 162. The Caronia case, however, dealt with truthful off-label promotion. False off-label promotion, like that at issue in this Article, is not protected by the First Amendment.

2. See generally Katrice Bridges Copeland, Enforcing Integrity, 87 Ind. L.J. 1033 (2012) (describing, inter alia, Pfizer’s promotion of its drug Bextra for postsurgical pain despite the FDA’s finding that it was not safe for that use).

3. See infra Part III.A.

excluded pharmaceutical manufacturer. Thus, Medicare and Medicaid patients who have prescriptions for drugs produced by the excluded pharmaceutical company would have to pay for their drugs out of pocket or have their doctors prescribe a similar drug by a non-excluded pharmaceutical manufacturer. To avoid the potentially devastating consequences of exclusion on patients, the FDA opted not to pursue felony criminal charges against pharmaceutical manufacturers that engaged in off-label promotion. Instead, the FDA entered into Corporate Integrity Agreements that required the pharmaceutical companies to pay large fines and enact compliance measures designed to prevent the illegal promotional activity from recurring. In return, the government agreed not to pursue felony criminal charges or debar the pharmaceutical manufacturers from participation in federal health care programs.

The FDA’s approach seemed like a reasonable response to a complicated enforcement problem. For several years, there was a steady stream of Corporate Integrity Agreements with eye-popping fines as high as $3 billion and increasingly strict compliance measures. The harsh reality, however, was that pharmaceutical companies viewed the fines and compliance measures as nothing more than the cost of doing business. The profits to be gained from illegal promotion far exceeded the cost of the fines and compliance measures.

Thus, the Corporate Integrity Agreements were not enough to deter pharmaceutical companies from engaging in fraudulent promotional activity. As a result, the FDA began to see repeat offenders of the pharmaceutical marketing rules. Even when faced with a repeat offender, however, the FDA simply entered into a new Corporate Integrity Agreement, imposed a larger fine and harsher compliance measures, and either allowed the pharmaceutical company to designate a subsidiary to be criminally charged and debarred or charged the manufacturer with a

5. See generally Copeland, supra note 2 (explaining the reasons that the government entered into Corporate Integrity Agreements rather than pursuing exclusion and the most common requirements of those agreements).

6. See id.


8. See generally Copeland, supra note 2, (proposing alternative enforcement mechanisms to be used in place of Corporate Integrity Agreements).
misdemeanor, which would not automatically lead to exclusion. Therefore, pharmaceutical manufacturers still had little incentive to change their illegal promotional practices because the profits from off-label promotion outweighed the costs of fines and compliance measures.

The government had unleashed every weapon in its arsenal to combat fraud, or so the industry thought, before the FDA changed the focus of its enforcement strategy. In a March 4, 2010 letter to Senator Charles E. Grassley, Margaret Hamburg, the Commissioner of Food and Drugs, announced that the FDA intended to make use of individual misdemeanor prosecutions "to hold responsible corporate officials accountable." Hamburg also made it clear that the FDA intended to enhance and make better use of its debarment and disqualification procedures. In addition, the Office of Inspector General (OIG) of Health and Human Services and the Department of Justice (DOJ) both endorsed the new enforcement strategy. Thus, the FDA, OIG, and DOJ shifted their focus in pharmaceutical fraud cases from simply pursuing pharmaceutical companies to pursuing misdemeanor criminal charges against individual executives. This is a welcome change because potential criminal liability may be more likely to deter individual executives and incentivize effective monitoring.

The FDA is not, however, focused on targeting executives for their own misconduct. Instead, the FDA is pursuing misdemeanor criminal charges against executives for the criminal conduct of their subordinates. To support its theory of indirect criminal liability, the government has dusted off the responsible corporate officer doctrine. The responsible corporate officer doctrine permits the government to prosecute an executive for a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act regardless of the officer’s lack of awareness of misconduct if, by reason of the officer’s position in the company, she had the responsibility and authority either (1) to prevent the misconduct in the first place, or (2) promptly to correct the violation, but failed to do so. The responsible corporate officer doctrine comes from two Supreme Court cases, United States v. Dotterweich and United States v. Park, decided in 1943 and 1974 respectively.

9. Id. at 1055–64.
10. Letter from Margaret A. Hamburg, M.D., Comm’r, FDA to Charles E. Grassley, Ranking Member, Senate Comm. on Fin. (Mar. 4, 2010).
11. Id.
13. The doctrine is also known as the responsible relation doctrine or the Park doctrine. See United States v. Park, 421 U.S. 658 (1974).
15. See Park, 421 U.S. at 673–74.
The responsible corporate officer doctrine "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing." 18 Thus, the burden of complying with the law is placed on "a person otherwise innocent but standing in responsible relation to a public danger." 19 The government has already successfully obtained guilty pleas to misdemeanor violations of the Food Drug and Cosmetic Act 20 based on the responsible corporate officer doctrine. Many scholars have debated the fairness of criminal misdemeanor convictions based on the responsible corporate officer doctrine. 21 But the misdemeanor convictions are not the end of the story. Just as there are collateral consequences that flow from convicting pharmaceutical manufacturers, there are collateral consequences for executives as well. This Article fills a critical gap in the literature concerning the collateral consequences of a criminal conviction under the responsible corporate officer doctrine. Following criminal conviction, the OIG has the discretion to exclude executives from participation in federal health care programs. 22 The exclusion is not mandatory upon misdemeanor conviction and is considered to be a civil remedy. 23 The baseline period of exclusion is three years but can be increased based on aggravating factors. The OIG has sent executives notice that they have been excluded from participation in federal health care programs for periods as long as twenty years. 24 For an individual, exclusion means that the executive is no longer employable in the health care industry because any company that directly or indirectly receives money from federal health care programs cannot employ an excluded individual without jeopardizing its own participation in those programs. 25 As pharmaceutical companies often rely heavily on millions of dollars in revenue from Medicare and Medicaid reimbursements for their drugs, hiring a debarred executive could be akin to a death sentence for the company. Thus, the collateral consequence of the misdemeanor conviction is to take away the executive's livelihood.

Health care executives who potentially make millions of dollars are probably not the most sympathetic defendants. While they were in charge their companies violated the law and once charged they have ample access to resources for their

19. Id.
22. See infra Part III.A.
23. See infra Part III.A.
24. See infra Part III.B.
25. See infra Part III.A.
defense. Nevertheless, the imposition of debarment for a significant period of time without any showing of moral blameworthiness should give anyone pause. The violations at issue are strict liability misdemeanors, which do not require a showing of intent and are punishable by less than a year in jail. Through exclusion, the government is effectively transforming a strict liability misdemeanor violation that is not based on the executive's own misconduct into a felony. Exclusion is not meant to be punitive. The goal is supposed to be to protect the health care system from unscrupulous individuals. Absent a showing of moral blameworthiness on the part of health care executives who were in charge at the time the misconduct occurred, a period of exclusion longer than the three-year base level for permissive exclusions is a grossly disproportionate remedy. It is not enough to say that a showing of moral blameworthiness is unnecessary because exclusion is categorized as a civil sanction where, as here, the civil sanction is clearly more devastating than the criminal penalty attached to the misdemeanor conviction.

This Article argues that the government's exclusion of executives who have been convicted as "responsible corporate officers" for a period longer than three years without any showing of moral blameworthiness is misguided. The responsible corporate officer doctrine is flawed because under the doctrine it is irrelevant that the executive did not intend for the misconduct to occur. It is not a defense that the executive delegated responsibility in good faith. Nor is it a defense that the executive is not knowledgeable about or did not participate in the misconduct. The only potential defense is impossibility, but it has never been used successfully. Even if those shortcomings in the responsible corporate officer doctrine were overlooked due to the fact that it is a misdemeanor charge, the piling on of long periods of exclusion significantly raises the stakes for the executives. Part II of this Article sets forth the foundation for and justification of the responsible corporate officer doctrine. It also scrutinizes the shortcomings of the responsible corporate officer doctrine. Part III of this Article examines the collateral consequences of conviction as a responsible corporate officer. It uses the exclusion of Purdue Pharma executives as a case study to examine the justification for and problems with excluding executives who had no knowledge of wrongdoing. It argues that the collateral consequence of conviction—exclusion—is more devastating than the criminal sentence that an executive would face upon conviction. Part IV argues that a conviction as a responsible corporate officer does not demonstrate that the executive is morally blameworthy for the actions of subordinates. Further, it argues that despite the fact that exclusion is technically a civil remedy, it should be treated as a de facto criminal penalty in this context where it is the most serious

26. See infra Section III.

27. 67 Fed. Reg. 11,928, 11,928 (Mar. 18, 2002) (explaining that exclusion is meant to protect federal health care programs from "untrustworthy health care providers").
consequence that responsible corporate officers face as a result of conviction. This Article concludes that the collateral consequences of holding "responsible corporate officers" criminally accountable for the misconduct of their subordinates are disproportionate to the crime of conviction and should not be imposed for longer than three years absent a showing of moral blameworthiness.

II. BACKGROUND

The Food and Drug Administration regulates the pharmaceutical industry through the Food, Drug and Cosmetic Act (FDCA).\(^\text{28}\) Violations of the FDCA are considered to be public welfare offenses. Public welfare offenses are a special category of regulatory offenses that involve dangerous activities or materials. The Supreme Court has explained that these are crimes relating to activities that "a reasonable person should know is subject to stringent public regulation and may seriously threaten the community's health or safety."\(^\text{29}\) Because a reasonable person should be aware of the risks involved with activities proscribed by public welfare offenses, these crimes are an exception to the fundamental requirement that individuals should not be punished unless the government can demonstrate wrongful conduct along with a guilty mind.\(^\text{30}\) The Supreme Court has upheld the constitutionality of public welfare offenses that punish conduct in the absence of a \textit{mens rea} requirement. Although considered dicta, one important factor for the Court in permitting punishment for a crime without a \textit{mens rea} element was the relatively light punishment that an individual will receive for violating a public welfare offense.\(^\text{31}\)

The responsible corporate officer doctrine, which holds executives criminally responsible for the misconduct of subordinates, has only been applied to public welfare offenses. Ordinarily, it is considered to be "morally objectionable" to hold someone criminally responsible for the conduct of others "because it ignores the separateness of each person as a responsible autonomous agent."\(^\text{32}\) Thus, this Section critically examines the doctrinal foundation for the responsible corporate officer doctrine and the normative theories justifying it to determine if the moral objection can be overcome.

\begin{itemize}
\item \text{29.} Liparota v. United States, 471 U.S. 419, 433 (1985).
\item \text{30.} Id.
\item \text{31.} Morissette v. United States, 342 U.S. 246, 256 (1952) (explaining that "penalties commonly are relatively small, and conviction does no grave damage to an offender's reputation"); cf. Staples v. United States, 511 U.S. 600, 616 (1994) (holding that a gun regulation was not subject to public welfare doctrine in part because "the small penalties attached to [public welfare] offenses logically complement[] the absence of a \textit{mens rea} requirement").
\item \text{32.} Dennis J. Baker, \textit{The Moral Limits of Criminalizing Remote Harms}, 10 New Crm. L. Rev. 370, 370, 372–73 (2007) (arguing that a person "should only be held responsible for another's criminal harm when she is normatively involved in it").
\end{itemize}
A. Foundation of Responsible Corporate Officer Doctrine

The responsible corporate officer doctrine only applies to public welfare offenses. The doctrine grew from two Supreme Court cases dealing with violations of the FDCA.

In United States v. Dotterweich, the government charged Buffalo Pharmacal Company, Inc. and Joseph H. Dotterweich, the president and general manager of Buffalo Pharmacal Company, with violating the FDCA by shipping misbranded and adulterated drugs in interstate commerce. Buffalo Pharmacal Company purchased drugs from a wholesale manufacturer, repackaged them, and then shipped them to physicians who made mail orders. The drug shipments were alleged to be misbranded and adulterated because the labels placed on the drugs during repackaging misrepresented the ingredients and/or potency of the drugs. Dotterweich was not personally involved in repackaging or shipping the drugs. The jury convicted Dotterweich but not Buffalo Pharmacal Company. On appeal, the Second Circuit reversed Dotterweich's conviction. The appellate court found that the prohibition on shipping misbranded and adulterated drugs applied to the drug dealer (Buffalo Pharmacal Company), not an agent (Dotterweich), unless the “individual operated a corporation as his ‘alter ego’ or agent.” The court found that there was no evidence to support such a theory in this case.

The Supreme Court reversed the Second Circuit, finding that the FDCA “was designed to enlarge and stiffen the penal net and not to narrow and loosen it.” Thus, the Court found the appellate court’s construction of the FDCA too limiting and in contravention of the FDCA’s purpose to protect the “innocent public.” The Court found that Dotterweich was liable under the Act because he had a “responsible share” in the shipment of the misbranded and adulterated drugs despite the fact he did not have “consciousness of wrongdoing.” In the Court’s view, Dotterweich, as an executive in the company, was in a better position than the public to ensure that the drugs that were shipped in interstate commerce met the requirements of the consumer protection laws. As such, he had to bear the risk of

33. 320 U.S. 277 (1943).
34. Id. at 278.
36. Id. at 501–02 (explaining that the first charge was based on an interstate shipment of cascara compound which was labeled as Hinkle pills but contained an ingredient not found in Hinkle pills and the second charge was based on interstate shipment of digitalis tablets which were labeled as containing potency of one U.S.P. unit of digitalis but actually contained less than half of that).
37. Id. at 501.
38. Id. at 503.
39. Id.
40. Id.
42. Id. at 285.
43. Id. at 284.
those laws being violated, not the public. The Court declined to specify which group of employees stands in "responsible relation," describing any attempt to do so as "treacherous." Instead, the Court explained that these decisions would have to be made by relying on and trusting "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries."

Over three decades later, the Supreme Court decided United States v. Park, which reaffirmed the responsible corporate officer doctrine. In Park, the government charged Acme Markets, Inc. (Acme) and John R. Park, Acme's chief executive officer, with violating the FDCA by causing adulteration of food which had travelled in interstate commerce and which was held for sale in Acme's Baltimore warehouse. The information alleged that rodents contaminated the food in the Baltimore warehouse. Acme pleaded guilty to all five counts in the information, but Park pleaded not guilty and went to trial. The evidence at trial showed that an FDA inspector examined Acme's Baltimore warehouse and found evidence of rodent infestation of food in November and December of 1971 and again in March of 1972. On January 27, 1972, the FDA's Chief of Compliance for the Baltimore office sent a letter to Park detailing the sanitary violations at the Baltimore warehouse. Acme's Baltimore division vice president responded to the letter and explained the steps Acme was taking to remedy the violations. In the March 1972 inspection, the FDA inspector noted that there was some improvement in the sanitary conditions, but that there was still rodent activity in the warehouse. Park testified at trial that all Acme employees were under his general control, but the specific job of sanitation was handled by somebody else in the Acme organizational structure. He explained that after receiving the January 1972 letter from the FDA, he conferred with the vice president for legal affairs who told him that the problem was being investigated and handled by the Baltimore division vice president. Park stated that he did not think that there was anything else that he could have done that was not already being done by the Baltimore division vice president. On cross-examination, Park admitted that there was a prior problem with sanitation at the Philadelphia warehouse and that

44. Id. at 284–85.
45. Id. at 285.
46. Id.
47. 421 U.S. 658 (1975).
48. Id. at 660.
49. Id.
50. Id. at 660–61.
51. Id. at 661–62.
52. Id. at 662–63, n.3.
53. Id. at 662.
54. Id.
55. Id. at 663.
56. Id. at 663–64.
57. Id. at 664.
one individual had responsibility for the sanitation of both the Philadelphia and Baltimore warehouses.58 He further acknowledged that the sanitation problem at Baltimore meant that the system for dealing with sanitation “wasn’t working perfectly” and that he was ultimately responsible for the sanitation problem.59 The jury found Park guilty on all five counts of the information and fined him $250.60

On appeal, Park argued that the district court’s jury instructions were erroneous and that evidence of the sanitation problems at the Philadelphia warehouse should not have been admitted at trial.61 The district court instructed the jury that in order to find Park guilty they must find beyond a reasonable doubt each element of the offense. The district court also told the jury that “you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets.”62 Further, the judge explained that it was not necessary that the jury find that Park consciously did wrong or that he “personally participated in the situation” so long as they found that Park “had a responsible relationship to the issue” due to his position of authority in the company.63 The Fourth Circuit found that the instructions could have left the jury with the false impression that they could convict Park without any showing that he engaged in “wrongful action.”64 In particular, the court was concerned that those jury instructions permitted a conviction based only on the fact that Park was the president of Acme.65 The Fourth Circuit explained that Dotterweich dispensed with the need to prove “awareness of wrongdoing” but did not relieve the prosecutor of the burden to prove “wrongful action” on the part of the defendant.66 Accordingly, the Fourth Circuit reversed Park’s conviction and remanded the case to the district court for a new trial.67

The Supreme Court reversed the Fourth Circuit’s ruling and reinstated Park’s conviction.68 The Supreme Court found that the district court was not required to instruct the jury about the government’s burden to prove “wrongful action.”69 The Court explained that the government makes a prima facie case by demonstrating 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

58. Id. at 664–65.
59. Id.
60. Id. at 666.
63. Id.
64. Park, 499 F.2d at 841–42 (internal quotation marks omitted).
65. See id.
66. Id.
67. Id. at 843.
68. Park, 421 U.S. at 667.
69. Id. at 673.
violation complained of, and that he failed to do so." The Court’s view the defendant’s authority coupled with the requirements of the FDCA supplied the causal link needed for liability. The Court also noted that “[t]he concept of a ‘responsible relationship’ to, or a ‘responsible share’ in, a violation of the Act indeed imports some measure of blameworthiness.” Further, the Court found that the admission of evidence regarding the Philadelphia warehouse sanitation problem was appropriate to demonstrate that Park had reason to suspect that his subordinates were not dependable and that he needed to do something more to insure compliance with the FDCA. Finally, the Court recognized that there is a defense to liability when it would have been “objectively impossible” for the executive to prevent or correct the misconduct.

In the twenty years following the Park decision, the overwhelming majority of responsible corporate officer prosecutions were based on violations of environmental laws rather than the FDCA. The defendants in those environmental cases were rarely successful at challenging their responsible corporate officer convictions. There is one important difference, however, between the environmental cases and the FDCA cases. Many of the environmental statutes include “responsible corporate officer” in their definition of a “person” who could violate the statute. There is no such definition in the FDCA. Thus, there is a stronger statutory ground for bringing the responsible corporate officer prosecutions under the environmental laws than there is under the FDCA.

In the few cases that did involve the FDCA, the defendants unsuccessfully raised the impossibility defense. In United States v. Y. Hata & Co., the defendant owned a multi-food storage warehouse in Hawaii. The FDA inspected the facility

70. Id. at 673–74.
71. Id. at 674.
72. Id. at 673.
73. Id. at 677–78.
74. Id. at 673.
76. The highest likelihood of success in environmental cases comes when the statute at issue is a felony, as opposed to a misdemeanor, and the statute specifically requires a showing of intent. See, e.g., MacDonald & Watson Waste Oil Co., 933 F.2d at 52–53 (holding that a defendant could not be convicted of knowingly transporting and causing the transportation of hazardous waste to a facility without a permit based solely on the responsible corporate officer doctrine; there must be some showing that the defendant had knowledge or was willfully blind); White, 766 F. Supp. at 894–95 (explaining that although Dotterweich and Park do not require actual knowledge of the violation, such knowledge must be established when the statute at issue explicitly requires knowledge). But see Brittain, 931 F.2d at 1419 (finding that mens rea can be imputed by virtue of the defendant’s position of responsibility).
77. See, e.g., 33 U.S.C. § 1319(c)(6) (2012) (“For the purpose of this subsection, the term ‘person’ means . . . any responsible corporate officer.”).
78. 535 F.2d 508, 509 (9th Cir. 1976).
and discovered birds in the warehouse as well as excreta on bags of rice. The government charged the company and its president, Minoru Hata, with violating the FDCA. Hata argued that the district judge should have given the jury an instruction on objective impossibility. The Ninth Circuit, relying on Park, upheld the conviction. The court noted that Hata was aware of the bird infestation problem as early as August 1971 and tried numerous devices to keep the birds out of the warehouse and none of them were completely successful. Finally, in the spring of 1972, Hata decided to enclose the entire food storage area in a huge wire cage to prevent the birds from getting in the warehouse. The cage was not in place, however, when the FDA returned for inspections in May and June of 1972. The government argued that the impossibility defense was not available simply because the defendant argued that the problem could not be fixed in a timely fashion. In the government's view, they should have closed the warehouse. The court held that the impossibility defense was not available because in accordance with the duty of foresight and vigilance, the company should have considered and experimented with the cage long before the FDA inspection. The implication of the Hata decision is that the impossibility defense is not available if an individual experiments with certain measures but fails to solve the problem.

In United States v. Starr, the government charged Cheney Food Corporation and its secretary-treasurer, Dean Starr, with three counts of violating the FDCA due to a mice infestation that contaminated food stored in the company's warehouse. The FDA inspected the warehouse in the autumn of 1972 and discovered several violations of the FDCA. The FDA inspector spoke with Starr, who was in charge of sanitation, about the violations. While the FDA inspector was still at the warehouse, Starr ordered the warehouse janitor, Marks, to correct the situation. A month later, the FDA inspector came back for the second inspection. Marks told the inspector that the warehouse still had a problem with mice and that he had not taken the corrective action that Starr ordered him to take in response to the problem. Starr argued that the facts supported an objective impossibility defense because the contamination resulted from the mice fleeing a
recently plowed nearby field which was a “natural phenomenon.” The Ninth Circuit again rejected this argument because it required “only a minimum of foresight” to recognize and prepare for such a problem. Starr also argued that Marks sabotaged the company by refusing to comply with clean-up instructions. In rejecting this argument, the court relied on the month-long gap between the two inspections and the fact that Starr never checked on Mark's progress in correcting the violations. Ultimately, the court found that “[t]he standard of ‘foresight and vigilance’ encompasses a duty to anticipate and counteract the shortcomings of delegates.” The implication of the Starr case was that delegation to a subordinate was not an adequate justification for relieving the person in charge from liability for the violation.

B. Philosophical Underpinnings of the Doctrine

The lower courts and scholars have struggled with identifying the foundation of the responsible corporate officer doctrine. It is not clear from the Park and Dotterweich decisions how the actus reus and mens rea are satisfied in each case. In particular, the opinions do not specify whether the actus reus is satisfied based on the personal acts and/or omissions of the responsible corporate officer or if the actus reus is satisfied vicariously based on the acts and/or omissions of the responsible corporate officer's subordinates. Nor is it clear whether there is any mens rea requirement for the responsible corporate officer. If there is a mens rea requirement, it is not evident whether negligence in failing to adequately supervise one's subordinates would satisfy the requirement or whether a higher level of mens rea would be needed. The difficulty lies in the fact that the underlying offense, misdemeanor misbranding, is a strict liability crime. Strict liability crimes dispense with the typical mens rea requirements and impose criminal liability without regard to fault. Thus, some of the confusion concerns whether the responsible corporate officer doctrine relieves the prosecutor of the need to prove mens rea or whether there is no need to prove mens rea because the underlying crime is a strict liability offense. The Supreme Court and many scholars have conflated the issues of actus reus and mens rea in discussing the justification for the doctrine.

Professor Norman Abrams argues that Justice Frankfurter's opinion in Dotterweich could be given three different interpretations. First, the opinion could be interpreted to establish “strict, vicarious liability” for executives because the opinion refers to executives being punished under the statute “without any

93. Id. at 514–15.
94. Id. at 515.
95. Id.
96. Id. at 515–16.
97. Id. at 516.
conscious fraud’ or ‘though consciousness of wrongdoing be totally wanting.’”

Second, the opinion could be interpreted not to resolve the question of the required mens rea for the statute. Third, the opinion could be interpreted to imply a mens rea element based on “Justice Frankfurter’s characterization of those who are guilty of the offense as ‘all who do have such a responsible share in the furtherance of the transaction.’” In Professor Abrams’s view, the “strict, vicarious liability” view is the most commonly accepted view. Nevertheless, Professor Abrams seems to be in favor of a view that requires a showing of at least negligence on the part of the responsible corporate officer. Professor Abrams argues that the notion of a “responsible share” shows some measure of culpability for the defendant. Where the actus reus exists, the notion of “responsible share” amounts to showing that the defendant was at least negligent in either acting or failing to act. Professor Abrams argues that the responsible share language “establishes that the corporate officer was in a position to exercise some control over the situation that produced the violation.” Thus, it seems that in Professor Abrams’s view the actus reus is the officer’s omission and the required mens rea is negligence.

Professor Kathleen Brickey takes exception to Professor Abrams’s assertion that the “commonly accepted view of Dotterweich is that the Court ‘established strict, vicarious liability for corporate executives.'” Professor Brickey argues that even if the opinion imposed strict liability, Justice Frankfurter’s opinion did not establish “whether liability was vicarious or personal.” It was never established whether Dotterweich’s liability stemmed from his own culpable acts and/or omissions or from acts of his subordinate that were imputed to him. Professor Brickey argues that when looking at the responsible share standard of liability it is important to put the Park and Dotterweich cases in their appropriate context of public welfare offenses. Once that is taken into account, Professor Brickey argues that despite the Court’s ambiguous language in describing the notion of responsible share, the Court was not imposing a requirement that the prosecutor demonstrate the mens rea of the executive. When speaking of blame and responsible share, Professor Brickey maintains that the Court was not concerned

98. Abrams, supra note 21, at 464 (quoting United States v. Dotterweich, 320 U.S. 277, 281 (1943)).
99. Id.
100. Id. at 465.
101. Id. at 465–66.
102. Id. (explaining that strict liability does not “dispense with a culpability approach so much as it frees the prosecutor from having to prove culpability in the particular case”).
103. Id. at 466.
105. Id.
106. Id.
107. Id. at 1345–46.
108. Id. at 1363–64.
with moral blameworthiness. Instead, the Court was chiefly concerned with factual blame. That makes sense in a strict liability case involving a public welfare offense.

As Professor Brickey explains, the key issue in these strict liability cases based on the responsible share doctrine is whether there has been an act or omission and whether the prosecution can establish causation. In Dotterweich, the Court explained that liability will be imposed on “those who possess authority and supervisory responsibility when their failure to exercise such authority and to discharge their responsibility results in a violation.” Professor Brickey argues that this liability is justified because the important public interests involved in maintaining a safe food and drug supply require imposing the “‘highest standard of care’ on those in the chain of distribution ‘who execute the corporate mission.’” It appears that Professor Brickey views the actus reus for a responsible corporate officer conviction as an omission and finds that there is no mens rea requirement.

Professor Todd S. Aagaard argues that the conventional wisdom explaining the responsible corporate officer doctrine needs to be reexamined. Professor Aagaard rejects the idea that the responsible corporate officer doctrine is justified because it is used in cases involving public welfare offenses. He also rejects the notion that the responsible corporate officer doctrine dispenses with the mens rea requirement. In Professor Aagaard’s view, the only way to justify the responsible corporate officer doctrine is to view it as a crime of omission where a contractual duty to prevent certain harms exists and the violation of that duty leads to an outcome “that would be a criminal offense if it were caused by affirmative conduct.” The contractual relationship exists due to the individual’s relationship to the employer. The employer delegates the duty to prevent the company from violating the law to the responsible corporate officer. When dealing with a criminal omission, Professor Aagaard argues that knowledge is demonstrated by showing that the defendant is “aware of both the duty to act and the facts of the

109. Id.
110. Id.
111. Id. at 1345–46.
112. Id. at 1362 (citing United States v. Park, 421 U.S. 658, 671 (1975)).
113. Id. (quoting Park, 421 U.S. at 671–72).
115. Id. at 1269–70 (explaining that although the Court mentions the public welfare doctrine in both Dotterweich and Park, it is too general a concept and does not provide adequate guidance “for deciding where and why the responsible relation doctrine should apply”).
116. Id. at 1271 (arguing that if a public welfare offense is relevant to the mental state required for the crime, then that mental state or lack thereof exists without reference to the prosecution being based on the responsible corporate officer doctrine).
117. Id. at 1273–81.
118. Id. at 1281.
119. Id. at 1282.
situation that trigger[s] the duty.”120 Knowledge can also be proved if the government can demonstrate that the responsible corporate officer purposefully decided not to avail herself of the facts that would trigger her duty to act.121 It is not clear, however, why knowledge as opposed to some lesser form of mens rea is required. Finally, Professor Aagaard argues that the responsible corporate officer doctrine is not based on vicarious liability despite the fact that the defendant is being prosecuted for the criminal conduct of her subordinates.122 In his view, the executive who is being held responsible under the responsible corporate officer doctrine is being held accountable for his own failure to act to prevent the subordinate from engaging in the misconduct.123 Thus, the defendant has satisfied both the actus reus and mens rea of the offense herself without referring to the conduct of the subordinate.124

It is no small task to decipher the justification for the responsible corporate officer doctrine based on the Dotterweich and Park cases. The language of the opinions does not leave one with a clear impression of whether the executive is guilty for her own acts or the acts of her subordinates. Further, it is unclear whether the Court viewed an executive’s failure to prevent misconduct as a culpable act or if that was only true in the cases before the Court where the executives had knowledge of the problems. Professor Aagaard’s explanation of the responsible corporate officer doctrine is appealing because it appears to provide a moral justification for punishing individuals for the criminal conduct of their subordinates by recasting the wrongdoing to consist of the executive’s failure to act. For the more recent cases, at least, Professor Aagaard’s explanation falls short because it fails to explain situations where there is liability in the absence of awareness of the underlying misconduct. Without some awareness of misconduct or the risk of misconduct, it is unclear how the duty to act would be triggered. Similarly, Professor Abrams’ justification for the responsible corporate officer doctrine attempts to find a moral justification for punishing executives who were not directly involved in the wrongdoing. He characterizes the Court’s description of a “responsible share” as demonstrating culpability. If the individuals had some culpability for the misconduct, then holding them criminally responsible would certainly be less objectionable. But, the Court also talked about the fact that these individuals are “otherwise innocent” and that they need not be aware of any wrongdoing. Ultimately, Professor Brickey’s explanation for the responsible corporate officer doctrine seems the most plausible because it takes account of the

120. Id. at 1288 (explaining that in a situation with affirmative misconduct as opposed to an omission, knowledge would be satisfied if the act was done “voluntarily and intentionally, and not because of mistake or accident or other innocent reason”).
121. Id. (citing United States v. Ramsey, 785 F.2d 184, 189 (7th Cir. 1986)).
122. Id. at 1289–90.
123. Id.
124. Id.
unique situation involving public welfare offenses. Further, it reconciles the Court's confusing language about blame and responsibility with the assertion that the executives need not be knowledgeable about the misconduct and but for their relationship of authority they are "otherwise innocent." It makes sense that the Court would be concerned with factual blame, as opposed to moral blame, because violations of the FDCA are strict liability offenses where issues of moral blame are typically irrelevant.

As the FDA ramps up enforcement of the health care laws by prosecuting responsible corporate officers,125 it will be critical to determine what level of supervisory control an executive must have to be held criminally responsible. That question has remained unanswered in the Supreme Court and lower court opinions. Specifically, with respect to pharmaceutical fraud involving off-label promotion, is it enough that the illegal promotional activities took place someplace in the executive's command or is it necessary that the individual have specific responsibility in the chain of command for the individuals who engaged in wrongful behavior? It seems that the level of control over the subordinates would be an important factor in justifying a conviction based on the responsible corporate officer doctrine. In addition, the newer cases do not involve allegations that the executives were aware of the violation. Many of the cases that the courts have faced thus far, such as Park, Hata, and Starr, involved situations where the government charged an individual who was aware of the potential violation but did not take any or enough actions to remedy the violation. It is not entirely clear if the justification for responsible corporate officer convictions can stand in situations where the executive never received any type of warning that misconduct might be taking place. If the justification is to stand, it is most likely on the basis of Professor Brickey's justification that the Court is not interested in moral blame when faced with these public welfare offenses.

III. EXCLUSION OF RESPONSIBLE CORPORATE OFFICERS

Federal prosecutors will most likely charge pharmaceutical executives under the responsible corporate officer doctrine for misdemeanor misbranding in violation

125. The FDA has issued guidance on responsible corporate officer prosecutions in its Regulatory Procedures Manual. FDA REGULATORY PROCEDURES MANUAL, SPECIAL PROCEDURES AND CONSIDERATIONS FOR PARK DOCTRINE PROSECUTIONS, § 6-5-3 (2011), available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3. The Regulatory Procedures Manual instructs FDA personnel to consider "the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation." Id. The Regulatory Procedures Manual also sets forth seven factors for FDA personnel to consider, including: (1) whether the violation harmed or could harm the public; (2) "whether the violation is obvious;" (3) whether the violation is part of a pattern of misconduct; (4) "whether the violation is widespread;" (5) the seriousness of the violation; (6) the quality of the evidence in support of the prosecution; and (7) whether the prosecution is good use of agency resources. Id.
of the FDCA. Misbranding is a misdemeanor offense punishable by less than one year in jail, unless it is undertaken "with the intent to defraud or mislead" in which case it is a felony punishable by up to three years in jail. Following a guilty plea or conviction, the executives are faced with both direct and collateral consequences of their criminal convictions. The direct consequences of conviction are those that the judge imposes at sentencing, such as jail time, restitution, disgorgement, and probation. In contrast, the sentencing court is not responsible for imposing collateral consequences of criminal convictions. Collateral consequences are the "civil restrictions that flow from a criminal conviction." There are two types of collateral consequences. The first type of collateral consequences are sanctions that occur automatically upon conviction. The other type involves discretionary disqualifications that an administrative agency has the authority to impose on a case-by-case basis. In the case of health care executives convicted as responsible corporate officers, the most severe collateral consequence of conviction is the OIG's discretionary authority to exclude the corporate officers from participation in federal health care programs.

This Section examines the OIG's wide-ranging authority to impose the collateral consequence of exclusion from participation in federal health care programs and determine its length. It also scrutinizes the OIG's use of its discretionary authority to exclude Purdue Pharma executives, who were convicted as responsible corporate officers but were unaware of their subordinates' wrongdoing, for twenty years. Further, this Section assesses the effect of long periods of exclusion on executives.

A. Collateral Consequences: Exclusion

The Social Security Act grants the Secretary of the Department of Health and Human Services the power to exclude individuals and entities from participation in

126. See 21 U.S.C. § 331(a) (2012) (prohibiting "the introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded"). Under the FDCA, a drug or device is misbranded if its label is false or misleading. 21 U.S.C. § 352(a) (2012). A drug is also misbranded if it does not contain "adequate directions for use." 21 U.S.C. § 352(f).


129. Nora V. Demleitner, Preventing Internal Exile: The Need for Restrictions on Collateral Sentencing Consequences, 11 STAN. L. & POL'Y REV. 153, 154 (1999). In contrast, direct consequences of criminal conviction are "limited to the penal sanction that will be imposed as a result of a plea of guilty." Jenny Roberts, The Mythical Divide Between Collateral and Direct Consequences of Criminal Convictions: Involuntary Commitment of "Sexually Violent Predators," 93 MINN. L. REV. 670, 678–79 (2008). The courts have struggled with distinguishing direct from collateral consequences and have put forth three different definitions of direct consequences. Id. at 689. Courts have looked at whether the consequence is (1) "definite, immediate and largely automatic"; (2) "punitive"; and (3) "within the control and responsibility of the sentencing court." Id. (internal quotations and citations omitted).


131. Id. at 717–18.
federal health care programs. The Secretary has delegated the exclusion authority to the OIG. Congress created the OIG in 1976 and tasked it with conducting audits and investigations “to reduce the likelihood of fraud and abuse” in the Medicare and Medicaid programs. The OIG has had the power to exclude since 1977. The OIG’s power to exclude individuals and entities that have engaged in fraud or abuse involving federal health care programs, such as Medicare and Medicaid, has grown exponentially over the years. If the OIG excludes an individual or entity from federal health care programs, those programs may not pay for any item or services furnished directly or indirectly by the excluded individual or entity. Congress created the exclusion remedy to “protect the Medicare and Medicaid programs and beneficiaries.”


133. OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN ON THE EFFECT OF EXCLUSION FROM PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS (May. 2013), available at http://oig.hhs.gov/exclusions/files/sab-05092013.pdf. The power was provided by the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142. Id. The objective of those amendments was to “strengthen the capability of the government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs.” Medicare and Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977). The amendments established the State Medicaid Fraud Control Units to investigate provider fraud and patient abuse. Medicare and Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 17, 91 Stat. 1175 (1977). The amendments also provided ninety percent federal funding for three years for the states to operate their Medicaid Fraud Control Units. Id.

134. In the beginning, the OIG’s power to exclude was confined to cases where a physician or other practitioner was criminally convicted for an offense involving the Medicare and Medicaid programs. OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN, supra note 133. The OIG first obtained the authority to exclude entities from participation in Medicare and Medicaid in 1981. Id. The Civil Monetary Penalties Law gave OIG the authority to impose exclusions on individuals and entities that submitted false or improper claims for payment by Medicare and Medicaid. Id. In 1987, the Medicare and Medicaid Patient and Program Protection Act (MMPPPA) enhanced anti-fraud efforts by giving the OIG more authority to impose administrative sanctions. SWENDIMAN, supra note 132, at 3–4; Pub. L. No. 100-93 (1987). The MMPPPA enhanced OIG’s authority to exclude by giving it the permissive power to exclude individuals or entities convicted of misdemeanors “relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or financial abuse.” S. Rep. 100–109 (1987), reprinted in 1987 U.S.C.C.A.N. 687. In 1996, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) further strengthened the OIG’s exclusion authority. Pub. L. No. 104-191, 110 Stat. 136 (1996). HIPAA gave the OIG more power to impose mandatory exclusions, set forth minimum periods of permissive exclusion, and created a new exclusion authority for “individuals with ownership or control interest in sanctioned entities.” Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting from Public Law 104-191, 63 Fed. Reg. 46,676 (Sept. 2, 1998) (to be codified at 42 C.F.R. pts. 1000, 1001, 1002, and 1005).

135. 42 C.F.R. § 1001.2.

[A]n exclusion from Federal health care programs effectively precludes an excluded individual or entity from being employed by, or under contract with, any practitioner, provider or supplier to provide any items and services reimbursed by a Federal health care program. This broad prohibition applies whether the Federal reimbursement is based on itemized claims, cost reports, fee schedules or PPS.

OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN, supra note 133.

136. OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN, supra note 133.
The OIG’s exclusion authority is mandatory in some cases and discretionary in others. Exclusion is mandatory if the individual or entity is convicted of a felony offense “relating to” health care fraud or the manufacture or distribution of a controlled substance.\textsuperscript{137} The mandatory exclusion period is a minimum of five years.\textsuperscript{138} Exclusion is permissive if the individual or entity is convicted of a misdemeanor offense “relating to” fraud in connection with the delivery of a health care item or service or the unlawful distribution of a controlled substance.\textsuperscript{139} Permissive exclusions are presumptively for a period of three years unless there are mitigating or aggravating circumstances that lead to either a shorter or longer period of exclusion.\textsuperscript{140} Importantly, the OIG also has permissive exclusion authority to exclude an entity controlled by a sanctioned individual.\textsuperscript{141} In addition, an entity will risk civil monetary penalties and its participation in federal health care programs if it employs an excluded individual to provide health care items or services that are reimbursable directly or indirectly by the federal health care programs.\textsuperscript{142} As a result, the practical effect of the exclusion of an individual is that

\textsuperscript{137} 42 U.S.C. § 1320a-7(a)(3), (4) (2012). A mandatory exclusion could result from a felony conviction “relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.” 42 U.S.C. § 1320a-7(a)(4). Exclusion is also mandatory if an individual or entity is convicted of a program-related crime or a crime related to patient abuse. 42 U.S.C. § 1320a-7(a)(1), (2).

\textsuperscript{138} 42 U.S.C. § 1320a-7(c)(3)(B). There is, however, an exception if the individual or entity is “the sole community physician or sole source of essential specialized services in a community” and the exclusion would impose a hardship on federal health care program beneficiaries. Id.

\textsuperscript{139} 42 U.S.C. § 1320a-7(b)(1), (3). The OIG also has permissive exclusion authority if (1) an entity or individual is convicted of obstruction of an investigation or audit concerning health care fraud and abuse, 42 U.S.C. § 1320a-7(b)(2); (2) an individual or entity has had its license to provide health services revoked or suspended, 42 U.S.C. § 1320a-7(b)(4); or (3) an individual or entity has been excluded or suspended under any federal or state program involving the delivery of health care. 42 U.S.C. § 1320a-7(b)(5).

\textsuperscript{140} 42 U.S.C. § 1320a-7(c)(3)(D). The OIG also has the permissive authority to exclude individuals who have a “direct or indirect ownership or control interest in a sanctioned entity and who know[] or should know of the action constituting the basis for the conviction or exclusion” and individuals who are officers or managing employees of the sanctioned entity. 42 U.S.C. § 1320a-7(b)(15)(A)(i), (ii). A sanctioned entity is one that has been excluded from federal or state health care programs or convicted of (1) any offense leading to a mandatory exclusion; (2) a misdemeanor relating to health care fraud or controlled substances; or (3) an offense relating to obstruction of a health care fraud investigation. 42 U.S.C. § 1320a-7(b)(15)(B)(i), (ii). Thus, the OIG can use an entity’s guilty plea to a misdemeanor offense to exercise its permissive authority to exclude owners, officers, or managing employees, even if the OIG did not exclude the entity. A person or entity is “convicted” of a criminal offense under the statute if the person or entity entered a plea of guilty that has been accepted by a court. 42 U.S.C. § 1320a-7(i)(3). The regulations provide that owners, officers, and managers should receive the same period of exclusion as the sanctioned entity. 42 C.F.R. § 1001.1051(c)(1) (2012). If the entity was not sanctioned, the owner, officer, or manager’s period of exclusion “will be determined by considering the factors that would have been considered if the entity had been excluded.” 42 C.F.R. § 1001.1051(c)(2).

\textsuperscript{141} 42 U.S.C. § 1320a-7(b)(8) (explaining that entities are controlled by individuals who have direct or indirect ownership in the entity and who are officers, directors, agents, or managing employees).

\textsuperscript{142} See OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN, supra note 133.

If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded by OIG, the provider may be subject to [Civil Monetary Penalty (CMP) liability if the excluded person provides services payable, directly or indirectly, by a Federal health care program. OIG may impose CMPs of up to $10,000 for each
the person is virtually unemployable by a health care provider. 143

The OIG has issued guidance on the factors it will examine to determine when permissive exclusion of owners, officers, and managing employees of a sanctioned entity is appropriate under § 1128(b)(15) of the Social Security Act. It has not issued guidance on the permissive exclusion of individuals convicted of misdemeanors “relating to” fraud. Nevertheless, the guidance on the exclusion of officers and managing employees may provide some insight into the OIG’s decision making into whether executives should be permissively excluded for misdemeanor convictions “relating to” fraud. Some of the factors for the exclusion of officers and managing employees seem pretty standard. The OIG will examine the circumstances of the misconduct and seriousness of the offense, the individual’s role in the sanctioned entity, the individual’s actions in response to the misconduct, and information about the entity. 144 Interestingly, the exclusion provision concerning officers and managing employees of sanctioned entities does not contain a knowledge requirement. 145 Perhaps that provides some justification for the OIG’s thinking that the knowledge of the executives should be irrelevant to the exclusion determination. Although the OIG states that it does not intend to exclude all officers and managing employees, it notes that it “has the authority to exclude every officer and managing employee of a sanctioned entity.” 146 The OIG defines a managing employee as any individual “who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity.” 147 In particular, the OIG identifies directors, managers, general managers, and administrators as potential “managing employees” under the act. 148 The OIG will employ a presumption in favor of exclusion that can only be overcome if there are “significant factors” that counsel against exclusion. 149 The OIG does not specify what “significant factors” might overcome the presumption in favor of exclusion. Perhaps the OIG is using the same presumption in favor of exclusion when it comes to executives of companies that have engaged in

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143. OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN, supra note 133, (explaining that there are two “limited” situations where a provider can employ an excluded individual: (1) “if Federal health care programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual,” or (2) if the provider only “employs or contracts with an excluded person to furnish items or services solely to non-Federal health care program beneficiaries.”).


145. Id.

146. Id.

147. Id.

148. Id.

149. Id.
fraudulent conduct. And, it is possible that the OIG believes that it has the authority to exclude any executive convicted of a misdemeanor "relating to" fraud.

The actual exclusion determination for executives who have been convicted of misdemeanor offenses "relating to" fraud remains a mystery. Once the OIG has decided to exclude an executive convicted of a misdemeanor offense "relating to" fraud, however, there are specific aggravating and mitigating factors that the OIG will examine to determine the length of the exclusion. As previously stated, the base period of exclusion for a permissive exclusion is three years.\textsuperscript{150} The OIG will increase the base period of exclusion if the acts committed by the individual or entity resulted in a financial loss of $5000 or more or the acts were committed over a year or more.\textsuperscript{151} In addition, the length of exclusion will increase if the individual or entity's acts had an adverse impact, whether it be physical or mental, on a program beneficiary.\textsuperscript{152} Further, the OIG will increase the exclusion period if the court imposed a sentence that included incarceration or if the entity or individual has a documented history of wrongdoing.\textsuperscript{153} Finally, the OIG can increase the length of exclusion if the individual or entity was convicted of crimes in addition to the crime that is the basis of the exclusion.\textsuperscript{154}

The OIG will shorten the length of exclusion if the conviction of the individual or entity was for three offenses or less and the amount of financial loss is less than $1500.\textsuperscript{155} In addition, the exclusion period will be reduced if the "individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability."\textsuperscript{156} Further, the OIG will decrease the length of exclusion if the individual or entity cooperated with the government and as a result of that cooperation others were (1) convicted or excluded; (2) investigated; or (3) subject to a civil monetary penalty.\textsuperscript{157} Finally, the OIG will shorten a period of exclusion if the health care items or services furnished by the sanctioned entity or individual are unavailable from other sources.\textsuperscript{158}

In short, the OIG has extensive authority to debar individuals and executives for a wide range of offenses. While there are base periods of exclusion based on whether the offense is a misdemeanor or felony, there are not any outer limits on the OIG's ability to increase the exclusion period beyond the base period through aggravating factors. In cases where the individual or entity is a grave danger to the federal health care programs, the power to increase the base period of exclusion will likely be seen as an advantage. In situations where the individual is convicted

\textsuperscript{150} 42 C.F.R. \$ 1001.201(b)(1) (2012).
\textsuperscript{151} 42 C.F.R. \$ 1001.201(b)(2)(i)-(ii).
\textsuperscript{152} 42 C.F.R. \$ 1001.201(b)(2)(iii).
\textsuperscript{153} 42 C.F.R. \$ 1001.201(b)(2)(iv)-(v).
\textsuperscript{154} 42 C.F.R. \$ 1001.201(b)(2)(vi).
\textsuperscript{155} 42 C.F.R. \$ 1001.201(b)(3)(i).
\textsuperscript{156} 42 C.F.R. \$ 1001.201(b)(3)(ii).
\textsuperscript{157} 42 C.F.R. \$ 1001.201(b)(3)(iii)(A)-(C).
\textsuperscript{158} 42 C.F.R. \$ 1001.201(b)(3)(iv).
as a responsible corporate officer, however, the authority to extend the base period of exclusion is potentially subject to misuse or abuse.

B. Purdue Pharma

A prominent example of the OIG’s use of its broad exclusion authority is the Purdue Pharma case. The FDA investigated Purdue Pharma\(^{159}\) for marketing violations concerning its pain drug OxyContin.\(^{160}\) OxyContin is a time-released version of oxycodone and is intended for long-term relief of “moderate to severe pain.”\(^{161}\) Purdue Pharma’s market research showed that doctors had concerns about the drug’s abuse potential, side effects, and risk of patient addiction.\(^{162}\) Thus, Purdue Pharma engaged in a “campaign of misinformation” to allay the concerns of doctors and increase sales of OxyContin.\(^{163}\) From approximately January 1996 to June 2001, Purdue Pharma supervisors and employees marketed and promoted OxyContin as less addictive than other pain medications because of OxyContin’s twelve-hour-release.\(^{164}\) Specifically, supervisors claimed that intravenous abuse was more difficult with OxyContin, that it created less risk of addiction than immediate release opioids, that patients would not develop a tolerance to the drug or experience withdrawal symptoms, and that it caused less euphoria than immediate-release opioids.\(^{165}\) Even though the FDA-approved label stated that the “[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug,”\(^{166}\) Purdue Pharma never provided the FDA with any clinical studies that proved that OxyContin was less addictive than immediate-release versions of oxycodone.\(^{167}\) Indeed, Purdue Pharma’s own studies demonstrated that patients experienced addiction to OxyContin and that they suffered from withdrawal symptoms upon terminating its use.\(^{168}\)

After a five-year investigation into Purdue Pharma’s marketing of OxyContin,

\(^{159}\) Ultimately, however, the government pursued criminal charges against Purdue Frederick Company, Inc., a subsidiary of Purdue Pharma. Thus, the Information and plea agreement references Purdue Frederick Company, Inc. rather than Purdue Pharma. This Article refers to the company as Purdue Pharma because the executives were employed by Purdue Pharma, not Purdue Frederick.

\(^{160}\) Oxycontin is “an opioid analgesic approved to be taken every twelve hours. OxyContin is a controlled-release form of oxycodone and is a Schedule II controlled substance with an abuse liability similar to morphine.” Information, United States v. The Purdue Frederick Company, Inc., No. 1:07CR00029 at 1 (W.D. Va. May 10, 2007) [hereinafter Information].

\(^{161}\) Id. at 5.


\(^{163}\) Id. at 5.

\(^{164}\) Information, supra note 160, at 5–6, 15. The information does not specify the number of supervisors and employees involved in the unlawful promotion. Similarly, the information does not specify where these supervisors and employees were on the Purdue hierarchy.

\(^{165}\) Id.

\(^{166}\) Id. at 5.

\(^{167}\) Id. at 4.

\(^{168}\) Goldenheim, DAB No. 2268, at 6.
the government entered into a global settlement with Purdue Pharma that included a Corporate Integrity Agreement, a fine, and a plea of guilty by Purdue Frederick Company, Inc. (a subsidiary of Purdue Pharma), to felony misbranding with intent to defraud or mislead.\textsuperscript{169} Because the government charged Purdue Frederick Company, Inc., Purdue Pharma was not subject to exclusion from federal health care programs. In addition to the charges against the subsidiary, the government charged three Purdue Pharma executives—Michael Friedman, Howard Udell, and Paul D. Goldenheim—as responsible corporate officers, with misdemeanor counts of introducing a misbranded drug into interstate commerce in violation of the FDCA.\textsuperscript{170} Although each executive held various positions throughout his tenure at Purdue Pharma, at the time they were charged Michael Friedman was President and Chief Executive Officer, Howard Udell was Executive Vice President and Chief Legal Officer, and Paul Goldenheim, who left Purdue Pharma in 2004, was the Executive Vice President of Worldwide Research & Development and Chief Scientific Officer.\textsuperscript{171} All three of the high-level executives entered guilty pleas to the misdemeanor misbranding charge.\textsuperscript{172} The district court accepted the plea agreements even though they did not impose prison sentences because of an "absence of government proof of knowledge by the individual defendants of the wrongdoing."\textsuperscript{173}

On March 31, 2008, the OIG sent notices to Friedman, Udell, and Goldenheim and informed them that they would each be excluded from participation in federal health care programs for twenty years.\textsuperscript{174} The exclusions were based on their misdemeanor convictions as responsible corporate officers. According to the Inspector General, the misbranding offense "relat[ed] to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service," and "to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance."\textsuperscript{175} Because these were permissive exclusions, the base period of exclusion would have been three years. Any increase in the exclusion period would have to be justified on the basis of aggravating factors.

The executives sought review of the Inspector General's decision. After briefing


\textsuperscript{171} Information, supra note 160, at 1–2.


\textsuperscript{173} United States v. Purdue Frederick Co., et al., 495 F. Supp. 2d 569, 576 (W.D. Va. 2007).

\textsuperscript{174} Goldenheim v. Inspector General, DAB No. 2268, at 7 (Dep't of Health & Human Servs. Aug. 28, 2009) (final admin. review).

\textsuperscript{175} Id.
was complete, the Administrative Law Judge (ALJ) reduced the period of exclusion to fifteen years based on information provided by the executives that demonstrated their cooperation with law enforcement officials (a mitigating factor). The executives argued that they had no intent to defraud and that their convictions rested solely on their status as responsible corporate officers rather than their own misconduct. The ALJ found that despite the fact that they were convicted as responsible corporate officers, their misbranding offenses were offenses “relating to fraud” because of the relationship between the executives’ conduct and Purdue’s fraudulent misbranding. Further, the ALJ found that even though the executives lacked personal knowledge of the misbranding, they were not “blameless” because they each acknowledged that they were responsible corporate officers who had the “responsibility and authority” to prevent in the first instance or to correct promptly the conduct that resulted in the drug’s misbranding. Finally, the ALJ determined that the fifteen year period of exclusion was reasonable due to the existence of three aggravating factors and only one mitigating factor.

On appeal, the executives argued that their convictions were not related to fraud because, unlike Purdue Frederick Company, Inc., they were not convicted of fraudulent conduct. The Departmental Appeals Board (DAB), however, was not convinced. It found, based on the plain language of the exclusion provision, that the statute “does not restrict exclusions to only offenses constituting or consisting of fraud, but requires merely that the offense at issue be one ‘relating to’ fraud.” The DAB found that an offense “relating to” fraud is one that has some “nexus” or “common sense connection” to fraud. In the DAB’s view, the misdemeanor misbranding offense clearly related to fraud because without Purdue Frederick’s fraudulent misbranding there would not have been any charges against the executives. Thus, the executives’ lack of knowledge concerning or role in the fraudulent conduct was irrelevant.

The executives also argued that their exclusions were improper because the exclusions did not serve the remedial purpose of the exclusion statute. The exclusion statute is meant to protect federal health care programs from untrust-
worthy individuals.\textsuperscript{186} The executives argued that they were not untrustworthy because there was no evidence that they "acted, or failed to act, knowingly, intentionally, recklessly, negligently, or in any manner that is in the slightest degree personally blameworthy."\textsuperscript{187} The DAB found, however, that the executives' failure to prevent or discover the ongoing fraudulent conduct while they were in charge meant that they were culpable and to blame for the misconduct of Purdue's employees.\textsuperscript{188} As such, the ALJ could have reasonably concluded that they were not "reliable or worthy of confidence."\textsuperscript{189} Ultimately, the DAB upheld the exclusion but reduced it to a period of twelve years because it found that the ALJ increased the period of exclusion based on an aggravating factor that was not supported by substantial evidence.\textsuperscript{190}

The executives sought review of the final decision excluding them from participation in federal health care programs for twelve years in federal district court.\textsuperscript{191} Again, the executives argued that their misbranding offense was not an offense "relating to" fraud and that the period of exclusion was unreasonable because they lacked culpability.\textsuperscript{192} The District Court rejected both of the executives' arguments and held that the Secretary's decision was supported by substantial evidence.\textsuperscript{193} The court applied the two-step framework from \textit{Chevron, U.S.A. Inc. v. Natural Resource Defense Council, Inc.}\textsuperscript{194} to review the DAB's decision that an offense "relating to" fraud is one that has some "nexus" or "common sense connection" to fraud.\textsuperscript{195} The court found that the DAB's interpretation was reasonable because it comported with the plain meaning of the term and was consistent with prior courts' interpretations of similar language in the exclusion statute.\textsuperscript{196} The court also affirmed the twelve-year exclusion period because the length of exclusion was within the Secretary's discretion and was supported by the record.\textsuperscript{197}

\textsuperscript{186} \textit{Id.} at 14.
\textsuperscript{187} \textit{Id.}
\textsuperscript{188} \textit{Id.} at 16–17 (explaining that under \textit{Park} and \textit{Dotterweich} their "convictions under the FDCA mean[t] that, as Purdue's senior executives, they had, but failed to exercise, the duty and responsibility, and the power and authority, to learn about and curtail the fraudulent activities of Purdue employees"). The Appellate Division also noted that if the executives wanted to demonstrate that the misconduct occurred despite their vigilance, they should have gone to trial and argued that they were powerless to prevent the fraudulent conduct. \textit{Id.} at 17.
\textsuperscript{189} \textit{Id.} at 18.
\textsuperscript{190} \textit{Id.} at 25–26 (explaining that the ALJ was wrong to find that the crimes of the executives had an adverse impact on program beneficiaries because there was no showing of a causal connection between the misbranding and the individuals who abused or were addicted to OxyContin).
\textsuperscript{191} See 42 U.S.C. § 1320a-7(f)(1) (2012) (stating that any excluded individual or entity is eligible for judicial review of the exclusion).
\textsuperscript{193} \textit{Id.} at 117.
\textsuperscript{194} 467 U.S. 837 (1984).
\textsuperscript{195} \textit{Friedman}, 755 F. Supp. 2d at 107–10.
\textsuperscript{196} \textit{Id.} at 107–08.
\textsuperscript{197} \textit{Id.} at 117.
On appeal to the D.C. Circuit, the Purdue executives argued that in order to be excluded based on a misdemeanor conviction related to fraud the misdemeanor conviction “must comprise the ‘core elements’ of fraud, one of which is scienter.” A misdemeanor misbranding offense is a strict liability crime and does not have a mens rea requirement. The D.C. Circuit found that the “circumstance-specific approach,” which required the court to examine the facts and circumstances of conviction to determine if the conviction was “factually related to fraud,” was appropriate. As the executives’ convictions were based on being in charge during the time that Purdue supervisors and employees committed felony misbranding with intent to defraud or mislead, it would be nearly impossible to argue that the executives’ misdemeanor misbranding convictions were not factually related to fraud. Thus, the D.C. Circuit’s adoption of the circumstance-specific approach sealed the Purdue executives’ fate and the exclusion was upheld.

The Purdue executives had more success, however, with respect to their challenge to the length of their exclusions. The Purdue executives argued that the Secretary had departed from prior agency decisions and failed to justify the departure. In particular, the cases that the DAB cited in upholding the twelve-year exclusion were inapposite because they involved mandatory exclusions with a minimum exclusion period of five years. Thus, the DAB could not rely on those cases to justify the period of exclusion for the Purdue executives. Accordingly, the D.C. Circuit found that the decision of the DAB concerning the length of exclusion was arbitrary and capricious and remanded the case for reconsideration.

In dissent, Judge Williams argued that the Secretary’s broad interpretation of “misdemeanor relating to fraud” took the phrase out of the context of the exclusion statute. He explained that the context in this statute “suggests a requirement of at least some approximation of the moral turpitude associated with ‘fraud’ itself.” Thus, Judge Williams found the Secretary’s definition of “relating to” as requiring a nexus was not an “analytically reasonable interpretation.”

199. Id. at 820.
200. Id. at 816 (explaining that the executives were convicted “for their admitted failure to prevent Purdue’s fraudulent marketing of OxyContin”).
201. Id. at 824 (explaining that the Purdue executives “do not dispute they are excludable under this circumstance-specific approach”).
202. Id. at 826.
203. Id. at 827.
204. Id. at 828.
205. Id. (explaining that the case would be remanded to the district court “with instructions to remand it to the agency for further consideration consistent with this opinion”).
206. Id. at 831 (Williams, J., dissenting) (explaining that the “meaning of a statute must not be confused with its simple linguistic potential”).
207. Id.
208. Id. at 832.
C. Lessons From the Exclusion of the Purdue Pharma Executives

The remarkable thing about the Purdue Pharma case is not just that the executives received twelve-year exclusions for the wrongdoing of their subordinates; it is that the connection between their conduct and the sanction was so attenuated. There was no evidence put forth that the executives knew about the misbranding of OxyContin. Indeed, their convictions did not require any showing of mens rea because misdemeanor misbranding was a strict liability offense. Their exclusion was based solely on the notion that their misdemeanor convictions were convictions “relating to” fraud. Of course, fraud requires a showing of scienter which could not be shown in the executives’ case. Thus, to find that a misdemeanor strict liability offense that required no mens rea was a conviction “relating to” fraud, which required mens rea, the ALJ explained that the executives’ misdemeanor misbranding convictions were based on the company’s conviction for fraudulent misbranding.

Even if one were to accept the broad definition given to “relating to,” the Secretary still failed to justify the executives’ twelve-year exclusion in light of the goal of the exclusion statute. The purpose of exclusion is essentially risk prevention. The government needs to be able to safeguard the federal health care programs and their participants from individuals who have defrauded the government or caused some other program—related harm. In that sense, the exclusion is for utilitarian reasons because the excluded individual’s loss from the inability to participate in federal health care programs is outweighed by the need to prevent an untrustworthy individual from harming the program in the future. If the exclusion period is severely disproportionate to the potential harm of the individual, however, the exclusion begins to look like it is motivated by a desire to punish rather than a desire to protect the federal health care programs.

Thus, if an individual is to be excluded, then the exclusion period should be proportional to the harm inflicted by the individual and the potential for future harm by the individual. As Professor Ewald has argued, “[w]hen the punitive elements of a sentence are premised on proportionality, the collateral consequences of conviction should be held to the same standard.” Because the prosecutor recognized that the individual executives had no knowledge of or involvement in the misconduct, they received three years of probation and paid large fines. As the district court judge explained in accepting the plea deals, “in the absence of government proof of knowledge by the individual defendants of the

209. The purpose of exclusion is to protect federal health care programs and participants from “untrustworthy healthcare providers, i.e., individuals and entities whose behavior has demonstrated that they pose a risk to program beneficiaries or to the integrity of these programs.” 67 Fed. Reg. 11,928, 11,928 (Mar. 18, 2002).

wrongdoing, prison sentences are not appropriate. But, neither the exclusion nor its length related specifically to the conduct of the executives or their culpability. Instead, the Secretary applied aggravating factors to lengthen the period of exclusion from its base level of three years due to the actions of others. The aggravating factors—financial losses to government programs, duration of the offenses, and the impact of those offenses on individuals—do not relate to the failure of the executives to discover and remedy the misconduct. It is unclear how an extended period of exclusion is warranted for an individual based solely on the conduct of others. The OIG should exclude an individual based on the risk that the individual poses to federal health care programs. At a minimum, the length of exclusion for the individual should be tied to the wrongdoing and risk that the individual will violate the law in the future.

IV. THE MORAL BLAMEWORTHINESS OF RESPONSIBLE CORPORATE OFFICERS

The fundamental problem with imposing significant collateral consequences on individuals convicted as responsible corporate officers is that neither their prosecution nor their collateral consequences are based on their intent or conduct. In most cases, it is based on a failure to act. As the Supreme Court explained in Morissette v. United States, "to constitute guilt there must be not only a wrongful act, but a criminal intention." Strict liability regulatory offenses, such as violations of the FDCA, are the exception to the principle that criminal conduct must be accompanied by moral blameworthiness.

With strict liability regulatory offenses, the concern is the protection of society. "The objective of the law is not to cure or change the mental processes of the defendant. There is no thought of social treatment or rehabilitation. The law's aim is not reformatory, but almost exclusively deterrent, to prevent future repetitions of similar offenses." If the prosecutor actually had to prove "specific authorization or actual knowledge and acquiescence," she would be unable to obtain a conviction in most cases because of "secret instructions and covert understandings" between the wrongdoer and the responsible corporate officer. The common thinking is that in these cases, which ordinarily involve misdemeanor offenses and minor criminal penalties, "the courts can afford to

212. 342 U.S. 246 (1952).
213. Id. at 274 (quoting People v. Flack, 26 N.E. 267, 274 (N.Y. 1891)) (internal quotations omitted).
214. Morissette, 342 U.S. at 257 (1952) (quoting People v. Roby, 18 N.W. 365, 366 (Mich. 1884)) ("Many statutes which are in the nature of police regulations, as this is, impose criminal penalties irrespective of any intent to violate them, the purpose being to require a degree of diligence for the protection of the public which shall render violation impossible") (internal quotations omitted).
216. Id.
217. There are, however, strict liability felony offenses such as statutory rape and felony murder.
disregard the individual in protecting the social interest."\textsuperscript{218} In particular, the courts can turn a blind eye to the "defendant's state of mind or lack of individual blameworthiness."\textsuperscript{219}

Given that violations of the FDCA could potentially lead to serious injury or death, it makes sense to have the responsible corporate officer doctrine as a strong deterrent for corporate executives. When it comes to the initial misdemeanor criminal conviction and minor criminal punishment, the interests of the public are paramount and outweigh an executive's lack of moral blameworthiness in a given case. The question becomes, however, whether that justification holds when there are significant and long lasting collateral consequences that attach to that conviction. This Section contends that it does not. It argues that responsible corporate officers should not be debarred for a period greater than three years, the statutory baseline for permissive exclusion, without a showing that the officer is morally blameworthy for her subordinates' transgressions.

A. Exclusion is a Harsh Remedy

Exclusion from participation in federal health care programs for a prolonged period of time, while technically a civil penalty, is far harsher than the potential criminal penalty for a misdemeanor misbranding violation. Using the example of the Purdue executives, the criminal penalty for their misdemeanor misbranding violations included fines, disgorgement, and three years of probation. Even if they had been sent to prison, the maximum sentence would have been less than a year. In contrast, the OIG initially wanted to debar the executives for a period of twenty years. Thus, the proposed collateral consequences of their convictions would have lasted seventeen years after their probation ended. Ordinarily, once an individual has completed probation, the individual has "paid his or her debt to society" in the eyes of the law.\textsuperscript{220} Indeed, Professor Nora Demleitner argues that collateral consequences that "are not discontinued within a reasonable period of time ... interfere with the ex-offender's rehabilitative efforts by continuing to stigmatize and label him."\textsuperscript{221} The exclusions effectively ended the careers of the Purdue Pharma executives in the health care industry and forever labeled them as untrustworthy criminals.

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\item [218.] Francis Sayre, \textit{Public Welfare Offenses}, 33 COLUM. L. REV. 55, 69–70 (1933). \textit{See also} Morissette, 342 U.S. at 256 (explaining that "penalties commonly are relatively small, and conviction does no grave damage to an offender's reputation").
\item [219.] Sayre, \textit{Criminal Responsibility, supra} note 215, at 720.
\item [220.] Robert M.A. Johnson, \textit{Collateral Consequences}, CRIM. JUST., Fall 2001, at 32, 32.
\item [221.] Demleitner, \textit{supra} note 129, at 161–62 (arguing that "[o]nly strong preventive reasons can justify long or permanent collateral consequences" that continue after "probation, parole, or supervised release has expired"). \textit{See also} Margaret Colgate Love, \textit{Starting Over with a Clean Slate: In Praise of a Forgotten Section of the Model Penal Code}, 30 FORDHAM URB. L.J. 1705, 1705 (2003) (explaining that because the collateral consequences of a criminal conviction remain after the criminal sentence has been served, ex-offenders are deprived of the "tools necessary to reestablish themselves as law-abiding and productive members of the free community").
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Professor Gabriel Chin argues that these types of overly restrictive collateral consequences bear a striking resemblance to a form of punishment that the United States once had: "civil death." In the nineteenth century, civil death statutes took away the civil and political rights of felons "on the theory that they ceased to exist as legal persons after their conviction." Convicted felons were unable to inherit or bequeath property. Felons could not enter into contracts. They were also unable to vote. In essence, convicted felons were no longer protected by the law. Eventually legislators recognized that the ex-felons would need to be full participants in society.

In the 1980s and 1990s, however, federal and state legislatures began enacting collateral consequences that would severely restrict ex-offenders’ ability to reintegrate into society. Federal laws barred people with convictions from many public benefits and encouraged their exclusion from government employment and contracts. In addition to the growth in collateral consequences, there has also been increased access to and awareness of criminal records, which makes it more difficult for ex-offenders to reintegrate once they have paid their debt to society. Professor Chin argues that these collateral consequences are the new form of "civil death." As he explains it, "[f]or many people convicted of crimes, the most severe and long-lasting effect of conviction is not imprisonment or fine. Rather, it is being subjected to collateral consequences . . . ." While Professor Chin’s work focuses extensively on the loss of civil rights and public benefits that follow a


223. Deborah Labelle, Bringing Human Rights Home to the World of Detention, 40 COLUM. HUM. RTS. L. REV. 79, 85 (2008). See also Michael Pinard, Reflections and Perspectives on Reentry and Collateral Consequences, 100 J. CRIM. L. & CRIMINOLOGY 1213, 1214 n.9 (2010) (explaining that civil death has been defined as “the condition in which a convicted offender loses all political, civil, and legal rights”) (quoting Alec C. Ewald, supra note 210, at 1049 n.13).


225. Id.

226. Chin, supra note 222, at 1790.

227. See Love, Starting Over, supra note 221, at 1707–08; Chin, supra note 222, at 1790.

228. Chin, supra note 222, at 1790.


230. Love, Paying Their Debt to Society, supra note 229, at 771.

231. Chin, supra note 222, at 1790.

232. Id. at 1791.
felony conviction, such as the right to vote, he also warns of the consequences of conviction from less serious offenses.\textsuperscript{233} He explains that “[m]erely escaping incarceration” does not insulate someone from the harsh collateral consequences that follow conviction.\textsuperscript{234} Further, with respect to the right to contract with the government, he argues that “for a person who must work for a living, loss of the right to do business with the government—or work in any regulated industry—could result in exclusion as complete as civil death under the nineteenth-century statutes.”\textsuperscript{235} It is these collateral consequences of conviction that become the “most important part” of the conviction.\textsuperscript{236}

There is no question that for health care executives “the most important part” of conviction is exclusion from participation in federal health care programs. Debarred health care executives cannot contract with the government or work for any health care company that contracts with the government except in very limited circumstances. The health care industry is one of the largest industries in the United States. It accounts for approximately 18\% of the United States’ gross domestic product.\textsuperscript{237} Thus, excluded health care executives are unable to access employment in a large segment of the economy. As Professor Demleitner has argued, exclusion from “vast segments of the labor market . . . parallels the effect of restrictions on the ex-offender’s right to contract in the nineteenth and early twentieth centuries.”\textsuperscript{238} As a result of the exclusion, the expertise that these health care executives have gathered over the course of their careers becomes worthless.

In addition, health care executives have no way of demonstrating that they have been rehabilitated and deserve reinstatement prior to the end of the exclusion period. Even upon completion of the exclusion period, reinstatement is not automatic. The excluded individual must make a written request to the OIG for reinstatement.\textsuperscript{239} The written request is not a mere formality. Among other things, the OIG must make a determination that the individual has not engaged in any further actions like those that formed the basis of the exclusion and that the

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\item \textsuperscript{233} Id. at 1806 (explaining that an individual who is facing twenty-five years in prison is probably not so concerned about the loss of a license to practice in a particular industry, but for a person only facing probation, the loss of license or other benefit can be “disastrous”).
\item \textsuperscript{234} Id.
\item \textsuperscript{235} Id. at 1802.
\item \textsuperscript{236} Id. at 1806.
\item \textsuperscript{237} Louise Radnofsky, \textit{Steep Rise in Health Care Costs Projected}, \textit{Wall St. J.}, June 12, 2012, http://online.wsj.com/article/SB10001424052702303768104577462731719000346.html?KEYWORDS=medicare (explaining that in 2010 the health care industry was 17.9\% of gross domestic product and that by 2021 it will be 19.6\% of gross domestic product).
\item \textsuperscript{238} Demleitner, \textit{supra} note 129, at 156.
\item \textsuperscript{239} 42 C.F.R. § 1001.3001(a)(1) (2012). After receiving a written submission for reinstatement, the OIG will request “specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies and such others as may be necessary to determine whether reinstatement should be granted.” 42 C.F.R. § 1001.3001(a)(3). If the requested information is not provided to the OIG, the exclusion will be continued. 42 C.F.R. § 1001.3001(a)(4).
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individual will not do so in the future.\textsuperscript{240} Even upon reinstatement, however, a health care executive who has been debarred for an extended period of time may find it difficult to obtain a position in the health care industry because their expertise in the industry will be stale. In addition, any potential employer may be hesitant to hire someone who has been excluded for such a long period of time. There will either be a large gap or a complete change in industry that will be readily apparent on a health care executive's resume. The subject of the exclusion and the loss of professional capital over time is certain to come up in an interview. Thus, even after the exclusionary period has ended, there are still significant hurdles to reentering the health care field that an executive may be unable to clear. As a result, a long period of exclusion is not just a harsh remedy; it is also the modern day equivalent of "civil death" for health care executives.

B. The Government Should Prove Moral Blameworthiness Before Imposing a Prolonged Period of Exclusion

1. A Prolonged Period of Exclusion is de facto Criminal Punishment

Executives who have committed the crime of being in charge when wrongdoing occurred have little choice but to plead guilty to a misdemeanor misbranding conviction based on the responsible corporate officer doctrine. The likelihood of raising a successful defense at trial is low. That result is likely justified given the potential health and safety dangers involved in these cases and the relatively minor direct criminal consequences that flow from conviction. As explained above, however, the collateral consequence of a prolonged period of exclusion is far more devastating than the direct criminal consequences of conviction. To avoid problems of over deterrence, it is important that the sanction fits the crime. As Professor Samuel Pillsbury has argued, "[t]o say that a punishment is deserved means more than that an offender was responsible for a crime and should be punished; it also means that the punishment matches the crime."\textsuperscript{241} If the OIG wants to impose a period of exclusion greater than the base level of three years on a responsible corporate officer, the OIG should be required to demonstrate that the officer is

\textsuperscript{240} 42 C.F.R. § 1001.3002(a)(1) (2012). The OIG must also determine that the exclusion period ended and that there is no other basis for continuing the exclusion period. \textit{Id}. In making its determination, the OIG will consider the actions of the excluded individual before and after the notice of exclusion; whether all of the fines and penalties due to the federal or state government have been paid; whether the individual complies with conditions of participation; and whether the individual has submitted or caused claims to be submitted for payment from federal health care programs. 42 C.F.R. § 1001.3002(b). If the OIG grants the request for reinstatement, it will provide written notice to the excluded individual informing the individual of the reinstatement date. 42 C.F.R. § 1001.3003(a) (2012). In addition, OIG will inform CMS and all applicable federal and state health care programs of the reinstatement. \textit{Id}.

morally blameworthy for the misconduct. Otherwise, the debarment will be seen as unjust.

One obvious objection to requiring a showing of moral blameworthiness before imposing a period of exclusion exceeding the three year base period is that moral blameworthiness is only considered necessary in criminal law. Indeed, exclusion from federal health care programs is not considered to be a criminal penalty. Exclusion has been characterized as a civil sanction.242 For some, that would be the end of the inquiry. They would probably argue that because exclusion is a civil sanction, the mens rea of the executive subject to exclusion is irrelevant. This is especially true where, as here, there was no requirement of mens rea to obtain a conviction. Perhaps that would be convincing if the executive was subject to exclusion based on a conviction due to his own misconduct.

The civil sanction justification is not satisfying given the ramifications of exclusion in the context where the government has convicted executives of misdemeanor misbranding offenses based on the conduct of others. Indeed, as Margaret Colgate Love has argued, “collateral consequences are increasingly understood and experienced as criminal punishment, and never-ending punishment at that.”243 Further, as explained by Professor Chin, “[w]hether or not any individual collateral consequence is punishment, the overall susceptibility to collateral consequences is punishment. This is the case at least when, as now, there is a vigorous, existing network of collateral consequences.”244

Thus, while exclusion may not technically be a criminal sanction, its imposition is much more serious than the criminal penalties associated with a misdemeanor misbranding conviction. If the government is going to impose “civil death” on an executive then the exclusion should either be based on a conviction for the executive’s personal misconduct or the executive’s awareness of or participation in

242. See, e.g., Hudson v. United States, 522 U.S. 93, 103 (1997) (refusing to apply double jeopardy where a banker was debarred and then criminally charged for the same conduct by explaining that the fact that debarment authority was given to an administrative agency is “prima facie evidence that Congress intended to provide for a civil sanction”). The Supreme Court explained that a civil sanction can be considered to be so punitive that it is transformed into a criminal sanction, but that certain factors must exist before the court can make such a determination. In particular, the court found the factors listed in Kennedy v. Mendoza Martinez, 372 U.S. 144, 168-69 (1963), to be persuasive. Those factors include:

(1) “[w]hether the sanction involves an affirmative disability or restraint”; (2) ‘whether it has historically been regarded as a punishment”; (3) ‘whether it comes into play only on a finding of scienter”; (4) ‘whether its operation will promote the traditional aims of punishment—retribution and deterrence”; (5) ‘whether the behavior to which it applies is already a crime”; (6) ‘whether an alternative purpose to which it may rationally be connected is assignable for it”; and (7) ‘whether it appears excessive in relation to the alternative purpose assigned.’

Id.


244. Chin, supra note 222, at 1825–26.
her subordinate’s misconduct. Thus, a responsible corporate officer conviction that is based on the actions of subordinates where the executive is unaware of the misconduct should not form the basis for a prolonged period of exclusion. If the government wants to exclude an executive who was convicted because she was in charge at the time the misconduct within the company occurred, the exclusion should be based on the executive’s own moral blameworthiness. Thus, there should be some showing that the executive acted negligently, recklessly, knowingly, or purposefully in failing to recognize or remedy the misconduct of subordinates.

2. Responsible Corporate Officers are not Always Morally Blameworthy for the Actions of their Subordinates

Responsible corporate officers may be held criminally accountable for the conduct of their subordinates but that does not mean that they are always morally blameworthy for that misconduct. It is true that corporate officers in the health care field voluntarily take on positions of responsibility in companies that may potentially harm the health, safety, and welfare of the public. As a result, those officers are “under a moral duty to perform that role carefully.”

And, because part of their role is to supervise subordinates, there may be situations where corporate officers are morally blameworthy for their employees’ misconduct. For example, if the executive instructs or encourages the wrongdoing then she is morally blameworthy for it. Nevertheless, a mere showing that the executive failed to detect and correct or prevent the wrongdoing is not the same as saying that the executive had a hand in the misconduct and is morally blameworthy for it. Moral blameworthiness is not demonstrated simply by virtue of the officer’s position in the company. There needs to be some measure of culpability.

While there are many theories of moral responsibility, this Article accepts the formulation by Professor Peter Arenella. Professor Arenella explains that in order to assign moral blame to an individual’s conduct, four conditions must exist: “[a] (1) moral agent must be implicated in (2) the breach of a moral norm that (3) fairly obligates the agent’s compliance under circumstances where that (4) breach can be fairly attributed to the agent’s conduct.” Generally, to find that someone is morally blameworthy for causing harm the actor must “have some


246. An individual may only be characterized as a moral agent if the individual has the ability to make judgments concerning morality and to take actions that conform to those moral judgments. Peter Arenella, Convicting the Morally Blameless: Reassessing the Relationship Between Legal and Moral Accountability, 39 UCLA L. Rev. 1511, 1518 (1992) (explaining that individuals who do not have the potential for “moral concern, judgment, and action” are undeserving of moral blame). Individuals who suffer from mental impairments and young children are generally considered not to be moral agents. Id. at 1518–19.

247. Arenella, supra note 246, at 1518.
form of knowledge, reason, and control of their actions before they can be fairly blamed for what they have done." 248

Responsible corporate officers are certainly moral agents who have the capacity to make moral judgments and take actions in conformity with those judgments. While regulatory offenses such as misbranding may not be based on morality or have moral content, they are morally wrongful in the sense that they are done "in violation of a legal norm." 249 In addition, responsible corporate officers, as members of the health care industry, are obligated to comply with the FDCA. Therefore, the sole question with respect to responsible corporate officers is whether the breach of a moral norm by a subordinate can be fairly attributed to the officer's conduct.

As Professor Arenella explains, to satisfy the fair attribution principle, first "there must be a voluntary act as well as causation between a defendant's act and any resulting harm." 250 But, the responsible corporate officer doctrine lacks the "traditional requirement[] to show a connection between the individual and the particular wrong." 251 It does not conform to ordinary notions of causation and blame. Professor Stanford Kadish explains that:

[w]e are responsible for ourselves and for what our actions cause in the physical world, and we may cause things to happen unintentionally as well as intentionally. However, what other people choose to do as a consequence of what we have done is their action and not ours. Our actions do not cause what they do in the sense that our actions cause events. 252

Thus, causation and blame are tricky concepts in the context of the responsible corporate officer doctrine. In many responsible corporate officer cases, the only way to show causation is by omission. As Professor Brickey explains, "proof that the officer had the responsibility and the power to prevent the violation and that he failed to fulfill the duty to do so establishes the required causal link between the officer and the violation." 253 But, the notion that one person causes the actions of another runs counter to our idea that each person is an autonomous actor. "We regard a person's acts as the products of his choice, not as an inevitable, natural result of a chain of events." 254 While causation based on a factual connection (or chain of events) between the officer and the violation may be justified in the corporate context and thus sufficient for a misdemeanor conviction based on the

248. Id. at 1517.
250. Arenella, supra note 246, at 1523.
251. Petrin, supra note 21, at 299.
254. Kadish, supra note 252, at 333.
responsible corporate officer doctrine, it is insufficient to show that an action is fairly attributable to an executive.

Second, for an action to be fairly attributable there must be proof of mens rea with respect to the individual’s act or risked harm. With a misdemeanor misbranding offense, however, there is no requirement of mens rea. Notwithstanding the views of Professors Abrams and Aagaard, a finding that a responsible corporate officer is guilty of a strict liability misdemeanor offense does not establish culpability. As Professor Brickey makes clear, “while one might well conclude that the [Park] Court’s language . . . would support the proposition that liability must be predicated upon a finding of minimal culpability or negligence, within the context of the Park opinion the premise is unsound.” There is no explicit mens rea requirement in either the offense of conviction or in the responsible corporate officer doctrine. Thus, while there may be some cases where responsible corporate officers are culpable for the conduct of their subordinates, a conviction alone does not demonstrate that culpability. Some additional showing will be necessary to demonstrate that the wrongdoing can be fairly attributed to the responsible corporate officer’s conduct.

To prove that the actions of subordinates are fairly attributable to the responsible corporate officer, there needs to be some showing that the executive in charge intended for the wrongdoing to occur. As Professor Kadish explains, “[w]e become accountable for the liability created by the actions of others . . . only when we join in and identify with those actions by intentionally helping or inducing them to do those actions; in other words, by extending our wills to their action.” Without some showing of intentionality, through negligence, recklessness, knowledge, or purpose, there can be no finding that the actions of the subordinate are attributable to the executive. Thus, in the ordinary case there would be no showing of moral blameworthiness.

This is not to discount, of course, the fact that it would be difficult to prove the moral blameworthiness of a responsible corporate officer. This is particularly true if the executive is a high level official such as a Chief Executive Officer. It is unlikely that the high level official’s participation in the wrongdoing would be documented. Further, the executive might become aware of misconduct but choose not to intervene. The executive’s discovery of the misconduct and subsequent decision not to get involved may similarly go unmemorialized. In many cases, the prosecutor would have to rely upon circumstantial evidence to prove culpability. While both of these scenarios are realistic in a large corporation, the fact that these situations could occur are not enough to relieve the prosecutor of the burden to

255. Arenella, supra note 246, at 1523.
256. Brickey, supra note 104, at 1364 (emphasis added) (examining the Court’s language in Park where it rejects the lower court’s view that a finding of guilty requires a showing of “personal wrongdoing” demonstrated by “gross negligence and inattention in discharging his corporate duties and obligations”).
prove that the officer is morally blameworthy before imposing the harsh remedy of a long period of exclusion. While the public certainly has an interest in these proceedings just like they do in criminal misdemeanor misbranding cases, the public’s interest is no longer paramount. In short, the justification for holding responsible corporate officers accountable without a showing of moral blameworthiness does not hold up when the executive is facing a career-ending exclusion.

3. Aggravating Factors Should be Based on the Moral Blameworthiness of the Responsible Corporate Officer

If there are to be aggravating factors that increase the period of exclusion beyond three years, they should be based on the moral blameworthiness of the responsible corporate officer. They should not be based solely on the harm caused by subordinates. For example, it may be appropriate to consider the corporate hierarchy to determine whether the individuals who engaged in wrongdoing reported directly to the responsible corporate officer or whether they were separated by multiple levels of management. If the individuals who committed the misconduct reported directly to the responsible corporate officer, then the executive’s failure to discover or prevent the wrongdoing is more egregious. In addition, it would make sense to consider compliance measures that the executive may have failed to execute. If the executive could have discovered the misconduct by simply following compliance procedures, then the executive bares more blame for the misconduct. Further, if there were reports of misconduct but the executive ignored them, then the executive should be held accountable for the wrongdoing. The bottom line is that the period of exclusion should be tied directly to the executive’s level of culpability for the acts of her subordinates.

V. CONCLUSION

The FDA should be commended for its efforts to raise the stakes in cases of pharmaceutical fraud. Targeting executives who were in charge at the time that misconduct occurred at the pharmaceutical company sends a strong message that the FDA does not take violations of the drug marketing rules lightly. It holds the executives accountable and gives them strong incentives to monitor their subordinates. After obtaining a conviction, however, the FDA should not impose the collateral consequence of exclusion for more than three years without first demonstrating that the executive is morally blameworthy for the misconduct. While exclusion may be a civil remedy, it is the most damaging remedy that an executive can face. A long period of exclusion could amount to “civil death” that takes away an executive’s livelihood. Further, a long period of exclusion is disproportionate to the harm caused by the executive’s failure to prevent or detect wrongdoing. Thus, the FDA should require a showing that the executive is morally blameworthy for the misconduct of her subordinates before imposing a prolonged period of exclusion.