Note

When the Punishment Does Not Fit the Crime: Exclusions from Federal Health Care Programs Following Convictions Under the Responsible Corporate Officer Doctrine

*Sasha Ivanov**

Abstract

To combat violations of the Federal Food, Drug, and Cosmetic Act, the government has recently chosen to target individual corporate officers in the pharmaceutical and medical device industries instead of just sanctioning the companies themselves. Prosecution of these officers has proceeded under the responsible corporate officer doctrine, a doctrine created by the U.S. Supreme Court as a way to impose criminal liability for public welfare offenses under a strict liability standard. Recently, the Office of Inspector General of the Department of Health and Human Services has used its statutory authority under the Social Security Act to exclude corporate officers convicted under this doctrine from participation in federal health care programs. These exclusions have devastating consequences for officers' careers.

Because the responsible corporate officer doctrine was originally formed in the context of public welfare offenses, which are associated with minor penalties, the exclusions have gone beyond what the Court could have foreseen when it formed the doctrine. The Social Security Act should be amended to limit the exclusionary authority to only those officers who have been convicted

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of fraud, not those officers who are convicted solely using the burden-lowering responsible corporate officer doctrine.

Table of Contents

Introduction

In 2007, Purdue Frederick Company, a subsidiary of the drug company Purdue Pharma ("Purdue"), was convicted of felony fraudulent misbranding of the pain medication OxyContin.[1] The company had marketed OxyContin "as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."[2] The company signed a plea agreement in which it agreed to pay approximately $600 million in fines and restitution.[3] Three corporate officers of Purdue also pled guilty to misdemeanor drug misbranding.[4] Unlike traditional criminal liability, which requires a culpable mental state, appellants argued here that there was no evidence that the officers knew of, or participated in, any of the company's wrongdoing.[5] In addition to receiving probation and paying millions of dollars in fines, the officers were excluded from federal health care programs for twelve years[6]—essentially a death sentence for their careers.

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1 *See* Friedman v. Sebelius, 686 F.3d 813, 816 (D.C. Cir. 2012).

2 United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 571 (W.D. Va. 2007).

3 *See Friedman*, 686 F.3d at 816.

4 *See id.*

5 *See id.* at 818.

6 *See id.* at 816.

Under the responsible corporate officer doctrine, the Department of Justice has prosecuted individual officers of pharmaceutical and medical device companies for violations of the Federal Food, Drug, and Cosmetic Act ("FDCA")[7] using a strict criminal liability standard.[8] In addition to imposing heavy fines and prison time, the Office of Inspector General ("OIG") of the Department of Health and Human Services has exercised its exclusionary authority under the Social Security Act[9] to exclude officers convicted under the responsible corporate officer doctrine from participation in federal health care programs, including Medicare and Medicaid.[10] Exclusion from these programs can be tantamount to a career death sentence for these executives because they are virtually unable to find work in the life sciences or health care industries for the duration of the exclusion.[11]

Using convictions under the responsible corporate officer doctrine as a basis for exclusion from federal health care programs is arguably contrary to the Supreme Court's intentions in upholding a strict, vicarious criminal liability standard for violations of the FDCA. The provisions of the Social Security Act that are the basis for the OIG's exclusionary authority in these cases should therefore be amended to exclude only individuals who have actually been convicted of fraudulent offenses.

Part I provides background information on the FDCA and the responsible corporate officer doctrine as a prosecution device for public welfare offenses, including analysis of the Supreme Court's seminal decisions *United States v. Dotterweich*[12] and *United States v. Park*.[13] Part II details the OIG's new exclusionary authority under the Social Security Act and its extreme consequences in the context of the responsible corporate officer doctrine. Part III focuses on the recent resurgence of the responsible corporate officer doctrine and OIG exclusions, specifically the government's stance that prior measures have been insufficient to fight violations in the health care industry. Part

7 Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301–399f (2012).

8 *See infra* Part I.

9 Social Security Act, 42 U.S.C. ch. 7 (2012).

10 *See, e.g.*, Harkonen v. Sebelius, No. C 13-0071 PJH, 2013 WL 5734918, at *2 (N.D. Cal. Oct. 22, 2013); *see also Friedman*, 686 F.3d at 824; United States v. Huggins, Crim. No. 09-403-3, 2011 WL 6180623, at *2, *13 (E.D. Pa. Dec. 13, 2011). The *Harkonen* case is less applicable to this Note because the corporate officer in that case had been actually convicted of wire fraud. *See Harkonen*, 2013 WL 5734918, at *4.

11 *See infra* Part II.B.

12 United States v. Dotterweich, 320 U.S. 277 (1943).

13 United States v. Park, 421 U.S. 658 (1975).

III also argues that OIG exclusions go beyond the Supreme Court's expectations for public welfare offenses. This Part examines case studies of corporate officers who have been convicted under the responsible corporate officer doctrine and subsequently excluded from federal health care programs. Finally, Part IV proposes that Congress amend the Social Security Act to allow only exclusions following convictions of actual fraud.

I. The FDCA, Public Welfare Offenses, and Origins of the Responsible Corporate Officer Doctrine

The FDCA regulates products that affect people's health, including medical devices and pharmaceuticals. The Supreme Court has interpreted this statute as imposing a strict liability standard because it does not include intent as an element of its violations.[14] The rationale behind this standard is that the FDCA is a public welfare statute, which is intended to protect public health and safety, and generally involves small penalties and no serious harm to the individual's reputation.[15] In two seminal cases, the Court upheld this strict liability standard for the FDCA and held that corporate officers could be criminally liable for their companies' violations regardless of personal knowledge or involvement.[16]

A. *The Federal Food, Drug, and Cosmetic Act*

Congress enacted the FDCA in 1938 to give the federal government more authority to deal with abuses in the food, drug, medical device, and cosmetic industries.[17] The FDCA mandates regulations such as premarket approval of new drugs, legally enforceable food standards, and prohibition against false advertising of drugs.[18] In general, the FDCA regulates products that are essential to health and for which people cannot know the processes by which they are made, treated, or work. Congress's purpose for the FDCA was to "touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection."[19]

With regard to the health care industry, violations of the FDCA include "[t]he introduction or delivery for introduction into interstate

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14 *See infra* Part I.A.

15 *See infra* Part I.B.

16 *See infra* Part I.C.

17 *See The 1938 Food, Drug, and Cosmetic Act*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm (last visited Mar. 11, 2016).

18 *See id.*

19 United States v. Dotterweich, 320 U.S. 277, 280 (1943).

commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."[20] The FDCA also prohibits "[t]he adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce."[21] A misbranding violation can occur, for example, if a drug or medical device has a false or misleading label, the contents of a label are improper, if required information on a label is not prominently displayed, or if the label has inadequate warnings.[22] An adulteration violation can occur when, for example, a drug or device is poisonous or unsanitary, if there are inadequate controls during manufacture, if the strength or quality differs from the official compendium, if it is mixed or substituted with another substance, or if a device is not in conformity with performance standards.[23]

For a first time offense, violations of these provisions can result in imprisonment for not more than one year, a fine up to $1000, or both.[24] For a second offense of the FDCA, or if the violations occur with the "intent to defraud or mislead," the penalties increase to imprisonment for up to three years, a fine up to $10,000, or both.[25]

These penalty provisions of the FDCA imply a strict liability standard because, by their language, they do not require a knowledge or intent element.[26] The FDCA does not include words such as "knowingly" or "intentionally" when describing violations that would suggest an intent requirement.[27] Although some commentators have argued that the FDCA sets up a negligence standard, or some other kind of standard,[28] because of the missing intent language, the provisions of the FDCA considered here have most commonly been inter-

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20 21 U.S.C. § 331(a).

21 *Id.* § 331(b).

22 *See id.* § 352.

23 *See id.* § 351.

24 *Id.* § 333(a)(1) ("Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.").

25 *Id.* § 333(a)(2) ("Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.").

26 *See* United States v. Buffalo Pharmacal Co., 131 F.2d 500, 502 n.2 (2d Cir. 1942) ("That intention is not necessarily an element of the offense under the existing Act is made very clear by section 303, 21 U.S.C.A. § 333(a) and (b) where different penalties are provided for simple violations and for violations 'with intent to defraud or mislead.'").

27 *See supra* notes 20–23 and accompanying text.

28 *See, e.g.*, Jennifer Bragg, John Bentivoglio & Andrew Collins, *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 FOOD & DRUG L.J. 525, 528 (2010).

preted as imposing a strict liability standard.[29] This view of the FDCA conforms to the limited practice of using strict liability for public welfare offenses.[30] The public welfare offense rationale argues that some industries are so closely related to public health and safety that a strict liability standard is necessary to guard against both intentional and accidental violations.[31]

B. *Public Welfare Offenses*

Violations of the FDCA, which regulates food, drugs, medical devices, and other products that affect public health and safety, are widely considered to be public welfare offenses.[32] These offenses emerged as the world changed and as there was rapid urbanization, increased travel, and widespread distribution of products and goods.[33] This "wide distribution of goods" led to increased regulation of the industries producing those goods and elevated the duties of those who controlled those regulated industries, specifically those industries that affected "public health, safety or welfare."[34]

Public welfare offenses are generally those violations that are governed by statutes that regulate activities for the betterment of society.[35] These statutes regulate "potentially harmful or injurious items"[36] and often regulate not affirmative acts but neglect or inaction where a duty of care exists.[37] Earlier examples of public welfare offenses included improper selling of alcohol, selling adulterated milk, housing regulation violations, and labor law violations.[38] Because of the sensitive nature of the products that the FDCA regulates, violations of the FDCA fall in the public welfare offense category.[39]

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29 *See, e.g.*, Friedman v. Sebelius, 686 F.3d 813, 818 (D.C. Cir. 2012) ("Misdemeanor misbranding does not necessarily require a culpable mental state because a conviction for the offense may be . . . predicated upon the responsible corporate officer doctrine, which entails strict liability.").

30 Kimberly Bolte, *Shot Through the Heart: The FDA Gives All Health Care Company Executives a Bad Name Under the Controversial Strict-Liability Misdemeanor Provision of the Federal Food, Drug, and Cosmetic Act*, 6 BROOK. J. CORP. FIN. & COM. L. 593, 604–05 (2012).

31 *See* Andrew C. Baird, Comment, *The New* Park *Doctrine: Missing the Mark*, 91 N.C. L. REV. 949, 958 (2013).

32 *See id.* at 958; Bolte, *supra* note 30, at 597–98, 605

33 *See* Morissette v. United States, 342 U.S. 246, 254–55 (1952).

34 *Id.*

35 *See* United States v. Balint, 258 U.S. 250, 252 (1922) (noting that the purpose of these statutes is "social betterment" as opposed to punishment "in cases of *mala in se*").

36 Staples v. United States, 511 U.S. 600, 607 (1994).

37 *Morissette*, 342 U.S. at 255.

38 *See id.* at 256–58.

39 *See supra* note 32 and accompanying text.

Public welfare offenses developed in the twentieth century as a type of crime that did not include an intent element—an exception to the presumption in the U.S. legal system that mens rea is required for a person to be held criminally liable.[40] Unlike other criminal offenses, public welfare offenses are characterized by a strict liability standard that does not make intent a required element of the crime.[41] The Supreme Court has recognized that there exist "'public welfare' or 'regulatory' offenses, in which [it has] understood Congress to impose a form of strict criminal liability through statutes that do not require the defendant to know the facts that make his conduct illegal."[42]

The purpose of the strict liability standard is to protect the public in situations where a person's mere negligence can harm society.[43] A violation of the strict liability standard can occur before any harm has actually occurred because the risk of the harm can be enough to violate the statute.[44] Strict liability is imposed because the violator is in a better position to avoid the harm than the defenseless public and may be able to avoid the harm by exercising reasonable care.[45] It follows that a malicious will is not necessary to violate a public welfare offense statute because the harm can occur with or without the malicious will but with serious consequences for public health and safety.

The Supreme Court has allowed public welfare offenses to dispense with the mens rea requirement in large part because of the small penalties associated with these crimes.[46] When justifying the strict liability component of public welfare offenses, the Court has said that "penalties commonly are relatively small, and conviction does no grave damage to an offender's reputation."[47] The cases that first de-

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40 *See Morissette*, 342 U.S. at 250 ("The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil."); *see also* George B. Breen & Jonah D. Retzinger, *The Resurgence of the* Park *Doctrine and the Collateral Consequences of Exclusion*, J. HEALTH & LIFE SCI. L., June 2013, at 90, 100.

41 *See Staples*, 511 U.S. at 607.

42 *Id.* at 606.

43 *See* United States v. Balint, 258 U.S. 250, 252–53 (1922) ("[W]here one deals with others and his mere negligence may be dangerous to them, as in selling diseased food or poison, the policy of the law may, in order to stimulate proper care, require the punishment of the negligent person though he be ignorant of the noxious character of what he sells.").

44 *See Morissette*, 342 U.S. at 255–56 ("Many violations of such regulations result in no direct or immediate injury to person or property but merely create the danger or probability of it which the law seeks to minimize.").

45 *See id.* at 256.

46 *See Staples*, 511 U.S. at 617–18.

47 *Morissette*, 342 U.S. at 256.

fined public welfare offenses had penalties such as "fines or short jail sentences, not imprisonment in the state penitentiary."[48] For example, in *Commonwealth v. Raymond*,[49] the defendant was convicted of killing a calf less than four weeks old for the purpose of selling and the maximum penalty was six months in jail or a fine up to $200.[50] In *People v. Snowburger*,[51] the defendant was convicted of selling adulterated mustard and the maximum penalty was a $500 fine or imprisonment in the county jail.[52]

The Court has noted that to impose a severe penalty on a person convicted of a crime that does not include a mens rea requirement violates some sense of fairness.[53] "In a system that generally requires a 'vicious will' to establish a crime, imposing severe punishments for offenses that require no *mens rea* would seem incongruous."[54] The Court noted that it was under such considerations, i.e., small penalties and little harm to the defendant's reputation, that the Court was willing to uphold criminal statutes with strict liability standards.[55] It was under such an understanding of public welfare offenses and the FDCA that the responsible corporate officer doctrine emerged.

C. *Origins of the Responsible Corporate Officer Doctrine:* Dotterweich *and* Park

The responsible corporate officer doctrine began in two Supreme Court cases, *United States v. Dotterweich*[56] and *United States v. Park*.[57] In these seminal cases, the Supreme Court interpreted the FDCA to require both strict and vicarious criminal liability for individuals whose companies had violated the Act. First, in *Dotterweich*, the Court held that, under the FDCA, individual officers of the company could be prosecuted for violations of the statute and noted that the usual mens rea requirement for crimes was absent.[58] About thirty years later, the Court upheld in *Park* the strict liability standard set forth in *Dotterweich* by holding that corporate officers could be held criminally liable for violations of the FDCA despite a lack of knowl-

48 *Staples*, 511 U.S. at 616.
49 Commonwealth v. Raymond, 97 Mass. 567 (1867).
50 *Id.*
51 People v. Snowburger, 71 N.W. 497 (Mich. 1897).
52 *Id.* at 498.
53 *See Staples*, 511 U.S. at 616–17; *see also* Breen, *supra* note 40, at 108.
54 *Staples*, 511 U.S. at 616–17 (citing 4 William Blackstone, Commentaries *21).
55 *See* Morissette v. United States, 342 U.S. 246, 253–56 (1952).
56 United States v. Dotterweich, 320 U.S. 277 (1943).
57 United States v. Park, 421 U.S. 658 (1975).
58 *See Dotterweich*, 320 U.S. at 280–81.

edge of, or participation in, the company's wrongdoing.[59] Both decisions were justified by the public welfare nature of the offenses.

1. United States v. Dotterweich

The formation of the responsible corporate officer doctrine began in 1943 when the Supreme Court decided *Dotterweich*.[60] In that case, the company, Buffalo Pharmacal Company, and its President, Joseph H. Dotterweich, were prosecuted for violations of the FDCA.[61] The violations consisted of three counts of purchase and shipment in interstate commerce of misbranded and adulterated drugs.[62] The company had bought drugs from a manufacturer and then repackaged them for sale with labels that did not contain accurate information regarding ingredients or potency.[63] The jury found Dotterweich guilty of all three counts but, interestingly, found the company not guilty.[64] As a result of the conviction, Dotterweich received a fine of $500 per count and probation for sixty days for each count.[65] The Court of Appeals for the Second Circuit reversed Dotterweich's conviction on the grounds that the company was the only "person" subject to prosecution.[66]

The Supreme Court disagreed with the Second Circuit's interpretation that individuals did not constitute a "person" for purposes of the FDCA. The Court noted that while the statutory definition of "person" includes corporations, "the only way in which a corporation can act is through the individuals who act on its behalf."[67] Thus the Court allowed the prosecution of individuals, not just business entities, for violations of the FDCA.[68]

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59 *Park*, 421 U.S. at 672–73.

60 *See* Noël Wise, *Personal Liability Promotes Responsible Conduct: Extending the Responsible Corporate Officer Doctrine to Federal Civil Environmental Enforcement Cases*, 21 STAN. ENVTL. L.J. 283, 302 (2002).

61 *Dotterweich*, 320 U.S. at 278.

62 *Id.*

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

64 *Dotterweich*, 320 U.S. at 278.

65 *Buffalo Pharmacal*, 131 F.2d at 501.

66 *Id.* at 503. Under 21 U.S.C. § 321(e) (2012), "[t]he term 'person' includes individual, partnership, corporation, and association." The Second Circuit, in *Buffalo Pharmacal*, argued that while the statutory definition of "person" does include individuals, Congress could not have intended "person" to include agents of the company because "[i]t would be extremely harsh to charge [the agent] criminally with the risks of the business as the drug dealer is himself charged." *Buffalo Pharmacal*, 131 F.2d at 503.

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

68 *Id.* at 284.

Additionally, the Supreme Court interpreted violations of the FDCA under a strict liability standard, i.e., with no mens rea requirement.[69] The Court stated that legislation such as the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."[70] The violations of the FDCA, such as misbranding or adulterating drugs in this case, could occur "without any conscious fraud at all."[71] In a move that has brought much controversy to the responsible corporate officer doctrine, the Court refused to define the class of people who could be subject to prosecution under this statute.[72]

The Court's rationale for dispensing with a knowledge or intent requirement for these violations was the public welfare character of the offenses. Because drugs and food—when not taken care of or sold properly—can seriously injure or kill people, Congress decided to take the burden off the innocent party and to put the burden on the person "standing in responsible relation to a public danger."[73] The statement "standing in responsible relation" has been interpreted later to mean not only those individuals who caused the violation, but also those who could have corrected or prevented the violation due to their position in the company.[74] The *Dotterweich* Court noted that "[h]ardship there doubtless may be" on the unknowing officer under a strict liability standard, but Congress has chosen to put the hardship on the party in the best position to know of the potential violations.[75] In order to regulate properly an industry so closely tied with public health and safety, it was necessary to hold agents of the companies strictly liable for any violations.[76]

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69 *See, e.g.*, Baird, *supra* note 31, at 951 & n.12 ("The most common [interpretation of *Dotterweich*] is that the case established strict, vicarious liability for corporate executives." (quoting Norman Abrams, *Criminal Liability of Corporate Officers for Strict Liability Offenses—A Comment on* Dotterweich *and* Park, 28 UCLA L. REV. 463, 464 (1981))).

70 *Dotterweich*, 320 U.S. at 281. The Second Circuit also interpreted the language of the FDCA not to include intent as a requirement. *See Buffalo Pharmacal*, 131 F.2d at 502 n.2.

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

72 *Id.* at 285 ("It would be too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation."); *see also* Amiad Kushner, *Applying the Responsible Corporate Officer Doctrine Outside the Public Welfare Context*, 93 J. CRIM. L. & CRIMINOLOGY 681, 699 n.117 (2003).

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

74 *See* United States v. Park, 421 U.S. 658, 673–74 (1975).

75 *Dotterweich*, 320 U.S. at 284–85.

76 *Id.* at 280–81 ("The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation.").

2. United States v. Park

In 1975 the Supreme Court, in its decision in *Park*, expanded upon the responsible corporate officer doctrine that originated in *Dotterweich*.[77] In *Park*, the company, Acme Markets, Inc., and its President, John R. Park, were charged with five counts of misdemeanor violations of the FDCA due to adulterated foods.[78] Acme Markets, a national food chain, held interstate shipments of food in warehouses that had been exposed to rodent contamination.[79] The Food and Drug Administration ("FDA") had notified Park several times of the unsanitary conditions of the warehouses.[80] The company pled guilty to the misdemeanor but Park pled not guilty.[81] At trial, Park conceded that ensuring sanitary conditions for shipments was one of his responsibilities "in the entire operation of the company" and that he had delegated that responsibility to "dependable subordinates."[82] The jury found Park guilty and he was sentenced to pay a $50 fine for each of the five counts.[83] The Court of Appeals for the Fourth Circuit reversed Park's conviction because "some act of commission or omission is an essential element of every crime."[84]

The Supreme Court reversed the Fourth Circuit's decision and held that Park had been prosecuted and convicted properly under the FDCA because the statute allows the conviction of officers who "have the power to prevent or correct [FDCA] violations."[85] Just as in *Dotterweich*, the Court justified its holding on the public welfare nature of violations of the FDCA.[86] The Court noted that requiring such "foresight and vigilance" of corporate officers was "beyond question demanding" and "perhaps onerous," but stated that these officers had voluntarily taken positions in companies that dealt in products and services so closely related to the public welfare.[87] Therefore, it is rea-

77 Because this case is critical to the development of the responsible corporate officer doctrine, this doctrine is often also called the "*Park* Doctrine." The terms "responsible corporate officer doctrine" and "*Park* Doctrine" are interchangeable; however, this Note will use "responsible corporate officer doctrine" for consistency.

78 *Park*, 421 U.S. at 660.

79 *Id.* at 661–62.

80 *Id.*

81 *Id.* at 661.

82 *Id.* at 664.

83 *Id.* at 666.

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

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

86 *See id.* at 672.

87 *Id.*

sonable for the public to expect that these officers will exercise such "foresight and vigilance."[88]

The Court also reiterated the strict liability standard of the FDCA that it had set forth in *Dotterweich*: "The Act does not, as we observed in *Dotterweich*, make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.'"[89] While the Court did allow for an impossibility defense if the defendant was "powerless" to correct or prevent the violations, the Court also noted that Congress, through the Act, required "the highest standard of foresight and vigilance."[90] The Court suggested that this "highest standard" does not require knowledge or intent and that failure to prevent or correct violations would violate the Act.[91]

The Court then offered that corporate officers can act to avoid prosecutions in these cases because "the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."[92] Again, however, the Court did not clearly define a responsible corporate officer for purposes of the FDCA, and instead stated that a "defendant [who] had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of" could be held liable under this doctrine.[93] While forming a succinct definition of a responsible corporate officer would be admittedly difficult, the ambiguity of the Court's statement gave little guidance to both potential targets of prosecution and prosecutors.[94] The Court did note that a defendant should not be found guilty solely because of his position in the company; some other indication of responsibility vis-à-vis the violation was necessary.[95] While this point scaled back the potentially more extreme interpretation of this case, it still put a whole new class of individuals at risk for prosecution under the doctrine.[96]

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88 *Id.*

89 *Id.* at 672–73.

90 *Id.* at 673 (internal quotation marks omitted).

91 *Id.* at 672–73.

92 *Id.* at 672.

93 *Id.* at 673–74.

94 *See, e.g.*, Joshua D. Greenberg & Ellen C. Brotman, *Strict Vicarious Criminal Liability for Corporations and Corporate Executives: Stretching the Boundaries of Criminalization*, 51 AM. CRIM. L. REV. 79, 94 (2014).

95 *Park*, 421 U.S. at 674.

96 *See* Martin Petrin, *Circumscribing the "Prosecutor's Ticket to Tag the Elite"—A Critique of the Responsible Corporate Officer Doctrine*, 84 TEMP. L. REV. 283, 300–01 (2012).

Through *Dotterweich* and *Park*, the Court set up the responsible corporate officer doctrine as a public welfare offense with a strict, vicarious liability standard. At the time, the penalties attached to violating the FDCA were minor.[97] However, only a couple years after the Court decided these cases, the Department of Health and Human Services began using the responsible corporate officer doctrine to further punish executives for their companies' violations.[98]

II. Office of Inspector General Obtains Exclusionary Authority

Two years after *Park*, the Department of Health and Human Services received authority under the Social Security Act to exclude individuals and businesses from federal health care programs, including for violations of the FDCA.[99] At the time the Supreme Court first introduced the responsible corporate officer doctrine in *Dotterweich*, and later reaffirmed it in *Park*, the penalties for violations of the FDCA were fairly small.[100] In contrast, exclusions from federal health care programs can have devastating consequences for those individuals[101] and greatly diverge from the minor penalties associated with public welfare offenses.[102]

A. *Development of the OIG's Exclusionary Authority*

In 1977, the Social Security Act gave the Secretary of Health and Human Services the authority to exclude certain individuals and busi-

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97 *See supra* notes 65, 83 and accompanying text.

98 While this Note focuses on the use of exclusions under the responsible corporate officer doctrine, there have been other challenges to the penalties incurred by executives under the responsible corporate officer doctrine. There is a case currently pending before the Eighth Circuit challenging a three-month prison sentence for officers of Quality Egg LLC who pled guilty to "misdemeanor introductions of adulterated shell eggs into interstate commerce" under the responsible corporate officer doctrine. *See* Appellants' Opening Brief at 17, United States v. DeCoster, No. 15-1890 (8th Cir. July 21, 2015). The officers argue that a prison sentence following a responsible corporate officer doctrine conviction violates due process because it is based on supervisory liability and that it violates the Eighth Amendment's prohibition on criminal punishments that are "grossly disproportionate to the offense committed." *Id.* at 22–24. However, this case does not deal with exclusions from health care programs following conviction under the doctrine.

99 *See* Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 7(a), 91 Stat. 1175, 1192–93 (1977) (codified as amended at 42 U.S.C. § 1320a-7 (2012)).

100 *See Park*, 421 U.S. at 665–66 ($50 fine per count); United States v. Buffalo Pharmacal Co., 131 F.2d 500, 501 (2d Cir. 1942) ($500 fine per count and sixty days probation per count).

101 *See* Baird, *supra* note 31, at 970.

102 *See supra* Part I.B.

ness entities from participating in federal health care programs.[103] Medicare and Medicaid are two of the federal health care programs to which exclusion applies.[104] The Medicare and Medicaid Patient and Program Protection Act of 1987 allowed the Secretary to delegate his exclusionary authority to the OIG.[105]

In the Social Security Act, section 1320a-7(a) for mandatory exclusion currently reads that the Secretary of Health and Human Services "shall exclude . . . individuals or entities from participation in any Federal health care program" in cases of "[f]elony conviction relating to health care fraud."[106] Section 1320a-7(b) for permissive exclusion reads that the "Secretary may exclude" individuals or entities who are convicted "of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct . . . in connection with the delivery of a health care item or service . . . ."[107]

In the only circuit court case to discuss the legality of these exclusions, *Friedman v. Sebelius*,[108] the D.C. Circuit determined that the phrase "relating to fraud" in the permissive exclusion section of the Act authorized the government to exclude those individuals who were convicted of a misdemeanor that was factually related to fraud even if they were not proven to have any fraudulent intent.[109] Thus, in *Friedman*, even though the officers were only convicted of misdemeanor misbranding of a drug, the court found that the company's fraudulent misbranding conviction stemmed from the same events as the officers' convictions and therefore the officers' convictions were factually related to fraud.[110] It can be inferred from the *Friedman* case that when-

103 Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 7(a), 91 Stat. 1175, 1192–93 (1977) (codified as amended at 42 U.S.C. § 1320a-7 (2012)).

104 42 U.S.C. § 1320a-7b(f)(1) defines "Federal health care program" as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government . . . ." 42 U.S.C. § 1320a-7b(f)(1) (2012).

105 Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 3(j), 101 Stat. 680, 688.

106 42 U.S.C. § 1320a-7(a)(3).

107 *Id.* § 1320a-7(b)(1).

108 Friedman v. Sebelius, 686 F.3d 813 (D.C. Cir. 2012). This is the appeal of a district court case involving one of the Purdue officers discussed in the Introduction of this Note. *See supra* notes 1–4 and accompanying text

109 *See id.* at 824.

110 *See id.* ("[The officers'] convictions for misdemeanor misbranding were predicated upon the company they led having pleaded guilty to fraudulently misbranding a drug and they admitted having 'responsibility and authority either to prevent in the first instance or to promptly correct' that fraud; they did neither.").

ever a company is convicted of a fraudulent offense for certain incidents, and an officer is convicted of an offense related to the same incidents, then that officer will be at risk of exclusion.

The OIG's use of exclusions is not meant to be punitive and is instead meant to regulate health care programs.[111] Rather than punishing corporate officers, the exclusions are supposed to help the OIG fight fraud in health care programs by "removing . . . those who pose the greatest risk to programs and beneficiaries."[112] The OIG believes that "untrustworthy health care providers" who have shown that they are a danger to health care programs or their beneficiaries pose this great risk.[113] Health care exclusions do not, however, only target those individuals who have demonstrated their untrustworthiness or unscrupulousness by committing fraud against Medicare or Medicaid. Instead, because of the responsible corporate officer doctrine and the D.C. Circuit's reasoning in *Friedman*, officers who are convicted solely because of their position in an offending company can be excluded from these programs.[114] Additionally, while the OIG claims that exclusions are not meant to be punitive, the effects of exclusion on executives go far beyond mere deterrence.

B. Extreme Consequences of Exclusion

Exclusion from federal health care programs can be career-ending for those excluded individuals because they cannot find employment in the health care field for the duration of their exclusionary period.[115] As a federal regulation detailing the OIG's authority makes clear: "Exclusion means that items and services furnished, ordered or

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111 *OIG Outlook 2013: Chief Counsel to the IG, Gregory E. Demske*, OIG (Oct. 24, 2012), https://oig.hhs.gov/newsroom/podcasts/2012/outlook/demske-trans.asp (last visited Mar. 31, 2016) ("[Roberta Baskin][:] So, you're not really thinking about [exclusion] in a punitive way? [Gregory Demske][:] No, not at all. The exclusion is a remedy to protect the programs going forward . . . .").

112 *Improved Efforts to Combat Health Care Fraud: Hearing on Serial No. 112-0S1 Before the Subcomm. on Oversight of the H. Comm. on Ways & Means*, 112th Cong. 32 (2011) [hereinafter Morris Statement] (statement of Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services).

113 Medicare and Federal Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 67 Fed. Reg. 11,928, 11,928 (Mar. 18, 2002) (to be codified at 42 C.F.R. pts. 1001, 1003, 1005, 1008); *see also* Katrice Bridges Copeland, *The Crime of Being in Charge: Executive Culpability and Collateral Consequences*, 51 AM. CRIM. L. REV. 799, 804 (2014) ("Exclusion is not meant to be punitive. The goal is supposed to be to protect the health care system from unscrupulous individuals.").

114 *See Friedman*, 686 F.3d at 824.

115 Baird, *supra* note 31, at 970 ("Exclusion is effectively a 'death sentence' for a career in the health care industry.").

prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid and all other Federal health care programs until the individual or entity is reinstated by the OIG."[116] Companies that receive federal health care funding can employ an excluded individual only if the company is able to pay that individual from exclusively private funds and if the services done by the excluded individual relate exclusively to "non-federal program patients."[117] Exclusion can be devastating because almost all health care companies in the United States receive money from some government health program,[118] and the exception criteria is difficult to meet, giving those companies little choice but to avoid hiring excluded individuals.[119]

As an example, in 2011, Scott Harkonen, the former CEO of the biotech company InterMune, was excluded by the OIG for a period of five years.[120] Harkonen had been convicted of wire fraud after his company disseminated a press release with overstated evidence for a benefit of a drug made by InterMune.[121] Harkonen resigned after his conviction in 2009, and as of 2013, he was still unemployed.[122]

The financial repercussions following exclusion can be severe. For example, executives in the pharmaceutical industry make a median base salary of $240,000 per year,[123] so if an executive is excluded for five years, he can lose about $1.2 million in salary over that time period. In the case of the Purdue executives who were excluded for twelve years,[124] they could lose almost $3 million in salary during the exclusion period.

Even once the exclusion period ends, the corporate officer may still struggle to find employment in the life sciences or health care industries because of the stigma associated with exclusion.[125] Exclu-

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116 Program Integrity—Medicare and State Health Care Programs, 42 C.F.R. § 1001.2(d) (2014) (definition of "exclusion").

117 Publication of the OIG Special Advisory Bulletin on the Effect of Exclusion From Participation in Federal Health Care Programs, 64 Fed. Reg. 52,791, 52,793 (Sept. 30, 1999).

118 *See* Breen, *supra* note 40, at 97–98; *see also* Baird, *supra* note 31, at 970.

119 For more information on the effects of exclusion from federal health care programs, see Publication of the OIG Special Advisory Bulletin on the Effect of Exclusion From Participation in Federal Health Care Programs, 64 Fed. Reg. at 52,791–94.

120 *See* David Brown, *The Press-Release Conviction of a Biotech CEO and Its Impact on Scientific Research*, WASH. POST (Sept. 23, 2013), http://www.washingtonpost.com/national/health-science/the-press-release-crime-of-a-biotech-ceo-and-its-impact-on-scientific-research/2013/09/23/9b4a1a32-007a-11e3-9a3e-916de805f65d_story.html.

121 *See id.*

122 *See id.*

123 AM. ASS'N OF PHARM. SCIENTISTS, 2014 SALARY SURVEY 22 (2014).

124 *See infra* Part III.B.1.

125 *See* Breen, *supra* note 40, at 110.

sion is a serious stigma in the health care field because it "represents to the public that the executive is responsible for fraud and abuse and cannot be trusted to further participate in federal healthcare programs."[126] One commentator also suggests that the highly specialized knowledge that executives have regarding compliance with regulations in their field may not be easily transferrable to other industries—further hurting their chances at reemployment.[127] Additionally, threat of exclusion can affect the way that officers approach both corporate positions and plea bargains for prosecutions under the responsible corporate officer doctrine.[128]

Because the Department of Health and Human Services only received its exclusionary authority in 1977, two years after the Supreme Court decided *Park*, the Court could not have foreseen that convictions under the responsible corporate officer doctrine would be used as a basis for exclusion from federal health care programs.[129] At the time that *Dotterweich* and *Park* were decided, penalties for public welfare offenses were generally small monetary fines.[130] A career-ending and highly stigmatizing penalty such as exclusion far exceeds what penalties for public welfare offenses looked like at the time that the Supreme Court upheld the strict, vicarious liability standard for responsible corporate officer doctrine convictions.[131]

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126 *Id.* at 112. Another source has called exclusion "a censure" and "the equivalent of an official shaming." *See* Stacy Clark, *The OIG Means Business This Time: The Increasing Use of Strict Liability in Excluding Pharmaceutical Executives from Federal Health Care Programs*, 40 J.L. MED. & ETHICS 171, 171 (2012) (quoting Dune Lawrence, *Howard Solomon's Career May Meet a Sad End*, BLOOMBERG BUS. (July 14, 2011, 5:45 PM), http://www.bloomberg.com/bw/magazine/howard-solomons-career-may-meet-a-sad-end-07142011.html).

127 *See* Breen, *supra* note 40, at 110.

128 *See, e.g.*, Abraham Gitterman, *Executives Should Think Twice Before Accepting Pleas 'Relating to Fraud': The Expansion of Exclusion Under the* Park *Doctrine*, 25 HEALTH LAW. 1, 3 (2013) (citing Shannon Thyme Klinger & Patrick M. Kellermann, *Understanding* Friedman v. Sebelius*: What You Should Know About the Government's Approach to Permissive Exclusion*, 2 FOOD & DRUG L. INST. UPDATE 53, 56 (2011)).

129 *See Exclusions FAQ*, OIG, http://oig.hhs.gov/faqs/exclusions-faq.asp (last visited Mar. 13, 2016) (noting that the Department of Health and Human Services first began implementing exclusions in 1977); *see also* United States v. Park, 421 U.S. 658, 658 (1975).

130 *See supra* Part I.B.

131 *See, e.g.*, Bragg, *supra* note 28, at 533–34. For a discussion of how exclusions may violate the Due Process Clause, see Breen, *supra* note 40, at 107–17.

III. Contemporary Uses of the OIG's Exclusionary Authority Extend Beyond the Supreme Court's Intent for Public Welfare Offenses

After a few decades of dormancy,[132] the responsible corporate officer doctrine saw a resurgence in the new millennium. The government, dissatisfied with the effectiveness of alternative regulatory measures at curbing abuses in the life sciences industry, announced its intent to increase prosecutions under the doctrine.[133] In turn, the OIG of the Department of Health and Human Services began excluding officers convicted under the doctrine from federal health care programs. The actions against Purdue, Synthes, Inc., Forest Pharmaceuticals, and KV Pharmaceutical demonstrate how the OIG exclusions apply in situations where officers were actually culpable of fraud and in situations where the officers committed no fraudulent acts.[134] Exclusions in the latter situations take penalties beyond what the Supreme Court intended for public welfare offenses with strict liability standards.

A. Resurgence of Prosecutions Under the Responsible Corporate Officer Doctrine

The government chose to reintroduce the responsible corporate officer doctrine for violations of the FDCA because of continued abuses in the life sciences and health care industries.[135] The government recognized that alternative measures were not fully effective against large companies with large bank accounts.[136] Additionally, the government was hesitant to exclude the companies themselves for fear of indirectly hurting the public.[137] Instead, the government announced its intent to use increasingly the responsible corporate officer doctrine and OIG exclusions to regulate the industry.

1. Alternative Regulatory Measures Have Been Insufficient to Deter Abuses in the Life Sciences and Health Care Industries

In the past few years, responsible corporate officer doctrine prosecutions have been used more widely, at least in part, because other

132 *See infra* notes 147–50 and accompanying text.

133 *See infra* Part III.A.2.

134 *See infra* Part III.B.

135 *See infra* Part III.A.1.

136 *See id.*

137 *See id.*

methods of regulation are not working.[138] For example, in the past, the government had been implementing corporate integrity agreements, deferred prosecution agreements, and civil penalties, but there was concern that the impact was minimal and business was continuing as usual.[139] Companies may have been viewing these corporate integrity agreements or penalties as simply "a cost of doing business."[140]

Additionally, the life sciences industry in the United States is "too big to nail."[141] The great need for pharmaceuticals and medical devices means that the government cannot criminally prosecute these companies effectively.[142] A conviction of the company would also mean excluding the company from federal health care programs and thus making the products unaffordable or unavailable for a large number of people.[143] If a company is convicted of a felony, and therefore mandatorily excluded from federal health care programs pursuant to section 1320a-7(a) of the Social Security Act, then there is a chance it will go out of business and no longer make the drugs or medical devices that the public needs.[144]

The government believes that responsible corporate officer doctrine prosecutions and exclusions may be better than the alternatives. By excluding individual executives of those companies instead of the companies themselves, the OIG can punish companies' violations of the FDCA without risking the public's welfare.[145]

Prosecutions under the responsible corporate officer doctrine and health care program exclusions also have a strong deterrent effect. In industries like pharmaceuticals and medical devices, "where some possibility of catastrophic harm is unavoidable even in well-managed firms, effective deterrence requires enforcement calibrated to harm, not fault, in order to sufficiently account for the unique character of

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138 *See, e.g.*, Kathleen M. Boozang, *Responsible Corporate Officer Doctrine: When Is Falling Down on the Job a Crime?*, 6 St. Louis U. J. Health L. & Pol'y 77, 85–86, 89 (2012).

139 *See id.* at 85–86.

140 *Id.* at 86.

141 *Id.* at 87.

142 *See id.* at 87–88.

143 *See id.*; *see also* Morris Statement, *supra* note 112, at 32–33 ("Some hospital systems, pharmaceutical manufacturers, and other providers play such a critical role in the care delivery system that they may believe that they are 'too big to fire' and thus OIG would never exclude them and thereby risk compromising the welfare of our beneficiaries.").

144 *See* Boozang, *supra* note 138, at 87–88. Boozang also notes that even if the company does not entirely go out of business, it may sell its patents and assets (OIG permitting), and this would take time during which the product would not be on the market. *See id.*

145 *See* Morris Statement, *supra* note 112, at 33.

the risks."[146] Because the responsible corporate officer doctrine dispenses with the usual concept of fault in criminal offenses, it has a strong deterrent effect on corporate officers in the industry to avoid any harm and not just negligent harm.

2. *Announcement of the Resurgence of Responsible Corporate Officer Doctrine Prosecutions*

The government used the responsible corporate officer doctrine to prosecute some FDCA cases in the 1960s and 1970s but stopped these prosecutions by the late 1980s.[147] One explanation for this decline is that the government wanted to avoid judicial scrutiny that could overturn this useful tool of prosecution.[148] Another explanation is that the sanctions procured by convictions under the doctrine were not worth the cost of bringing the actions in the first place.[149] In any case, the doctrine remained dormant for several decades. In the past five years, however, there has been renewed governmental interest in the doctrine.[150]

The resurgence of the responsible corporate officer doctrine was due at least in part to continuing violations of the FDCA by corporations.[151] The government was worried that companies viewed the financial penalties following settlements to be simply "a cost of doing business."[152] In 2010, the Government Accountability Office published a report that criticized the FDA's oversight of its Office of Criminal Investigations, which ensured compliance with the law.[153] As a response, FDA Commissioner Margaret Hamburg wrote a letter to Senator Charles Grassley stating that the FDA would increasingly recommend misdemeanor prosecutions under the responsible corporate

146 Patrick O'Leary, *Credible Deterrence: FDA and the* Park *Doctrine in the 21st Century*, 68 FOOD & DRUG L.J. 137, 148 (2013); *see also* United States v. Balint, 258 U.S. 250, 252–53 (1922). But O'Leary brings up a strong counterargument that harms that result from non-negligent behavior are not subject to deterrence. O'Leary, *supra*, at 148.

147 *See* Jason M. Crawford, *A Bitter Pill for the Pharmaceutical Industry? HHS-OIG's Enforcement of the Responsible Corporate Officer Doctrine*, 17 QUINNIPIAC HEALTH L.J. 45, 50 (2014).

148 *See id.*

149 *See* Breen, *supra* note 40, at 101; O'Leary, *supra* note 146, at 148–49.

150 *See, e.g.*, Joseph F. Savage, Jr. & Maren Klawiter, *The Revival of the Responsible Corporate Officer Doctrine?*, 26 HEALTH LAW. 32, 32–33 (2013).

151 *See supra* Part III.A.1; *see also* Clark, *supra* note 126, at 172.

152 Morris Statement, *supra* note 112, at 33.

153 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-221, FOOD AND DRUG ADMINISTRATION: IMPROVED MONITORING AND DEVELOPMENT OF PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF CRIMINAL AND MISCONDUCT INVESTIGATIONS 25 (2010).

officer doctrine.[154] Commissioner Hamburg's letter also stated that the FDA would "enhance its procedures" regarding exclusion and debarment actions, and that it "will clarify the circumstances under which such administrative actions may proceed concurrently with pending criminal investigations and prosecutions."[155]

As a result, the OIG published guidance for exclusions that delineated factors to consider when deciding whether to exclude a particular corporate officer.[156] The publication of this guidance suggested that the OIG intended to use its exclusionary authority more aggressively than it had in the past.[157] Then, in 2011, the FDA released criteria for consideration for recommending responsible corporate officer doctrine misdemeanor prosecutions.[158] At least one commentator believes that the release of the criteria means that prosecutions under the doctrine will be used more widely in the future.[159] In fact, the OIG did escalate its use of its exclusionary authority against corporate officers of companies in the life sciences industry.

B. OIG's Use of Its Exclusionary Authority: Three Case Studies

While prosecutions for violations of the FDCA under the responsible corporate officer doctrine are not new, recently the OIG of the Department of Health and Human Services began to use its exclusionary authority to exclude convicted officers from federal health care programs. Not all of these officers were actually convicted of a fraud-

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154 Letter from Margaret A. Hamburg, Comm'r of Food and Drugs, FDA, to Senator Charles E. Grassley 2 (Mar. 4, 2010) (on file with *The George Washington Law Review*).

155 *Id.*

156 OIG, GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT 2–4 (2010) [hereinafter OIG GUIDANCE]. These factors include: "circumstances of the misconduct and seriousness of the offense," the "individual's role in sanctioned entity," the "individual's actions in response to the misconduct," and "information about the entity." *Id.*

157 Clark, *supra* note 126, at 172.

158 FDA, REGULATORY PROCEDURES MANUAL § 6-5-3 (2011). The criteria include the officer's position in the company and if the officer had authority to fix or prevent the illegal behavior. *Id.* Other factors include:

> 1. Whether the violation involves actual or potential harm to the public; 2. Whether the violation is obvious; 3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings; 4. Whether the violation is widespread; 5. Whether the violation is serious; 6. The quality of the legal and factual support for the proposed prosecution; and 7. Whether the proposed prosecution is a prudent use of agency resources.

Id. The manual notes that knowledge of or participation in the violation are not necessary for prosecution but may be a factor to consider when deciding whether or not to recommend prosecution. *Id.*

159 *See, e.g.*, Baird, *supra* note 31, at 968.

ulent offense; some had no evidence against them that suggested they had committed any fraud.[160] These officers were excluded solely because of their convictions under the responsible corporate officer doctrine.[161] On top of severe court-imposed penalties, including fines and imprisonment, convicted officers have been subjected to career-ending exclusion even in cases where there was no evidence of personal wrongdoing.[162] The following are case studies examining instances in which the OIG has excluded individual corporate officers from federal health care programs following convictions under the responsible corporate officer doctrine.

1. *Purdue Pharma*

In this case, three executives were convicted under the responsible corporate officer doctrine of misdemeanor misbranding of a drug.[163] Additionally, the company was convicted of felony fraudulent misbranding of OxyContin.[164] The convictions came after unnamed Purdue employees "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."[165] The plea agreement between the company and the government resulted in a five-year probation, $500,000 fine, and $600 million in other monetary sanctions—but not exclusion.[166] The officers' repercussions following their own plea deals were 400 hours of community service, a $5000 fine, three-year probation, and disgorgement of all compensation received from Purdue, totaling about $34.5 million.[167] Based on these convictions, the Department of Health and Human Services excluded the three officers from federal health care programs for twelve years pursuant to section 1320a-7(b) of the Social Security Act.[168]

The officers sought review of the health care program exclusion in federal district court, claiming that (1) section 1320a-7(b) did not authorize the officers' exclusion, and (2) even if it did, the decision by

160 *See infra* Parts III.B.1, III.B.3.

161 *See id.* Note that Marc Hermelin of KV Pharmaceutical was excluded a few months before pleading guilty to violations of the FDCA as a responsible corporate officer. *See* Crawford, *supra* note 147, at 53–54.

162 *See infra* Parts III.B.1, III.B.3.

163 *See* Friedman v. Sebelius, 686 F.3d 813, 816 (D.C. Cir. 2012).

164 *See id.*

165 United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 571 (W.D. Va. 2007).

166 *See Friedman*, 686 F.3d at 816.

167 *See id.*

168 *Id.* at 817 (citing 42 U.S.C. § 1320a-7(b) (permissive exclusion)).

the government was "unsupported by substantial evidence and was arbitrary and capricious" due to an inadequate explanation for the allegedly unprecedented length of time of their exclusion.[169] The court, focusing on the meaning of the term "relating to fraud"[170] in the Social Security Act, held that "section 1320a-7(b)(1)(A) authorizes the Secretary to exclude from participation in Federal health care programs an individual convicted of a misdemeanor if the conduct underlying that conviction is factually related to fraud."[171] Thus, the court found that even though the Purdue executives had not been convicted of fraud, because of their positions in the company, their conduct leading to conviction for drug misbranding was "factually related to fraud" and their exclusions were proper.[172]

2. *Synthes, Inc.*

In the matter of Synthes, Inc. ("Synthes"), because of the strong evidence that the President of Synthes was personally involved in the company's wrongdoing, the government used the responsible corporate officer doctrine as a tool to lower its burden of proof during prosecution.[173] Michael D. Huggins[174] was the President of Synthes, a medical device corporation with a subsidiary, Norian Corp., which manufactured bone cements.[175] Huggins pled guilty as a responsible corporate officer to charges of introduction into interstate commerce of adulterated and misbranded medical devices.[176] The bone cement did not have the necessary premarket approval for the uses for which

169 *Friedman*, 686 F.3d at 816.

170 42 U.S.C. § 1320a-7(b)(1)(A). This section of the Social Security Act states that permissive exclusion is authorized for convictions "of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct . . . in connection with the delivery of a health care item or service . . . ." *Id.*

171 *Friedman*, 686 F.3d at 824.

172 *Id.* ("The Appellants do not dispute they are excludable under this circumstance-specific approach: Their convictions for misdemeanor misbranding were predicated upon the company they led having pleaded guilty to fraudulently misbranding a drug . . . ."). The D.C. Circuit reversed and remanded the decision back to the district court, however, because the Secretary's decision as to the length of exclusion was arbitrary and capricious. *See id.* at 828.

173 *See* Andrew R. Ellis, Note, *The Responsible Corporate Officer Doctrine: Sharpening a Blunt Health Care Fraud Enforcement Tool*, 9 N.Y.U. J.L. & Bus. 977, 1016–17 (2013).

174 Three other officers of Synthes were also convicted and excluded from federal health care programs for similar offenses, but for the sake of clarity, this Note will focus only on the President, Michael Huggins.

175 *See* United States v. Huggins, Crim. No. 09-403-3, 2011 WL 6180623, at *2 (E.D. Pa. Dec. 13, 2011).

176 *Id.*

Synthes marketed it, and several patients had died during unapproved clinical trials.[177]

The court upheld Huggins's sentence of nine months imprisonment and a $100,000 fine because there was substantial evidence that Huggins not only knew of the violations, but was himself involved in the wrongdoing.[178] The court noted that all the violations had occurred "with [Huggins's] full knowledge, or under his command and control."[179] Following Huggins's conviction under the responsible corporate officer doctrine, the OIG of the Department of Health and Human Services excluded Huggins from federal health care programs using its permissive exclusionary authority.[180] Based on the evidence accumulated against Huggins during his time at Synthes, it is possible that he would have been convicted of fraudulent misbranding had his case gone to trial.

3. *Forest Pharmaceuticals*

In Forest Pharmaceuticals ("Forest"), the government tried to expand its health care exclusionary authority when it started exclusionary proceedings against an executive who had not been convicted of any crime. The government prosecuted Forest for distributing an unapproved antidepressant as well as the off-label promotion of another antidepressant.[181] Forest pled guilty to three counts, including misdemeanor counts of distributing an unapproved drug and misbranding a drug in interstate commerce.[182] Pursuant to the plea agreement, Forest had to pay a $150 million fine and forfeit $14 million in assets in addition to entering a corporate integrity agreement with the Department of Health and Human Services.[183]

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177 *See id.* at *2, *6, *8–9.

178 *See id.* at *14 ("He committed much of the illegal conduct himself. The scope of this behavior and the magnitude of the wrong perpetuated on unsuspecting users of the untested, and unapproved, product was extreme.").

179 *Id.*

180 Huggins's exclusion can be found using the OIG's online registry of exclusions, found at *Exclusions Search Results: Individuals*, OIG, https://exclusions.oig.hhs.gov/searchresults.aspx (search for Michael Huggins) (specifying that Huggins's exclusion type is "conviction relating to program of health care fraud"). The OIG's website does not specify the time period of Huggins's exclusion.

181 *See* Press Release, U.S. Dep't of Justice, Drug Maker Forest Pleads Guilty (Sept. 15, 2010) [hereinafter Forest Press Release], http://www.justice.gov/opa/pr/drug-maker-forest-pleads-guilty-pay-more-313-million-resolve-criminal-charges-and-false.

182 *See id.*

183 *See id.*

Howard Solomon, Forest's CEO and President, was notified that the OIG was considering excluding him from federal health care programs.[184] Unlike other cases of exclusion, Solomon had never been charged with or convicted of a crime.[185] The OIG's decision was met with sharp backlash from both Forest and critics in the press.[186] Later, the OIG informed Solomon that it had decided to no longer pursue exclusion in his case.[187] It is unclear what the OIG's exact reasoning was behind dropping the exclusionary proceedings, but commentators have suggested that factors may have included issuance of the OIG guidance criteria for exclusions and mitigating evidence such as a robust compliance program.[188] Despite the decision to drop the proceedings, the matter of Forest marks an attempt by the OIG to expand even farther the use of a controversial tool.

4. KV Pharmaceutical

The CEO of KV Pharmaceutical ("KV") was excluded by the OIG prior to any criminal convictions, but there were significant indications that he was involved in the company's FDCA violations.[189] In 2010, Ethex Corp., a subsidiary of KV, pleaded guilty to felony counts of misbranding drugs and failure to file appropriate reports with the FDA.[190] The company, through a subsidiary, had sold oxycodone and hydromorphone as oversized tablets and, after receiving complaints from customers, decided not to take corrective action or report to the FDA.[191] Marc Hermelin was the CEO of KV at this time and the government put forth proof that he both knew about the violations and had made the decision to take no action.[192]

The OIG chose to exclude Hermelin before he had been charged with or convicted of any criminal conduct because of the evidence that

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184 Crawford, *supra* note 147, at 54; Ellis, *supra* note 173, at 1019.

185 *See* Ellis, *supra* note 173, at 1019–20 (suggesting that the OIG was "employing the vicarious liability perspective of the RCO Doctrine in its attempt to exclude Solomon from [federal health care programs]").

186 *See, e.g.*, *id.* at 1019 (citing Alicia Mundy, *U.S. Effort to Remove Drug CEO Jolts Firms*, WALL ST. J. (Apr. 26, 2011, 12:01 AM), http://www.wsj.com/articles/SB10001424052748704123204576283283851626952).

187 *See id.* at 1019–20.

188 *See id.* at 1020; *see also* Crawford, *supra* note 147, at 54–55.

189 O'Leary, *supra* note 146, at 168.

190 *See* Anna Edney, *KV Pharmaceutical's Hermelin Resigns After U.S. Ban*, BLOOMBERG BUS. (Nov. 17, 2010, 4:51 PM), http://www.bloomberg.com/news/articles/2010-11-17/kv-pharmaceutical-s-hermelin-resigns-after-u-s-ban-will-sell-stake.

191 *See* Information at 3, United States v. Hermelin, No. 4:11-CR-85-ERW (E.D. Mo. Mar. 10, 2011), ECF No. 1.

192 *See* O'Leary, *supra* note 146, at 168–69.

implicated him in the company's fraudulent activity.[193] After his exclusion, Hermelin pled guilty in March 2011 to two counts of misdemeanor misbranding under the responsible corporate officer doctrine.[194] Hermelin was sentenced to thirty days in jail and ordered to pay $1.9 million in financial penalties.[195]

C. Cases Demonstrate that the Responsible Corporate Officer Doctrine Has Gone Beyond the Supreme Court's Intent for Public Welfare Offenses

As the cases of Purdue, Synthes, Forest, and KV demonstrate, strict criminal liability combined with career-ending penalties goes beyond what the Supreme Court could have imagined the responsible corporate officer doctrine would be used for at its inception.[196] When the Supreme Court decided the seminal cases of the doctrine, *Dotterweich* and *Park*, it allowed for strict liability for violations of the FDCA because it was a public welfare statute.[197] At that time, public welfare offenses were characterized by "relatively small [penalties], and conviction [that] does no grave damage to an offender's reputation."[198] The penalties imposed on the defendants in *Dotterweich* and *Park* involved relatively small monetary fines and a few weeks of probation.[199] The purpose of a strict liability standard for the responsible corporate officer doctrine was to regulate industries that affected public safety and welfare,[200] not to punish severely individuals who may not have been personally involved in the wrongdoing. When *Dotterweich* and *Park* were decided, the OIG did not yet have authority to exclude parties from federal health care programs under the Social Security Act.[201]

The Purdue, Synthes, Forest, and KV exclusions (and attempted exclusions) demonstrate the OIG's willingness to exercise its exclusionary authority for convictions based on the responsible corporate officer doctrine. While the executives at Synthes and KV could arguably have been convicted of fraud offenses, there was no evidence that

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193 *See* Gitterman, *supra* note 128, at 5.

194 *See id.*

195 *See id.*

196 *See supra* Parts I.B, I.C.

197 *See* United States v. Dotterweich, 320 U.S. 277, 280–81 (1943); *see also* United States v. Park, 421 U.S. 658, 672 (1975).

198 Morissette v. United States, 342 U.S. 246, 256 (1952).

199 *See supra* notes 65 and 83 and accompanying text.

200 *See Dotterweich*, 320 U.S. at 280–81.

201 *Exclusions FAQ*, OIG, http://oig.hhs.gov/faqs/exclusions-faq.asp (last visited Mar. 13, 2016) (noting that exclusionary authority was first exercised in 1977).

the officers in Purdue and Forest would have met the elements of a fraud offense without the burden-lowering help of the responsible corporate officer doctrine.[202] The officers in Purdue and Forest were not shown to have been personally involved in the companies' wrongdoing or shown to have had any knowledge of the violations.[203] Notwithstanding, three officers of Purdue were excluded from federal health care programs following their convictions under the doctrine, in addition to large fines, probation, and community service.[204] The President of Synthes was excluded by the OIG in addition to a nine-month prison sentence and a heavy fine.[205] The CEO of KV was excluded from health care programs as well as ordered to thirty days jail time and a serious monetary fine.[206] For these officers, exclusion from federal health care programs is tantamount to a career death sentence, because they may be unable to find work in that industry for the duration of the exclusion and potentially beyond.[207]

The foregoing punishments are significantly more debilitating than the slap-on-the-wrist penalties in *Dotterweich* and *Park*.[208] While the Supreme Court may have envisioned that officers would receive fines and perhaps a short jail visit under the FDCA, it is unlikely that the Court intended for a doctrine with a strict liability standard to result in career-ending exclusions with severe repercussions for an offender's reputation.[209] While the results in Synthes and KV may have been the same, if either Purdue or Forest reached the Supreme Court today it is unclear whether the Court would uphold the exclusions based on a responsible corporate officer doctrine conviction.[210]

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202 *See supra* Part III.B.

203 *See id.*

204 *See* Friedman v. Sebelius, 686 F.3d 813, 816 (D.C. Cir. 2012).

205 *See* United States v. Huggins, Crim. No. 09-403-3, 2011 WL 6180623, at *1, *13 (E.D. Pa. Dec. 13, 2011).

206 Gitterman, *supra* note 128, at 5.

207 *See supra* Part II.B.

208 *See* Bragg, *supra* note 28, at 533.

209 *See id.* ("Exclusion from federal health care programs was not imposed or even contemplated, since that collateral punishment—a routine consequence of criminal convictions in the health care field today—did not exist at the time of *Park* or *Dotterweich*.").

210 *See id.* at 534 ("If the Court knew at the time of *Dotterweich* and *Park* that much higher penalties would be sought for RCO convictions, it may not have endorsed the doctrine; if a RCO case reached the Court today, it might not stand.").

IV. Proposal to Amend the Social Security Act to Prohibit Exclusions Based Solely on Responsible Corporate Officer Doctrine Convictions

Congress should amend both the permissive and mandatory exclusion provisions of the Social Security Act to make punishments following convictions under the responsible corporate officer doctrine more consistent with the Supreme Court's view of public welfare offenses. The proposed amendments would make exclusions based only on convictions of fraud—or another listed offense—and not on convictions "relating to fraud,"[211] thereby ensuring that individuals who are convicted using only the burden-lowering doctrine will not receive the potentially career-ending penalty of exclusion. Under this proposed amended Social Security Act, the cases of Purdue and Forest would have turned out differently, because the executives in those cases were not shown to have personally committed any fraud.[212] The executives in the Synthes and KV cases would most likely still have been excluded by the OIG because there was strong evidence that they were personally involved in their companies' violations.[213] Other proposed solutions are inadequate to solve this issue of excessive punishment, either because they attempt to circumvent the Supreme Court's decisions in *Dotterweich* and *Park*, or because the OIG has broad discretion to exclude and has shown its willingness to do so.

A. *Amend the Social Security Act to Make Exclusions Based on Convictions of Fraud and Not "Relating to Fraud"*

In order to make punishments following responsible corporate officer doctrine convictions more congruent with the Supreme Court's intent for public welfare offenses, Congress should amend the Social Security Act to make exclusions based on actual convictions of fraud,[214] and not on convictions "relating to fraud."[215] In the case of the Purdue executives, "[t]heir convictions for misdemeanor misbranding were predicated upon the company they led having pleaded guilty to fraudulently misbranding a drug,"[216] and their exclusions were based on those convictions and not on actual evidence of individ-

211 *See supra* note 109 and accompanying text.

212 *See supra* Part III.B.

213 *See supra* Part III.B.

214 A "conviction of fraud" here would mean any fraud conviction that actually requires proof of fraudulent intent, i.e., not a conviction under the strict liability standard of the responsible corporate officer doctrine.

215 *See* 42 U.S.C. § 1320a-7(b)(1)(A) (2012).

216 Friedman v. Sebelius, 686 F.3d 813, 824 (D.C. Cir. 2012).

ual fraudulent intent. The amendments will ensure that exclusions from federal health care programs will apply only to individuals who had fraudulent intent and not those who were convicted solely because of the strict liability standard of the doctrine. As a result, the FDCA will still accomplish its regulatory purposes, but punishments will also be more consistent with those the Court envisioned for public welfare offenses.

The Social Security Act should be amended to avoid the tenuous link between the statutory language of "relating to fraud" and convictions based solely on the lowered standards of the responsible corporate officer doctrine. The amended Act will allow the Secretary to exclude individuals or entities who have been convicted of fraud or another offense in connection with health care, but not allow for the exclusion of individuals who are convicted solely based upon their senior position in an offending company. To achieve this goal, it is necessary to amend both the mandatory and permissive exclusion sections of the Social Security Act.

Section 1320a-7(a),[217] the mandatory exclusion section of the Act, should be amended as follows:

> (a) Mandatory exclusion. The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a-7b(f) of this title): . . .
>
> (3) Felony conviction ~~relating to~~ of health care fraud. Any individual or entity that has been convicted for an offense . . . in connection with the delivery of a health care item or service . . . of fraud or a criminal offense consisting of a felony relating to ~~fraud,~~ theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

Section 1320a-7(b),[218] the permissive exclusion section of the Act, should be amended as follows:

> (b) Permissive exclusion. The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a-7b(f) of this title): . . .
>
> (1) Conviction ~~relating to~~ of fraud. Any individual or entity that has been convicted . . .

217 42 U.S.C. § 1320a-7(a).

218 *Id.* § 1320a-7(b).

> (A) of misdemeanor fraud or a criminal offense consisting of a misdemeanor relating to ~~fraud,~~ theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct . . . in connection with the delivery of a health care item or service . . . ."

The proposed amendments to the Social Security Act will protect officers who have not been actually convicted of fraud but have been convicted under the FDCA due to their position in a company from career-ending exclusion. Those officers who were actually involved in wrongdoing and fraudulent activity can still be excluded for either felony or misdemeanor convictions under the proposed amendments if their convictions were for fraud or one of the other listed offenses. This way, the strict liability standard of the responsible corporate officer doctrine remains consistent with the Supreme Court's intent for public welfare offenses, i.e., punishments are not so severe as to ruin completely an offender's career or reputation.[219]

B. Purdue, Synthes, Forest, and KV Revisited

Under the proposed amendments to the Social Security Act, the outcome in Purdue would have been different. While the company in that case was convicted of felony fraudulent misbranding, the officers were convicted only of misdemeanor misbranding of a drug.[220] Although the officers were in a position of authority within the company, there was no evidence that they had the intent to misbrand the drug or that they knew of the company's violations.[221] Because the amended statute no longer allows exclusion for misdemeanors unless they are actually of fraud related to health care (or one of the other listed offenses), the OIG would not have the authority to exclude the officers pursuant to that section of the Act.

In the Synthes case, however, the result would have likely remained the same even with the proposed amended statute. The court in that case noted that the officer was fully aware of the company's wrongdoing and was even involved in many of the violations.[222] The

219 *See supra* Part I.B.

220 *See Friedman*, 686 F.3d at 816.

221 *See* Friedman v. Sebelius, 755 F. Supp. 2d 98, 102 (D.D.C. 2010), *rev'd*, 686 F.3d. 813 (D.C. Cir. 2012); *see also Friedman*, 686 F.3d at 818 (noting additionally that "[m]isdemeanor misbranding does not necessarily require a culpable mental state because a conviction for the offense may be, and in this case was, predicated upon the responsible corporate officer doctrine, which entails strict liability").

222 *See* United States v. Huggins, Crim. No. 09-403-3, 2011 WL 6180623, at *13 (E.D. Pa. Dec. 13, 2011).

court mentions many instances of the officer intentionally disregarding the FDA's orders, and notes that he "misled the FDA during . . . [an] inspection" and "participated in drafting Synthes' fraudulent and deceptive response [to the FDA]."[223] Based on these findings, it is likely that the officer could have been convicted of fraud along with the other offenses. In that situation, a highly culpable and irresponsible corporate officer would rightfully be excluded from federal health care programs under the amended Act.

Under the proposed amendments to the Act, the officer in the Forest case would not be subject to exclusionary proceedings. While the OIG rightfully dropped the action following backlash from the press,[224] the proceedings should not have been commenced in the first place. The officer was never charged with any involvement in, or knowledge of, the company's off-label promotion of drugs, and he had never been charged with or convicted of a crime.[225]

In the KV case, the executive would have likely still been excluded from federal health care programs. The government brought forth evidence that the executive had "instructed KV employees to minimize written communications about KV's oversized tablet manufacturing problems"[226] and to "do nothing" in response to complaints regarding the tablets, as well as evidence of his personal knowledge that the company failed to make required reports to the FDA.[227] This sort of personal involvement in the company's violations would make it very likely that the executive could have been found guilty of a fraudulent offense without use of the burden-lowering responsible corporate officer doctrine.

C. Other Proposals to Resolve Issues with Punishments Following Convictions Under the Responsible Corporate Officer Doctrine

Other proposed solutions to this problem of excessive punishment do not protect officers who have not personally committed any wrongdoing while also staying within the bounds of the Supreme Court's formulation of the responsible corporate officer doctrine. Changing prosecution to include only truly culpable employees and changing the standard of liability to gross negligence are incongruent

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223 *See id.* at *14.

224 *See supra* notes 184–88 and accompanying text.

225 *See* Ellis, *supra* note 173, at 1019–20.

226 O'Leary, *supra* note 146, at 168 (quoting Information ¶ 19, United States v. Hermelin, No. 4:11-CR-85-ERW (E.D. Mo. Mar. 10, 2011)).

227 *See id.* at 169 (quoting Information ¶ 9, United States v. Ethex Corp., No. 4:10-CR-117-ERW (E.D. Mo. Mar. 2, 2010)).

with the strict, vicarious liability standard that the Supreme Court set out in *Dotterweich* and *Park*.[228] Using compliance programs as a judicially recognized defense still does not protect those executives who were not personally involved in, or knew of, any wrongdoing by the company.[229] Finally, the argument that OIG exclusion is not a problem because the OIG is restrained in choosing its targets is greatly weakened by the Forest case study.

1. Change Prosecution to Include Only Culpable Employees

Andrew C. Baird, in his Comment, *The New* Park *Doctrine: Missing the Mark*, suggests that one way to fix the shortcomings of the responsible corporate officer doctrine is to change targets of prosecution under the doctrine and put liability on the culpable employees.[230] Baird's argument is that prosecuting the culpable individuals will increase diligence throughout the many levels of the corporate structure, and it would "reverse the incentive for executives to distance themselves from potentially violative activities."[231]

While this suggestion would incentivize responsibility in lower levels of a corporation, it is contrary to the Supreme Court's decisions in *Dotterweich* and *Park*. The Court specifically wanted to put the liability on those "in responsible relation" to the violations,[232] and not just on the actually culpable employees. Baird's proposal would be workable had the Court not specified that it intended to hold those in responsible positions to the violations liable because of the public welfare nature of the statute.[233]

2. Change the Standard of Liability from Strict Liability to Gross Negligence

Baird also suggests changing the standard of liability for prosecutions under the responsible corporate officer doctrine from strict liability to gross negligence.[234] Baird argues that (1) this would help bridge the gap between the strict liability standard set forth in the statute and the more negligence-type standard used in the court, and

228 *See supra* Part I.C.

229 *See infra* Part IV.C.3.

230 Baird, *supra* note 31, at 994–95.

231 *Id.*

232 United States v. Dotterweich, 320 U.S. 277, 281 (1943).

233 *See id.* at 280–81; *see also* United States v. Park, 421 U.S. 658, 672 (1975).

234 Baird, *supra* note 31, at 995–96.

(2) a negligence standard would aid companies in determining who is and who is not a responsible corporate officer.[235]

While both of Baird's contentions may be true, the Supreme Court in *Dotterweich* and *Park* implicitly set out a strict liability standard.[236] The Court specifically said that there is no need for personal knowledge or participation in the violations,[237] thereby taking out the actus reus necessary for a negligence standard.[238]

3. *Compliance Programs as a Judicially Created Defense*

Andrew R. Ellis, in his Note, *The Responsible Corporate Officer Doctrine: Sharpening a Blunt Health Care Fraud Enforcement Tool*, argues that in order to counteract the responsible corporate officer doctrine's "extreme sanctions," compliance and monitoring programs set up by the officers prior to conviction should constitute a judicially created defense.[239] Ellis argues that allowing these programs as a defense "would transform what is now a rather blunt enforcement tool into a sharper, more just device."[240] Ellis further argues that the OIG should consider whether the corporation and officer had compliance programs in place when deciding whether to exclude the officer from federal health care programs as a way to target the more culpable individuals.[241]

Although Ellis's suggestions would make the application of the doctrine and exclusion more fair, they still leave officers who do not have the requisite mens rea or actus reus vulnerable to exclusion. Those officers who do not have robust compliance programs in place, and were not personally involved in the company's wrongdoing, would still be subjected to the strict liability standard of the doctrine, and therefore at risk for OIG exclusion. Although Ellis's suggestions might ameliorate the situation, they still do not make punishments following conviction under the doctrine consistent with the Supreme Court's intent for public welfare offenses.

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235 *Id.*

236 *See supra* Part I.C.

237 *See Dotterweich*, 320 U.S. at 280–81; *see also Park*, 421 U.S. at 672–73.

238 *But see Park*, 421 U.S. at 678–79 (Stewart, J., dissenting) (stating that the majority used the "language of negligence").

239 Ellis, *supra* note 173, at 984.

240 *Id.*

241 *See id.*

4. OIG Exclusion Is Not a Problem Because the OIG Is Restrained in Choosing Targets for Exclusion

Jason M. Crawford, in his Article, *A Bitter Pill for the Pharmaceutical Industry? HHS-OIG's Enforcement of the Responsible Corporate Officer Doctrine*, argues that concern over OIG exclusions based on the responsible corporate officer doctrine is "overstated."[242] Crawford argues that the OIG has been restrained in choosing who to exclude and will avoid excluding those executives who have no personal involvement in, or knowledge of, the company's violations, and who have vigorous compliance programs established.[243] Crawford uses three examples, including Purdue[244] and Forest,[245] to show that the OIG has been judicious in its use of its exclusionary authority.[246]

On the contrary, the OIG's use of its exclusionary authority in the Purdue and Forest cases shows its willingness to target officers who have not been shown to be personally involved in any wrongdoing. There was no showing that the officers in Purdue participated in or knew of the company's violations, and the officer in Forest had not even been charged with or convicted of a crime.[247] The Forest matter particularly demonstrates how ready the OIG is to exclude because the officer was shown to have implemented a strong compliance program.[248] Although the OIG's Guidance for Implementing Permissive Exclusion Authority may make the OIG more restrained in who it chooses to exclude,[249] the current Social Security Act permits the OIG to exclude officers who are not traditionally culpable of the company's violations.[250]

The foregoing proposed solutions and arguments either do not fully protect executives not convicted of a fraudulent offense, or they are inconsistent with the Supreme Court's description of the responsible corporate officer doctrine. Amending the Social Security Act will, however, fully protect non-fraudulent executives from exclusion while keeping the Court's strict, vicarious liability standard for violations of the FDCA.[251]

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242 Crawford, *supra* note 147, at 47.

243 *See id.*

244 *Id.* at 55–56.

245 *Id.* at 54–55.

246 *See id.* at 53–56.

247 *See supra* Part III.B.1–3.

248 *See supra* Part III.B.3.

249 *See generally* OIG GUIDANCE, *supra* note 156.

250 *See supra* Part III.

251 *See supra* Part IV.

Conclusion

The OIG exclusions take punishment far beyond what the Supreme Court could have foreseen for public welfare offenses when it upheld a strict criminal liability standard for convictions under the responsible corporate officer doctrine. Public welfare offenses are generally limited to minor penalties and minor harm to an offender's reputation, while OIG exclusions are essentially career-ending for executives. Because the OIG did not get its exclusionary authority until after the two seminal cases that set up the doctrine were decided, the Supreme Court could not have foreseen that the doctrine would be used as a basis for these types of exclusions. To counteract the excessive repercussions for which corporate officers are currently at risk, the Social Security Act should be amended to require officers to be actually convicted of fraudulent activity before they are excluded from federal health care programs. The amended Act would allow exclusions of actually culpable officers without ruining the lives of those officers whose sole guilt was being in charge.