NORTH CAROLINA LAW REVIEW

Volume 91 | Number 3 Article 6

3-1-2013

The New Park Doctrine: Missing the Mark

Andrew C. Baird

The New *Park* Doctrine: Missing the Mark*

INTRODUCTION

In 2008, the House Energy and Commerce Subcommittee on Oversight and Investigations conducted a hearing on the Food and Drug Administration's ("FDA") investigation of an external researcher accused of fraudulently conducting clinical studies.[1] Special witness Senator Charles Grassley, then Ranking Member of the Senate Finance Committee and a reputed protector of federal

1. *See* Press Release, Office of Senator Charles Grassley, Grassley Law Recovers Another $2.8 Billion of Taxpayer Money Otherwise Lost to Fraud (Dec. 19, 2011), *available at* http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=38341.

health spending programs,[2] expressed serious concern over the FDA's management of its Office of Criminal Investigations ("OCI"), the office responsible for managing the Agency's criminal investigations.[3] Specifically calling out problematic interactions between Senate staff and OCI officials, the Senator's statements formed the basis for a Government Accountability Office ("GAO") investigation into the operational effectiveness of OCI's internal procedures. Two years later, in January 2010, the GAO released its report on the investigation, highlighting several systematic recommendations for the OCI to implement.[4]

In response to congressional and GAO concerns over the OCI issue, President Obama's FDA Commissioner, Dr. Margaret A. Hamburg, penned a letter to Senator Grassley in March 2010 emphasizing the FDA's commitment to implementing remedial measures.[5] Amongst the Commissioner's commitments was a plan to increase the use of misdemeanor prosecutions "to hold responsible corporate officials accountable."[6] This plan marked the official return of the long-dormant responsible corporate officer doctrine ("RCO doctrine") in the pharmaceutical and health care industries. Also known as the *Park* doctrine in the pharmaceutical context,[7] the Commissioner's letter only confirmed what her agency and its parent, the Department of Health and Human Services ("HHS"), had already begun: a regulatory offensive against pharmaceutical and health care entities and their executives.[8]

---

2. *Id.* Grassley's reputation for stringent government oversight stems largely from the success of his 1986 Amendments to the False Claims Act, which have netted recoveries over $30 billion since their passage. *See id.*

3. *See Keteck Clinical Study Fraud: What Did Aventis Know?: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 110th Cong. 78 (2008) (statement of Sen. Charles E. Grassley, Member, H. Comm. on Energy and Commerce).

4. *See* 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 2 (2010), http://www.gao.gov/new.items/d10221.pdf [hereinafter GAO Report].

5. Letter from Margaret Hamburg, Comm'r, Food & Drug Admin., to Sen. Chuck Grassley, Member, H. Comm. on Energy and Commerce (Mar. 4, 2010), http://www.fdalawblog.net/files/fda-grassley-ltr.pdf.

6. *See id.* at 2.

7. The term "*Park* doctrine" is occasionally used because the government's use of this prosecution doctrine was solidified in the 1975 case *United States v. Park*, 421 U.S. 658 (1975).

8. *See* Letter from Margaret Hamburg to Sen. Chuck Grassley, *supra* note 5. For evidence that the Obama Administration has become more aggressive in its pharmaceutical regulatory prosecution, see James S. Cohen & Michael W. Peregrine, *The*

As the FDA, HHS, and Department of Justice ("DOJ") more aggressively enforce a certain class of health care offenses, the *Park* doctrine has reemerged as an attractive legal mechanism to help achieve these agencies' goals of increased compliance and obedient executives.[9] Originally established in 1943 in *United States v. Dotterweich*[10] and again in 1975 in *United States v. Park*,[11] the *Park* doctrine is a prosecution approach available to government prosecutors in criminal actions against individual pharmaceutical and health care executives for misconduct committed by their subordinates. Based on theories of vicarious liability, responsible corporate officership, and strict liability, the *Park* doctrine is notably unique in that it can result in a personal criminal conviction for misdemeanor offenses, even when the particular defendant neither committed the violation nor was aware of the conduct that caused the violation.[12] The doctrine fell out of use for nearly two decades after its genesis in the 1970s, but has recently reemerged as a potent and, as this Comment will argue, misplaced regulatory enforcement tool.[13]

The renewed use of the *Park* doctrine is the main focus of this Comment. While this new use differs from the doctrine's original formulation in several respects, it may best be characterized by the type of legal penalties that can now follow from a *Park* doctrine conviction.[14] Of these penalties, the most alarming is the recently

---

Return of the Responsible Corporate Officer Doctrine, NAT'L L.J. (Mar. 14, 2011), http://www.mwe.com/info/pubs/NLJ_031411.pdf. For evidence that the Administration has become more aggressive in the entire health care sector, see Letter from Attorney Gen. Eric Holder and Sec'y Kathleen Sebelius to the Am. Hosp. Ass'n et al. (Sept. 24, 2012), *available at* http://www.nytimes.com/interactive/2012/09/25/business/25medicare-doc.html.

9. *Park* doctrine prosecutions have thus far been used almost exclusively to enforce provisions of the Food, Drug, and Cosmetic Act (FDCA) § 1, 21 U.S.C. § 301 (2006), but there is nothing limiting its use only to this particular piece of legislation.

10. 320 U.S. 277 (1943).

11. 421 U.S. 658 (1975).

12. This common understanding of the doctrine is premised on the Supreme Court's language in *Dotterweich*. *See Dotterweich*, 320 U.S. at 281 (noting that the legislation under which the case was brought "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing"); Norman Abrams, *Criminal Liability of Corporate Officers for Strict Liability Offenses—A Comment on* Dotterweich *and* Park, 28 UCLA L. REV. 463, 464 (1979) ("The most common [interpretation of *Dotterweich*] is that the case established strict, vicarious liability for corporate executives.").

13. *See* John R. Fleder, Douglas B. Farquhar & Thomas Scarlett, *FDA and the* Park *Doctrine*, FDA L. BLOG, at 19–26 (Oct. 10 2010), http://www.fdalawblog.net/files/fda-and-the-park-doctrine.pdf.

14. The primary penalty of concern to health care executives is the exclusion penalty, a sanction that prevents an individual from working for any entity that receives funding from any federal health care program (and also penalizes any entity that employs an excluded individual). *See* Social Security Act § 1128, 42 U.S.C. § 1320a-7 (2006).

approved usage of HHS's exclusion authority.[15] Exclusion is an administrative penalty levied by HHS against individuals who are deemed to pose a threat to the integrity of the federal health care programs, whereby the excluded individual is prohibited from obtaining any reimbursement from any federal health care program, or working for any company that receives such reimbursements.[16] The federal health care exclusion authority effectively functions to prevent a convicted individual from working for or with any entity that receives funding from a federal health program for a period of years.[17]

Under the authority of the Social Security Act ("SSA"), the Secretary of HHS is responsible for excluding individuals.[18] The SSA sets out the circumstances under which an individual or entity must be excluded (mandatory exclusion) and when an individual may be excluded (permissive exclusion).[19] The former applies to more serious cases of criminal conduct as well as certain felonies; the latter applies to a series of less serious criminal charges, including misdemeanors relating to fraud or the delivery of controlled substances.[20] Regardless of how the conviction arises, either through a traditional conviction based on direct individual mens rea or through a more attenuated *Park*-type approach, an exclusion penalty effectively renders the excluded individual incapable of continuing his or her career in the health care field for the given sentence.[21]

It is important to properly distinguish between the *Park* doctrine and the exclusion penalty. Exclusion only comes into play once an

15. *See* Friedman v. Sebelius, 686 F.3d 813, 816, 820, 823 (D.C. Cir. 2012) (holding that HHS is permitted to exclude individuals who are convicted for health care offenses under the *Park* doctrine).

16. *See Background Information*, DEP'T HEALTH & HUMAN SERVS., OFF. OF INSPECTOR GEN., https://oig.hhs.gov/exclusions/background.asp (last visited Oct. 27, 2012) (outlining the various reasons an individual may be excluded).

17. *See* 42 U.S.C. § 1320a-7(c).

18. *See id.*

19. *See id.*

20. For example, individuals convicted of the more egregious offense of felony health care fraud under 42 U.S.C. § 1320a-7(a)(3) are subject to mandatory exclusion with a minimum term of five years, whereas individuals convicted of the less egregious offense of misdemeanor health care fraud under 42 U.S.C. § 1320a-7(b)(1)(A) are potentially subject to permissive exclusion for a minimum term of three years.

21. Peter Suber, *An Open Access Mandate for the National Institutes of Health*, 2 OPEN MED. 39, 39 (2008), *available at* http://www.openmedicine.ca/article/viewarticle/213/135. Because of the size of the Medicare and Medicaid markets (not to mention other markets driven by federal health spending), nearly every American pharmaceutical company, regardless of size, receives some money from a federal health program.

individual has been convicted of an offense that is eligible for either mandatory or permissive exclusion.[22] The *Park* doctrine, on the other hand, is one particular legal theory that lawyers at the HHS Office of Inspector General ("OIG") may use to secure such an exclusion-eligible conviction, but certainly not the only one.[23] If an individual knowingly or intentionally commits an exclusion-eligible offense, the *Park* doctrine is unnecessary, but the exclusion penalty may still be applied.[24]

This Comment focuses on the recent and increasing link between the *Park* method of conviction and the accompanying exclusion penalty and examines the implications of this combination for corporate counsel and executive officers in the health care and pharmaceutical industries. The types of offenses that trigger exclusion eligibility are generally known as public welfare offenses, a class of offenses that fits neatly into other forms of criminal offenses ("such as those against the state, the person, property, or public morals").[25] Historically, penalties for these types of offenses were "relatively small, and conviction [did] no grave damage to an offender's reputation."[26] However, the availability of the exclusion penalty in the wake of a *Park* conviction has changed the tenor of the historical relationship between violation and punishment. To demonstrate just how serious the concern around *Park* liability has become, insurance companies in early 2012 began offering personal insurance against losses resulting specifically from *Park* doctrine convictions, even covering losses stemming from exclusion penalties.[27]

The combination of the *Park* prosecution and the application of the exclusion penalty raises legitimate fairness concerns. Combining a *Park* prosecution and the exclusion penalty represents a severe

22. See 42 U.S.C. §§ 1320a-7(a)(1)–(a)(4) and §§ 1320a-7(c)(3)(G)(i)–(ii) for offenses mandating exclusion; see also §§ 42 U.S.C. § 1320a-7(b)(1)–(b)(16) for offenses that may result in exclusion.

23. *See id.* § 1320a-7(b)(15) (stating that individuals controlling a sanctioned entity may be similarly sanctioned under the statute).

24. Exclusion can be attached to any exclusion-eligible conviction, regardless of the prosecution theory through which that conviction occurs. *See supra* note 22 and accompanying text.

25. Morissette v. United States, 342 U.S. 246, 255 (1952) (discussing the nature of public welfare offenses).

26. *Id.* at 256.

27. *See* Anna Gaynor, *Marsh, Allied Word Partner on Responsible Corporate Officer Coverage*, BUS. INS. (Feb. 9, 2012, 12:06 PM), http://www.businessinsurance.com/article/20120209/NEWS07/120209867; *see also* Kathleen M. Boozang, *A New Insurance Product: Responsible Corporate Officer Doctrine Defense Insurance*, HEALTH REFORM WATCH (Mar. 8, 2012), http://www.healthreformwatch.com/2012/03/08/a-new-insurance-product-responsible-corporate-officer-defense-insurance/.

sanction against business leaders who, despite their best efforts, may simply have been unaware of the particular criminal conduct occurring at their company. But the main legal reason this new formulation of the *Park* doctrine should raise concern is that HHS did not possess the authority to exclude individuals from the health care industry until 1977, two years *after* the Supreme Court considered and narrowly approved the use of the *Park* doctrine and its controversial ability to extend liability to responsible directors, officers, and executives.[28] In debating the legality of the government's ability to secure convictions of individuals using the doctrine, the Court was operating in light of then-existing federal penalty and sentencing guidelines, which did not include exclusion.[29] In other words, because the risks involved in the outcome of a *Park* prosecution are now so much more severe than those that existed under the original sentencing practices, there is no applicable Supreme Court precedent for the current doctrinal use.

In the original *Park* doctrine cases, courts applied much less severe penalties, typically fines or temporary sales injunctions of certain products.[30] The exclusion authority in the context of a *Park* prosecution should be viewed as an entirely different circumstance since it restricts an individual's freedom to pursue his or her choice of employment via a quasi-strict liability prosecution approach.

The potential harm of a *Park*-exclusion penalty goes further. Executive stability in today's economy often plays a role in a corporation's market value.[31] In a public corporation, the unexpected removal of a leading executive harms not only the executive himself, but also the corporation's management structure and, ultimately, the shareholders.[32]

---

28. The exclusion authority did not exist in its modern form until 1996, with the passage of HIPAA. *See* H.R. REP. NO. 95-3, at 1–2 (1977).

29. United States v Park, 421 U.S. 658, 670–71 (1975).

30. *See, e.g., id.*; United States v. Dotterweich, 320 U.S. 277, 285 (1943); United States v. Starr, 535 F.2d 512, 515–16 (9th Cir. 1976); United States v. Y. Hata & Co., 535 F.2d 508, 512 (9th Cir. 1976).

31. *See* Elisabeth Dedman & Stephen W-J Lin, *Shareholder Wealth Effects of CEO Departures: Evidence from the UK*, 8 J. CORP. FIN. 81, 100 (2000) ("CEO departure announcements generally induce a negative market reaction. . . . Regression analysis provides further evidence of the importance investors attach to succession problems, with a positive and significant coefficient being obtained on the replacement indicator variable. . . . [CEO] [d]epartures due to dismissal . . . are consistently associated with a negative market reaction.").

32. *See, e.g., Fortinet Shares Fall on CFO Departure: Fortinet Shares Fall After CFO Announces Plans to Move to Yahoo*, YAHOO! FIN. (Sept. 26, 2012, 12:52 PM), http://finance.yahoo.com/news/fortinet-shares-fall-cfo-departure-165226402.html (noting that shares of Fortinet, a $3 billion corporation, dropped nearly four percentage points on

This Comment will approach the problems with the modern *Park* doctrine from historical, legal, and practical perspectives. Part I details the history of the doctrine, focusing generally on the concepts and theories that create its foundation and specifically the two seminal cases that established the doctrine: the 1943 case of *United States v. Dotterweich* and its progeny, *United States v. Park* (for which the doctrine is named). While the *Park* doctrine was officially set out in *Dotterweich*, it was not until the 1970s and 1980s that courts began to decide cases that helped develop the original structure into a more robust doctrine.[33]

Part II addresses the doctrinal controversy surrounding the standard by which corporate officers should be held liable under *Park*. This analysis consists of a comparison between the language used by the Supreme Court in the *Dotterweich* and *Park* cases and legal scholarship on the criminal law notions of mens rea and strict liability.

In light of this discussion, Part III details how the recent *Park* cases depart from the former understanding of the doctrine and, more importantly, how the arrival of the exclusion authority in this type of prosecution represents an overreaching penalty for convicted corporate officers in light of the "objectively possible" conduct standard utilized in these cases.

Part IV argues that the renewed use of the *Park* doctrine in conjunction with the exclusion penalty does not harmonize with the original use of the doctrine or with the purpose of the exclusion authority.[34] Without the correct temper, the use of *Park* prosecutions makes for a clumsy industry regulation tool and leaves drug executives and their corporate counsels guessing when and if the government will bring a *Park* action. Furthermore, the new *Park* doctrine changes the plea calculus in response to the original underlying government actions against a corporation. The theory here is that, if the executive knows that he may be excluded on account of the corporation's initial misdemeanor guilty plea, he may seek to thwart any attempts by the corporation to plead guilty to the

---

the news of the CFO's departure); *see also* Dedman & W-J Lin, *supra* note 31, at 100 (outlining how CEO departure negatively affects market value).

33. *See infra* Parts I.A–B.

34. *See* Tamar Nordenberg, *Inside FDA: Barring People from the Drug Industry*, U.S. FOOD & DRUG ADMIN. (Mar. 1997), http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm139627.htm (describing exclusion authority as not a punishment, but a method to protect the public).

initial misdemeanor claims and ultimately steer more corporate resources to their defense.

I. HISTORICAL BACKGROUND

After finding its genesis in *United States v. Dotterweich* in 1943 and *United States v. Park* in 1975, officials at the FDA and DOJ used the original *Park* doctrine through the 1970s and into the 1980s.[35] As the 1980s continued, *Park* prosecutions became less and less frequent as institutional trends at the DOJ made other prosecution tactics more appealing.[36] But starting in the latter part of the 2000s, the doctrine began to resurface.[37]

A. *The Original Cases*

The *Park* doctrine is a mixture of strict and vicarious liability.[38] Its unique characteristic lies in courts' ability to punish a non-participatory executive defendant separately and in addition to the public welfare penalty levied on the corporate entity.[39] The first American case to formally recognize the validity of this type of liability was *Dotterweich*.[40] In *Dotterweich*, a pharmacy company in New York was alleged to have violated the Federal Food, Drug, and Cosmetic Act ("FDCA") by shipping adulterated and misbranded drugs in interstate commerce.[41] The president of the company, Mr. Joseph H. Dotterweich, did not participate in the shipments or even

35. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 19–26. For the history of the *Park* doctrine, this account, written by men who held positions as senior lawyers at the Department of Justice and FDA's Counsel Office during the 1970s and 1980s, is often used as the primary first-hand account of departmental dynamics that occured during this time period. It provides unique insight behind the opaque language of *Park* doctrine court opinions. This document is a one-of-a-kind source in its ability to communicate a perspective of the operational realities at work in these departments at the time the modern *Park* doctrine was developed and tested.

36. *See id.* at 30.

37. *See, e.g.*, United States v. Miller, No. 08-00023-01CR (W.D. Mo. 2009).

38. *See* Meyer v. Holley, 537 U.S. 280, 287, 289 (2003) (referring to the RCO doctrine as a form of "vicarious" liability); 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 (2011) ("[T]he RCO doctrine establishes a highly unfortunate species of liability: in its most extreme form, the doctrine creates a rare type of strict *and* vicarious liability in which an individual can be guilty through the acts of others with no culpable state of mind.").

39. *See, e.g.*, United States v. Hodges X-Ray, Inc., 759 F.2d 557, 561 (6th Cir. 1985) (affirming the lower court's use of the RCO doctrine to hold the president and majority shareholder of a medical equipment manufacturing company personally liable for the company's failure to conform its devices to specific health care regulations).

40. 320 U.S. 277 (1943).

41. *Id.* at 278.

know that they had been carried out.[42] The judges at the United States Court of Appeals for the Second Circuit did not find it problematic that, at the trial court level, the corporation had been acquitted of the charges for which Dotterweich was found to be vicariously liable.[43] After the circuit court reversed Mr. Dotterweich's conviction, the Supreme Court again reversed, noting that the relevant language in the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."[44]

Extending criminal liability to Mr. Dotterweich represented an additional step in the Court's move toward recognizing strict liability principles in the name of the public welfare.[45] In *Dotterweich*, the Court continued in this vein and employed a balancing test, pitting the public interest against the individual's interest.[46] This sounds like a typical procedure to determine due process,[47] but here the Court simply weighed which interest should win out over the other.[48] Specifically, the Court weighed the danger that the availability of the misbranded drugs posed to the public against the importance of not applying guilt to an individual that had not personally created the

42. *Id.* at 286 (Murphy, J., dissenting) ("There is no proof or claim that [Dotterweich] ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction.").

43. *See* United States v. Buffalo Pharmacal Co., 131 F.2d 500, 502 (2d Cir. 1942), *aff'd sub nom.* United States v. Dotterweich, 320 U.S. 277 (1943).

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

45. *See, e.g.*, United States v. Balint, 258 U.S. 250, 251–53 (1922) (recognizing that Congress, in the interest of protecting the public welfare, had created certain offenses that dispensed with the traditional common law requirement of scienter).

46. *Dotterweich*, 320 U.S. 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. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. *In the interest of the larger good* it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." (emphasis added) (citing *Balint*, 258 U.S. at 252)).

47. *See generally* Mathews v. Eldridge, 424 U.S. 319 (1976) (establishing a factor-based test for determining procedural due process); Bd. of Regents of State Coll. v. Roth, 408 U.S. 564 (1972) (establishing the contours of procedural due process); Goldberg v. Kelly, 397 U.S. 254 (1970) (same); Cafeteria Workers v. McElroy, 367 U.S. 886 (1961) (same); Joint Anti-Fascist Refugee Comm. v. McGrath, 341 U.S. 123 (1951) (same); N. Am. Cold Storage Co. v. Chicago, 211 U.S. 306 (1908) (same); Dixon v. Alabama, 294 F.2d 150 (5th Cir. 1961) (same); Bailey v. Richardson, 182 F.2d 46 (D.C. Cir. 1950) (same).

48. *Dotterweich*, 320 U.S. at 285 ("Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.").

danger, but still stood "in responsible relation" to it.[49] The phrase "in responsible relation" was the bridge that the Court relied on to connect the misconduct to Mr. Dotterweich, in spite of the fact that he had nothing to do with the shipments that triggered the FDCA violation in the first place.[50]

The Court's rationale for using the "in relation to" link was predicated on three grounds. First, the Court cited the purpose of the FDCA legislation as the primary driver behind expanding misdemeanor liability to Dotterweich.[51] The familiar public welfare rationale holds that some areas of corporate practice mix with certain dimensions of human life that are so unguarded and fragile that strict liability is the most effective method of preventing and discouraging violations, even accidental ones.[52] "The purposes of this legislation thus touch phases of the lives and health of people which, in circumstances of modern industrialism, are largely beyond self-protection."[53]

In addition to the public welfare, the Court offered two other reasons for its decision, both subtler than the obvious desire to protect human health. The first is that this form of personal liability, or more accurately, the *threat* of this form of personal liability, is a form of industry regulation in itself.[54] The Court's precise language reads:

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as *effective means of regulation* . . . . If the 1938 Act were construed as it was [at the circuit court], the penalties of the law could be imposed only in the rare case where the corporation is merely an individual's *alter ego*. Corporations carrying on an illicit trade would be subject only to what the House Committee described as a "license fee for the conduct of an illegitimate business."[55]

In other words, the FDCA purports to regulate food and drug corporations by subjecting the officers of those corporations to

---

49. *Id.* at 281.

50. *Id.*

51. *Id.* at 280.

52. *Id.* at 281; *see also* United States v. Balint, 258 U.S. 250, 254 (1922) ("Congress weighed the possible injustice of subjecting an innocent seller to a penalty against the evil of exposing innocent purchasers to danger from the drug, and concluded that the latter was the result preferably to be avoided.").

53. *Dotterweich*, 320 U.S. at 280.

54. *Id.* at 282–83.

55. *Id.* at 280–83 (emphasis added).

personal criminal liability; otherwise, any penalty imposed on the corporation will eventually be baked into the price of doing business. For present purposes, the Court's view that the threat of personal criminal liability is a form of corporate regulation serves as a segue to the other subtle reason for finding Dotterweich guilty: the intractable bind between the actions of the corporate entity and corporate officers.[56]

The Court explained this inextricable bind clearly: "[T]he only way in which a corporation can act is through the individuals who act on its behalf."[57] The Court then stated, "Congress has preferred to place [liability] upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."[58] Yet, after announcing these general principles for finding liability in an individual responsible corporate officer, the Court made no attempt to help identify how a person comes to be a responsible officer or who stands "in responsible relation to" a given FDCA violation.[59]

Thankfully, this cliffhanger is right where the 1975 case of *United States v. Park* picked up.[60] It was not until the decision in *Park*, more than forty years after *Dotterweich*, that the Supreme Court began to give more meaning to this special type of personal executive liability.[61] *Dotterweich* created the outline; *Park* colored it in.

The facts of *Park* are unremarkable. Mr. John Park, President of Philadelphia's Acme Markets, Inc. ("Acme"), a national grocery chain, was charged with violating the FDCA for allowing food, which had traveled in interstate commerce, to become exposed to rodents in an Acme-owned warehouse.[62] The company pled guilty to the charges, accepting responsibility for allowing certain foodstuffs to be subject to rodent infestation. Park, on the other hand, pled not

56. *Id.* at 281 ("[T]he only way in which a corporation can act is through the individuals who act on its behalf.").

57. *Id.*

58. *Id.* at 285.

59. *Id.* ("To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, to wit, to send illicit goods across state lines, would be mischievous futility.").

60. 421 U.S. 658 (1975).

61. *See* Abrams, *supra* note 12, at 467 (noting the similarity between the two cases and making the observation that the three primary interpretations of *Dotterweich* "suggest that, although the time interval between the two cases was long, it was but a short step to *Park*").

62. *Park*, 421 U.S. at 658.

guilty.[63] As the president of the rather large food corporation, Park had no personal connection with the particular circumstances surrounding the violation and was fully unaware of the negligence that caused it.[64]

Acme did have some notice about the violation, however; the company had been warned about the problematic condition of its warehouses in prior letters from the FDA in 1972.[65] Without success, Park argued in his defense that, after hearing of the FDA letter,

> [H]e . . . conferred with the vice president for legal affairs, who informed him that the Baltimore division vice president "was investigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter." Park testified that he did not "believe there was anything [he] could have done more constructively than what [he] found was being done."[66]

The Court, relying generally on the principle of the responsible corporate officer from *Dotterweich*, disagreed with Park and determined his relationship with the misconduct was such that it was appropriate to sanction him as well as the corporation.[67]

According to the *Park* majority, the government can produce a prima facie case by demonstrating that a corporate officer possessed the "responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."[68] Thus, simply by virtue of his or her position in the corporate structure, an officer can be held guilty if the government shows he or she has some level of responsibility, even remotely, over the operation wherein the violation occurred. Notably, the liability can arise from either a retrospective failure or a prospective one.[69] As the *Park* Court laid out:

> *Dotterweich* and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission . . . the Act imposes not only a positive duty to seek out and remedy violations when they

63. *Id.* at 661.
64. *Id.* at 663.
65. *Id.* at 662. This notice is an important aspect of this case that will be relevant to later discussion of the doctrine's modern application.
66. *Id.* at 663–64 (citation omitted).
67. *Id.* at 676.
68. *Id.* at 674.
69. *Id.* at 672.

> occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.[70]

By taking this view, the entirety of a corporate officer's role in a company was now subject to an aggressive form of personal liability.[71]

However, the Court recognized one affirmative defense: "the Act, in its criminal aspect, does not require that which is objectively impossible."[72] In other words, if the actions that could have prevented the misconduct were impossible, then not having taken those actions is an affirmative defense. This theoretically left room for those complete and unexpected accidents, but still placed a duty on pharmaceutical and health care executives to take extraordinary care not only in their own actions, but in the institutional designs and hierarchical structures that they managed.

*B. Post-*Park *Developments*

After *Park* made its way through the court system, use of its underlying prosecution approach arose from time to time into the 1980s, and both procedural and tactical norms were established.[73] While many of these cases were settled outside of court,[74] the few that

---

70. *Id.*

71. Justice Stewart's dissent, joined by Justices Marshall and Powell, deserves momentary examination as well. The argument put forward by the three Justices stresses that the *Park* majority in fact misread or overread *Dotterweich*. The dissent accuses the majority of allowing a hollow jury instruction to stand and convict Park: "The instructions . . . expressed nothing more than a tautology. They told the jury: 'You must find the defendant guilty if you find that he is to be held accountable for this adulterated food.' In other words: 'You must find the defendant guilty if you conclude that he is guilty.' " *Id.* at 679 (Stewart, J., dissenting). The three dissenters believed this type of judge-jury interaction ran counter to the deeply imbedded notions of judge and jury roles. The dissenters pointed out that instructions such as this eliminate the need for the jury to apply law to facts and instead merely asks them to base their determination of guilt on a sense of social justice. *Id.* at 682. The group argued that basing society's most damning judgment—criminal liability—on such volatile measures of right and wrong was offensive to the whole notion of the court, the enterprise whose purpose is to guide juries in criminal cases. *Id.* at 682–83.

72. *Id.* at 673 (majority opinion).

73. *See, e.g.*, United States v. Gel Spice Co., 773 F.2d 427, 435 (2d Cir. 1985); United States v. Y. Hata & Co., 535 F.2d 508, 510–11 (9th Cir. 1976); United States v. Starr, 535 F.2d 512, 524–25 (9th Cir. 1976); United States v. Abbott Labs., 505 F.2d 565, 573–74 (4th Cir. 1974); United States v. Shapiro, 491 F.2d 335, 336–37 (6th Cir. 1974); United States v. General Nutrition, Inc., 638 F. Supp. 556, 563–64 (W.D.N.Y. 1986); United States v. Torigian Labs., Inc., 577 F. Supp. 1514, 1529–31 (E.D.N.Y. 1984); United States v. New Eng. Grocers, 488 F. Supp. 230, 232–33 (D. Mass. 1980); United States v. Treffiletti & Sons, 496 F. Supp. 53, 55–56 (N.D.N.Y. 1980); United States v. Acri Wholesale Grocery Co., 409 F. Supp. 529, 535 (S.D. Iowa 1976).

74. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 30 ("U.S. Attorneys often declined to bring *Park* cases: Those brought typically settled with guilty pleas.").

were fully heard marked actual progress in terms of doctrinal development. The first was *United States v. Y. Hata & Co.*[75] In this case, Minoru Hata, the president of a company that owned a food storage warehouse, was convicted for the adulteration of rice stores by birds that had been able to get into the facility.[76] Hata admitted that he had been aware of the problem, but argued that he had made multiple attempts to prevent the birds from getting into the warehouse.[77] Hata's appeal rested primarily on the claim that he did not receive the proper jury instruction on the "objectively impossible" defense.[78] Although he claimed to have maintained the standard set out in *Park*, the "highest standard of foresight and vigilance," Hata argued that it was nevertheless objectively impossible for him to have conceived of the idea of a wire cage surrounding the facility until he actually did, at which point it was too late.[79] The appellate court disagreed, noting that "[o]ne maintaining far less than the requisite 'highest standard of foresight and vigilance' would have recognized as early as August 1971 that implementation of a wire cage system would substantially, if not completely, prevent access by thieving and untidy birds."[80] As was common at the time for *Park* misdemeanor convictions, Hata was required to pay penalties but did not receive any jail time.[81]

The other doctrinally relevant case after *Park* was *United States v. Starr*,[82] also testing the viability of the "objectively impossible" defense.[83] In this case, also from the Ninth Circuit, the secretary-treasurer of Cheney Brothers Food Corporation, Dean Starr, had particular management responsibility over the sanitation of the corporation's warehouses.[84] The clearing of a nearby field resulted in a rodent infestation.[85] The secretary-treasurer first attempted to argue that it would have been "objectively impossible" for him to foresee such a chain of events, but the appellate court agreed with the district

75. 535 F.2d 508 (9th Cir. 1976).
76. *See id.* at 509.
77. *Id.* at 511.
78. *Id.* at 510.
79. *Id.* at 511.
80. *Id.*
81. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 24.
82. 535 F.2d 512 (9th Cir. 1976).
83. *See id.* at 512.
84. This specific management responsibility was distinct from that which accompanied the positions of the defendant executives in *Park* and *Dotterweich* where the executive defendants were more attenuated from the underlying criminal misconduct. *See id.* at 514.
85. *Id.* ("The warehouse had been infested with mice after an adjoining field was plowed for farming.").

court that someone exercising the *Park* standard of the highest "foresight and vigilance" would have been able to predict and prevent this outcome.[86] Next, Starr argued that prevention on his part was "objectively impossible" because, after becoming aware of the rodent problem, he specifically instructed one of his employees to take measures to rectify the situation and that the employee simply did not carry out the orders.[87] Even this was not sufficient in the court's eyes since the secretary-treasurer did not attempt to ensure that the employee had followed orders until the FDA conducted a second inspection of the facility a full month after the unsanitary conditions were originally discovered.[88] At sentencing, the secretary-treasurer was ordered to pay $200 for each of the three counts of adulteration.[89]

However, while only a few cases helped advance an understanding of how courts should apply the doctrine, it was during this same span in the late 1970s and early 1980s that procedural norms arose as well. Perhaps the most important of these procedures was the "305 hearing," a preliminary hearing required by FDCA section 305[90] between the FDA and the person accused of committing a prohibited act.[91] Section 305 is titled "Hearing Before Report of Criminal Violation" and reads:

> Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.[92]

These hearings between the accused and the FDA were of critical importance because they were the first time the accused could confront his accusers. More importantly, they gave the accused individual the chance to stop a full DOJ investigation before it began and, in some cases, actually succeeded.[93] "There is only one tactic in preparing for a Section 305 hearing and that is to put together sufficient information to convince the District Director either that a

86. *See id.* at 515–16.

87. *Id.* at 514 ("[Mr. Starr's assistant treasurer] reprimanded the warehouse janitor, Marks, and ordered him to make corrections. Marks had not complied as of the second inspection one month later.").

88. *See id.* at 516.

89. *Id.* at 514.

90. 21 U.S.C. § 335 (2006).

91. See *id.* § 331 for a list of acts currently prohibited by the FDCA.

92. *Id.* § 335.

93. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 28.

violation did not occur or that, if it did, the circumstances are such that prosecution would accomplish no real purpose."[94]

Yet, despite the importance of this hearing opportunity, in the 1991 case *Kent v. Benson*,[95] the Eleventh Circuit reexamined the original *Dotterweich* case and, looking past the more famous principles that carried through to *Park*, concluded that a 305 hearing is technically not required in *Park* doctrine prosecutions.[96] This perspective did, in fact, have precedent even before *Dotterweich*, but not on a national scale.[97] The reasoning behind this view was more thoroughly explained by the Seventh Circuit in 1998:

> When a defendant is morally culpable for failing to know or guess that he is violating *some* law (as would be the case of someone who committed a burglary without thinking—so warped was his moral sense—that burglary might be a crime), we rely on conscience to provide all the notice that is required.... And sometimes, though the law is obscure to the population at large and nonintuitive, the defendant had a reasonable opportunity to learn about it, as in the case of persons engaged in the shipment of pharmaceuticals who run afoul of the criminal prohibitions in the federal food and drug laws.[98]

This trend continued all the way to codification. As of April 1, 2011, the FDA formally removed the requirement to offer 305 hearings to potential *Park* defendants.[99]

Despite its early use at the FDA, by the late 1980s, *Park* prosecutions had become much rarer. While part of the reduction in enforcement may be credited to the overall decrease in agency power under the Reagan administration,[100] some former DOJ prosecutors credit this drop-off to limitations of departmental resources, and, more importantly, to the overriding view in the Department that the

---

94. Raymond D. McMurray, *Section 305 Hearings—Defense Considerations*, 31 FOOD DRUG COSM. L.J. 386, 388 (1976) (discussing the primary strategies and tactics to consider after notification of a 305 hearing with the FDA).

95. 945 F.2d 372 (11th Cir. 1991).

96. *See id.* at 373 (presumably reading *Dotterweich*'s discussion of defendant's request for a 305 hearing: "We agree ... that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution.").

97. *See* United States v. Commercial Creamery Co., 43 F. Supp. 714, 715 (E.D. Wash. 1942) (explaining that 305 hearings are technically administrative in nature and therefore their absence does not divest a court of its jurisdiction).

98. United States v. Wilson, 159 F.3d 280, 295 (7th Cir. 1998).

99. *See* 21 CFR § 7.84(a)(3) (2011).

100. *See* Edmund L. Andrews, *A Scandal Raises Serious Questions at the F.D.A.*, N.Y. TIMES, Aug. 13, 1989, at F11.

sanctions imposed on convicted *Park* defendants were simply not worth the effort necessary to bring the actions in the first place.[101] Fueling this view was frustration with federal judges who understood Title 18 offenses much better than the FDCA, as well as judges who simply believed that, in light of the overloaded circuit dockets, *Park* prosecutions were more appropriately handled by civil penalties.[102]

In response to the 1989 generic drug scandal, Congress urged the FDA to implement enhanced oversight of its criminal investigation operations.[103] The congressional pressure resulted in the creation of the Office of Criminal Investigations ("OCI"), which was tasked with reporting incidents up to DOJ.[104] With DOJ determining which cases should be pursued, the established "bottom up" prosecution paradigm that had prevailed at the FDA became a thing of the past.[105]

C. *Renaissance and the Exclusion Authority*

After nearly two decades of disuse, the *Park* doctrine was recently put back into play by the FDA and DOJ. In 2007, HHS secured a guilty plea from the Purdue Frederick Company ("Purdue") for the felony of "misbranding OxyContin, a prescription opiod [sic] pain medication, with the intent to defraud or mislead."[106] From this corporate conviction arose additional guilty pleas from three of Purdue's former top executives for the misbranding in their positions as responsible corporate officers, each a misdemeanor offense.[107] The executives presumably made their plea decision on the assumption that any penalty or sanction assessed to them personally would be in keeping with those from traditional (but now distant) *Park* convictions. However, in response to the pleas, HHS OIG

101. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 30.

102. *Id.* at 30, 32.

103. *See Criminal Investigations, History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/iceci/criminalinvestigations/ucm123041.htm (last visited Jan. 15, 2013). The 1989 generic drug scandal was revealed when it was discovered that FDA officials had been accepting bribes from certain generic drug companies in exchange for speedy reviews during the drug approval process. *See id.* The findings led to major criticism from the public and Congressional oversight committees. *See id.*

104. *Id.*

105. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 33.

106. United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 570 (W.D. Va. 2007).

107. *See* Friedman v. Sebelius, 755 F. Supp. 2d 98, 101 (D.D.C. 2010) The three executives in question were the former Chief Executive Officer Michael Friedman, Executive Vice President and Chief Legal Officer Howard R. Udell, and Chief Scientific Officer Paul D. Goldenheim. *Id.* at 101 n.5. They were originally each given a term of exclusion for twenty years, but HHS OIG revised the terms to fifteen years after the executives produced mitigating evidence demonstrating that they had been fully cooperative with law enforcement officials. *Id.* at 103.

issued orders of exclusion for the three executives, each with a term of fifteen years.[108] After a Departmental Appeals Board reduced the term to twelve years, the executives appealed the decision to the federal courts where the decision was affirmed by the United States District Court for the District of Columbia[109] and reaffirmed by the D.C. Circuit.[110]

The doctrine was used again in securing a 2009 guilty plea from executives at Chemnutra, Inc. for selling misbranded pet food.[111] Executives at Syntheses, Inc. also pled guilty in 2009 while facing a *Park* prosecution for the off-label promotion of a specific type of bone cement.[112] In early 2011, former KV Pharmaceutical Co. CEO Marc Hermelin pled guilty to two counts of being the responsible corporate officer in connection with a failure to prevent and correct the distribution of oversized morphine sulfate pills.[113] Hermelin was excluded from interacting with any entity that does business with a federal health care program for a term of twenty years.[114]

In a surprisingly aggressive use of the *Park* approach in 2011, HHS OIG unexpectedly informed Forest Laboratories, Inc. CEO, Howard Solomon, that it intended to use the exclusion authority against him in connection with the company's 2010 guilty plea to a misdemeanor for off-label marketing of the popular antidepressants Celexa and Lexapro.[115] Although the corporation's plea agreement included $313 million in fines for the violations, it contained nothing

---

108. *Id.* at 103.

109. *Id.* at 117.

110. Friedman v. Sebelius, 686 F.3d 813 (D.C. Cir. 2012) (affirming the lower court's decision to exclude the corporate officers, but reversing as to the length of time of the exclusion).

111. DANIEL R. MARGOLIS, MARK R. HELLERER & AARON S. DYER, PILLSBURY WINTHROP SHAW PITTMAN LLP., CLIENT ALERT: FDA TO BRING MORE CRIMINAL CHARGES AGAINST EXECUTIVES FOR COMPANIES' FDCA VIOLATIONS 2 (2010), http://www.pillsburylaw.com/siteFiles/Publications/D98DF569EA917C29C8CE406316FA213C.pdf.

112. *See* United States v. Huggins, No. 09-403-3, 2011 U.S. Dist. LEXIS 142869, at *4–6 (E.D. Pa. Dec. 13, 2011); United States v. Higgins, No. 09-403-4, 2011 U.S. Dist. LEXIS 140343, at *25–26 (E.D. Pa. Dec. 7, 2011).

113. *See* Joe Whittington & Andrew Harris, *Ex-KV Pharmaceutical CEO Hermelin Pleads Guilty to Drug Label Law Breach*, BLOOMBERG (Mar. 10, 2011), http://www.bloomberg.com/news/2011-03-10/ex-kv-pharmaceutical-ceo-hermelin-pleads-guilty-to-drug-label-law-breach.html.

114. *See* Jim Doyle, *After Long, Strange and Profitable Trip, Ex-KV Chief Resigns in Scandal*, ST. LOUIS DISPATCH, Nov. 18, 2010, at A1, *available at* http://www.stltoday.com/business/local/article_abb31b54-2521-515e-b60d-1603fe5f90a2.html.

115. *See* Alicia Mundy, *U.S. Efforts to Remove Drug CEO Jolts Firms*, WALL ST. J., Apr. 26, 2011, at A1.

about Mr. Solomon.[116] This unexpected use of the *Park* approach in conjunction with the exclusion authority shocked the corporation.[117] According to a top health care white-collar defense attorney, the action against Mr. Solomon was a "game changer."[118]

This increase in *Park* actions stems in large part from a reinvigorated emphasis on adversarial regulatory tactics by the FDA and the need for a more effective criminal investigation capacity. This renewed emphasis grew out of criticism that began in 2009 with a report from the GAO critiquing the FDA's management of its criminal investigations operation.[119] GAO released another report in January 2010 criticizing the FDA's capacity to regulate criminal conduct in the pharmaceutical sector.[120] In response to this mounting criticism, FDA Commissioner Margaret Hamburg wrote the aforementioned letter to Senator Grassley in March 2010,[121] formally committing the FDA to improving their utilization of both the *Park* doctrine and exclusion authority.[122]

If this was not enough to place drug manufacturers on notice, on April 22, 2010, in a speech to the Food and Drug Law Institute, the FDA's Chief Counsel for Litigation, Eric Blumberg, speaking about an increased focus on executive prosecution, said to a room full of industry lawyers, "Very soon, and I have no one particular in mind, some corporate executive is going to be the first in a long line . . . . So it's going to happen."[123] Furthermore, in February 2011, the FDA finally released a set of criteria that Commissioner Hamburg had mentioned in the Grassley letter, which are to be used "for consideration in selection of misdemeanor prosecution cases."[124] The criteria, located in section 6-5 of the FDA's online Regulatory Procedures Manual, are titled "Special Procedures and

116. *Id.*
117. *Id.*
118. *Id.*
119. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-807, OVERSIGHT OF CLINICAL INVESTIGATORS: ACTION NEEDED TO IMPROVE TIMELINESS AND ENHANCE SCOPE OF FDA'S DEBARMENT AND DISQUALIFICATION PROCESSES FOR MEDICAL PRODUCT INVESTIGATORS (2009), *available at* http://www.gao.gov/new.items/d09807.pdf.
120. *See* GAO Report, *supra* note 4.
121. Letter from Comm'r Margaret Hamburg to Sen. Charles Grassley, *supra* note 5.
122. *Id.*
123. FDA Deputy Chief Counsel for Litigation Eric Blumberg, Remarks at the Food and Drug Law Institute Annual Conference (Apr. 22, 2010), *available at* http://www.fairwarning.org/2010/08/fda-eyes-prosecutions-to-toughen-enforcement/. Interestingly, Blumberg was a contributing author for one of the Government's briefs in the original *Park* case. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 39.
124. Letter from Comm'r Margaret Hamburg to Sen. Charles Grassley, *supra* note 5, at 2.

Considerations for Park Doctrine Prosecutions."[125] The heart of the guidelines reads as follows:

> When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation. Other factors to consider include but are not limited to:
>
> 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.[126]

From a practical standpoint, whether these criteria give any actual insight into how FDA attorneys will evaluate potential *Park* claims any differently than other criminal claims has been called into question.[127] Nevertheless, for the purposes of this Comment, the mere fact that the criteria have been established and distributed adds to the body of evidence suggesting that *Park* prosecutions will become more prevalent in the near future.

The odd marriage between the *Park* doctrine and HHS's exclusion authority is the most puzzling result of this new direction in FDA and HHS OIG prosecution. In essence, an exclusion is the separation of an individual or corporation from federal health care operations, meaning that an excluded entity is prohibited from

125. *See* FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL, INSPECTIONS, COMPLIANCE, ENFORCEMENT, AND CRIMINAL INVESTIGATIONS, § 6-5-3, at 6-49 to 6-50 (2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3.

126. *Id.*

127. *See, e.g.*, Anne K. Walsh, *FDA Finally Releases "Non-Binding" Park Doctrine Criteria*, FDA L. BLOG (Feb. 6, 2011), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/fda-finally-releases-non-binding-park-doctrine-criteria.html.

receiving any payments from any federal health care program[128] (Medicare, Medicaid, etc.) for a specified term.[129] Additionally, no payment may be made to any entity employing or contracting with an excluded individual or company.[130] Exclusion and its cousin, debarment, are two of the most potent tools that HHS has to enforce industry regulations in the health care and pharmaceutical industries.[131] The main difference between the two penalties is scope. Exclusion is effectively an exile from the health care industry since excluded individuals may not work for, or with, any company that receives federal health care funding.[132] Debarment, on the other hand, is still restrictive, but only prohibits a debarred individual from "providing services in any capacity to a person that has an approved or pending drug product application."[133] In other words, debarment primarily prevents individuals from working for or with drug companies, while exclusion prevents individuals from working for or with almost any company that provides health services. HHS maintains publicly available lists of individuals and entities that have either been excluded or debarred, thus preventing them from reentering the health care market.[134]

128. A federal health care program is defined as "any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program as defined in this section." 42 C.F.R. § 1001.2(d) (2011).

129. 42 U.S.C. § 1320a-7 (2006).

130. *See id.* §§ 1395y(e), 1396a(a)(39); 42 C.F.R. § 1001.1901 (2011).

131. Exclusion is often referred to as a "devastating" punishment. *See, e.g.*, Joe Carlson, *Career-Devastating Punishment: Four Former Synthes Execs Excluded from Medicare for Roles in Surgery Case*, MODERNHEALTHCARE.COM (Oct. 20, 2012, 12:01 AM), http://www.modernhealthcare.com/article/20121020/MAGAZINE/310209971 (subscription required); *Violations of Corporate Integrity Agreement Trigger Divestiture Action by HHS OIG*, SKADDEN.COM (June 14, 2012), http://www.skadden.com/newsletters/Violations_of_Corporate_Integrity_Agreement_Trigger_Divestiture_Action_by_HHS_OIG.pdf (describing exclusion as "the death knell for careers and companies alike").

132. *See Exclusions, Background Information*, DEP'T HEALTH & HUMAN SERVS., OFF. INSPECTOR GEN., https://oig.hhs.gov/exclusions/background.asp (last visited Oct. 27, 2012).

133. 21 U.S.C. § 335a(a)(2) (2006).

134. *See Exclusions Program*, DEP'T HEALTH & HUMAN SERVS., OFF. INSPECTOR GEN., http://oig.hhs.gov/exclusions/index.asp (last visited Jan. 19, 2013); *Inspections, Compliance, Enforcement, and Criminal Investigations*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm (last visited Jan. 19, 2013).

Exclusion is effectively a "death sentence" for a career in the health care industry.[135] In 2010, the federal government paid the bill for nearly thirty percent of all national health expenditures, thus making it difficult to identify health companies or health service providers in America that receive no money from any governmental health program.[136] Many state medical assistance programs are covered by this ban as well because they operate on grant funding from the federal government.[137] 42 U.S.C. § 1396a(a)(39) insures that these state-run but largely federally funded programs do not offer excluded individuals a loophole to remain connected to the federal health system.[138] In order to be eligible for the flow of federal health grants coming out of various federal agencies,

> [a] State plan for medical assistance must provide that the State agency shall exclude any specified individual or entity from participation in the program under the State plan for the period specified by the Secretary, when required by him to do so pursuant to section 1320a–7 of this title or section 1320a–7a of [Title 42].[139]

With this provision, the federal health care system becomes largely sealed off from individuals who are excluded by the HHS Secretary.

Although only recently coupled with the *Park* doctrine, the exclusion authority originated on January 4, 1977, when, after mounting pressure surrounding the insufficiency of existing penalties against Medicare and Medicaid fraud and abuse, two democratic congressmen, Representative Paul G. Rogers from Florida[140] and Representative Dan Rostenkowski from Illinois, introduced the Medicare-Medicaid Anti-Fraud and Abuse Amendments in the House Ways and Means Subcommittee.[141] The timing of the bill's passage relative to the 1975 *Park* case is significant. Had the case

---

135. SCOTT MCBRIDE & SUMMER D. SWALLOW, BNA'S HEALTH CARE FRAUD REPORT: THE KISS OF DEATH: OIG'S EXCLUSION AUTHORITY 1 (Jan. 12, 2011), http://www.bakerlaw.com/files/Uploads/Documents/News/Articles/HEALTHCARE/2011/HCFraud_Report_McBride_Swallow_1-2011.pdf.

136. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES 2010: SPONSOR HIGHLIGHTS 2–4 (2010), http://www.cms.gov/NationalHealthExpendData/downloads/sponsors.pdf.

137. 42 U.S.C. § 1396a(a)(39) (2006).

138. *Id.*

139. *Id.*

140. Representative Rogers was one of the most important legislators for health care issues of his time, earning him the nickname "Mr. Health." *See* Dennis Hevesi, *Paul G. Rogers, 87, Dies; 'Mr. Health' in Congress*, N.Y. TIMES, Oct. 15, 2008, at A33.

141. Jennifer O. Sullivan, Cong. Research Serv., 77-243 ED, Medicare-Medicaid Anti-Fraud and Abuse Amendments—P.L. 95-142 3 (Nov. 16, 1977).

arisen *after* Congress passed the Medicare-Medicaid Anti-Fraud and Abuse Amendments, the Court would have been operating under different circumstances. Because the exclusion penalty did not exist until 1977, two years after the Court issued its ruling in *Park*, the Justices were unable to consider the extent to which the *Park* doctrine could be used. Indeed, at the time *Dotterweich* and *Park* were decided, this theory of liability would only have resulted in nominal monetary penalties to the defendants.[142]

It was not until 1996 with the passage of the mammoth Health Insurance Portability and Accountability Act ("HIPAA") that the modern exclusion authority came into existence.[143] The Act increased the ability of HHS OIG to use exclusions by: "(1) broadening the OIG's mandatory exclusion authority; (2) establishing minimum exclusion periods for certain discretionary exclusions; and (3) establishing a discretionary exclusion authority applicable to owners, officers and managers of sanctioned entities."[144] The third category is at issue here. Under section 1128(b)(15) of the Social Security Act, HHS is statutorily permitted to exclude someone merely by virtue of his or her role in a sanctioned corporate entity.[145] Since *Park* established that such responsible corporate officers can be held liable for conduct that the officer neither committed nor knew of,[146] this particular flavor of exclusion can become particularly worrisome. The ability for government prosecutors to establish exclusion eligibility for officers and managers based on the corporation's sanction poses legitimate liability concerns for managers and officers who oversee regulated activity. In late 2010, HHS OIG made available guidance of this particular type of exclusion (codified under section 1128(b)(15)).[147]

In essence, the exclusion authority, with its ability to effectively end an individual's career in the health care sector, gives HHS OIG significant leverage in collecting fines and arriving at favorable settlements. In the 2011 fiscal year, HHS OIG brought 723 criminal

142. *See infra* text accompanying notes 215–16.

143. Health Insurance Portability and Accountability Act (HIPAA), Pub. L. No. 104-191, § 211, 110 Stat. 1936, 2003–05 (1996) (codified as amended at 29 U.S.C. § 1181 (2006)).

144. McBride & Swallow, *supra* note 135, at 2.

145. Social Security Act § 1128, 42 U.S.C. § 1320a-7(b)(15) (2006).

146. United States v. Park, 421 U.S. 658, 673 (1975).

147. *See* DEP'T. OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT (Oct. 20, 2010), http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

actions against individuals or entities "engaged in crimes against HHS programs."[148] More than 600 of these were criminal actions for health-care-related offenses, which netted $3.6 billion in expected recoveries.[149]

II. THE MENS REA CONTROVERSY OVER THE *PARK* DOCTRINE

One of the primary debates surrounding the use of the *Park* doctrine is its capacity to subject individuals to an exclusion or debarment via strict liability.[150] But the question underlying this controversy is more appropriately framed as one of the responsible officer defendant's mens rea. While the statutes and case law cling to a strict liability standard, there are still strong arguments that a negligence (or a high negligence) standard is more in line with the pertinent case patterns and legislative history. This inquiry is particularly important since *Park* and *Dotterweich* were both decided when the exclusion authority was wholly unavailable to the regulators at HHS.[151] With such a dramatic penalty now available to administrative agencies for certain FDCA and health care offenses, determining whether the doctrine emphasizes strict liability or, alternatively, a high form of negligence will be useful in understanding how regulators view the doctrine's mechanics in modern practice.

A. Arguments for a Negligence Standard

The most robust argument that a high negligence standard, rather than a strict liability standard, is being used is borne out by the case law. In *Park*, there is technically no mention of a strict liability

148. DEP'T. OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., SEMIANNUAL REPORT TO CONGRESS APRIL 1, 2011–SEPTEMBER 30, 2011, at i (2011), http://oig.hhs.gov/reports-and-publications/archives/semiannual/2011/fall/HHS-OIG-SAR-Fall2011.pdf.

149. *Id.* at III-1.

150. *See, e.g.*, Abrams, *supra* note 12, at 464–67 (outlining three different interpretations of the conduct standards set up by *Park* and noting that the most common is a strict liability standard). *But see, e.g.*, United States v. New England Grocers Supply Co., 488 F. Supp. 230, 235–37 (D. Mass. 1980) ("Under this [alternative] interpretation, the impossibility defense would serve as an affirmative defense, incorporating an objective element—use of extraordinary care—into a strict liability offense."); *Corporate Crime: Regulating Corporate Behavior Through Criminal Sanctions*, 92 HARV. L. REV. 1227, 1264–65 (1979) (arguing that "[w]ith the impossibility defense, the strict liability standard as applied to indirect actors becomes in practice a standard of extraordinary care").

151. *Park* was decided in 1975, two years before Congress created the exclusion authority in the Office of the Secretary of HHS. *See* Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 7(a), 91 Stat. 1175, 1192–93 (1977).

standard.[152] In fact, the majority committed the final three paragraphs of its opinion to the type of notice that Mr. Park should have gained in dealing with his hierarchy of subordinates.[153] The Court relied on evidence whose very "purpose was to demonstrate that [Park] was on notice that he could not rely on his system of delegation to subordinates to prevent or correct insanitary conditions."[154] Regardless of whether Mr. Park did indeed heed such notice, the Court answered in the negative.[155] However, the fact that the Court took the time to explain the importance of notice in Mr. Park's situation seems to belie any definitive reliance on strict liability. If strict liability were in full effect, notice would not be necessary at all. Furthermore, the majority emphasized their view that "[t]he duty imposed by Congress on responsible corporate agents is, we emphasize, one that requires the highest standard of foresight and vigilance."[156] As the dissent quickly points out about the majority's use of the terms "notice" and "duty," "This is the language of negligence."[157]

In *United States v. Y. Hata & Co.*, an important doctrinal case from 1976, the Ninth Circuit similarly held a responsible officer liable because he did not carry out his duty to protect his warehouse from known bird entry to the extent that he should have.[158] The same duty and notice pattern was established in *United States v. Starr* when the Ninth Circuit found that Mr. Starr's position in a food management company imputed on him a duty to act with "foresight and vigilance" in order to correct the infestation of rodents of which he was aware.[159]

---

152. However, three years after the *Park* opinion was handed down, the Supreme Court heard *United States v. U.S. Gypsum Co.*, 438 U.S. 422 (1978), and attempted to clarify its position in *Park*. Importantly, between *Park* and *Gypsum*, only one membership change occurred on the Court when Justice Stevens replaced Justice Douglas in late 1975. *Gypsum* partly addressed the fit between a scheme of vicarious strict liability and criminal violations of the Sherman Act. In a footnote to the *Gypsum* opinion (which overall illustrated a general distaste for vicarious strict liability in this context, *see Gypsum* 438 U.S. at 440–43), the Court indirectly clarified that *Park* had set up a strict liability standard, holding that "antitrust laws differ in this regard from, for example, laws designed to insure that adulterated food will not be sold to consumers. In the latter situation, excessive caution on the part of producers is entirely consistent with the legislative purpose." *Id.* at 441–42 n.17.

153. United States v. Park, 421 U.S. 658, 678 (1975).

154. *Id.* at 677–78.

155. *Id.* at 678.

156. *Id.* at 673.

157. *Id.* at 679 (Stewart, J., dissenting).

158. *See* United States v. Y. Hata & Co., 535 F.2d 508, 511 (9th Cir. 1976).

159. United States v. Starr, 535 F.2d 512, 515 (9th Cir. 1976) ("[T]he duty of 'foresight and vigilance' requires the defendant to foresee and prepare for such an occurrence, whether it be deemed 'natural' or 'artificial.' " (citations omitted)).

Similarly, in a 1985 action against Eli Lilly, the pharmaceutical company's Director for Medicine, Research and Development in the U.K. pled nolo contendere to charges that he neglected his duty to report four deaths and six illnesses caused by the company's drug Oraflex.[160] The common theme throughout these cases is that the prosecutions were all predicated on the premise that the executives had or should have had notice of the criminal misconduct, but chose not to adequately act on that knowledge. These cases, all descendants of *Park*, comprise an odd progeny for the Supreme Court case that is reputed for its ability to use strict liability in order to reach officers who otherwise would have no connection to the underlying criminal conduct.

Interestingly, most commentary on the *Park* doctrine fails to notice that, although the law may have indeed permitted FDA to prosecute responsible officers on a pure strict liability basis (where no knowledge or intent existed), FDA actually had an institutional practice of ensuring that prosecutions were only brought when there was evidence that the responsible corporate officer knew or should have known about the problematic conditions.[161] In an obscure journal article from 1976, Sam Fine, the former FDA Associate Commissioner for Compliance, wrote, "We insist . . . that our prosecution recommendations include a factual record which demonstrates that every individual charged either knew or should have known of the violative conditions set forth, and was in a position to do something about those conditions but failed to do so."[162] This belies the need for strict liability. If the letter of the law has consistently expressed the preference for a strict liability standard, but FDA and DOJ have only actually brought cases where the fact patterns fit a lower negligence standard, it sheds some light on the confusion that has steadily built around the precise dynamics of the *Park* doctrine's conduct requirements.

Moreover, there is evidence that the original *Dotterweich* Court was acutely aware of the door they were opening to strict liability and in turn showed sensitivity to the fact that they were handing government prosecutors a very large legal club. In discussing the difficulty of determining who should be liable under this new strict vicarious liability theory, the *Dotterweich* Court noted that "[i]n such

160. *See* Fleder, Farquhar & Scarlett, *supra* note 13, at 24.

161. *See* Sam D. Fine, *The Philosophy of Enforcement*, 31 FOOD DRUG COSM. L.J. 324, 329 (1976).

162. *Id.*

matters the good sense of prosecutors . . . must be trusted."[163] And then in the majority's final paragraph of the opinion, it reiterated, "Our system of criminal justice necessarily depends on 'conscience and circumspection in prosecuting officers.' "[164] The Government was, no doubt, aware of this dynamic when it wrote in its brief for *Park* that it would only bring cases when there was enough evidence to prove that the individual defendant had some notice of the underlying misconduct:

> Even if investigation discloses the elements of liability, and indicates that an official bears a responsible relation to them, the agency will not ordinarily recommend prosecution unless that official, *after becoming aware of possible violations*, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.[165]

A final point of support for the negligence standard can be found in the legislative history of the FDCA itself. In the Senate report that accompanied the original bill, the authors were clear that liability should not be extended to directors or officers who authorized subordinates to perform lawful duties when those subordinates took it upon themselves to act unlawfully.[166] Under a strict liability standard, liability could easily reach officers and directors who engaged in this form of delegation. Thus, if strict liability had been the preference of Congress, it may be presumed that a discussion of the nature of an officer's relation to a criminal offense would not appear so explicitly in the legislative history. Even more revealing is the fact that draft versions of the FDCA included express language implementing a strict liability standard for directors and officers that was ultimately removed in the bill's final iteration. The removed language read:

> [W]henever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be

163. United States v. Dotterweich, 320 U.S. 277, 285 (1943).

164. *Id.* (internal quotation marks and citations omitted).

165. Plaintiff's Summary Judgment Reply Brief at 13, Friedman v. Sebelius, 755 F. Supp. 2d 98 (D.D.C. 2010), *rev'd*, 686 F.3d 813 (D.C. Cir. 2012) (No. 1:09-cv-02028-ESH) (emphasis added) (quoting Brief of United States at 31–32, United States v. Park, 421 U.S. 648 (1975) (No. 74-215)).

166. S. REP. NO. 73-493, at 22 (1934) ("It is not, however, the purpose of [section 18(b)] to subject to liability those directors, officers, and employees, who merely authorize their subordinates to perform lawful duties and such subordinates, on their own initiative, perform those duties in a manner which violates the provisions of the law.").

> a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation.[167]

The fact that this language, which so clearly and definitively sets up a strict liability standard, was removed in the bill's final version demonstrates that Congress had a clear opportunity to include a strict liability standard, but made a conscious decision not to do so.[168] This type of negative construction is precisely the method the Court used in interpreting the meaning of the Taft-Hartley Act's silence regarding the president's authority to seize private industrial assets in order to resolve labor disputes during times of war in the Steel Seizure Cases.[169]

B. *Arguments for a Strict Liability Standard*

The pattern of notice and duty and the legislative history raises the question: is the famous strict liability standard of the *Park* doctrine a misunderstanding? While the above evidence is interesting, this Comment argues that the strict liability standard is still the correct approach to understanding the doctrine. There are three main observations that support this strict liability reading. First, strict liability was definitively the standard that the Court in *Dotterweich* announced when it determined that the purpose of the FDCA was to protect the public welfare and "enlarge and stiffen the penal net" that shielded it from dangerous conditions, however accidental or innocent their cause.[170] This interpretation is consistent with common public welfare statutes that penalize violations of laws that protect the public well being by punishing even those individuals who lacked any

---

167. *Dotterweich*, 320 U.S. at 291 (Murphy, J., dissenting) (citing S. 5, 75th Cong. § 2(f) (1937); S. 5, 74th Cong. § 707(b) (1936); S. 5, 74th Cong. § 709(b) (1935); S. 2000, 73d Cong. § 18(b) (1934); S. 2800, 73d Cong. § 18(b) (1934); S. 1944, 73d Cong. § 18(b) (1933)).

168. This form of reasoning is not unfamiliar to congressional and Supreme Court observers. In Justice Hugo Black's formalist majority opinion in the *Steel Seizure Case* that condemned the President's wartime authority to seize private steel industry assets, he reasoned that, since Congress had formally "rejected an amendment [to the Taft-Hartley Act] which would have authorized such governmental seizures in cases of emergency," it indicated that Congress had thereby not authorized the President to take such actions on his own initiative. Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 586 (1952).

169. *See id.* (concluding that Congress had definitely rejected the President's power to resolve labor disputes via the seizure technique by defeating an amendment to the Taft-Hartley Act in 1947).

170. *Dotterweich*, 320 U.S. at 282; *see also* United States v. Y. Hata & Co., 535 F.2d 508, 511 (9th Cir. 1976) ("One maintaining far less than the requisite 'highest standard of foresight and vigilance' would have recognized as early as August 1971 that implementation of a wire cage system would substantially, if not completely, prevent access by thieving and untidy birds.").

intent to cause the violation to occur.[171] It is frustrating for those who understood *Dotterweich* this way that the Court in *Park*, the formal extrapolators of *Dotterweich*, did not treat this issue as clearly as it could have.[172]

Second, § 331 of the FDCA (the section that defines prohibited acts) does not set up a scheme with a definitive mens rea requirement.[173] Section 331 begins with the language: "The following acts and the causing thereof are prohibited . . . ."[174] These words do not contain any intent or knowledge requirement, but instead operate only to outlaw the specific enumerated actions.[175] Thus, a court need not consider any intent or knowledge factors when determining whether a violation occurred because the statute contains no such requirement. In determining culpability under the FDCA, all a court needs to decide is whether the facts show that one of the prohibited actions occurred.[176]

Additional support for attributing a strict liability standard to the *Park* doctrine is the falsity of the "objectively impossible defense." The objective impossibility defense is supposed to give responsible officers an opportunity to demonstrate that, despite their best efforts,

---

171. *See, e.g.*, Clean Water Act § 101, 33 U.S.C. § 1251 (2006). The Senate Report that accompanied the Clean Water Act noted specifically that "[c]riminal liability shall . . . attach to any person who is not in compliance with all applicable Federal, State and local requirements and permits and causes a POTW [publicly owned treatment works] to violate any effluent limitation or condition in any permit issued to the treatment works." S. REP. NO. 99-50, at 29 (1985). In *United States v. Weitzenhoff*, 35 F.3d 1275 (9th Cir. 1993), the Ninth Circuit held that when a person "knowingly engages in conduct that results in a permit violation, regardless of whether the polluter is cognizant of the requirements or even the existence of the permit," that person will be guilty of the violation. *Id.* at 1284; *see also* United States v. Int'l Minerals & Chemical Corp., 402 U.S. 558, 565 (1971) (holding that actual knowledge of an environmental regulation designed to reduce the risk of handling hazardous material is not a necessary condition for establishing liability).

172. The term "strict liability" does not appear once in *Park*. The Court only announced a conduct standard as follows:

> The Act does not, as we observed in *Dotterweich*, make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.' The duty imposed by Congress on responsible corporate agents is, we emphasize, one that requires the highest standard of foresight and vigilance, but the Act, in its criminal aspect, does not require that which is objectively impossible.

United States v. Park, 421 U.S. 658, 672–73 (1975) (quoting *Dotterweich*, 320 U.S. at 281).

173. *See* Federal Food, Drug, and Cosmetic Act § 1, 21 U.S.C. §§ 301, 331 (2006) (describing acts within the food and drug industries that constitute violations).

174. *Id.* § 331.

175. *Id.*

176. Of the fifty-four prohibited acts listed in FDCA § 331, four of them do carry individualized knowledge requirements that do not apply to the remainder of the list. *See id.* §§ 331(w), (gg), (jj)(1), (yy).

they were helpless to prevent the criminal conduct and, at least in name, it does so: "To establish the impossibility defense the corporate officer must introduce evidence that he exercised extraordinary care, but was nevertheless unable to prevent violations of the [FDCA]."[177] But, as was demonstrated in the earlier cases, the success of the defense ultimately rests on the fact finder's individualized sense of what constitutes a sufficient effort.[178] The fact finder enjoys the luxury of being able to second guess the corporate official's actions. As such, the defense has never worked in a defendant's favor.[179]

Furthermore, impossible actions, by definition, cannot occur. If the defense is read in converse, it appears much less appealing to the defendant: if it is possible for the corporate officer to have known about and to have been able to prevent or promptly correct the criminal misconduct, then failure to do so may result in liability. In other words, as long as a court determines that it would have been possible for the officer to prevent a FDCA violation, an argument of powerlessness is overcome and liability attaches. In FDCA violations then, if the court can come up with an operational strategy that would have theoretically prevented the violation and the officer had not taken this course of action, liability can be proscribed.[180]

Doctrinally, the notion of something being "objectively impossible" is convenient if the end goal is to convict those parties who are only indirectly connected to the underlying misconduct. It is not a measure of likelihood or probability, but only possibility. In other words, it is a black or white determination: something either is possible or it is not. This binary characteristic makes the entire notion of impossibility highly unstable because it is contingent on what the fact finder believes to be possible. It is flimsy at best and subject to individual manipulation at worst, giving the advantage to the fact

177. United States v. Gel Spice Co., 773 F.2d 427, 434–35 (2d Cir. 1985) (quoting United States v. New England Grocers Co., 488 F. Supp. 230, 234 (D. Mass. 1980)).

178. *See supra* text accompanying notes 84–94.

179. A search of every case that cites *Park* wherein the objective impossibility defense was raised and addressed reveals that no court, state or federal, has ever sided with a defendant raising this argument. *See* United States v. Y. Hata & Co., 535 F.2d 508, 511–12 (9th Cir. 1976); United States v. Starr, 535 F.2d 512, 515–16 (9th Cir. 1976); Hujazi v. Superior Ct. of California, No. CV 11-9219-ODW(E), 2012 WL 3076338, at *8 (C.D. Cal. Jul. 26, 2012); United States v. Ellison, 112 F. Supp. 2d 1234, 1239 (D. Col. 2000); United States v. Gel Spice Co. Inc., 601 F. Supp. 1205, 1213 (E.D.N.Y. 1984); United States v. Torgian Laboratories, Inc., 577 F. Supp. 1514, 1530 (E.D.N.Y. 1984); *New England Grocers Co.*, 488 F. Supp. at 236–37; People v. Matthews, 9 Cal. Rptr. 2d 348, 354 (Cal. Ct. App. 1992); McNeely v. United States, 874 A.2d 371, 388 (D.C. 2005); Waste Conversion, Inc. v. Commonwealth, 568 A.2d 738, 743 (Pa. Commw. Ct. 1990).

180. *See Y. Hata & Co.*, 535 F.2d at 511–12.

finder to come out where he wants. Working with the Second Circuit's explanation of the defense,[181] the fact finder must first determine whether the actions taken by the responsible officer constitute extraordinary care.[182] This is essentially a subjective inquiry since it requires the fact finder to determine whether the officer's action (or lack of action) fell below the normal standard of conduct for others in similar situations. This standard is akin to the reasonable person standard, except that it asks the jury or judge to assess the situation according to the reasonable pharmaceutical executive. If the defendant's action fell below that reasonable executive standard, the fact finder must then determine whether there was some other action that could have prevented or corrected the misconduct.[183] Objectively speaking, it is almost always possible for an executive to know of and/or prevent a specific act. Despite how highly unlikely it is that a subordinate who has chosen to commit a prohibited act decides nevertheless to tell the responsible officer of his actions, it is still *possible* that the subordinate might do so, and therefore fails the objective impossibility standard. For example, in the world of off-label marketing, if a subordinate salesman at a pharmaceutical company took it upon himself to market a certain drug product for an off-label use (a FDCA prohibited act), in theory, it is still objectively possible for the salesman to tell the responsible officer about the illegal effort and therefore prevent the misconduct from occurring. Thus, the argument that it was objectively impossible for the responsible officer to know of the misconduct will not provide a defense.

But this is where the overwhelming subjectivity of the inquiry arises and the defense loses much of its ability to shield the officer-defendant. In the face of all the evidence presented by the government and the defense, the fact finder must ultimately try to determine to what extent a given preventative action would have been possible.[184] It requires the fact finder to conjure some alternative course of action and determine the possibility of its conception,

181. *Gel Spice Co.*, 773 F.2d at 434–35.

182. *Id.* ("To establish the impossibility defense the corporate officer *must introduce evidence that he exercised extraordinary care*, but was nevertheless unable to prevent violations of the [FDCA]." (emphasis added)).

183. *Id.* ("To establish the impossibility defense the corporate officer must introduce evidence that he exercised extraordinary care, *but was nevertheless unable to prevent violations* of the [FDCA]." (emphasis added)).

184. *Id.* ("*To establish the impossibility defense* the corporate officer must introduce evidence that he exercised extraordinary care, but was nevertheless unable to prevent violations of the [FDCA]." (emphasis added)).

execution, and success.[185] The impossibility inquiry requires the fact finder to put himself in the shoes of the officer-defendant and ask if he would have then considered the preventative actions impossible.[186] Given this series of inquiries, and the reality that the fact finder benefits from perfect hindsight, it should not come as a surprise that "[t]he impossibility defense has rarely been raised, and has never been satisfied."[187]

Other evidence that *Park* set up a strict liability standard appears in dicta from subsequent circuit court opinions. For example, the Fifth Circuit, functioning in a labor law context, cited to *Park*'s notion of strict vicarious liability in order to hold an executive responsible for the safety of his employees:

> [I]t is a common regulatory practice to impose a kind of strict liability on the employer as an incentive for him to take all practicable measures to ensure the workers' safety, the idea being that the employer is in a better position to make specific rules and to enforce them than the agency is.[188]

Earlier in 1978, the United States District Court for the Northern District of New York made the distinction between the strict liability standard and one with more of a negligence function. In this FDCA adulteration case, the district court noted:

> To allow the defendants to avoid liability under the Act merely by testing samples of the product, which samples prove negative for contamination, would be to obliterate the standard of absolute liability imposed by the Food, Drug and Cosmetic Act

185. This is precisely how the Ninth Circuit has approached the analysis of the impossibility defense. *See Y. Hata & Co.*, 535 F. 2d at 511 (rejecting the defendant's impossibility defense by holding that "[o]ne maintaining far less than the requisite 'highest standard of foresight and vigilance' would have recognized as early as August 1971 that implementation of a wire cage system would substantially, if not completely, prevent access by thieving and untidy birds").

186. *Id.* ("A wire cage is scarcely a novel preventive device. One maintaining far less than the requisite 'highest standard of foresight and vigilance' would have recognized as early as August 1971 that implementation of a wire cage system would substantially, if not completely, prevent access by thieving and untidy birds.").

187. *See Corporate Crime: Regulating Corporate Behavior Through Criminal Sanctions*, *supra* note 150, at 1263. It is quite possible, however, that the reason the impossibility defense has never been successfully used is that prosecutors at DOJ and HHS only choose to bring cases where they are certain the defense will not succeed.

188. Allied Prods. Co. v. Fed. Mine Safety & Health Review Comm'n, 666 F.2d 890, 893 (5th Cir. 1982).

> and subtly inject into the statute an element of scienter, or conscious awareness of guilt.[189]

This subtlety of the negligence standard that the district court found lurking in the lessons of *Park* and *Dotterweich* may also help explain the pattern of cases where a high negligence standard was employed.[190]

With government health care prosecutions on a sharp rise,[191] this split between *Park* doctrine explanation and execution has left an area of growing legal importance largely grey.[192] Perhaps the ambiguity was not so worrisome when government prosecutions were less frequent and the exclusion authority was not yet available to HHS regulators, but with the advent of such a sweeping penalty in combination with the higher number of suits, executives and their corporate counsels may take a more careful look at the precise dynamics of their compliance efforts.

III. HOW THE NEW LANDSCAPE FUNDAMENTALLY CHANGES THE *PARK* CALCULUS

A. The Strict Liability Standard of Conduct in Modern Context

The combination of the *Park* doctrine's confusing legal standards with its recent attachment to the exclusion penalty sets up an unusual regulatory landscape for corporate defense teams in the pharmaceutical and health care sectors. When the doctrine was originally fashioned in the 1970s and 1980s, the cases against individuals typically resulted in fines, fees, and corrective orders.[193] For example, the defendant in *Dotterweich* received a penalty of $500 and probation for a period of sixty days.[194] In *Park*, it was even less:

189. United States v. Morton-Norwich Prods., Inc., 461 F. Supp. 760, 763 (N.D.N.Y. 1978) (citations omitted).

190. *See supra* text accompanying notes 153–58.

191. *See* Mackenzie Weinger, *Health Fraud Busts Rise Sharply*, POLITICO (Aug. 30, 2011), http://www.politico.com/news/stories/0811/62306.html ("Federal prosecutions of health care fraud have skyrocketed and are set to rise 85 percent in 2011 over last year because of the Obama administration's stepped up emphasis on enforcement.").

192. *See* Jennifer Bragg, John Bentivoglio & Andrew Collins, *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 FOOD & DRUG L.J. 525, 528–33 (2010) (detailing the confusion over the mens rea requirement of the RCO doctrine).

193. *See supra* Parts I.A–B.

194. United States v. Buffalo Pharm. Co., 131 F.2d 500, 501 (2d Cir. 1942), *rev'd*, 320 U.S. 277 (1943). Calculating in today's dollar value, this amount would only come to approximately $6,500. *See* Bragg, Bentivoglio & Collins, *supra* note 192, at 533.

$250 in fines and no probation.[195] While those types of penalties are still available to authorities today (albeit at much higher monetary levels),[196] the threat of multi-year exclusions looms over misdemeanor violations in ways that were not envisioned when the doctrine was originally blessed by the Supreme Court in the mid-1970s. As recent examples demonstrate, guilty pleas can generate millions in enforcement fees, jail time, and industry exclusion.[197]

The fact that a penalty of such disruption is available in connection with strict liability is difficult to resolve with traditional views of strict criminal liability. In reviewing the nature of strict liability in a 1952 opinion, the Supreme Court noted that such a standard has been found appropriate in scenarios where penalties or sanctions "are relatively small, and conviction does no grave damage to an offender's reputation."[198] This view is wholly inconsistent with the recent linkage of *Park's* strict liability standard and the modern version of the exclusion penalty. It is not difficult to imagine that, if the *Dotterweich* or *Park* cases had come before the Court after the exclusion penalty was in effect, the Court's views on the nature of strict liability would have led to a different outcome.

The problem is that the use of the *Park* doctrine's immense extension of liability will overshoot its intended purpose in an era of new hyper-regulation. It is a problem of imbalance and misplaced intent. Both concerns have now begun to play out in the federal courts. In the past three years, the FDA, HHS OIG, and DOJ have brought a handful of cases that have appeared to function as warnings to other medium and large pharmaceutical and health care corporations.

B. United States v. Purdue Frederick Co. *and* Friedman v. Sebelius—*Standard of Conduct*

Comparing recent cases, such as *United States v. Purdue Frederick Co.*[199] and its offspring appeal *Friedman v. Sebelius*,[200] helps

195. *See* United States v. Park, 499 F.2d 839, 840 (4th Cir. 1974), *rev'd*, 421 U.S. 658 (1975) ("The jury found Park guilty on all counts and he was fined a total of $250.").

196. *See* 18 U.S.C. § 3571 (2006) (laying out the minimum monetary recoveries, jail sentences, and exclusion options available for FDCA violations and health care fraud); 21 U.S.C. § 333(a) (2006).

197. *See supra* notes 112–15 and *infra* notes 198–201, 212, and accompanying text (presenting the outcomes of three recent *Park* doctrine cases).

198. Morrissette v. United States, 342 U.S. 246, 256 (1952) (discussing the general temper of strict liability and its use in the American criminal justice system).

199. 495 F. Supp. 2d 569 (W.D. Va. 2007).

200. 686 F.3d 813 (D.C. Cir. 2012).

illustrate the doctrinal changes from the original cases covered earlier in this Comment.[201] This pair of cases has garnered a fair amount of industry and media attention because HHS, in its original administrative order, decided to exclude the three executive defendants from the health care industry for a period of twenty years.[202] The sheer length of the individual exclusions roused industry observers, and people outside of the health care field began paying attention. As previously discussed,[203] in 2007, the government brought a corporate criminal action against the Purdue Frederick Co. ("Purdue"), charging it with misbranding the drug OxyContin with an intent to defraud or mislead.[204] OxyContin is a pain medication that is often used to treat mild to severe pain after medical procedures. The government also charged three of Purdue's executives for the misbranding as responsible corporate officers.[205] Armed with evidence that Purdue had claimed in its marketing and sales practices that OxyContin was less addictive (and therefore safer) than other brands of oxycodone (the primary ingredient in OxyContin), the government received a guilty plea both from the corporation and from the three executives.[206]

The first notable difference between the primary *Purdue* action and the pattern of cases established under the original *Park* doctrine is the conceded lack of knowledge on behalf of the executive defendants. As established in the pattern of earlier cases, *Park* prosecutions were only brought where there was enough evidence to fulfill a negligence standard (instead of the easier strict liability standard that was formally expressed in the law).[207] In *Purdue*, however, this standard changed. Since the main issue in this case was simply whether the court could accept the plea agreements as fair and equitable,[208] direct attention was called to the terms of those

201. *See supra* Part I.A–B.

202. *See* Friedman v. Sebelius, 755 F. Supp. 2d 98 (D.D.C. 2010), *rev'd*, 686 F.3d 813 (D.C. Cir. 2012).

203. *See supra* text accompanying notes 106–20.

204. *See* 21 U.S.C. §§ 331(a), 333(a)(2) (2006).

205. *See* United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 571 (W.D. Va 2007). The three executives were Michael Friedman, the former Purdue CEO; Howard Udell, the executive Vice President and Chief Legal Officer, and Paul Goldenheim, the former chief scientific officer. *See id.* at 570 n.2.

206. *Id.*

207. *See supra* Part II.A.

208. In sentencing, federal courts are not bound by the terms of a plea agreement. *See* FED. R. CRIM. P. 11(c)(1)(C).

agreements as they related to the underlying facts of the case.[209] Notably, the district court for West Virginia accepted the executive defendants' plea agreements, all of which expressly stated that none of them ever had any personal knowledge of the underlying misconduct, but would nevertheless accept guilt based solely on their position as a responsible corporate officer.[210]

After the court in *Purdue* accepted the plea agreements of the individual defendants,[211] HHS regulators, conviction in hand, used the statutory authorities under 42 U.S.C. § 1320a-7(b)(1) and (3) to enforce a permissive exclusion on each individual executive for a period of twenty years.[212] Section 1320a-7(b)(1) predicates exclusion on the conviction of a misdemeanor offense "relating to fraud . . . in connection with the delivery of a health care item or service."[213] After multiple administrative hearings (and one failed court visit)[214] in which they argued that this penalty was too severe given the amount of money and probation time the defendants had accepted as part of their plea agreements ($34 million amongst all three), the executives had their exclusion terms reduced, but only down to twelve years.[215] They then filed suit against HHS.[216] After the district court for West Virginia affirmed the exclusion, the D.C. district court's opinion addressed both the standard of conduct required for a conviction and the reasonableness of the exclusion decision.[217]

On the legality of the exclusion, the district court simply reiterated the statutory law on the ability of the Secretary of HHS to apply the penalty, noting that, despite defendants' lack of knowledge, they were guilty because of their status as responsible corporate officers and therefore legally subject to the decision.[218] Like the Secretary's original decision, the district court did not elaborate on

209. *See generally* Agreed Statement of Facts, *Purdue Frederick Co.*, 495 F. Supp. 2d 569 (No. 07CR00029), 2007 WL 1423894 (outlining the facts that were agreed upon by both parties).

210. *See Purdue*, 495 F. Supp. at 571.

211. The three individual defendants, in addition to the $100,000 required HHS fine, agreed to pay a total of $34.5 million to the Virginia Medicaid Fraud Division's Income Fund. *See id.* at 573. Defendant Friedman agreed to pay $19 million, and defendants Udell and Goldenheim agreed to pay $8 million and $7.5 million, respectively. *Id.* at n.3.

212. *See* Friedman v. Sebelius, 755 F. Supp. 2d 98 (D.D.C. 2010), *rev'd*, 686 F.3d 813 (D.C. Cir. 2012).

213. 42 U.S.C. § 1320a-7(b)(1)(A)(ii) (2006).

214. *Friedman*, 755 F. Supp. 2d at 103 (dismissing on grounds of failure to exhaust administrative remedies).

215. *See id.* at 104.

216. *See id.*

217. *See id.* at 105–06.

218. *Id.* at 113.

what the term "in relation to" meant under the convicting statute, 42 U.S.C. § 1320a-7(b)(1)(A)(ii). This failure to do so left a gap in the legal analysis that unfortunately was unaddressed by the circuit court on appeal as well. In spite of this problem, there is one notable line in this opinion that does a good job demonstrating the drift between the original use of the *Park* doctrine and its more recent installment. Federal District Judge Ellen Segal Huvelle wrote: "Moreover, plaintiffs can hardly be heard to argue now, over three years after pleading guilty to the criminal charges against them, that they did not engage in any 'wrongful' or 'culpable' conduct."[219] Judge Huvelle's skepticism here misses the point and exposes the fundamental shift that has taken place. Whereas the district court for West Virginia (and FDA) were fully accepting of the defendants' claims that they had no personal knowledge of the underlying misconduct,[220] Judge Huvelle dismisses those claims altogether, as if the passage of time has had some effect on the validity of their statements during an earlier stage of the litigation. She notes that "[i]t strains credulity to argue that . . . they . . . 'were convicted based solely on their *status* as senior executives, without any culpability or wrongful action on their part at all.' "[221] Of course, this is precisely what the accepted terms of the plea agreement expressed. In no way did the executives' position at Purdue bear on their personal culpability as to the off-label marketing violations. Judge Huvelle's dismissal of this fact is plainly incorrect.

What's more, it is wholly unnecessary for Huvelle to make such a claim to begin with if the standard of the *Park* doctrine is truly one of strict liability, since strict liability offenses, by definition, carry no requirement of moral wrongfulness or culpability. This view is also consistent with the FDA's guidance on *Park* prosecutions, which stresses that a responsible corporate official can be held liable "without proof that the corporate official acted with intent or even negligence."[222] If intent or moral wrongfulness play no role in a strict liability offense, and the mutually accepted plea agreement expressly released the individuals from wrong doing, it seems highly disingenuous for Judge Huevelle to admonish the defendants for their role in the violation.

---

219. *Id.* at 111.

220. *See supra* text accompanying note 211.

221. *See Friedman*, 755 F. Supp. 2d at 111 (quoting Memorandum of Points and Authorities in Support of Plaintiff's Motion for Summary Judgment at 3, *Friedman*, 755 F. Supp. 2d 98 (No. 09-2028 (ESH)).

222. *See* FOOD & DRUG ADMIN., *supra* note 125, § 6-5-3.

Perhaps most alarming is the district court's wielding of the exclusion authority while demonstrating a lack of understanding about the U.S. health care industry. Health care in the United States has become highly government-dependent, with federally funded programs providing nearly one-third of national medical expenditures.[223] The importance of federal funding in the pharmaceutical industry is even more pronounced. Between 1998 and 2010, the growth in federal funding for basic drug and disease research was nearly equal to that provided by the private sector.[224] In both the health care and pharmaceutical sectors, identifying a company that receives absolutely zero federal funds, "directly or indirectly,"[225] is nearly impossible. Yet, despite this reality, Judge Huvelle decided that the "consequences of exclusion are not nearly as dire as plaintiffs contend, as plaintiffs remain free to seek private employment at a company that does not rely on federal or state funds."[226]

In the D.C. Circuit's review of Judge Huevelle's decision, it approved the combination of the *Park* conviction and subsequent exclusion penalty, but reversed the district court judge's affirmation of the length of exclusion, finding that the twelve-year duration was arbitrary and capricious.[227] Because HHS had not cited any past instances where it had issued such a lengthy exclusion (the longest to date had been four years),[228] the circuit court held that the decision could not be supported by past precedent.[229] While this technical reversal may have helped reduce the term of the exclusion for the executive defendants, it implicitly approved HHS's use of the exclusion penalty predicated on a *Park* doctrine conviction. The court, like the Secretary and district court, approved of drawing a connection between the executives and the necessary fraud via the words "relating to" in that their conviction for the corporation's off-

223. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 136, at 3.

224. *See* CONGRESSIONAL BUDGET OFFICE, PHARMACEUTICAL R&D AND THE EVOLVING MARKET FOR PRESCRIPTION DRUGS 3 (2009), *available at* http://www.cbo.gov/ftpdocs/106xx/doc10681/DrugR&D.shtml#1044432.

225. OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, 64 Fed. Reg. 52791, 52793 (Sept. 30, 1999).

226. *See Friedman*, 755 F. Supp. 2d at 98.

227. *See* Friedman v. Sebelius, 686 F.3d 813, 828 (D.C. Cir. 2012).

228. *Id.* (citing Paulette White Jackson, DAB 1915 (2004); Roberto Kutcher-Olivio, DAB 1837 (2002)).

229. *Id.*

label marketing was a misdemeanor "relating to" fraud under § 1320a-7(b).[230]

However, in his dissent, Judge Williams confronted this glaring lack of definition for the words "relating to": "Very troublingly, without such an effort at seeking the legal meaning of the disputed clause, we have a reading by the Secretary that offers none of the 'precision and guidance [that] are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.' "[231] Judge Williams's comment calls on HHS to develop perceivable regulatory thresholds before enforcing such a disruptive administrative penalty. Indeed, he is channeling the Supreme Court's own warning from *Dotterweich* that reminded government regulators that, when dealing with such a potent legal doctrine, "the good sense of prosecutors . . . must be trusted."[232]

C. *New Regulations—Public Protection or Profit?*

While the development of the *Park* doctrine's standard of conduct in *Purdue* and *Friedman* is at play in other recent situations,[233] another change from the original *Park/Dotterweich* framework has arrived in the regulations and laws that surround it. As a general public welfare measure, the aim of the statutes that define the *Park* doctrine are glossed, at least in name, with protecting the health and safety of the public: "The purpose of exclusion is to protect the Medicare, Medicaid, and all Federal health care programs from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care."[234] However, evidence on how the government is using the exclusion authority demonstrates that other motivations are afoot.

As stated earlier, general health care fraud actions are increasing at an alarming rate.[235] With eighty-five percent more claims year-

230. *Id.* at 824. The Court agreed with the Secretary using the term "nexus" between the executive's convictions and the statutory basis for their exclusion. *See id.*

231. *Id.* at 831 (Williams, J., dissenting in part, concurring in part, and concurring in the judgment) (quoting FCC v. Fox Television Stations, 132 S. Ct. 2307, 2317 (2012)).

232. United States v. Dotterweich, 320 U.S. 277, 285 (1943). Indeed, these words were written before the exclusion penalty existed.

233. *See, e.g.*, United States *ex. rel.* Gobble v. Forest Labs., 729 F. Supp. 2d 446 (D. Mass. 2010); *see also* Vanessa O'Connell & Michael Rothfield, *U.S. Targets Drug Execs*, WALL S. J., Sept. 13, 2011, at B1.

234. Anderson v. Thompson, 311 F. Supp. 2d 1121, 1124 (2004) (citing S. REP. NO. 100-109, at 2 (1987), *as reprinted in* 1987 U.S.C.C.A.N. 682, 682).

235. *See* Weinger, *supra* note 191.

over-year between 2010 and 2011,[236] the message to the industry is clear: enforcement is on the rise. What is also clear is the government's renewed appetite for collecting fees and settlement payments. In 2011 alone, the government collected over $1.2 billion in payments from just five pharmaceutical settlements.[237] The amount of money to be made in this area of regulation is enormous.

While enforcement of health care and FDCA provisions is consistent with increased protection of the public health (and the government's programs), a legislative move in 2010 amending the Patient Protection and Affordable Care Act ("PPACA") revealed another side of the government's policy motivations. In the original version of PPACA that was signed into law on March 23, 2010, section 6502 increased the severity of the exclusion penalty so that any guilty plea by an individual or subsidiary company would necessarily also result in the exclusion of the entire parent enterprise from all Medicaid payments simply by virtue of association.[238] Under a purely protectionist-minded regulatory state, this makes perfect sense: The increased severity of the exclusion authority in section 6502 was logically connected with a desire for higher deterrence.

However, after HHS attorneys quickly realized that this new requirement was interfering with their ability to settle cases quickly, they asked Congress to get rid of section 6502 altogether.[239] On December 15, 2010, less than one year after PPACA passed, H.R. 4994 was signed into law as the Medicare and Medicaid Extenders Act of 2010.[240] Section 205(a) of the new bill repealed the strict terms of PPACA section 6502.[241] By default, this move placed HHS in the original situation with its less stringent, but more flexible exclusion

236. *Id.* ("Federal prosecutions of health care fraud have skyrocketed and are set to rise 85 percent in 2011 over last year because of the Obama administration's stepped up emphasis on enforcement.").

237. HOPE S. FOSTER ET AL., MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO PC, 2011—THE YEAR IN REVIEW: TRENDS IN HEALTH CARE ENFORCEMENT 4 (Jan. 31, 2012), http://www.mintz.com/newsletter/2012/Advisories/1618-0112-NAT-HCED/1618-0112-NAT-HCED_index.pdf.

238. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6502, 124 Stat. 119, 776 (2010) (codified as amended at 42 U.S.C. § 1396a(a)(78) (2010)), *repealed by* Medicare and Medicaid Extenders Act of 2010, Pub. L. No. 111-309, § 205(a), 124 Stat. 3285, 3290 (codified at 42 U.S.C. § 1396a(a) (2012)).

239. *See* Alan M. Kirschenbaum, *Notorious Affiliate Exclusion Provision of PPACA Repealed*, FDA L. BLOG (Dec. 21, 2010, 8:16 AM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/12/notorious-affiliate-exclusion-provision-of-ppaca-repealed.html.

240. *See* Medicare and Medicaid Extenders Act of 2010 § 205(a), 124 Stat. at 2390.

241. *See id.*

maneuvers secured.[242] This quick shift represents the fact that, in some material way, the motivation behind using the *Park* doctrine to generate more exclusion scenarios for pharmaceutical and health care corporations is driven not by the increased protection of the public, but by a desire to maintain an increasing flow of settlement money into government collection accounts. If public welfare protection was truly the full motivation for the exclusion actions (as the statute claims), the more severe penalty that was briefly available would have been the most logical choice.

D. Changing the Corporation's and Individual's Plea Calculus

Taken all together, one would assume that the above changes from the original *Park* doctrine would, if the pharmaceutical industry functions like others, result in an increased amount of settlements.[243] To a large extent, this view is correct. Rising litigation costs and conventional wisdom suggest that companies and individuals both, on average, would rather settle claims than risk higher penalties in the event of an adverse jury ruling. However, in dealing with *Park* prosecutions, the three-way dynamic between the corporation, the corporation's implicated responsible officer, and the government prosecutor becomes much more complex. The main difference is that, in two-way negotiations, opposing parties will typically interact with each other to reach a mutually agreeable (but not necessarily desirous) set of terms, while three-way negotiations wherein none of the parties' interests are congruent with one another will result in a different and more complex set of considerations.[244] A corporation's desire to strike a quick plea bargain with the government (as lethargy usually decreases an opposing party's willingness to compromise) is countered by the personal interests of a responsible officer within the

242. *See* Kirschenbaum, *supra* note 239 ("The provision would have severely constrained the Department of Justice's ability to negotiate settlements that would impose appropriate penalties on drug and device manufacturer without harming Medicaid beneficiaries.").

243. *See* John H. Langbein, *On the Myth of Written Constitutions: The Disappearance of Criminal Jury Trial*, 15 HARV. J.L. & PUB. POL'Y 119, 121 (1992) (noting that plea bargaining "has become the ordinary dispositive procedure of American criminal justice").

244. For an excellent discussion on the increased complexity in hostile three-party negotiations scenarios, see generally D. Marc Kilgour & Steven J. Brams, *The Truel*, 70 MATHEMATICS MAG. 315, 315 (discussing the various ways in which three-party games differ from two-party games: "In duels, the interest of game theorists lies in the nature and timing of each player's actions against its opponent. In truels, another strategic consideration comes into play—namely, that a player must also decide which, if either, opponent to fire at, bringing in the target aspect of a confrontation").

corporation since, once the government has the corporation's guilty plea with an agreed statement of facts in hand, pegging those events to the individual responsible corporate officer position would not be difficult in a strict liability framework. In other words, if the government can secure, via the corporation's admission, that a violation occurred, all the government prosecutor needs to do is establish that some corporate officer stood in a responsible relation to the activity that caused the violation.

Yet, this is only one version of a three-party hostile negotiation. This initial three-party scenario presumes that the government values the plea bargains (or convictions) of the corporation and the individual equally.[245] If we introduce an element of preference on behalf of the government, the relationships between the three parties becomes even more complex. This second modified version of the settlement negotiation is more consistent with actual *Park* doctrine scenarios since the government may often prefer to secure one party's guilty plea over another. In highly publicized cases, for example, "convictions of individuals can be more impactful than convictions of corporations."[246] It is not difficult to imagine a situation where the government, in dealing with the corporation directly, might take measures to incentivize the corporation to agree to a precise version of facts in the plea bargain in order to make it easier to define the individual as a responsible officer. This might occur in high-profile cases where putting a face to a crime is popularly desirable. If, on the other hand, the government is more interested in getting at a corporation's vast resources, it would be in the government's favor to incentivize the individual to disclose certain pieces of information to make that recovery easier.[247] In either scenario, the government stands to benefit by playing the corporate defendant and its responsible corporate officer off one another.

---

245. *See* Bragg, Bentivoglio & Collins, *supra* note 192, at 536.

246. *Id.*

247. A good example of this scenario possibly occurred in 2005 when "Eli Lilly pled guilty to one misdemeanor misbranding count and paid $36 million to settle allegations that the company marketed its drug Evista for off-label uses." BRENT J. GURNEY ET AL., WILMER CUTLER PICKERING HALE AND DORR LLP, THE CRIME OF DOING NOTHING: STRICT LIABILITY FOR CORPORATE OFFICERS UNDER THE FDCA, at F-18 (2007), http://www.wilmerhale.com/files/Publication/7b1c0866-a547-48c7-86d0-04d0449c03d7/Presentation/PublicationAttachment/c5eda281-2dae-4154-a0f8-13b817f25b52/The_Crime_of_Doing_Nothing.pdf. The off-label marketing plan was comprehensive and included "sales representative training materials, a press release, a consumer magazine ad, and unsolicited letters to physicians discussing Evista's use in breast cancer prevention." *Id.* Yet, despite such ripe circumstances for a *Park* prosecution against Eli Lilly's executives, no such action was brought. *See id.*

Battles between a corporation and its management often throw a company into havoc and damage shareholder value. For example, the aftermath of one of these settlement scenarios is currently being played out in bitter lawsuits between a pharmaceutical company, KV Pharma, and its ex-CEO, who voluntarily stepped down after receiving a twenty-year exclusion penalty from the FDA.[248] The competing suits each claim that the other party was responsible for the non-recall of problematic morphine tablets in 2008.[249] The disruption was large. Not only will the ex-CEO no longer be able to participate in any health care or pharmaceutical company that receives any federal funding for the twenty year period, but the company itself, in an attempt to recover from the fines levied, "recalled its drugs, laid off three-quarters of its employees and halted its manufacturing operations for almost two years."[250] If settlement is typically the desired outcome,[251] pharmaceutical firms and their executives must be wary of their relative bargaining positions to one another and to the government in order to avoid situations analogous to the KV-Pharma situation.[252]

IV. POLICY PROBLEMS AND PROPOSALS

A. Policy Concerns

The ultimate effect of this general move toward increased utilization of a strict liability enforcement tool is the transformation of the threat of personal liability into a formal mechanism of industry regulation. Aside from the implications that such a shift poses to traditional notions of criminal liability, this overarching policy decision has significant practical implications as well.

First, it may create artificial and inefficient management structures in large corporations in order to distance upper executives from potential misconduct at a lower level. Additionally, "executives might go overboard in designing and implementing expensive

248. *See* George Miller, *KV Pharma, Ex-CEO Battle of Recall Responsibility*, FIERCE PHARMA MANUFACTURING (Oct. 31, 2011), http://www.fiercepharmamanufacturing.com/story/kv-pharma-ex-ceo-battle-over-recall-responsibility/2011-10-31.

249. *See id.*

250. Andrew McConaghie, *Crisis in the Boardroom: 2011's Most Dramatic Departures*, INPHARM (Jan. 11, 2012, 10:51 AM), http://www.inpharm.com/news/170776/crisis-boardroom-2011-s-most-dramatic-departures.

251. Erik Luna, *Traces of a Libertarian Theory of Punishment*, 91 MARQ. L. REV. 263, 263, 281 (2007) (noting that ninety percent of criminal cases are now concluded with a plea bargain).

252. *See* notes 112–13 and accompanying text.

procedures to reduce the probability of corporate crimes."[253] These tactics may often result in layers of executive middle-management, which in turn hurt a corporation's flexibility.[254] The trend toward setting up corporate compliance offices, a practice encouraged by liability-minded lawyers, may be motivated by the increased risks of executive liability.[255] Indeed, many white collar defense lawyers suggest increasing internal controls and reporting capabilities as a direct response to the increase in RCO liability.[256] When decisions to add costly layers of management are based on the hopes that such layers will shield certain individuals at the top of the management structure from responsible corporate officer liability, there is increased potential for shareholders to suffer the consequences since the cost and rigidity of these layers may reduce the overall value of the corporation.

Second, the *Park* doctrine's growing application of strict and vicarious liability to individual officers within the health care and pharmaceutical industries should act as a warning to executives and corporate counsel in other industries. The supposed rationale for this flavor of liability in health-related sectors is to protect the public welfare and deter government fraud, but extending it to other industries that handle areas of significant public importance (i.e., banking) does not seem like a large leap. It is surprising that *Park* liability is not enforced against large banks, given the fact that large financial institutions sit in an arguably "responsible relation" to the fiscal demise of many Americans through evidence of depleted retirement funds and illegal home loan approvals.[257] Indeed, last year law firms began publishing client alerts detailing the increased

253. *See Corporate Crime: Regulating Corporate Behavior Through Criminal Sanctions*, *supra* note 150, at 1272.

254. *See* HERBERT A. SIMON, ADMINISTRATIVE BEHAVIOR: A STUDY OF DECISION-MAKING PROCESSES IN ADMINISTRATIVE ORGANIZATION 142–45 (3d ed. 1976).

255. *See* Roderick L. Thomas & Mark B. Sweet, *Can You Survive a Fraud Investigation? Part 1: A Practical Guide to Preparing for Government Investigations*, METROPOLITAN CORP. COUNS. (Feb. 17, 2012, 9:05 AM), http://www.metrocorpcounsel.com/articles/17914/can-you-survive-fraud-investigation-part-1-practical-guide-preparing-government-inves.

256. *See, e.g.*, *id.*

257. *See* Peter J. Henning, *Is That It for Financial Crisis Cases?*, N.Y. TIMES DEALBOOK (Aug. 13, 2012, 11:22 AM), http://dealbook.nytimes.com/2012/08/13/is-that-it-for-financial-crisis-cases/ ("New laws would not make it any more likely that senior executives could be pursued *unless they included liability as a 'responsible corporate officer'* for the conduct of underlings without having to prove an executive's knowledge or recklessness." (emphasis added)).

attention to government enforcement of financial fraud.[258] *Park* liability would fit easily into such a regulatory effort.

A third concern surrounding the future of the *Park* doctrine is its application to off-label marketing. Off-label marketing occurs when a pharmaceutical company sales representative markets drugs to physicians for uses other than those that have been approved by the FDA. This practice is an actionable health care offense under 21 U.S.C. § 331 and therefore may set the grounds for the criminal conviction of a responsible corporate officer under *Park* strict personal liability.[259] The validity of criminalizing off-label promotion can be debated from a policy perspective, but the FDA has consistently held that marketing any non-approved use, no matter its proven medicinal purposes, is illegal until the use is officially sanctioned by the Agency.[260]

However, companies still occasionally engage in the practice when they have hard data on hand that their unapproved use actually works to treat a certain condition, and engaging in this kind of truthful off-label promotion has been met with some legal success.[261] In the recent decision in *Sorrell v. IMS Health, Inc.*,[262] the Supreme Court struck down a Vermont law prohibiting drug companies' use of their own data about the prescription trends of individual doctors and pharmacists.[263] Such data can potentially be used to target product-

258. *See, e.g.*, *Criminal Actions Against Failed Bank Executives*, JONES DAY (April 2011), http://www.jonesday.com/abc2.aspx?url=/newsknowledge/publicationdetail.aspx%3Fpublication%3D4c78cf38-5bda-43f7-a6d2-7843accdc86f%26RSS%3Dtrue%26print%3Dtrue%26section%3DResults.

259. *See* 21 U.S.C. § 311(k) (2006).

260. *See* Coleen Klasmeier & Martin H. Redish, *Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection*, 37 AM. J.L. & MED. 315, 318 (2011) ("[T]he FDA has categorically banned manufacturers of drugs and devices from promoting their use for unapproved purposes to the medical profession."). *But see* United States v. Caronia, 703 F.3d 149, 168–69 (2d Cir. 2012) (holding that a promotion of a prescription drug for a non-approved use is permissible so long as the promotion is truthful).

261. This is because a doctor may still prescribe a drug for a non-approved use without any interference from the FDA and because the FDA recognizes the innovative benefits that can flow from off-label prescriptions. *See "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices—Information Sheet*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm (last updated Aug. 10, 2011) ("Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment."); *see also* Klasmeier & Redish, *supra* note 260, at 318 ("[M]anufacturers are in a unique position to provide valuable information about off-label uses to the medical profession.").

262. 131 S. Ct. 2653 (2011).

263. *Id.* at 2659.

marketing efforts to specific doctors and medical practices. Going further, the Second Circuit, relying on the *Sorrell* decision, also recently reversed a doctor's conviction for off-label marketing based on the fact that, despite promoting a drug for an off-label use, the promotion itself was truthful and therefore considered protected speech under the First Amendment.[264] Without going too far into First Amendment analysis, the Supreme Court's and Second Circuit's rulings set the stage for a reconsideration of off-label marketing policy. While this is the general trend in *Park* doctrine application, these decisions represent at least one major area of pharmaceutical regulation in which the doctrine may begin to decline.

B. Policy Alternatives

We no longer live in an economy where pharmaceutical companies and health care corporations can be fully overseen by any one individual. A cursory glance over the employment numbers of any major pharmaceutical companies helps demonstrate the scope of these mammoth organizations. For example, Johnson & Johnson employs 114,000 people, maintains locations in sixty countries, and sells its products in nearly every country in the world.[265] It also has 1,549 executives.[266] The notion that a single individual can stand in responsible relation to every action of this humongous population is unrealistic. In this sense, the industry has simply outgrown the key rationale behind the *Park* doctrine that a CEO can be accountable for everything that occurs at his or her pharmaceutical company. By using a strict liability standard for FDCA and health care fraud offenses, executives are incentivized to actually reduce their oversight since such a management approach reduces their responsibility for any underlying violation. This could include creating intermediate semi-executive bodies or avoiding making key management decisions.

Placing liability on the actual actors culpable for any violation, as opposed to on the company's executives, would have a positive operational effect in two ways. First, it would help reverse the incentive for executives to distance themselves from potentially

264. *See Caronia*, 703 F.3d at 166 ("As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government's goals of preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs.").

265. Johnson & Johnson, Annual Report (Form 10-K), at 1–2 (Feb. 25, 2011).

266. *See Johnson & Johnson Company Information*, HOOVERS, http://www.hoovers.com/company/Johnson__Johnson/rfxtci-1.html (last visited Nov. 11, 2012).

violative activities. Second, it would help breed more individual responsibility further down the ranks of a corporation's employment structure. Furthermore, such a regulatory move would be consistent with viable principles of business organization that have created significant value for shareholders. The theory is that, if liability extends further down the corporate ladder, those employees who also would become subject to a legal penalty for their misconduct will operate with increased diligence. This model of decentralized authority has found success in the real world. AES, now one of the world's largest energy providers, has operated on a decentralized structure from its beginning in the early 1980s.[267] At its height in 2000, AES employed more than 10,000 people in nineteen countries, yet kept less than thirty employees total at its headquarters.[268] Two researchers explained that at AES "[b]usiness development is the responsibility of almost everyone . . . including relatively junior people."[269] Roger Sant, long-time CEO of AES, commented that a driving philosophy at a company had always been that "[t]he organization has assumed that their people are good, that they really want to make a difference; that you don't need to control them; that you can depend on them."[270]

Another policy alternative suggested by food and drug law attorney Ariel Glasner is to simply adjust the standard of conduct under which *Park* doctrine actions may be brought from a strict liability standard to a gross negligence standard.[271] This change would not require a complete overhaul of existing statutory language or administrative practice, and would still require a corporate officer to be diligent in his perception and prevention of violations. Such a change would also help resolve the dissonance between the strict liability standard expressed in the letter of the law and the apparent negligence standard that has traditionally accompanied *Park* prosecutions.[272] This change would also be more consistent with the

267. NIKOLAI ROGOVSKY & EMILY SIMS, CORPORATE SUCCESS THROUGH PEOPLE: MAKING INTERNATIONAL LABOUR STANDARDS WORK FOR YOU 58 (2002).

268. *Id.*

269. *Id.*

270. *Id.* at 59.

271. Ariel Glasner, *Are Misdemeanor Prosecutions Under the* Park *Doctrine an Effective Mechanism for Deterring Violations of the Federal Food, Drug, and Cosmetic Act?*, FDLI'S FOOD & DRUG POL'Y F., July 26, 2011, at 1, 5, http://www.fdli.org/resources/resources-standard-detail-view/are-misdemeanor-prosecutions-under-the-park-doctrine-an-effective-mechanism-for-deterring-violations-of-the-federal-food-drug-and-cosmetic-act-.

272. See *supra* Part III for a discussion of the historical variance between these two standards.

standards expressed in the *Park* case, as the Court never mentioned the use of strict liability.[273] Most importantly, using a negligence standard would help define for companies who qualifies as a responsible corporate officer. The current FDA guidelines on the definition expressly state that defining who is and is not a responsible corporate officer is futile.[274] While no black-letter definition needs to be set out, companies would be better able to understand what positions qualify for such a definition based on a negligence standard's insistence on what any one particularly responsible corporate officer should have known or should have done. With the current strict liability standard, corporate counsel can be left guessing at precisely which acts or omissions of a particular responsible corporate officer will result in a *Park* prosecution. The negligence standard would help bring better-defined standards to this situation, which should result in more predictability about what exposes corporate officers to liability.

CONCLUSION

The dynamics of modern *Park* doctrine cases represent a fundamental shift away from the original function and intent of the doctrine as it was understood at its founding and development in the 1970s. Not only have the mechanics of the doctrine been altered, but there is evidence to suggest that it serves an entirely different purpose from its original form. While there are laudable goals at hand in its use, the overall structure, particularly in conjunction with the use of the exclusion authority, depicts a regulatory movement that is more concerned with the ends than with the means. Despite the prophylactic effects and the doctrine's sheer power that it holds over the pharmaceutical and health care industries, it has come at the expense of distorting the delicate and controversial concept of strict liability and turning it into an oversized tool of legal leverage.

ANDREW C. BAIRD*

273. *See* United States v. Park, 421 U.S. 658, 670–71 (1975).
274. *See* FOOD & DRUG ADMIN., *supra* note 125, § 6-5-3.