THE RESPONSIBLE CORPORATE OFFICER DOCTRINE: SHARPENING A BLUNT HEALTH CARE FRAUD ENFORCEMENT TOOL

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I.
INTRODUCTION

You are a sixty-year-old health care executive at a large public company with hundreds of employees, and one of the employees responsible for marketing and advertising makes material misstatements about the efficacy of your product. Despite being ignorant of and uninvolved in her actions, you are charged with a misbranding misdemeanor, fined a large sum of money, and excluded from dealing with any federal health care programs for fifteen years—a sentence that harms your finances and your reputation and effectively ends your career as a health care executive. While this story would have been farcical several years ago, it is now a distinct possibility due to some key changes to health care fraud enforcement strategies.

In response to the recent increase in health care fraud, which now costs U.S. taxpayers an estimated $80 billion per year,[1] federal prosecutors and agencies have made two key alterations to their enforcement strategies against alleged fraudulent actors in the health care context: (1) they have increased the application of the RCO Doctrine, and (2) they have augmented the RCO Doctrine with permissive exclusion from federal health care programs as an additional deterrent.

The RCO Doctrine was created in the 1940s through judicial statutory interpretation to extend strict liability from corporations and the low-level individuals who actually commit the harmful act to the more senior officers in the firm when they stand in "responsible relation" to misconduct that endangers the public welfare.[2] While the RCO Doctrine has been applied in a wide variety of contexts—including securities vio-

1. FBI, HEALTH CARE FRAUD, http://www.fbi.gov/about-us/investigate/white_collar/health-care-fraud (last visited Mar. 1, 2013). It should be noted that the validity of these Medicare numbers as an accurate measure of health care fraud are in doubt. *See, e.g.*, Joan H. Krause, *Following the Money in Health Care Fraud: Reflections on A Modern-Day Yellow Brick Road*, 36 AM. J.L. & MED. 343, 346 (2010) ("More importantly, while these figures certainly indicate a serious problem with the accuracy of Medicare payments, they tell us very little about the extent of *fraud* in the federal health care programs.").

2. United States v. Dotterweich, 320 U.S. 277, 284-85 (1943). The RCO Doctrine has developed over time to include both strict liability crimes, such as those found under the Food, Drug and Cosmetic Act of 1938, and crimes that require proof of knowledge, such as the Clean Water Act. *See* United States v. Brittain, 931 F.2d 1413 (10th Cir. 1991) (using the RCO Doctrine to impute scienter and affirm conviction under the Clean Water Act). *But see, e.g.*, United States v. MacDonald & Watson Waste Oil Co., 933 F.2d 35 (1st Cir. 1991) (overturning RCO Doctrine convictions as applied to violations of the RCRA and the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") by requiring scienter). Imputing scienter via the RCO Doctrine is a more recent development that has inspired caution among commentators. *See, e.g.*, Truxtun Hare, *Reluctant Soldiers: The Criminal Liability of Corporate Officers for Negligent Violations of the Clean Water Act*, 138 U. PA. L. REV. 935 (1990); Note, *Fiduciary Duties: Expanding the Use of the RCO Doctrine to Statutes with a Scienter Requirement*, 9 U. MIAMI BUS. L. REV. 235 (2001); Marjorie P. Gabbett, *Eroding the Resource Conservation and Recovery Act's Scienter Requirement Regarding Responsible Corporate Officers*, 14 HAMLINE J. PUB. L. & POL'Y 49 (1993). Judges have never imputed knowledge in this way in the health care context, so an analysis of this *mens rea* construction will not be discussed in this article.

lations,[3] meat misbranding,[4] antitrust,[5] and the Resource Conservation and Recovery Act ("RCRA"),[6] among others[7]—the U.S. Food and Drug Administration (the "FDA") has specifically renewed its interest in the RCO Doctrine as a means of protecting the welfare of citizens and of federal health care programs. For example, FDA Commissioner Margaret Hamburg wrote a letter in March 2010 that indicated, among other things, the FDA's intent to "increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable."[8] In January 2011, the FDA followed through by releasing "Special Procedures and Consideration for Park Doctrine Prosecutions" as an update to the FDA Regulatory Procedures Manual to account for these new measures.[9]

The RCO Doctrine manifests in two ways. First, it can lighten the burden of proving *mens rea* by allowing prosecutors—in some cases—to impute scienter by virtue of an officer's position of authority and responsibility in the organization.[10] Since the health care fraud crimes to which the RCO Doctrine is currently applied are strict liability crimes, the imputation of *mens rea* will not be further explored in this Note. Second, it can lighten the burden of proving *actus reus* by ena-

3. *See, e.g.*, Wittenberg v. Gallagher, 2001 WL 34048121 (Ariz. Ct. App. Nov. 20, 2001).

4. *See, e.g.*, United States v. Jorgensen, 144 F.3d 550 (8th Cir. 1998).

5. *See, e.g.*, United States v. Wise, 370 U.S. 405 (1962).

6. *See, e.g.*, United States v. Dee, 912 F.2d 741 (4th Cir. 1990).

7. For a complete and regularly updated list, see Randy J. Sutton, Annotation, *"Responsible Corporate Officer" Doctrine or "Responsible Relationship" of Corporate Officer to Corporate Violation of Law*, 119 A.L.R.5th 205 (2004).

8. Letter from Margaret A. Hamberg, Comm'r of Food and Drugs, to Senator Charles E. Grassley (Mar. 4, 2010), *available at* http://www.grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf.

9. FDA REGULATORY PROCEDURES MANUAL § 6-5-3, *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3 [hereinafter FDA MANUAL].

10. For a discussion of the RCO Doctrine and its effects on *mens rea* standards in the environmental context, see, for example. Ronald M. Broudy, *RCRA and the Responsible Corporate Officer Doctrine: Getting Tough on Corporate Offenders by Sidestepping the Mens Rea Requirement*, 80 KY. L.J. 1055, 1072-73 (1992); Sidney M. Wolf, *Finding an Environmental Felon Under the Corporate Veil: The Responsible Corporate Officer Doctrine and RCRA*, 9 J. LAND USE & ENVTL. L. 1 (1993).

bling prosecutors to convict higher-level officers for crimes that occurred on their watch (and that they perhaps even consciously avoided) rather than restricting punishment for those crimes to the lower-level, front-line employees that physically carried out the act. Thus, the RCO Doctrine does not just increase the potency of enforcement against individual actors—it can create an entirely new set of defendants to which these statutes apply by implicating both the fraudulent actor and her superior officer(s).[11]

On the other hand, OIG's exclusionary authority introduces a new means of deterring the corporate actor. Under this authority, OIG is able to prohibit payments from federal health care programs ("FHCPs")[12] to excluded individuals and entities and to withhold payments to parties who employ or contract with excluded individuals.[13] Although OIG's exclusionary authority has developed over decades, OIG released updated guidance in October 2010 that strengthened the application of their exclusionary authority under 42 U.S.C. § 1320a–7(b)(15).[14] In March 2011, the then-current Chief Counsel of OIG pledged to use OIG's exclusionary authority to "alter the cost-benefit calculus of the corporate executives who run these companies" in response to his concerns that

11. *See* discussion *infra* Part II.D.

12. FHCPs are defined as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program." 42 C.F.R. § 1001.2(d) (2007).

13. Publication of the OIG Special Advisory Bulletin: The Effect of Exclusion from Participation in Federal Health Care Programs, 64 Fed. Reg. 52791, 52793 (Sept. 30, 1999) [hereinafter OIG Bulletin].

14. *See* OFFICE OF INSPECTOR GEN., GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT (Oct. 20, 2010), *available at* https://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf [hereinafter OIG GUIDANCE]. Also in October 2010, FDA Deputy Chief-in-Charge of Litigation Eric Blumberg proclaimed that settlements with indicted pharmaceutical companies were insufficient deterrence for off-label drug promotion and encouraged federal prosecutors to "criminally charge individuals at all levels of the company." Anna Edney, *Drugmaker CEOs May Be Targets for U.S. FDA in Off-Label Cases, Lawyer Says*, BLOOMBERG, Oct. 14, 2010, *available at* http://www.bloomberg.com/news/2010-10-14/drugmaker-executives-may-become-targets-of-fda-for-off-label-promotions.html (last visited Mar. 11, 2013).

penalties and fines were being considered an acceptable "cost of doing business" for these executives.[15]

The FDA and OIG have both outlined utilitarian ideals to their new initiatives: the FDA regards the RCO Doctrine as a "valuable enforcement tool,"[16] and OIG has targeted individuals who consider monetary sanctions a mere "cost of doing business."[17] Since the motive behind these initiatives is to "protect the [federal] programs"[18] and not to further punish violators of the law—i.e., the motive is apparently utilitarian and not retributive—these relatively new tools of criminal enforcement and their collateral effects on corporate liability in health care warrant examination using principles of law and economics and optimal deterrence theory.[19]

Under optimal deterrence theory, it is well established that an ideal enforcement regime enforces liability at both the individual and corporate levels.[20] In short, the efficacy of individual liability is limited by finite personal wealth and the expense of externally monitoring individuals within firms, and the efficacy of corporate liability is constrained both by corporations' limited ability to impose heavy internal sanctions on employees and by individuals' ability to maintain thinly capitalized entities and to protect their individual assets by "hiding" behind the corporate veil.[21] Of course, the benefits of individual liability include the fact that it targets the most culpable actor(s) without burdening shareholders for their crimes, and the benefits of corporate liability include motivating corporations to increase the probability of fraud detection through internal monitoring and compliance programs.[22]

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15. *Improving Efforts to Combat Health Care Fraud: Hearing Before the Subcomm. on Oversight of the H. Comm. on Ways and Means*, 112th Cong. 5-6 (2011) (statement of Lewis Morris, Chief Counsel to the Inspector General, U.S. Dep't of Health & Human Services), *available at* https://oig.hhs.gov/testimony/docs/2011/morris_testimony_03022011.pdf.

16. *See supra* text accompanying note 33.

17. *See supra* text accompanying notes 58-60.

18. *See supra* test accompanying notes 58-60.

19. For a discussion of optimal deterrence principles, see, for example, A. Mitchell Polinsky & Steven Shavell, *Punitive Damages: An Economic Analysis*, 111 HARV. L. REV. 869 (1998) and Richard A. Posner, *An Economic Theory of the Criminal Law*, 85 COLUM. L. REV. 1193 (1985).

20. *See* discussion *infra* Parts II.A, II.B.

21. *See* discussion *infra* Parts II.A, II.B.

22. *See* discussion *infra* Parts II.A, II.B.

In the health care context, OIG exclusions simply provide additional deterrence to both corporate and individual actors beyond monetary sanctions and imprisonment,[23] but the effects of the RCO Doctrine are more complex. To illustrate, if we assume that the corporate officer being targeted by prosecutors actually committed some *actus reus*, then the RCO Doctrine merely eases the prosecutor's burden of proving *actus reus*. However, if we assume that the corporate officer is entirely uninvolved in and unaware of the fraudulent activity, then the effect of the RCO Doctrine is to turn corporate officers into "mini-entities" by using strict respondeat superior liability—similar to strict corporate liability—to encourage them to create or augment internal monitoring and compliance regimes vis-à-vis their employees. While such a system may have its merits from a utilitarian perspective, its application to individuals, especially when combined with individual OIG exclusions, can lead to harsh results that are simply not parallel to a corporate application.

Furthermore, these effects play out differently in closely held and publicly held firms due to the differences in agency costs between the two corporate subtypes. Closely held companies—wherein shareholders either act simultaneously as managers or have significant control over them—do not share the storied separation of ownership and control that is found in publicly held firms;[24] therefore, the incentives against criminal and civil liability for statutory violations are more parallel for shareholders and managers in that context. In publicly held firms—wherein ownership is divided among a large group of non-dominant shareholders—directors (elected by the shareholders) and managers (employed by the directors) have control over the business operations of the company with relatively minimal input from the shareholders. This separation creates the infamous agency cost problem that has been a subject of scholarly debates for decades.[25] Given these differences

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23. It should be noted, however, that the trend has been to exclude individuals and not to exclude entities as part of a Corporate Integrity Agreement ("CIA"). See, for example, the discussion of KV Pharmaceutical in Part III.B, *infra*.

24. *See generally* ROBERT CHARLES CLARK, CORPORATE LAW 772-84 (1986) (describing private, closely held companies).

25. For the seminal piece on the separation of ownership and control, see generally Michael C. Jensen & William Meckling, *Theory of the Firm: Mana-*

and others, which will be discussed in Part II, rational actors within each type of firm will face different calculi, and the effects of the RCO Doctrine on each calculus will vary.

This Note asserts that the increasingly frequent and severe applications of the RCO Doctrine and of OIG's permissive exclusionary authority introduce significant and detrimental changes to traditional notions of corporate and individual liability that warrant changes to the current system. Combining OIG's potentially career-ending exclusions with the strict respondeat superior liability of the RCO Doctrine can result in extreme sanctions against individuals with little or no involvement in the crimes with which they are charged. As such, the combination of these two measures should be applied with utmost caution, and, in its current form, the RCO Doctrine should be utilized only as a way of lightening the prosecutorial burden of proof against officers whose *actus reus* is likely based on the facts. For officers who are not as obviously culpable, the RCO Doctrine should not be applied. However, if it is applied, there should be a judicially created defense akin to that of the *Caremark* standard whereby corporate officers are protected from an RCO Doctrine conviction if they have acceptable compliance and monitoring programs in place. Because the utility of the RCO Doctrine in this scenario is, as in strict corporate liability, to encourage internal monitoring and compliance programs, such a defense would be triggered only when the corporate officer met the desired end prior to conviction. Furthermore, when a corporate officer's participation in the fraud is either weakly supported by evidence or is otherwise unlikely, OIG should consider the presence of these internal monitoring and compliance measures when deciding whether or not to exclude individuals from FHCPs. These measures would transform what is now a rather blunt enforcement tool into a sharper, more just device.

This Note is separated into four parts and proceeds as follows. Part I will discuss the events leading up to the current state of the law, including the origins of the RCO Doctrine, the recent measures on behalf of the FDA to encourage its use in prosecution, and OIG's intent to increasingly apply their exclusionary authority against individuals. Part II will examine

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gerial Behavior, Agency Costs and Ownership Structure, 3 J. FIN. ECON. 305 (1976).

the traditional picture of corporate liability in closely held and publicly held firms and how the RCO Doctrine and OIG's exclusionary authority operate within those regimes. Part III will discuss recent applications of these enforcement tools, and Part IV will provide suggested reforms to the current system.

II.
Part I: A Background on the RCO Doctrine and Federal Agencies' Exclusionary Authority

In response to the growth in health care fraud, Congress and federal enforcement authorities have increased anti-fraud measures in recent years through a variety of means. For example, in FY2012 the Department of Justice (the "DOJ") opened 1,131 new criminal health care fraud investigations, had 2,032 such investigations pending, and filed criminal charges in 452 cases.[26] During the same period, the DOJ was also active in civil cases, opening 885 new civil health care fraud investigations with 1,023 civil investigations pending.[27] In FY2012, the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS") excluded 3,131 individuals and entities from federal health care programs "based on criminal convictions for crimes related to Medicare and Medicaid (912) or to other health care programs (287); for patient abuse or neglect (212); and as a result of licensure revocations (1,463)."[28] Additionally, OIG levied civil monetary penalties against individuals and entities and conducted many audits and evaluations to help programs with oversight and efficiency.[29]

Among the means used to boost enforcement are the increased uses of both the RCO Doctrine and of OIG's permissive exclusion authority. Before entering into a discussion of corporate and individual liability regimes and a normative discussion of the costs and benefits of these measures, this Note will first examine their respective histories and recent developments.

26. The Dep't of Health and Human Services & The Dep't of Justice, Health Care Fraud and Abuse Control Program Ann. Rep. for Fiscal Year 2012, 1-2 (2013), [hereinafter Health Care Fraud Report].

27. *Id.*

28. *Id.* at 2.

29. *Id.*

A. *Origins in* Dotterweich *and* Park

1. United States v. Dotterweich

The RCO Doctrine was first recognized in the 1943 Supreme Court case *United States v. Dotterweich* in which the Buffalo Pharmacal Company and its president and general manager, Joseph Dotterweich, appealed convictions for shipping "adulterated or misbranded" drugs under the Food, Drug and Cosmetic Act of 1938 ("FDCA").[30] The FDCA's purpose is to protect the public welfare from dangerous food, drugs, and cosmetics by giving oversight authority to the FDA.[31] At issue in this particular case is 42 U.S.C. § 331(a), which is a strict liability misdemeanor prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded" by any "person."[32] In short, Buffalo Pharmacal purchased drugs from other manufacturers, repackaged them, and distributed them under the company's own label;[33] however, in two instances the drugs were mismarked during repackaging, and the mistake was not discovered before the drugs entered interstate commerce.[34] Although the company was eventually acquitted,[35] a jury found Dotterweich guilty of two counts of shipping misbranded drugs and one count of shipping adulterated drugs despite a lack of evidence that he was aware of the misconduct.[36] In fact, "Dotterweich had no personal connection with either shipment, but he was in general charge of the corporation's business and had given gen-

30. 320 U.S. 277 (1943).

31. *Id.* at 280.

32. *Id.* at 278.

33. *Id.*

34. United States v. Buffalo Pharmacal Co., 131 F.2d 500, 501-02 (2d Cir. 1942) *rev'd sub nom.* United States v. Dotterweich, 320 U.S. 277 (1943).

35. *Id.* at 501 ("For some unexplainable reason [the jury] disagreed as to the corporation's guilt.").

36. Brief of Respondent at 5, United States v. Dotterweich, 320 U.S. 277 (1943) (No. 5) 1943 WL 54822 at *5 ("There is no proof in this case that he personally gave any instructions with reference to either of the shipments set forth in the informations [sic], except that he admitted, as did the head of the shipping department, that general instructions had been given to the shipping clerk . . . and that the shipping clerk used his own previous experience as well as his common sense in the conducting of that department of the corporation.").

eral instructions to its employees to fill orders received from physicians."[37]

On appeal, the Second Circuit noted that "only the corporation was the 'person' subject to prosecution unless, perchance, Buffalo Pharmacal was a counterfeit corporation serving as a screen for Dotterweich."[38] Finding insufficient evidence to convict Dotterweich under this "alter ego" theory of liability, the Second Circuit reversed the lower court's ruling.[39]

The Supreme Court, however, did not employ the Second Circuit's alter ego theory of liability, and their novel reasoning served as the foundation for what we now call the RCO Doctrine. Reversing the prior ruling, the Court stated that a public welfare statute "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing . . . [and] puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[40] This interpretation was based on the Court's idea that, although "person" in the statute refers to the corporation, corporations act solely through the actions of individuals.[41] As a result, in situations where the public welfare is at stake, the Court found it appropriate to hold employees with a "responsible relation" to the crime liable for corporate actions.[42] In this case, Dotterweich was considered to be in responsible relation by virtue of his general oversight over the actions of the company, even though he was not involved in the physical misbranding, adulterating, or shipping of the drugs.[43] The Court refused to define the category of employees that stand in responsible relation, opting instead for case-by-case review by prosecutors, judges, and juries.[44]

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

38. *Dotterweich*, 320 U.S. at 279.

39. *Id.* at 282-83.

40. *Id.* at 281.

41. *Id.* ("[F]rom the point of view of action the individuals are the corporation.").

42. *Id.* at 280-81.

43. *See id.* at 280-86.

44. *Id.* at 285 ("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. In such matters the good sense of prosecutors,

2. United States v. Park

Decades later, the Court sought to clarify the "standard of liability of corporate officers under the FDCA as construed in *Dotterweich*" by granting certiorari in *United States v. Park*.[45] The defendant in this case was John Park, the chief executive officer of Acme Markets, a large retail food chain with around 36,000 employees, 874 retail locations, and 16 warehouses.[46] John Park was found guilty under the FDCA of shipping food that had been exposed to rodents in storage warehouses, i.e., "adulterated food."[47] Because of his position as chief executive officer, and because he was generally aware of Acme's previous sanitation violations, he was found individually liable despite testimony that he had delegated oversight of sanitation to others.[48]

Park appealed the ruling to the Supreme Court, which found that the jury instructions were correct in requiring only a judgment that the "defendant had a responsible relation to the situation."[49] Importantly, the Court clarified that a corporate officer's title in the corporation would not be sufficient;[50] instead, the defendant must have had "authority and responsibility" to promptly and effectively address the rodent problem in order to convict him of these crimes under the RCO Doc-

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the wise guidance of trial judges, and the ultimate judgment of juries must be trusted.").

45. 421 U.S. 658 (1975).

46. *Id.* at 660.

47. *See id.*

48. *See id.* at 678. However, after finding out about the rodent violations, Park "was on notice that he could not rely on his system of delegation to subordinates to prevent or correct insanitary conditions at Acme's warehouses, and [ ] he must have been aware of the deficiencies of this system before the Baltimore violations were discovered." *Id.*

49. *Id.* at 674 (internal quotations omitted).

50. Later, in *United States v. Ming Hong*, the Fourth Circuit held that one's title as a corporate officer was not only insufficient, but also *unnecessary*. 242 F.3d 528, 528 (4th Cir. 2001) ("[T]o convict defendant as a responsible corporate officer, the Government was not required to prove that defendant was a formally designated corporate officer.") (internal quotations omitted). The Court, focusing on Hong's role and level of involvement in the company, found that the "gravamen of liability as a responsible corporate officer [depends on] whether the defendant bore such a relationship to the corporation that it is appropriate to hold him criminally liable for failing to prevent the charged violations of the CWA." *Id.* at 531.

trine.[51] In addition, the Court discussed in dicta a potential "impossibility defense" to charges under the RCO Doctrine, but Park did not offer evidence at trial that could prove the impossibility of corrective action.[52]

B. *The FDA's Intent to Encourage Use of the RCO Doctrine*

In the decades after *Dotterweich* and *Park*, the RCO Doctrine developed primarily in the enforcement of environmental statutes.[53] Until recently, it was rarely utilized in the health care context. However, after a couple of isolated uses that resulted in successful prosecutions, and in response to a very critical report from the Government Accountability Office ("GAO") highlighting weaknesses in FDA enforcement,[54] FDA Commissioner Margaret Hamburg wrote the aforementioned letter outlining an intention to promote misdemeanor prosecutions.[55] Shortly thereafter, the FDA updated its Regulatory Procedures Manual to provide specific guidance for prosecutions under *Park*.[56] In its guidance, the FDA enumerated a list of factors that its Office of Criminal Investigation ("OCI") will consider when deciding whether to refer a misdemeanor to the DOJ for prosecution under the RCO Doctrine.[57] Such fac-

51. *Park*, 421 U.S. at 674 (internal quotation marks omitted).

52. *Id.* at 673 ("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."). The term "impossibility defense" was not specifically used in the opinion, but it has subsequently become the generally accepted term for the defense.

53. For a discussion of the application of the RCO Doctrine in the environmental context before 2002, see Noël Wise, *Personal Liability Promotes Responsible Conduct: Extending the Responsible Corporate Officer Doctrine to Federal Civil Environmental Enforcement Cases*, 21 STAN. ENVTL. L.J. 283 (2002).

54. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-221, FOOD AND DRUG ADMINISTRATION: IMPROVED MONITORING AND DEVELOPMENT OF PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF CRIMINAL AND MISCONDUCT INVESTIGATIONS 10 (2010), *available at* http://www.gao.gov/new.items/d10221.pdf.

55. Letter from Margaret Hamburg, *supra* note 8.

56. *See* FDA MANUAL, *supra* note 9.

57. *Id.* The FDA estimates that OCI prosecution referrals result in around 200 convictions per year, leading to billions of dollars in fines and restitution since OCI's founding in 1992. *FDA Law Enforcers Protect Consumers' Health Inside the Office of Criminal Investigations*, FDA (Aug. 19, 2008, 8:18 PM), http://www.gmptrainingsystems.com/files/u2/pdf/FDA_OCI.pdf.

tors include "the individual's position in the company and relations to the violation, and whether the official had the authority to correct or prevent the violation." Additionally, "[k]nowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution," but they are considered "relevant" when deciding whether to forward a recommendation to the DOJ.[58]

C. *Exercise of the OIG's Permissive Exclusionary Authority*

1. *A Brief Background on OIG's Exclusionary Authority*

Since 1977, OIG has had the power to exclude violators of various healthcare provisions from FHCPs.[59] The pool of possible exclusion targets has expanded over time, from applying only to a "physician or other practitioner" convicted of a criminal offense involving FHCPs, to including any "individual or entit[y]" regardless of whether or not they have been convicted of such a crime (but with other limitations).[60] In 1999, as part of an effort "to eliminate fraud, waste, and abuse in [HHS] programs and to promote efficiency and economy in [HHS] operations,"[61] OIG received expanded authority to exclude individuals and entities from Medicare, Medicaid, and other FHCPs if they are found to be in violation of the Social Securities Act.[62] This statute and the accompanying regulations establish the terms for both mandatory and permissible exclusions and provide procedures for appeals and possible re-

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58. FDA MANUAL, *supra* note 9. Other factors mentioned in the manual include but are not limited to "(1) [w]hether the violation involves actual or potential harm to the public; (2) [w]hether the violation is obvious; (3) [w]hether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings; (4) [w]hether the violation is widespread; (5) [w]hether the violation is serious; (6) The quality of the legal and factual support for the proposed prosecution; and (7) [w]hether the proposed prosecution is a prudent use of agency resources." *Id.*

59. KIRKLAND ALERT: RECENT THREATENED EXCLUSION OF PHARMACEUTICAL COMPANY CEO REVEALS THE DANGERS OF INCREASINGLY AGGRESSIVE ENFORCEMENT UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT, Kirkland Ellis LLP (May 2011), http://www.kirkland.com/siteFiles/Publications/Alert_052711.pdf.

60. *Id.*

61. Publication of the OIG Special Advisory Bulletin: The Effect of Exclusion from Participation in Federal Health Care Programs, 64 Fed. Reg. 52,791, 52,792 (Sept. 30, 1999) [hereinafter OIG Bulletin].

62. 42 U.S.C. § 1320a-7.

instatement of excluded individuals and entities.[63] In addition to prohibiting payment from FHCPs to excluded individuals and entities, OIG also withholds payments to parties who employ or contract with excluded individuals.[64]

The number of excludable acts has also grown considerably over time. There are now four situations in which OIG is *forced* to exclude individuals and/or entities (a.k.a. mandatory exclusions): (1) program-related crimes, (2) offenses relating to patient abuse, (3) felonies related to healthcare fraud, and (4) felonies related to controlled substances.[65] In addition, OIG is now *empowered* to exclude individuals and entities (a.k.a. permissive exclusions) in sixteen situations, but the first (convictions related to fraud)[66] and the third (misdemeanor convictions related to a controlled substance)[67] are the ones most commonly used alongside the RCO Doctrine and will be the focus of this Note.[68]

2. *New Developments Regarding OIG Exercise of Exclusionary Authority*

As mentioned in the Introduction, OIG released an update to their exclusionary authority guidance in October 2010.[69] According to the statute authorizing OIG regulations and guidance, an individual who has an ownership interest in a sanctioned entity can be excluded if the individual "knows

63. *See id.*; 42 C.F.R. § 1003, 1005.
64. OIG Bulletin, *supra* note 61, at 52793.
65. 42 U.S.C. § 1320a-7(a)(1)-(4).
66. 42 U.S.C. § 1320a-7(b)(1).
67. 42 U.S.C. § 1320a-7(b)(3).
68. The sixteen situations are as follows: (1) convictions related to fraud, (2) convictions related to obstruction of an investigation or audit, (3) misdemeanor convictions related to controlled substance, (4) license revocations or suspensions, (5) exclusions or suspensions under federal or state health care programs, (6) claims for excessive charges or unnecessary services and failure of certain organizations to furnish medically necessary services, (7) fraud, kickbacks, and other prohibited activities, (8) entities controlled by a sanctioned individual, (9) failures to disclose required information, (10) failures to supply requested information on subcontractors and suppliers, (11) failures to supply payment information, (12) failures to grant immediate access, (13) failures to take corrective action, (14) defaults on health education loan or scholarship obligations, (15) individuals controlling a sanctioned entity, and (16) making false statements or misrepresentation of material facts. 42 U.S.C. § 1320a-7(b)(1)-(16).
69. *See* OIG GUIDANCE, *supra* note 14.

or should know'' of the action constituting the basis for the conviction or exclusion,[70] while officers or managing employees[71] of a company may be excluded solely because of their position within the sanctioned entity without considering scienter.[72] Because the statute sets the bar higher for owners than for officers and managing employees, OIG guidance prescribes a "presumption in favor of exclusion" for owners that may be overcome "if significant factors weigh against exclusion."[73] For officers and managing employees there is no presumption in favor of exclusion unless there is evidence that they knew or should have known of the misconduct, in which case the same presumption and mitigating factors may apply.[74] However, in the absence of such evidence, OIG outlines several factors to be considered in deciding whether or not to exclude. These factors include: (1) circumstances of the misconduct and seriousness of the offense; (2) the individual's role in the sanctioned entity; (3) the individual's actions in response to the misconduct; and (4) information about the entity, such as its size and structure.[75] Regarding the second factor, OIG will consider the individual's current and former positions, what level of managerial control is associated with that position, and what relation that position has to the underlying misconduct.[76] With regard to the third factor, OIG will

70. 42 U.S.C. § 1320a-7(b)(15)(A)(i).

71. A 'managing employee' is defined as "an individual, including a general manager, business manager, administrator, and director who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity." 42 U.S.C.A. § 1320a-5(b).

72. 42 U.S.C. § 1320a-7(b)(15)(A)(i)-(ii).

73. OIG GUIDANCE, *supra* note 14, at 1.

74. *Id.*

75. *Id.* at 2-4. Demske recently revealed plans for issuing updated guidance on exclusions sometime in early 2013 that will "include best practices for organizations and will also explain how the OIG resolves cases where an entity works with an excluded person." Fulbright & Jaworski LLP, Washington Health Care Update: OIG to Release Updated Guidance on Exclusion Authority, Oct. 9, 2012, http://www.fulbright.com/index.cfm?fuseaction=publications.detail&pub_id=5770&site_id=494. It is unclear whether this forthcoming guidance will be focused on excluding entities or will include updates on individual exclusions as well.

76. OIG GUIDANCE, *supra* note 45, at 3-4.

focus on the timeline of events and whether it would have been possible for the individual to prevent the misconduct.[77]

Interestingly, these statutory provisions are in the present tense, which, according to current OIG Chief Counsel Gregory Demske, limits OIG authority to those individuals who are (at the time of the proceedings) *current* owners, officers, or managing employees.[78] To reach individuals who are *former* owners, officers, or managing employees, OIG relies on 42 U.S.C. § 1320a–7(b)(1), which makes permissible exclusionary power available against "[a]ny individual or entity that has been convicted . . . of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct."[79] The key phrase is "relating to fraud"—it is within this phrase that the D.C. Circuit recently found authority for excluding former corporate executives who had pleaded guilty to a misbranding misdemeanor from federal healthcare programs.[80] Although the legal definition of the misbranding misdemeanor did not indicate that it was "related to" fraud in that it did not comprise all of the core elements of fraud, such as scienter, the D.C. Circuit found it sufficient that "the conduct underlying that convic-

77. *Id.* at 4. This is similar to the impossibility defense found in *Park*, 421 U.S. 658. *See supra* notes 45-52.

78. 42 U.S.C. § 1320a-7(b)(15)(A)(i)-(ii); Ed Silverman, *The OIG and Excluding Execs: Demske Explains*, PHARMALOT, June 6, 2011, *available at* http://www.pharmalot.com/2011/06/the-oig-and-excluding-execs-demske-explains/ ("The way our statute is written, we can only pursue a person who is in office of a convicted entity . . . we can't reach the former CEO . . . .") (last visited Mar. 11, 2013).

79. 42 U.S.C. § 1320a–7(b)(1)(A). In addition, Reps. Pete Stark and Wally Herger reintroduced a bipartisan bill in 2011 that would change the language of 42 U.S.C. § 1320a-7(b)(15) to include owners "with an interest *at the time of any of the conduct* that formed a basis for the conviction or exclusion," thus solving the "current" versus "former" distinction. H.R. Res. 675, 112th Congress, Strengthening Medicare Anti-Fraud Measures Act of 2011 (2011), *available at* http://beta.congress.gov/bill/112th-congress/house-bill/675/text. The Stark-Herger bill also proposes to add "any affiliated entity of a sanctioned entity" to § 1320a-7(b)(15), which would further expand liability to include company subsidiaries and other affiliation structures. *Id.* While these amendments would significantly expand the scope of potential defendants, the bill has lost momentum after being referred to subcommittee and may not regain it now that Pete Stark is no longer in office.

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

tion [was] *factually* related to fraud."[81] In other words, there was "a 'nexus' or 'common sense connection' between their convictions and those statutory bases for exclusion."[82] This method of holding individuals personally liable for corporate misconduct has been utilized with increasing frequency in recent years and will likely persist after being upheld by the D.C. Circuit.

As previously mentioned, former OIG Chief Counsel Lewis Morris vowed to use permissive exclusions to deter corporate executives by increasing what is at stake if discovered and convicted. .[83] Shortly after being appointed the new OIG Chief Counsel, Gregory Demske spoke with similar sentiment in a June 2011 interview when he stated that fines were insufficient deterrence and that "[t]he next logical step would be to exclude someone based on the fact they had been in a position of responsibility at a corporation when a crime occurred."[84] Interestingly, in a recent interview, Demske denied viewing exclusions as punitive measures, instead noting that "[t]he exclusion is a remedy to protect the [federal] programs going forward . . . . The punishment takes place with criminal and civil enforcement."[85]

Regardless of his position on the purpose of exclusions, the practical effects are indeed punitive and can be career-ending events for health care executives.[86] Since health care is such a specialized field, and since the footprint of FHCPs is so large, exclusion often precludes health care executives from any other equivalent job for which they are well suited based on their background and experience. In addition, any company that interacts with FHCPs is subject to civil monetary penalties if they "arrange[ ] or contract[ ] with" an excluded indi-

81. *Id.* at 824 (emphasis added).

82. *Id.* at 818.

83. *Improving Efforts to Combat Health Care Fraud: Hearing Before the Subcomm. on Oversight of the H. Comm. on Ways & Means*, 112th Cong. 5-6 (2011) (statement of Lewis Morris, Chief Counsel to the Inspector General, U.S. Dep't of Health & Human Services), *available at* https://oig.hhs.gov/testimony/docs/2011/morris_testimony_03022011.pdf.

84. PHARMALOT, *supra* note 78.

85. Transcript, *OIG Outlook 2013: Chief Counsel to the IG, Gregory E. Demske* (Oct. 24, 2012) (transcript available at https://oig.hhs.gov/newsroom/podcasts/2012/outlook/demske-trans.asp).

86. *Friedman*, 686 F.3d at 823.

vidual "for the provision of items or services for which payment may be made under such a program."[87] As a result, exclusions can be the most severe aspect of their punishment.[88]

III.
PART II: CORPORATE AND INDIVIDUAL LIABILITY THEORY

Assuming that the primary objective of the FDA and OIG in utilizing these new initiatives is in line with the goal of liability regimes in general—"enhancing social welfare by minimizing the net social costs of wrongdoing and its prevention"[89]—we must look at whether these specific applications of individual and corporate liability provide optimal deterrence. If all actors are rational,[90] the imposition of individual criminal liability is ideal where (1) individuals are willing and able to bear the full cost of their misconduct,[91] (2) where these individuals cannot be monitored and prosecuted by the government at a

87. 42 U.S.C. § 1320a-7a(a)(6). According to an OIG Special Advisory Bulletin from September 1999, "a provider or entity that receives Federal health care funding may only employ an excluded individual in limited situations. Those situations would include instances where the provider is both able to pay the individual exclusively with private funds or from other non-federal funding sources, and where the services furnished by the excluded individual relate solely to non-federal program patients." OFFICE OF THE INSPECTOR GEN. FOR THE DEP'T OF HEALTH & HUMAN SERVS., THE EFFECT OF EXCLUSION FROM PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS (Sept. 1999), *available at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm. In order to avoid running afoul of these provisions, employers are instructed to "check the OIG List of Excluded Individuals/Entities on the OIG web site (www.hhs.gov/oig) prior to hiring or contracting with individuals or entities." *Id.*

88. This is especially so if monetary sanctions are covered under the new and specially formulated insurance plans for responsible corporate officers. For an example of this type of coverage, visit https://usa.marsh.com/ProductsServices/MarshSolutions/ID/19546/RCO-Corporate-Response.aspx.

89. Jennifer Arlen & Reinier Kraakman, *Controlling Corporate Misconduct: An Analysis of Corporate Liability Regimes,* 72 N.Y.U. L. REV. 687, 691 (1997).

90. Clearly, the world is not full of rational actors. *See id.* at 696 ("[C]orporate agents may sometimes be neither savvy nor rational, and may therefore be unresponsive to individual liability alone.").

91. *See id.* at 695 ("[I]ndividual liability alone often cannot adequately deter corporate wrongdoing. A principal reason is that culpable agents frequently lack the assets to pay expected sanctions equal to the social costs of corporate wrongdoing[.]").

cost that does not exceed the benefit to social welfare,[92] and (3) where the firm's ability to internally sanction these individuals is sufficient to pay the social cost.[93] However, since the monetary consequences of misconduct often exceed an individual's wealth,[94] since externally monitoring and prosecuting these individuals can be very costly and inefficient,[95] and since a firm's ability to sanction employees is typically limited to withholding salary,[96] it is sometimes necessary to introduce entity liability. Thus, corporate liability is ideal (1) where individuals are not reliable payers of the full social cost of their misconduct, either because they are unwilling and "judgment-proof" or because they are insufficiently wealthy, (2) where external monitoring and prosecution of these individuals is prohibitively expensive, and (3) where internal sanctions are insufficient.

As briefly discussed in the introductory paragraphs, these means of enforcement affect closely held firms and publicly held firms in different ways due to the differences in agency costs and complexity between the two categories of companies. Furthermore, the distinction between closely held and publicly held firms goes further than the mere allocation of ownership and control. First, shareholders of closely held firms are more exposed to the firm's liability because there is not an efficient, public market on which to sell their shares. Second, some commentators have argued that shareholders of publicly held firms are "morally insulated" from the acts of the corporations in which they invest and are thus not exposed to the non-monetary repercussions of corporate sanctions such as shame and guilt.[97] Finally, closely held companies are typically smaller

92. *See id.*

93. A. Mitchell Polinsky & Steven Shavell, *Should Employees Be Subject to Fines and Imprisonment Given the Existence of Corporate Liability?*, 13 INT'L REV. L. & ECON. 239 (1993).

94. Arlen & Kraakman, *supra* note 89, at 695.

95. *Id.* at 696.

96. *See* Polinsky & Shavell, *supra* note 93, at 240.

97. *See, e.g.*, Einer Elhauge, *Sacrificing Corporate Profits in the Public Interest*, 80 N.Y.U. L. REV. 733, 760 (2005) ("[W]here managers have a substantial ownership stake, they are both more likely to experience social and moral sanctions (because responsibility is less diffused) and better able to resist pressure from shareholders who are insulated from social and moral sanctions. But where managers do not have large ownership stakes, they are

and easier to monitor than their publicly traded counterparts.[98]

The following subsections will examine corporate and individual liability theories in the context of closely held and publicly held firms and will subsequently discuss the effects of the RCO Doctrine and OIG exclusions on these established liability regimes.

A. *Pure Entity Liability Regimes*

In this Note, corporate and individual liability—including the RCO Doctrine and OIG exclusions—will be examined in two contexts: within closely held firms and within publicly held firms. This distinction is important because of key differences in incentives between actors in the two structures. Because owners are also managers in closely held companies, and because the fraudulent actor is thus either also a major shareholder (i.e., a shareholder-manager) or is very closely related to one (i.e., one of few employees), closely held firms have far fewer agency costs, have simpler structures, and are thus less expensive to monitor.[99] In contrast, publicly held firms separate ownership and control and tend to have more complicated hierarchies among managers and employees, i.e., they have higher agency costs and can be very expensive to externally monitor. These differences and others will shape the ensuing discussion of pure entity liability regimes in each type of firm.

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more likely to respond to the pressure of socially and morally insulated shareholders.").

98. *See, e.g.*, J.A.C. Hetherington & Michael P. Dooley, *Illiquidity and Exploitation: A Proposed Statutory Solution to the Remaining Close Corporation Problem*, 63 VA. L. REV. 1 (1977); Margaret Blair & Lynn Stout, *A Team Production Theory of Corporate Law*, 85 VA. L. REV. 247 (1999), *reprinted in* 24 J. Corp. L. 751 (1999). *But see* Frank H. Easterbrook & Daniel R. Fischel, *Close Corporations and Agency Costs*, 38 STAN. L. REV. 271 (1986). Additionally, for those closely held firms that are partnerships rather than corporations or limited liability corporations ("LLCs"), they differ from publicly held firms in that they possess corporate "personhood" such that they can sue, own property, and contract as an entity. *See, e.g.*, ALAN R. BROMBERG & LARRY E. RIBSTEIN, BROMBERG AND RIBSTEIN ON PARTNERSHIP § 1.03 (1988 & Supp. 2006). For the purposes of this article, that distinction will be eliminated by assuming that closely held "firms" are, in fact, corporations.

99. *See generally* ROBERT CHARLES CLARK, CORPORATE LAW 772-84 (1986) (describing private, closely held companies).

1. *Closely Held Firms*

In addition to the difference in external monitoring costs between closely held and publicly held firms, the above-listed differences alter the calculus of optimal deterrence in two ways. First, imposing strict corporate liability against closely held firms is efficient because the companies' actions can serve as accurate proxies for the actions of shareholder-managers given the close relationship between the individual and the entity in these firms.[100] In other words, targeting the company will often appropriately affect the shareholder in accordance with her guilt. Second, and contrary to the first, one important goal of strict corporate liability—to encourage corporations to minimize agency costs and increase the probability of detection through internal monitoring and compliance programs[101]—is not as beneficial for closely held firms because the relative lack of agency costs minimizes the benefits of such programs. Although internal monitoring is less helpful in this context, external oversight of and enforcement against the company is sufficiently inexpensive and effective that strict corporate liability was for many years applied primarily to closely held firms.[102]

The relative lack of agency costs in closely held firms makes entity liability seem somewhat equivocal: if the shareholders are also managers of the company, then they will guard against liability whether that liability is directed at them as individuals or as an entity. However, that conclusion makes two faulty assumptions. The first is the assumption that individuals are as easy to prosecute as the company that employs them. Indeed, one benefit of entity liability as applied to closely held firms is against otherwise judgment-proof employees.[103] This is partially a result of the inherent difficulty in proving individual wrongdoing compared with the ease of

100. PROSECUTORS IN THE BOARD ROOM: USING CRIMINAL LAW TO REGULATE CORPORATE CONDUCT 69-70 (Anthony Barkow & Rachel Barkow eds., New York University Press 2011) [hereinafter PROSECUTORS].

101. This is because firms, out of a desire to reduce their entity liability, will implement policies and programs that lead employees to reduce the risk of causing harm.

102. Mark Cohen, *Corporate Crime and Punishment: An Update on Sentencing Practices in the Federal Courts,* 71 B.U. L. REV. 247, 251-52 (1991) (noting that over 95% of firms convicted between 1984 and 1988 were closely held).

103. Arlen & Kraakman, *supra* note 89, at 692.

holding an entity strictly liable for the actions of its officers and employees, even in a closely held firm where the individual and the entity are closely related.[104]

The second faulty assumption is that both the individuals and the entity have unlimited capital with which to pay monetary sanctions. This assumption runs contrary to the rational actor theory of economic analysis, under which individuals will take advantage of an entity liability regime by keeping their companies thinly capitalized. This corporate "judgment-proofing" ensures that, if monetary sanctions are levied against the entity, the entity will have limited resources at risk,[105] and the individuals' personal assets will be protected by the corporate veil.[106] Such a mindset is especially dangerous in a situation (as is common in health care fraud) where misconduct is difficult to detect but results in a large social cost. Since this corporate judgment-proofing dramatically reduces the cost to the company of violating relevant laws, it has profound effects on the ex ante calculus. Furthermore, since the entity cannot pay the full social cost of their misconduct, society will pay the balance. There is far more risk of this kind of financial engineering in a closely held corporation than a publicly held corporation because shareholder-managers are both in control of the risky (but potentially lucrative) actions *and* in control of how thinly the entity is capitalized.

In addition to the reduction in compliance incentives that results from having a minimal amount of entity resources at

104. In addition, because prosecuting individuals under traditional theories of liability necessitates cooperation from the company for document discovery and witness testimony, and because closely held firms have more power to resist such requests given that there are fewer people to "convince" to be uncooperative, successful individual prosecution in this context may be more difficult. This is, however, a speculative assumption without any empirical backing of which I am aware.

105. *See, e.g.*, FRANK H. EASTERBROOK & DANIEL R. FISCHEL, THE ECONOMIC STRUCTURE OF CORPORATE LAW 61 (1991).

106. For a discussion on piercing the corporate veil, see, for example, Note, *Piercing the Corporate Law Veil: The Alter Ego Doctrine Under Federal Common Law,* 95 HARV. L. REV. 853 (1982). Professor Thompson conducted a survey in the 1990's that found fraud or misrepresentation to be nearly ubiquitous in veil piercing cases: courts allowed veil piercing in 94% of the misrepresentation cases but refused to pierce the veil in 92% of the cases where fraud or misrepresentation were absent. Robert B. Thompson, *Piercing the Corporate Veil: An Empirical Study,* 76 CORNELL L. REV. 1036, 1064-65 (1991).

risk, shareholder-managers will not be motivated to fully police misconduct for reasons of self-preservation.[107] In order to protect what little capital is at risk, they may have some incentive to prevent employee misconduct, but policing (i.e., reporting) existing misconduct will be discouraged under a pure entity liability regime. If the shareholder-managers are the source of misconduct, they will neither report nor impose internal sanctions on themselves out of self-interest; on the other hand, if non-shareholder employees are the wrongdoers, shareholder-managers may impose internal sanctions on those employees, but they will not report those employees to the government out of a fear of severe, unmitigated sanctions against the entity.[108]

2. *Publicly Held Firms*

Contrary to the characteristics of closely held firms, publicly held firms (1) separate ownership and control, introducing agency costs; (2) trade on public markets that are liquid and efficient; (3) are subject to increased oversight by virtue of their listing on public exchanges; (4) are owned by a dispersed mass of shareholders who, relative to their closely held counterparts, have a small percentage of their personal wealth at stake and are removed from the social and emotional consequences of corporate misconduct; and (5) are often large, complex organizations that are difficult to monitor.

In large, public firms, fraudulent actors are often not also significant shareholders, so the benefits of their fraudulent actions are more typically indirect via promotions and bonuses; as such, fraudulent actors have less at stake when publicly held firms are sanctioned, making entity liability a less-effective deterrent against fraud.[109] Since a manager's job is an "undiversifiable asset"—as opposed to the diversifiable nature of a shareholder's stake in a company—managers may not take high but attractive risks with corporate assets in order to minimize mistakes that could place their jobs at risk.[110] On the

107. PROSECUTORS, *supra* note 100, at 72.

108. *Id.*

109. Arlen & Kraakman, *supra* note 89, at 699 n.30.

110. Steven P. Croley, *Vicarious Liability in Tort: On the Sources and Limits of Employee Reasonableness*, 69 S. CAL. L. REV. 1705, 1715 (1996) (This "helps explain why corporations may be risk averse in practice even though share-

other hand, and more importantly for the purposes of this Note, managers may engage in highly risky fraudulent activity for private benefit without considering the shareholders' liability exposure.[111]

Furthermore, since compliance programs are carried out by employees and not by shareholders, there is another disconnect: employees bear the full cost of internal monitoring efforts but partake in only a small share of the benefits.[112] Therefore, pure entity liability for publicly held firms is inherently unfair and inefficient—employees and managers are not fully incentivized to monitor, which leads to misconduct, the consequences of which are born by shareholders. This manifestation of agency costs provides justification for individual liability in corporations, especially those that are publicly held; however, agency costs abound in publicly held firms, so entity liability must still be utilized as a motivation for the implementation of internal monitoring and compliance programs in order to close the gap.

Individual accountability can still exist within a pure entity liability regime if it comes from within the organization and not the state. Firms can eliminate the manager-employee agency cost problem if they structure internal monetary sanctions against wrongdoers that are sufficient to encourage optimal monitoring and compliance. Internal compliance programs that function in this way can be especially helpful for public firms because, unlike closely held firms, these larger firms can be very difficult to externally monitor without assistance from a formal internal program. However, companies are only able to sanction employees up to the level of their

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holders themselves are presumably risk-neutral."). In addition, there are mechanisms to reduce these costs: "Product markets, financial markets, shareholders themselves, professional norms, the managerial labor market, stock options, and legal duties all help to protect owners against runaway managers." *Id.*

111. *See id.*

112. *See, e.g., id.* at 1715-16; Arlen & Kraakman, *supra* note 89, at n.30. For a discussion on manager-employee agency costs, see Steven P. Croley, *supra* note 110, at 1715 ("Whereas managers have an interest in extracting as much labor value from employees, for example, employees have an interest in getting as much remuneration for as little labor as possible. For another example, many employees may have little at stake in a firm's long-term reputation, . . . whereas managers' interests often overlap with the reputational interests of the firm.").

salary, civil judgments against employees are difficult and rare, and dismissal may not have a high cost to rational actors if they have other job opportunities, so internal compliance programs alone are insufficient.[113]

Another shortcoming of internal monitoring and sanctions is that they do not prevent another problem with pure entity liability: policing.[114] If entities are held strictly liable for the misconduct of their employees, they are perhaps incentivized to monitor and enforce compliance, but they are discouraged from reporting that misconduct to the relevant authorities.[115] A rational entity will not place their financial welfare at risk by reporting the activity unless there are some benefits in doing so. Methods of encouraging policing will be discussed in subsection 3, *infra.*

Finally, as in closely held firms, publicly held firms at risk of corporate sanctions may have incentive to keep themselves thinly capitalized in order to minimize their losses if wrongdoing is discovered. However, publicly held firms are affected differently in three ways. First, employees likely do not have a sufficient stake in the entity for this type of equity protection to enter their ex ante decision-making in a significant way. Second, it is very likely in a publicly held health care company that the employees committing fraudulent acts are not the same individuals in charge of allocating the firm's finances, so maintaining a thinly capitalized firm specifically to make fraudulent schemes less risky is less of a possibility. Third, an efficient, informed public market provides oversight that may put additional pressure on these companies to keep themselves well-capitalized.

B. *Traditional Individual Liability*

1. *Closely Held Firms*

Adding individual criminal liability to an entity liability regime rectifies some of the issues described in the previous subsection.[116] Most importantly, it allows shareholder-managers

113. Polinsky & Shavell, *supra* note 93.

114. By policing, I am referring to reporting wrongdoing to the relevant authorities and assisting them with their ensuing investigation.

115. PROSECUTORS, *supra* note 100, at 72.

116. Traditional individual liability is applied to those who either direct or carry out a crime. *See, e.g.*, Kathleen F. Brickey, *Criminal Liability of Corporate*

who abuse the corporate form to be held individually liable for their misconduct in addition to whatever ownership stake they may have in the company. As a result, individual liability not only protects against the dangers of thinly capitalized firms, but it may also provide additional incentive for shareholder-managers to avoid personal misconduct. However, the possibility of individual liability upon discovery of wrongdoing may not be sufficient deterrence from lucrative fraudulent activity in thinly capitalized corporations when the probability of detection is low, even when one's entire personal wealth is at stake.[117]

2. *Publicly Held Firms*

As with closely held firms, combining individual and entity liability can address some of the shortcomings of pure entity liability regimes. For example, individual liability can reduce the agency cost problem by increasing the private cost of fraud; where internal individual sanctions are insufficient, state-imposed individual sanctions can provide the additional monetary risk necessary to deter rational actors from fraud.[118] Finally, despite the fact that a large share of the cost of monitoring (and a relatively small share of the benefits of compliance) is born by employees, they will be more likely to monitor if there is a chance of being found individually liable.

A significant shortcoming of individual liability is that it is often more difficult to prosecute an individual than an entity.

Officers for Strict Liability Offenses—Another View, 35 VAND. L. REV. 1337, 1338-42 (1982). Charges can be approached in three ways: (1) conspiracy, which is when an individual engages in a plan to commit a crime, (2) direct criminal activity, and (3) accomplice liability, which is assisting in the crimes of others. Sidney M. Wolf, *Finding an Environmental Felon Under the Corporate Veil: The Responsible Corporate Officer Doctrine and RCRA*, 9 J. LAND USE & ENVTL. L. 1, 10 (1993).

117. Interestingly, Professors Polinsky and Shavell note that, "[t]o the extent that employees face public sanctions, . . . a firm's liability should be reduced; if liability were not lowered, the price of the firm's product would exceed the social cost of production." Polinsky & Shavell, *supra* note 93, at 240.

118. Polinsky & Shavell, *supra* note 93, at 240 ("[I]n practice, the state can more easily collect criminal fines than firms can obtain civil judgments."). In addition, jail sentences are often given as an alternative to paying a criminal fine, which increases the motivation to pay; however, it is rare that jail sentences are imposed for nonpayment of a civil judgment. *Id.*

In the health care context, FDCA violations are strict liability violations;[119] however, the requisite *actus reus* still needs to be attributed to an individual in order to convict, and this can be difficult to prove in a large, publicly held corporation where responsibilities are often split between multiple individuals. Thus, it is reasonable for an individual to believe that her activity can be concealed or "lost" within a group of people responsible for the task in a large public company. There are two ways to solve this problem. First, employees can be deterred from fraudulent activity if the sanctions (both internal and external) levied against them are increased; this includes monetary fines and forfeitures, prison sentences, and OIG exclusions. Second, efforts to increase the probability of proving individual guilt, such as internal policing and the RCO Doctrine, can further deter individuals from misconduct.

Combining traditional individual liability with entity liability still does not protect against every possible bob and weave of the rational actor. Shareholder-managers will still refrain from self-inflicted sanctions and will still be hesitant to report the misconduct of non-shareholder employees to the government. The government's initiatives to remedy these problems—especially their methods of rewarding company efforts to prevent and police misconduct—are an attempt to alleviate the latter of these concerns and are the subject of the next subsection.

C. *Recent Changes in the Government's Approach to Corporate Liability*

In recent years, the government has undertaken initiatives to deter corporate crime through increases in both the severity and scope of their enforcement. In terms of severity, the criminal and monetary penalties against both individuals and corporations have increased dramatically in the last twenty-five years.[120] The DOJ has also increased the scope of its enforce-

119. *See* examples *infra* Part III.

120. *See* PROSECUTORS, *supra* note 100, at 69 (Prior to the mid-1980s, . . . sixty percent of federal corporate convictions resulted in the firm being fined $10,000; the average fine was only $45,790."). Five years after the Sentencing Guidelines were changed in 1991, "a publicly held firm convicted of a federal crime was subject to an average fine of $19 million in cases constrained by the Guidelines (in 1996 dollars)." *Id.* at 73.

ment efforts, not only by more frequently imposing individual liability for corporate misconduct,[121] but also by using threatened prosecution to coerce corporations into deferred prosecution agreements ("DPAs") and non-prosecution agreement ("NPAs" - the grouping of which is hereinafter "D/NPAs") that compel them to assist the DOJ in policing and preventing future misconduct.[122] Finally, The U.S Sentencing Commission has formulated provisions within the Sentencing Guidelines allowing for severity mitigation in exchange for compliance efforts.[123]

In general, these three developments have helped solve some of the enforcement problems described in the preceding subsections. First, managers are more likely to initiate compliance programs and are even more likely to self-report because of the "carrot" that these mitigation provisions provide. Second, managers are more likely to encourage compliance with relevant laws because of the bigger "stick" that increased individual liability represents. Finally, a threat of prosecution for suspected wrongdoing that leads to the adoption of a D/NPA can increase policing and prevention efforts if the company's fraudulent activity is discovered.[124]

1. *Closely Held Firms*

In the context of closely held firms, these particular DOJ initiatives provide little benefit. Mitigating provisions in the Sentencing Guidelines may not affect the calculus of the rational shareholder-manager—if the activity is sufficiently lucrative, they will simply not report their own wrongdoing. Furthermore, closely held firms, if narrowly defined as firms

121. *See, e.g., id.* at 74 ("[During the 1990's,] [p]rosecutors came to recognize that individual liability should be the cornerstone of the government's effort to deter crime and focused more attention on obtaining individual convictions.")

122. Similarly, OIG sometimes enters into corporate integrity agreements ("CIAs") with companies in exchange for agreeing not to exclude the entity. *See supra* note 23. These agreements often include monitoring requirements similar to those found in DPAs and NPAs. *Id.* Throughout this article, assume that CIAs are included in our discussions about DPAs and NPAs unless otherwise noted.

123. *See* U.S. SENTENCING GUIDELINES MANUAL ch. 8, §§ 8B1, 8D1.

124. However, there are inherent problems with the use of D/NPAs. For discussion, see PROSECUTORS, *supra* note 100.

where the actor is also a primary shareholder, do not benefit significantly from the internal compliance programs imposed in D/NPAs because the relative absence of agency costs and simple structure make monitoring easy without such formal programs. Finally, ex post adjustments like these may not alter the ex ante equation of a rational shareholder-manager; by the time these adjustments would take place, the public has already been harmed.[125] Therefore, DOJ-imposed internal monitoring regimes are not very effective in closely held firms due to the lack of agency costs, and, as a result, they are rarely applied to closely held firms.

2. *Publicly Held Firms*

Government efforts—including increased individual and corporate sanctions, mitigation provisions in the Sentencing Guidelines, and the advent of D/NPAs—have attempted to provide additional deterrence to fraudulent actors in publicly held firms by increasing the probability of detection. When compared with their influence on closely held firms, these initiatives should cause outsized positive effects on publicly held firms. For example, increased corporate sanctions may be more effective against public companies because they tend to be better capitalized.[126] Additionally, mitigation provisions, while fruitless against a rational actor who is both the wrongdoer and the monitor, encourage public companies to report their employees' misconduct to relevant authorities.

D/NPAs are also more beneficial when applied against publicly held firms. For instance, because the fraudulent actor is likely not also a major shareholder, and because public com-

125. *Id.*

126. This is only true up to the value of the social harm. Once the monetary sanctions to the corporation exceed the social harm, they are forced to increase the cost of their products to pay the additional cost. Polinsky & Shavell, *supra* note 93, at 255 ("[I]f the firm is made to pay more than the harm, it will set the price of its product above the sum of production costs and expected accident costs; consequently, consumption will be too low relative to the socially desirable level of consumption."). The exception to this is when the firm has a low probability of detection, as we often see in health care fraud. In this case, since the optimal liability should equal the cost of the harm divided by the probability of liability, punitive damages may be warranted. *Id.* Since the focus of this paper is on individual liability, we will not discuss this further with regard to entities.

panies are more likely to be well capitalized, the company is more likely to continue as a going concern after entity and individual sanctions are applied, so ex post measures like these can be beneficial. This is especially important in the health care context because these firms provide a necessary product or service to patients, and there is a social benefit to preserving the firm if it agrees to sufficient oversight going forward. Even outside the healthcare context, allowing a company to avoid prosecution is a better result for innocent shareholders.

D. *How the RCO Doctrine Affects the Rational Actor in Closely Held Firms*

1. *Closely Held Firms*

After analyzing the current system of corporate and individual liability, which includes recent efforts by the DOJ and the U.S. Sentencing Commission to alleviate weaknesses in the "old" system, it then becomes important to explore the necessity of the RCO Doctrine. Created and developed in the context of public welfare statutes, the RCO Doctrine can protect against the kind of calculus described in the preceding subsection: when faced with a profitable activity with a large societal cost and a low probability of detection, rational actors will carry on the activity if it is more lucrative than their potential losses multiplied by the probability of getting caught. Even in light of DOJ efforts to encourage compliance programs and self-reporting, and even in light of the DOJ's increasingly frequent targeting of individual wrongdoers, there is still less than a 100% probability of success in convicting individual offenders.

The imputation of *actus reus* that the RCO Doctrine enables can be viewed in two ways depending on the circumstances. The first perspective, which I will call the vicarious liability perspective, is that, if the prosecution strongly believes that the officer was not in any way complicit in committing the crime, they can utilize the RCO Doctrine to impute that act onto the officer. When used in this way, the RCO Doctrine becomes a vicarious liability standard akin to that of entity liability: the expectation is that, by holding officers strictly liable for the crimes of their employees, they will be motivated to enact internal monitoring programs to protect themselves from liability. On the other hand, if the prosecution strongly believes that the officer was complicit in the crimes, the RCO Doctrine simply serves the purpose of making that officer easier to convict. For the purposes of this Note, this second perspective will be referred to as the burden-lowering perspective. In the closely held context where employees are presumably less likely to engage in fraudulent activity without the complicity of their superiors, this burden-lowering perspective of *actus reus* is the one of importance.[127]

Under the burden-lowering perspective, by increasing the probability of individual conviction, the RCO Doctrine makes the expected value of fraudulent activity lower, but it still may not be sufficient to induce a rational actor to discontinue the fraudulent activity if the company is thinly capitalized. Thus, in the case of closely held, thinly capitalized firms, fraud can be a calculated activity with significant profit potential that is difficult to deter even by increasing the probability of individual liability upon discovery of wrongdoing. Furthermore, even if the RCO Doctrine increases the chance of individual liability upon discovery of wrongdoing, it may not move the needle very far in an ex ante calculation as long as the probability of detection is low. Prison sentences, given their high cost to the rational actor, can increase the expected cost of fraud and tip the balance away from fraudulent activity, but such sanctions are extreme and have only been applied twice in the health care context.[128] Furthermore, given the relaxed *actus reus* requirements under the RCO Doctrine, prison sentences not only raise concerns from a constitutional standpoint,[129] but

127. I realize that this distinction between perspectives can be difficult from the prosecutors' standpoint; however, as Oliver Wendell Holmes said in *United States v. Morissette,* "[e]ven a dog distinguishes between being stumbled over and being kicked." 342 U.S. 246, 252 n. 9 (1952).

128. Mark Hermelin, former CEO of KV Pharmaceutical, received a thirty-day jail sentence that was later reduced to seventeen days. *See* discussion *infra* Part III.B. In a more extreme application, four Synthes executives received prison sentences of between five and nine months. *See* discussion *infra* Part III.C.

129. For a discussion of the constitutional implications of the RCO Doctrine in the environmental context, see, for example, Truxtun Hare, *Reluctant Soldiers: The Criminal Liability of Corporate Officers for Negligent Violations of the Clean Water Act,* 138 U. PA. L. REV. 935, 973-75 (1990). However, the RCO Doctrine has repeatedly avoided being overturned on constitutional grounds, the most recent example of which is Judge Douglas Ginsburg's opinion in *Friedman v. Sebelius.* 686 F.3d 813, 824 (D.C. Cir. 2012) ("Section

they also run contra to the original notion behind the doctrine: protecting the public welfare by increasing an individual's chance of incurring relatively minor penalties.[130] When severe sanctions and imprisonment enter the equation, the RCO Doctrine has strayed far from its roots.

2. *Publicly Held Firms*

Because the size and structure of large public companies is such that there may be a larger degree of separation between responsible corporate officers and fraudulent actors, it is relatively difficult to convict individual offenders in public companies without the RCO Doctrine. Thus, efforts to increase the probability of conviction for culpable defendants increase ex ante deterrence. This represents the burden-lowering perspective discussed in Part II.D.1. The vicarious liability perspective, under which prosecutors who are confident that an officer was *not* complicit in a crime can nonetheless convict her by imputing *actus reus*, likely only applies in the publicly held context given our assumptions about closely held firms. By holding superior officers strictly liable for their inferiors' conduct, the RCO Doctrine transforms these officers into "mini-entities"—that is, they are motivated to implement internal compliance programs in order to minimize their own liability.

E. *How OIG's Exclusionary Authority Affects the Rational Actor in Closely Held Firms*

1. *Closely Held Firms*

Permissive exclusions provide additional deterrence to individuals and entities by increasing the downside of fraudulent activity. When applied to entities, permissive exclusions result in the removal of future revenues from FHCPs, which can put

1320a–7(b)(1), however, is not a criminal statute and, although exclusion may indeed have serious consequences, we do not think excluding an individual under 42 U.S.C. § 1320a–7(b) on the basis of his conviction for a strict liability offense raises any significant concern with due process.").

130. This stated purpose is a combination of the words from *Dotterweich* and *Park* that mention protection of public welfare and the language from *United States v. Morissette* regarding strict liability crimes, stating that they are tolerable partly because penalties are "relatively small, and conviction does no grave damage to an offender's reputation." *Morissette*, 342 U.S. at 256.

firms reliant on these programs out of business.[131] When applied directly to individuals, permissive exclusions merely augment the individuals' costs by placing both their current assets and their future revenue opportunities at risk. A combination of severe penalties, including monetary sanctions, prison sentences, and OIG exclusions can, in some cases, sufficiently alter the cost-benefit calculations of fraudulent activity to provide sufficient deterrence. However, although this may work from the vantage of optimal deterrence, whether it is right as a matter of policy is another matter and will be discussed in Part IV.

Because of the distinctions made in OIG guidance between owners and officers or managing employees, OIG exclusions may be applied differently to closely held firms than they are to publicly held firms. Recall that OIG adopts a presumption in favor of exclusion against owners of covered entities that is not applied against officers or managing employees of such entities unless the officers or managing employees knew or should have known of the misconduct.[132] Because shareholder-managers are more likely to exist in closely held firms, this amounts to a stricter application of OIG exclusions against officers in closely held firms than in publicly held firms. However, given the fact (as we have assumed it) that shareholder-managers in closely held firms are more likely to be complicit in the firm's wrongdoing than their publicly held counterparts, this distinction is unlikely to lead to an unfair result.

2. *Publicly Held Firms*

The effect of permissive exclusions on employees in publicly held firms is essentially the same as in closely held firms.[133] These measures can still augment individual liability

131. This is sometimes aptly referred to as the "corporate death penalty." *See, e.g.*, Remarks of John T. Bentivoglio, Special Counsel for Health Care Fraud & Chief Privacy Officer, U.S. Dep't of Justice, Symposium on Healthcare Internet and E-Commerce: Legal, Regulatory and Ethical Issues at 1165 (Mar. 27, 2000) (on file with author) ("For health care providers—including hospitals, doctors, HMOs, and others who rely extensively on federal programs for reimbursement, exclusion is the equivalent of a corporate death penalty.").

132. *See supra* text accompanying notes 69-77.

133. For a discussion on the effects of OIG exclusions on individuals in closely held firms, see discussion *supra* Part II.E.1.

by placing both future revenue streams and current personal wealth at risk. From a theoretical standpoint, there are two main differences between the closely held and publicly held contexts, and the effects are likely minimal. First, managers at publicly held firms typically make more money than those at closely held firms, and it may even take more experience to obtain one of those positions, so they may have more to lose. However, fraudulent activity in large public firms can be more profitable than in small, closely held firms, which could make up for the increase in potential losses. Second, for high-ranking executives, the additional publicity provided by the coverage of public companies may provide additional pressure to companies against hiring executives who were once excluded, even if their exclusion period has expired, further increasing what is at stake for the individual.

Despite the similarities from the vantage of corporate liability theory, the application of OIG exclusions against officers of large public companies may be different in practice because of the distinctions in OIG guidance described above. Since the officer or managing employee to which OIG exclusions are applied might not also be an owner in this context, they either must have known or should have known of the misconduct in order to be subject to a presumption in favor of exclusion.[134]

IV.
Part III: Current Applications of the RCO Doctrine and OIG Exclusions in the Health Care Context.

The prior two Parts of this Note have explained the backgrounds of the RCO Doctrine and OIG exclusions and have introduced the corporate and individual theories of liability taken into consideration when evaluating these enforcement tools. This Part will provide synopses of recent cases in which one or both of these tools have been applied.

A. *Purdue Frederick*

The highest-profile application of the RCO Doctrine and OIG exclusionary authority in the health care context is that of

134. *See id.*

Purdue Frederick ("Purdue"), a family-owned[135] pharmaceutical company that produced and marketed the popular opiate OxyContin.[136] In 2007, under charges that the drug had been falsely advertised as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications," Purdue pleaded guilty to the crime of felony misbranding.[137] During that time, three Purdue executives—Michael Friedman, Paul Goldenheim and Howard Udell[138]—pleaded guilty as individuals under the RCO Doctrine to misdemeanor misbranding under 21 U.S.C. §§ 331(a) and 333(a)(1) (provisions of the FDCA) for failing to prevent Purdue's fraudulent marketing.[139] Each of the executives was sentenced with 400 hours of community service, fined $5,000, placed on probation for three years, and forced to return compensation that, for the group, totaled approximately $34.5 million.[140] Of note, the Purdue executives did not admit to knowledge of or participation in the misconduct in their pleas; instead, they pleaded only to their "'responsibility and authority either to prevent in the first instance or to promptly correct' the misrepresentations certain unnamed Purdue employees made regarding OxyContin."[141]

In March 2008, a few months after the judgment, OIG excluded the Purdue executives from participating in FHCPs under 42 U.S.C. § 1320a–7(b)(1) and (3) *for twenty years*, which is several times the benchmark of three years.[142] The

135. Although Purdue Frederick was family-owned, it does not fit the description of a closely held firm as we have defined it in this Note.

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

137. *Id.* at 816. The company was thereby placed on probation for five years and imposed with monetary sanctions totaling around $600 million; of that amount, approximately $160 million was "restitution to federal and state health care agencies, which had been large buyers of the misbranded drug." *Id.*

138. The former president and chief executive officer, medical director, and general counsel, respectively. *See* Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html?pagewanted=all.

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

140. *Id.*

141. *Id.* at 817.

142. 42 U.S.C. § 1320a-7(c)(3)(D) (2006) ("[T]he period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating

length of the exclusion was based on three factors listed in the regulations: "the conduct underlying the convictions lasting more than one year, the amount of the financial loss, and the significant adverse physical or mental impact upon program beneficiaries."[143]

After multiple appeals, which resulted only in the reduction of the term of exclusion from twenty to twelve years, the D.C. Circuit agreed to hear the case. In a holding written by Senior Circuit Judge Douglas Ginsburg, the Court upheld the exclusion under 42 U.S.C. § 1320a–7(b)(1)—accepting the Secretary's broad interpretation of the aforementioned "relating to" language—but deemed the (now) twelve-year exclusion period to be arbitrary and capricious, resulting in a remand to the agency to justify the abnormally large exclusion period.[144]

This case is of particular importance for a couple of reasons. First, it is the first and only use of the RCO Doctrine combined with the OIG's exclusionary authority in the health care context to be upheld by a Court of Appeals. More significant, however, is the manner in which it was upheld; Judge Ginsburg ruled that 42 U.S.C. § 1320a–7(b)(1) authorizes OIG to exclude "an individual convicted of a misdemeanor if the conduct underlying that conviction is *factually* related to fraud."[145] The attorneys representing the Purdue executives argued that the misbranding misdemeanor could only be related to fraud if the "generic misdemeanor [ ] comprise[s] the core elements of fraud," including scienter.[146] That the underlying conduct was factually related to fraud because of a "common sense connection between their convictions and those statutory bases for exclusion" would thus be insufficient.[147] In ruling against this argument, Judge Ginsburg adopted a broad interpretation of "relating to" that allows individuals who have been convicted of a misdemeanor under the RCO Doctrine—that is, because of their position in the

circumstances."); *see* 42 C.F.R § 1003.106 (2013). Mandatory exclusions, on the other hand, "shall not be less than five years." § 1320a-7(c)(3)(B).

143. F.3d 813 at 817 (citing 42 C.F.R. § 1001.201(b)(2)(i)-(iii), § 1001.401(c)(2)(i)-(ii)).

144. *Friedman*, 686 F.3d at 828.

145. *Id.* at 824 (emphasis added).

146. *Id.* at 818 (internal quotation marks omitted).

147. *Id.* (internal quotation marks omitted).

company and not because of any proof or admission of their own misconduct—to be excluded by OIG from participation in FHCPs for the rest of their professional careers.

In this case, because the appeals occurred after a plea agreement, there may be some evidence regarding the *mens rea* of the Purdue executives that never entered the public record; however, the prosecution never alleged conscious wrongdoing in their briefs. In fact, the defense repeatedly asserted a lack of conscious wrongdoing that was never challenged in the judicial opinions.[148] Therefore, it appears that the prosecution was using the RCO Doctrine under the vicarious liability perspective, intending to hold an uninvolved and unaware corporate officer liable for employees' crimes in order to encourage other executives to engage in internal monitoring and compliance and to thereby avoid a similar result in the future.

Application of OIG's inclusionary authority in this case appears to be for a similar reason: by increasing what is personally at stake for crimes committed by subordinate employees, OIG is seeking to further alter the ex ante calculus of other similarly situated executives. However, instead of changing the ex ante calculus of a rational actor actively engaging in fraud, exclusion here appears to be aimed at augmenting the threat of strict liability under the RCO Doctrine to further motivate executives to enact internal monitoring and compliance programs. While this may serve the intended result, it does so at a high individual cost to executives in that they are not only exposed to personal criminal liability by virtue of their positions, but they are also now subject to career-ending sanctions. It is unclear whether or not these additional "teeth" are a necessary motivator in addition to this onerous application of the RCO Doctrine.

B. *KV Pharmaceutical*

In *United States ex rel. Conrad v. Ethex Corp.*,[149] KV Pharmaceutical was charged under the False Claims Act with allegedly

148. *See, e.g.*, Final Brief for Appellants at 11, Friedman v. Sebelius 686 F.3d 813 (2012) (No. 11-5028) ("Nothing in the Agreed Statement—or any other part of the record—indicates that appellants participated in the misleading marketing, knew about it, or recklessly or negligently ignored it.")

149. No. 02-cv-11738-NG (D. Mass.) (settlement announced Dec. 6, 2011).

"fail[ing] to advise the Centers for Medicare and Medicaid Services (CMS) that two unapproved products did not qualify for coverage under federal health care programs."[150] These charges emanated from DOJ allegations that KV Pharmaceutical (the parent company) and Ethex Corp. (a subsidiary) distributed morphine sulfate tablets of the wrong size and dosage.[151] As part of the settlement, KV Pharmaceutical agreed to pay $17 million in fines to federal and state health care programs and consented to forced dissolution of Ethex Corp. in order to avoid OIG exclusion.[152]

In addition to the charges against the company entity, CEO Mark Hermelin was charged individually with two misbranding misdemeanors under the FDCA after allegedly failing to correct the misbranding issues after they were brought to his attention by employees.[153] Utilizing the RCO Doctrine, the DOJ stated that, by virtue of his position as CEO, "Hermelin had the power, authority, and responsibility to prevent drug manufacturing problems in the first instance and promptly correct any drug manufacturing problems that did occur."[154] Hermelin pleaded guilty to the violations and, as part of the plea agreement, paid $1.9 million in fines and for-

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150. Press Release, U.S. Dep't of Justice, St. Louis-Based KV Pharmaceutical to Pay $17 Million to Settle False Claims Allegations (Dec. 6, 2011), http://www.justice.gov/opa/pr/2011/December/11-civ-1579.html.

151. *Former Drug Company CEO Sentenced to Jail Time, Ordered to Pay $1.9 Million in Fines, Forfeiture; Hermelin Pleads Guilty to Misdemeanor Misbranding in Connection with Oversized Tablet Production*, FDA ENFORCEMENT MANUAL NEWSLETTER (Thompson Publishing, Atlanta, GA), Apr. 2011 [hereinafter FDA NEWSLETTER].

152. U.S. Dep't of Justice, *supra* note 150 ("The federal share of the settlement is $10,158,695, and the state Medicaid share of the settlement is $6,841,305.").

153. *See* FDA NEWSLETTER, *supra* note 151. Further, the government alleged that Hermelin "(1) instructed employees to minimize written communications and limit distribution and discussion of any documents referencing the problems, given the 'business risk' created by written materials; (2) stated that Quality Assurance employees should be out of the 'information flow,' and (3) offered his views on what the root cause finding of the investigation should be." Robert T. Rhoad & Brian M. Castro, *Healthcare Executives in the Crosshairs: Navigating the Emerging Threat of Prosecution and Exclusion Under the Responsible Corporate Officer Doctrine*, HEALTH LAWYER, June 2012, at 10.

154. Government's Sentencing Memorandum, United States v. Hermelin, Crim. No. 4:11-CR-00085-ERW (E.D. Mo. Mar. 10, 2011).

feitures and spent 17 days in jail, marking the first time a prison sentence had ever resulted from a RCO Doctrine prosecution in health care.[155] In addition, in November 2010—mere months after OIG released new guidelines for permissive exclusion—OIG announced its exclusion of Hermelin from participation in FHCPs for a term of twenty years.[156]

In stark contrast to the Purdue case, the prosecution alleged, based on evidence from informants, that Hermelin specifically instructed employees to avoid written communication about the mislabeling and the investigation, attempted to segregate quality assurance personnel from the investigation, and failed to act after being made aware of the mislabeling.[157] Thus, the use of the RCO Doctrine here is under the burden-lowering perspective, whereby prosecutors simply seek to ease their burden of proof against a defendant who is likely to have engaged in the requisite *actus reus.* The prison sentence and OIG exclusion, which further increase the personal cost of Hermelin's fraudulent activity, serve their intended purpose of signaling to other potential fraudulent actors that their ex ante calculus should include these kinds of severe sanctions. This combination of the RCO Doctrine and OIG exclusion is a more appropriate application of these tools in that they apply to an officer that is responsible by virtue of his fraudulent activity and not merely due to his position in the company.

C. *Synthes*

In *U.S. v. Synthes,* the DOJ brought charges against Synthes (the parent company) and Norian (a subsidiary) for the use of bone cement in spinal surgery clinical trials without FDA authorization, after which Synthes engaged in a plea agreement with the DOJ.[158] Additionally, the DOJ accepted

155. Amended Judgment, United States v. Hermelin, No. 4:11-cr-00085-ERW-1 (E.D. Mo. Mar. 24, 2011) [hereinafter Hermelin Judgment]. The original sentence was for thirty days. *Id.* Hermelin also agreed to resign and to sell his personal shares in KV Pharmaceutical to avoid OIG exclusion of the company. *Former K-V Pharmaceutical Board Chairman Excluded by HHS,* THOMPSON (Nov. 17, 2010), *available at* http://www.thompson.com/public/newsbrief.jsp?cat=FOODDRUG&id=3237 [hereinafter K-V Newsbrief].

156. K-V Newsbrief, *supra* note 155.

157. *See* FDA NEWSLETTER, *supra* note 151.

158. United States v. Synthes Inc., Crim. No. 09-403-02, 2010 WL 4977512 (E.D. Pa. Dec. 7, 2010). Synthes and Norian paid $24.3 million in fines and

guilty pleas from four individual officers—the North American president, the president of the Spine Division, a senior vice president, and the regulatory director—to a misbranding misdemeanor under the FDCA through the RCO Doctrine. In their pleas, the defendant officers did not admit to wrongdoing, but instead only admitted to being "responsible corporate officers" when the misconduct occurred.[159] Despite this fact, the DOJ presented evidence during sentencing in late 2011 that the executives personally participated in fraudulent and deceptive conduct, which led to prison terms ranging from five to nine months and fines of $100,000.[160] This marked the first instance of the RCO Doctrine leading to significant prison sentences in this context, putting executives and defense attorneys on notice that the DOJ's aggression in this space was continuing to increase.[161] In October 2012, OIG officially excluded the four executives from participation in FHCPs.[162]

Like KV Pharmaceutical, the government alleged that the individual defendants were not only consciously aware of the wrongdoing, but were also active participants in the crimes of mislabeling, promoting the mislabeled cement, and lying to the FDA. While those allegations were never proven in court due to a plea agreement, the prosecution appeared to have again used the RCO Doctrine under the burden-lowering perspective. In addition, prosecutors used the OIG exclusion appropriately both to increase the potential costs of fraudulent activity and to protect FHCPs from these specific offenders.

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forfeitures as part of the plea agreement. In addition, Synthes was forced to sell Norian Corporation in order to avoid exclusion as an entity. Anna Grizzle, *Compliance Advice for Health Care Lawyers and Clients*, HEALTH CARE LAW ENFORCEMENT AND COMPLIANCE 14-15 (2012).

159. Government's Amended Presentence Memorandum, United States v. Huggins et al., Crim. No. 09-403-03-06, at 4 (E.D. Pa. Dec. 10, 2010), *available at* http://www.circare.org/lex/synthes/09cr00403_94_20100330.pdf ("The individual defendants, by virtue of their respective positions, were 'responsible corporate officers' at various time during the events described below.").

160. *Id.*

161. The former CEO of KV Pharmaceutical, Mark Hermelin, was the first health care executive to be given a prison sentence pursuant to a plea agreement under the RCO Doctrine, but his sentence was only for thirty days, which was later reduced to seventeen days. Hermelin Judgment, *supra* note 155.

162. OIG, List of Excluded Individuals and Entities, https://oig.hhs.gov/exclusions/exclusions_list.asp. This information was obtained from the OIG online list, and the length of their exclusion is unrecorded.

D. *Spectranetics*

In August 2010, three former executives of Spectranetics Corp. and an outside sales associate were charged with conspiracy, false statements, customs violations, and the introduction of adulterated and misbranded medical devices into interstate commerce.[163] Prior to that, the DOJ and OIG had begun their investigation into the company's practices in late 2008, and the company paid $5 million as part of a DOJ settlement in December 2009.[164] Despite the company's settlement, prosecutors indicted the four defendants using the RCO Doctrine, among other theories.[165] After a five-week jury trial in 2012, two defendants—former CEO John Schulte and former business development manager Trung Pham—were acquitted of the charges under the RCO Doctrine, but Schulte was found guilty on one count of making false statements to the FDA.[166] The prosecution later dropped the charges against a third defendant, former senior vice president of business development Obinna Adighije, while former outside sales associate Hernan Ricuarte pleaded guilty and has not yet been sentenced as of this writing.[167]

In this case, the government alleged that the individual defendants actively participated in the introduction of adulterated and misbranded medical devices into interstate commerce and lied both to internal Spectranetics investigators and to the FDA about their conduct. However, because two of the executives were acquitted in a jury trial, and because charges

163. Indictment, United States v. Schulte et al., No. 110CR00455 (D. Colo. Aug. 26, 2010); *see* Spectranetics Executives Indicted for Alleged Import Violations, 18 No. 12 GUIDE TO MED. DEVICE REG. NEWSLETTER 7 (Thompson Publishing, Atlanta, Ga), Oct. 2010.

164. Virginia A. Gibson et al., *The New Era of Responsible Corporate Officer Doctrine Enforcement*, RISK MGMT. (Aug. 29, 2012), http://www.rmmagazine.com/2012/08/29/the-new-era-of-responsible-corporate-officer-doctrine-enforcement/.

165. *See* United States v. Shulte et al., Crim. No. 110-CR-00-455, 2010 WL 3445925 (D.Colo.) (Trial Pleading).

166. *Winston & Strawn Successfully Defends High-Ranking Executive*, WINSTON & STRAWN LLP, http://www.winston.com/index.cfm?contentid=30&itemid=3893. The false statement conviction led to only one year of probation at sentencing.

167. Wayne Heilman & Rich Laden, *Former Spectranetics CEO Sentenced to Year of Probation*, THE GAZETTE (May 29, 2012), http://www.gazette.com/articles/former-139377-sentenced-year.html.

against a third were dropped, the evidence against the officers acting individually may not have been compelling. Thus, this appears to be an unsuccessful application of the RCO Doctrine under a burden-lowering perspective, and no OIG exclusions were applied.

E. *Forest Laboratories*

In September 2010, Forest Laboratories (the parent company) and Forest Pharmaceuticals Inc. (a subsidiary) entered into agreements with DOJ to avoid criminal charges—Forest Laboratories engaged in a corporate integrity agreement ("CIA"),[168] and Forest Pharmaceuticals pleaded guilty to the felony of obstruction of justice and two misbranding misdemeanors.[169] Although CEO Howard Solomon was never charged with any crime, OIG informed him in 2011 of their intent to exclude him from FHCPs by virtue of his position within a sanctioned entity.[170] Solomon vowed to challenge the action,[171] and, with support both from Forest Laboratories and from a chorus of critics in the press,[172] OIG dropped the

168. CIAs are agreements between potential health care fraud defendants and OIG entered into as part of a settlement. In these agreements, individuals or entities agree to a list of obligations in exchange for OIGs promise not to exclude them from FHCPs for the alleged crimes. Similar to a DPA or NPA, these obligations typically include the implementation of an internal compliance and oversight program and may also include heightened reporting requirements. Corporate Integrity Agreements, OFFICE OF THE INSPECTOR GEN. OF THE U.S. DEP'T OF HEALTH AND HUMAN SERVICES, https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp.

169. United States v. Forest Pharm, Inc., Cr. No. 10-10294-NG (D. Mass. Sept. 15, 2010). As part of the settlement, Forest Laboratories paid $313 million in penalties related to criminal and civil charges.

170. Press Release, Forest Laboratories, Inc., Forest Laboratories Chairman And CEO To Challenge "Unwarranted And Unprecedented" Potential Action To Exclude Him From Federal Healthcare Programs, (April 13, 2011), *available at* http://news.frx.com/press-release/corporate-news/forest-laboratories-chairman-and-ceo-challenge-unwarranted-and-unpreced (last viewed Feb. 22, 2013).

171. *Id.*

172. *See, e.g.*, Alicia Mundy, *U.S. Effort to Remove Drug CEO Jolts Firms*, WALL ST. J. (Apr. 26, 2011), http://online.wsj.com/article_email/SB1000142405 2748704123204576283283851626952-lMyQjAxMTAxMDIwNjEyNDYyWj. html. The response from the media was so overwhelming critical of OIG that they released a "fact sheet" to answer public concerns about the case. OIG Fact Sheet on Forest Laboratories, Inc. and the Inspector General's Exclusion Authorities, OFFICE OF INSPECTOR GEN. (May 10, 2011), *available*

exclusion proceedings.[173] This case marked the first time OIG had ever attempted to exclude an individual who had been neither charged with nor personally implicated in any crimes.

In an appeal to OIG, Solomon's attorneys drew attention to the fact that Solomon maintained a robust compliance program, reasonably relied on the opinions of FDA regulatory experts, was wholly unaware of some of the company's misconduct, and reacted quickly when made aware of misconduct.[174] Since Solomon was never brought before a court, and since OIG dropped the exclusionary action, there is no established reason to doubt his defensive statements. This successful defense implies that OIG took into consideration the fact that Solomon had an acceptable internal monitoring and compliance program in place. Despite the fact that this case is often criticized as a red flag to executives that OIG is becoming too aggressive with its exclusion authority, it is comforting that OIG allowed a defense based in part on a compliance program to stand. That kind of mitigation is a primary proposal of this Note with respect to both OIG exclusions and the RCO Doctrine.

One aspect of this case that remains concerning is the OIG appeared to be utilizing the strict liability principles of the RCO Doctrine in its application of exclusionary authority. There was no evidence brought by prosecutors that Solomon was involved in the fraud, so OIG presumably was employing the vicarious liability perspective of the RCO Doctrine in its attempt to exclude Solomon from FHCPs. This was unprecedented at the time and has not yet been repeated, but it raises the same issues as the vicarious liability perspective in the context of the RCO Doctrine.

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at http://oig.hhs.gov/publications/docs/press/2011/factsheet_051011.asp (last viewed June 25, 2011).

173. For more information about the events leading to OIG reversal, see Jim Edwards, *How Lobbyists Got Forest Labs' CEO Off the Hook With the Feds,* CBS MONEYWATCH (Aug. 8, 2011, 12:26 PM), http://www.cbsnews.com/8301-505123_162-42849400/how-lobbyists-got-forest-labs-ceo-off-the-hook-with-the-feds/.

174. *Ropes & Gray Alert: The OIG Backs Off Intended Exclusion of Forest Laboratories' CEO,* ROPES & GRAY LLP (Aug. 2011), http://www.ropesgray.com/files/Publication/da841eca-8696-4b97-8550-264dd67184d5/Presentation/PublicationAttachment/8020bc32-82fe-4c1a-9c0f-94514085216a/20110812_HC_GE_Alert.pdf.

F. *TMJ Implants*

The cases discussed thus far (with the exception of the GSK case) have dealt with application of the RCO Doctrine to violations of statutes such as the FDCA; however, *TMJ Implants, Inc. v. United States Department of Health & Human Services*[175] demonstrates the application of the RCO Doctrine to administrative proceedings.[176] In this case, TMJ Implants, a medical device manufacturer, and its founder and president, Dr. Robert Christensen, were charged with knowingly failing to submit seventeen medical device reports ("MDRs") to the FDA. The FDA mandates that every device manufacturer file an MDR "whenever the manufacturer . . . receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury."[177] Those who fail to meet this requirement are subject to CMPs[178] not to exceed $16,500 per violation.[179]

The FDA discovered through inspections that twenty-two events had taken place for which an MDR was mandatory.[180] After issuing a warning letter to Christensen regarding the infractions, Christensen still did not comply, but instead expressed disagreement with the FDA's position and asked for clarification through letters, phone calls, and meetings.[181] After months of back-and-forth communications, and after the FDA finally recognized seventeen MDR reports as being delinquent (five had been filed since the original FDA inspections),

175. 584 F.3d 1290 (10th Cir. 2009).

176. Exercising OIG's exclusionary authority is, itself, an administrative proceeding, but I am instead referring to other administrative proceedings such as the imposition of CMPs.

177. 21 U.S.C. § 360i(a)(1)(A). The purpose of the requirement is for quick FDA action to protect the health and safety of the public. Medical Device Reporting 49 Fed.Reg. 36,326, 36,326 (Sep. 14, 1984) ("Only if FDA is provided with such information will it be able to evaluate the risk, if any, associated with a device and take whatever action is necessary to reduce or eliminate the public's exposure to this risk.").

178. 21 U.S.C. § 333(f)(1)(A) ("[A]ny person who violates [the MDR requirement] shall be liable to the United States for a civil penalty.").

179. 21 C.F.R. § 17.2 (2011).

180. *TMJ Implants*, 584 F.3d at 1296.

181. *Id.* at 1296-97.

CMPs totaling $170,000 were levied against TMJ Implants and Christensen by an administrative law judge.[182]

After exhausting the available administrative appeals, the defendants sought judicial review before the Tenth Circuit.[183] As an individual defendant, Christensen argued that he could not be considered a "manufacturer," but the Tenth Circuit did not adopt this interpretation of the statute, citing *Park* and *Dotterweich* as support for holding individuals liable for corporate acts.[184] In response to Christensen's attempt to distinguish those two cases by virtue of being criminal rather than civil violations, the court noted that "the rationale for holding corporate officers criminally responsible for acts of the corporation, which could lead to incarceration, is even more persuasive where only civil liability is involved, which at most would result in a monetary penalty."[185] Christensen also argued that the FDA had not issued a final response to his appeal, therefore he could not have knowingly violated the statute; however, the Tenth Circuit ruled that one need not have a final response to be considered "apprised" of wrongdoing.[186]

This case is significant for two primary reasons. First, it is the first application of the RCO Doctrine to an administrative proceeding, which could lead to a huge expansion of the RCO Doctrine if it becomes a prosecutorial trend. Second, it is conceptually different from either the burden-lowering or the vicarious liability perspectives described in this Note in that it was used to justify including an individual in the definition of "manufacturer" to complete the statutory requirements for a violation.[187] Although unique, this fits most closely with the burden-lowering perspective since Christensen's conduct was undisputed. As such, it does not raise the same fairness issues as an application under the vicarious liability perspective.

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182. *Id.* at 1299.

183. *Id.* at 1294.

184. *Id.* at 1303 ("Section 333(f) states that 'any *person* who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty' . . . Moreover, in analogous circumstances, the Supreme Court has explicitly held that corporate officers may be liable for violations of the Food, Drug, and Cosmetic Act.") (emphasis added).

185. *Id.* (quoting United States v. Hodges X-Ray, Inc., 759 F.2d 557, 561 (6th Cir. 1985)).

186. *Id.* at 1302.

187. *See id.* at 1303.

V.
Part IV: Suggested Reforms to the Use of the RCO Doctrine and OIG Exclusions in the Health Care Context

A. *Monitoring and Oversight*

1. *Closely Held Firms*

One of the biggest dangers to the public welfare in the context of closely held firms is a rational actor in a thinly capitalized firm engaging in highly profitable fraudulent activity with a low probability of detection. This is because shareholder-managers in thinly capitalized firms will bear the full benefit of fraudulent activity but will only suffer corporate sanctions (as opposed to individual sanctions) to the extent that the entity capitalized. Although internal monitoring regimes are not as helpful in closely held firms as they are in publicly held firms due to fewer agency costs and a simpler employee hierarchy,[188] regulations that increase external monitoring of high-risk companies may help raise the probability of discovering harm, thus changing the calculus of a rational actor ex ante.[189] Professors Arlen and Kahan posit that, since increased oversight is warranted when corporations have insufficient assets to be deterred by corporate liability, external oversight that is specifically targeted at high-risk (i.e., thinly capitalized) firms can increase the probability of detection in the most potentially damaging cases.[190] Since any increase in the probability of detection can significantly alter the calculus of rational actors, I believe this an appropriate adjustment for government agencies to make to their current policies as applied to closely held firms.

188. *See* discussion *supra* Part II.C.1.

189. Jennifer Arlen & Marcel Kahan, *Corporate Governance Regulation Through Non-Prosecution,* 4, http://isites.harvard.edu/fs/docs/icb.topic1022797.files/Paper05_Arlen_02-21.pdf ("Regulation is superior to D/NPA mandates if it can be targeted at the source of the inefficiency, because regulation provides enhanced incentives for all firms plagued by the inefficiency.").

190. *Id.* Another purpose of monitoring outlined in the article is agency costs. *Id.* However, given the closely held context, these are either nonexistent or are marginalized.

2. *Publicly Held Firms*

Unlike closely held firms, in which we assume that the monitor is either also the fraudulent actor or is closely related to the actor, internal policing and prevention can be very effective in publicly held firms. For this reason, changes to the Sentencing Guidelines that prescribe, for example, lighter sentences if a company has an effective compliance program or reports misconduct to relevant authorities—with much lighter sentences if both of these things occur—can and do incent managers to police and prevent misconduct. D/NPAs can provide further benefit after wrongdoing is discovered by forcing companies to implement these programs in order to prevent future acts of fraud.

Still, the DOJ's system of D/NPAs is not optimal. First, the system enables prosecutors to play a very active role in corporate governance and to implement potentially costly and inefficient policies rather than leaving the job to civil and regulatory agencies that have, over decades, built significant expertise.[191] Second, it makes the business operations of these companies subject to prosecutorial discretion without any kind of a check or balance on their behavior.[192] To answer these three concerns, Professor Arlen concludes, and I concur, that external oversight and regulation of at-risk and indicted corporations is generally best left to civil and regulatory agencies.[193]

In a forthcoming article, Professors Arlen and Kahan propose two situations when external oversight can optimize deterrence beyond that of traditional corporate liability. First, as with closely held firms, ex ante oversight of thinly capitalized companies—which increases the probability of detection, changes the calculus of the rational actor, and thus reduces the risk of society bearing the cost of harm—should be initiated by civil and regulatory agencies.[194] Second, external oversight can make up for the inability of corporate liability to sufficiently account for agency costs; in this way, ex post D/NPAs

191. PROSECUTORS, *supra* note 100, at 80.

192. *Id.* It also raises important questions about whether the government should ever impose structural reforms on corporations, but these questions fall outside the purview of this article.

193. *See* Arlen & Kahan, *supra* note 189, at 46.

194. *See id.*

can be superior to ex ante regulation.[195] In either case, the DOJ may not be the best party to handle this oversight.[196] Regardless of the source, however, the internal monitoring and compliance that these N/DPAs implement provide valuable enforcement assistance.

B. *The RCO Doctrine*

The RCO Doctrine does make a material difference in prosecutorial success, as evidenced by the comparative results in actions against two publicly held companies—Synthes and Stryker. Recall that, in *Synthes*, the defendant officers did not admit any guilt to the crimes with which they were charged, but instead only admitted to being the officers with responsibility and authority to prevent the misconduct when it occurred.[197] The Synthes officers pleaded guilty, which resulted in significant penalties including five to nine months in prison, $100,000 fines, and exclusion from FHCPs.[198] The case against Stryker—another orthopedic medical device manufacturer—involved a very similar set of facts. Four high-level executives—the former president, sales director, and two regional sales managers—were charged with wire fraud and FDCA misbranding for off-label promotion similar to that of the Synthes executives.[199] However the Stryker executives were charged under a direct liability theory rather than the RCO Doctrine, and the case went to trial.[200] After a very brief trial, all four individual defendants were dismissed from the case, and the company settled for a misdemeanor plea agreement and a $15 million fine.[201] This result, which differs dramatically from the experience of the Synthes executives, illus-

195. *Id.* at 4 ("Government authorities cannot rely on corporate liability alone when agency costs infect the firm's policing activities. Moreover, in this situation, post-crime intervention to address agency costs, such as through D/NPAs, generally will be superior to ex ante intervention through regulation.").

196. *Id.*

197. *See* Government's Amended Presentence Memorandum, *supra* note 159, at 6.

198. *See* discussion *supra* Part III.C.

199. Indictment, United States v. Stryker, 09-CR-10330 (D. Mass. Feb. 2, 2012) ¶¶ 42, 48, 60.

200. John Steiner and Carolyn Fitzhugh McNiven, HEALTH LAW AND COMPLIANCE UPDATE § 10.03, at [A] (2013).

201. *Id.* at [A][1].

trates the inherent difficulty in proving guilt in a case involving a large public company without using the RCO Doctrine.[202]

1. *Closely Held Firms*

As previously discussed, only the burden-lowering perspective of the RCO Doctrine—that it makes culpable defendants easier to prosecute by easing the burden of proof for *actus reus*—applies in the closely held context. There is, thus, little chance of an unfair result when applied to closely held firms since the target of liability is more likely to be culpable. Thus, the RCO Doctrine, in its current form, is most appropriate in this scenario because it can increase the ex ante costs of fraudulent activity by increasing the probability of conviction upon discovery of wrongdoing without endangering the defendant to an overly harsh result.

2. *Publicly Held Firms*

There is a key distinction between the use of the RCO Doctrine in the closely held context and its use against publicly held firms. In our discussion of closely held firms, we assumed that the person of responsibility and authority to prevent the act was closely related to the actor, so the second perspective of the RCO Doctrine was the only applicable use. In a large public company with agency costs and a complex hierarchical structure, the first perspective of the RCO Doctrine, which applies a strict liability standard to a superior for the conduct of her inferiors, is also applicable.[203] As previously mentioned, this converts individuals into a sort of "mini-entity" by using strict liability to motivate them to impose internal compliance measures. However, under this first perspective, there is a much higher risk of imputing the *actus reus* on a corporate officer with no knowledge of the crime who had fully delegated that authority to someone else in good faith.

Although a finding of "blameless guilt" represents the danger of the RCO Doctrine to an individual, the RCO Doc-

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202. *See id.* (noting that "strategic errors" in the prosecution were amplified because the charges were made on a direct liability theory rather than the RCO Doctrine).

203. That is, according to our assumptions about closely held firms for the purposes of this article.

trine can also be beneficial for prosecutors against an individual who is purposefully turning a blind eye to a crime that benefits her in order to maintain a specter of innocence upon discovery. When applying the RCO Doctrine to these individuals (i.e., under the burden-lowering perspective), it is not unfair. It is, instead, justice. However, given the danger of wrongly imputing *actus reus* to the innocent manager under the vicarious liability perspective, there needs to be an additional protection for defendants beyond prosecutorial discretion in order to justify use of the RCO Doctrine against these individuals.

There is only one judicially recognized affirmative defense for responsible corporate officers against RCO Doctrine prosecutions once it is proven that *someone* at the firm committed a crime: the impossibility defense found in *Park* dicta.[204] However, this defense provides little assistance in that "impossibility" can be a tough wall to climb.[205] Indeed, this author has found only six instances where the defense was attempted, and none were successful; in five cases, the defense was rejected outright,[206] while one case was remanded to the lower court for more factual proof because the prosecution did not offer enough facts to eliminate reasonable doubt.[207] There is a large spectrum between possible and impossible, and even showing that the likelihood of successfully preventing the crime was very slim may not trigger this defense.[208]

204. *See Park*, 421 U.S. at 673.

205. For a discussion of the impossibility defense, see, for example, Todd W. Grant, *The Responsible Relationship Doctrine of United States v. Park: A Tool for Prosecution of Corporate Officers Under Federal and State Environmental Laws*, 11 TEMP. ENVTL. L. & TECH. J. 203, 207-16 (1992).

206. United States v. Y. Hata & Co., Ltd., 535 F.2d 508 (9th Cir. 1976) (rejected) U. S. v. Starr, 535 F.2d 512 (9th Cir. 1976); People v. Matthews, 7 Cal. App. 4th 1052, 9 Cal. Rptr. 2d 348 (2d Dist. 1992); United States v. Gel Spice Co., Inc., 601 F. Supp. 1205 (E.D.N.Y. 1984); Hujazi v. Superior Court of California, 890 F. Supp. 2d 1226, 1239 (C.D. Cal. 2012).

207. United States v. New England Grocers Supply Co., 488 F. Supp. 230 (D. Mass. 1980). To my knowledge, it was not successful on remand.

208. In the defense, the burden starts with the defendant(s) and then shifts to the government, after which the government must prove that it was *possible*. *See New England Grocers*, 488 F.Supp. 230, 236 ("The [impossibility] defense is raised when the defendant introduces a sufficient quantum of evidence as to his exercise of 'extraordinary care' so as to justify placing an additional burden on the government. At this point, the government must prove beyond a reasonable doubt that the defendant, by the use of ex-

Since the stakes are much higher for individuals than for entities, there should be a more substantial defense for individual defendants when strict respondeat superior liability is applied to them in the same way it is applied to corporations. A valuable analogy to examine with respect to individual liability mitigation is the *Caremark* standard imposed by Delaware courts.[209] Under *Caremark,* directors will not be held liable for failure to monitor unless they display a "sustained and systemic failure" to maintain "information and reporting systems . . . that are reasonably designed to provide to senior management and to the board itself timely, accurate information" about corporate compliance.[210] Interestingly, the *Caremark* court mentioned that "[n]either corporate boards nor senior officers can be charged with wrongdoing simply for assuming [the] integrity of employees and [the] honesty of their dealings on [the] corporation's behalf,"[211] which illustrates a significant departure from the treatment of officers under the vicarious liability perspective of the RCO Doctrine.

Despite the obvious differences between the *Caremark* context and that of the RCO Doctrine,[212] I propose that a simi-

traordinary care, was not without the power or capacity to correct or prevent the violations of the Act."). It should be noted that, with respect to the impossibility defense, courts appear to be displaying circular reasoning—the point of the impossibility defense is to protect against liability based solely on one's position, but the defense is consistently rejected, seemingly because the officer always has the "power" to prevent or correct the wrongdoing by virtue of their position. This opens up another paradigm from which to view the responsible corporate officer doctrine that is not otherwise discussed in this Note: If the impossibility defense exists, then there is some level of extraordinary care that would absolve the corporate officer of liability for wrongdoing, and, because any lesser efforts subject the corporate officer to personal liability, the officer has an implied duty to exercise that level of extraordinary care. Thus, liability under the RCO Doctrine can be viewed as an act of omission to carry out a particular duty and not simply the imputation of others' *acti rei* upon an otherwise innocent corporate officer. However, that does not appear to be the mainstream interpretation, and discussion on this topic will be limited to this footnote.

209. In re Caremark Int'l Inc. Derivative Litig., 698 A.2d 959 (Del. Ch. 1996).

210. *Id.* at 970.

211. *Id.* at 969.

212. There are many differences. Among them, as mentioned, the stakes are not as high in that the public health is often not at stake; however, in the case of large investment banks, for example, the effect on the public welfare can be significant. Furthermore, the decisions of the directors are business

lar standard should be applied to officers under the RCO Doctrine given the glaringly weak protections of the impossibility defense and given officers' vulnerability to prosecutorial discretion. As long as directors act in good faith when implementing a program to ensure adequate monitoring and information about the potentially fraudulent activities of their employees, they are not the optimal targets of the RCO Doctrine and should not be held strictly and individually liable for the rogue conduct of their employees. Since the purpose of treating officers as mini-entities is to encourage them to implement these types of monitoring and compliance controls, doing so prior to a potential prosecution eliminates the benefit of using the vicarious liability perspective of the RCO Doctrine. Without such a defense, the RCO Doctrine could impose sanctions on otherwise innocent individuals *without* being able to inform anyone's ex ante decision-making because there is no reasonable person to emulate in strict liability crimes.[213] A *Caremark*-like defense would allow the crime to remain a strict liability crime, but it would enable courts to build standards of reasonability that could positively affect the detection of fraudulent activity. Just as recent DOJ changes have turned corporate liability against public companies from a *de facto* strict liability regime to a *de jure* duty-based regime,[214] this would make similar changes to the way strict liability is applied against individuals.

Another way to achieve the same result is for the DOJ to adopt a policy of refraining from prosecuting officers who had set up these types of monitoring and compliance programs. One benefit of this method is that, unlike the *Caremark*-like defense—which would be available to all defendants, including those who would otherwise be prosecuted under the burden-lowering perspective of the RCO Doctrine—this DOJ policy would be applied only to those being prosecuted under the vicarious liability perspective. This may prevent culpable de-

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decisions subject to the uncertainties of the marketplace, while the decisions of managers are more concretely applied to employee actions. Similarly, directors in the *Caremark* context cannot "control" the effects of their business decisions in the same way managers can control the acts of their employees.

213. *See* Polinsky & Shavell, *supra* note 93, at 252.

214. This terminology is credited to Professor Arlen as used throughout PROSECUTORS, *supra* note 100.

fendants from hiding behind a compliance defense.[215] On the other hand, a DOJ-centric reform would subject defendants to the uncertainty of prosecutorial discretion, which may open the door for prosecutorial indiscretion to cause an unfair result since there still would not be a robust defense in place for well-meaning defendants who were not active participants in fraud.

In summary, the RCO Doctrine is a two-edged sword that prosecutors can use to either convict a culpable defendant or one that was uninvolved but in "responsible relation" to the crime. In the current system, I only endorse the use of the RCO Doctrine against the former defendant; its use against the latter defendant is only justified if there is a robust mitigation mechanism that takes into consideration existing monitoring and compliance programs.

C. *Permissive Exclusions*

1. *Closely Held Firms*

Increasing the possible cost of fraud can deter a rational actor from engaging in fraudulent activity. Increasing individual monetary sanctions is the simplest way to accomplish this goal, but individual wealth is limited and may not suffice. Prison sentences can further increase the cost, but the application of significant prison sentences to strict liability crimes is controversial and may raise constitutional issues.[216] Moreover,

215. However, this may not be much of an issue given that an effective compliance program would have discovered or prevented the wrongdoing, so it may be easy for prosecutors to prove that the programs were insufficient.

216. *See* United States v. Morissette, 342 U.S. 246, 256 (1952) ("[Strict liability, public welfare offenses are situations in which] penalties commonly are relatively small, and conviction does no grave damage to an offender's reputation."). For a discussion of the costs of imposing prison sentences, see John Coffee, Jr., *"No Soul to Damn; No Body to Kick": An Unscandalized Inquiry Into the Problem of Corporate Punishment*, 79 MICH. L. REV. 386, 401 (1981). For a discussion of the social costs of imprisonment, see, e.g., John Hagan, *Social Costs of Incarceration*, 21 AM. B. FOUND. RES. L., no. 3, Summer 2010, at 1-6, *available at* http://www.americanbarfoundation.org/uploads/cms/documents/abf_rl_summer_2010.pdf. Remember also that this imposition of prison sentences for misdemeanors is "limited by 'marginal deterrence' concerns—the state is limited in the sanction it can impose for relatively minor crimes by the need to impose greater sanctions on more serious crimes." Arlen & Kraakman, *supra* note 89, at 687, n.21.

such severe individual sanctions can have a negative net effect on commerce both when they deter otherwise qualified individuals from taking these jobs in the first place and when individuals accept the job but are suboptimally deterred from lawful risky activity.[217]

Permissive exclusions can augment the monetary cost to a rational actor in excess of currently available personal wealth and can be a good alternative to prison sentences as a means of doing so. However, despite these benefits, exclusions are not without drawbacks. For example, when applied to an entity, exclusions are only factored in as an increased cost of fraud when the entity can continue as a going concern after discovery of their wrongdoing; however, in a thinly capitalized and closely held firm, after heavy sanctions are applied both to an entity and to a major shareholder individually, this is not a likely possibility. Second, when applied to individuals, these exclusions do nothing to provide remuneration for public harms; if individuals were allowed to continue their careers under increased oversight, they may still be forced to repay the cost of their harms when eligible claimants sue them personally.[218] Third, permissive exclusions against individuals are draconian in that they are career-ending sanctions applied to strict liability crimes, especially when applied in combination with the RCO Doctrine where the *actus reus* to which the exclusion is applied may not belong to the excluded individuals.[219]

Still, permissive exclusion can be an effective tool. If exclusions help deter individuals and preserve the entity from crushing monetary sanctions and/or exclusion, then the entity may be able to continue providing valuable products and ser-

217. *See, e.g.*, Joshua Safran Reed, *Reconciling Environmental Liability Standards After* Iverson *and* Bestfoods, 27 ECOLOGY L.Q. 673, 697 (2000) ("For corporations to hire and retain qualified officers, they must protect them from criminal liability. To the extent that they are unable to provide this protection, well qualified officers will become scarcer and consumers will suffer as stock prices go down and product prices go up."); Jonathan R. Macey, *Agency Theory and the Criminal Liability of Organizations*, 71 B.U. L. REV. 315, 319 (1991) ("Excessive enforcement can exacerbate this proclivity toward excessive risk avoidance, in turn, stifling innovation and creativity and leading to a general decline in social wealth.").

218. What I mean is that, if DOJ fines and OIG sanctions drain the wealth of the entity and the individual, claimants against those entities and individuals will have no source for remuneration.

219. This is not as likely in closely held firms as it is in publicly held firms.

vices to the public.[220] This illustrates the often-overlooked possibility that these health care companies, while culpable, provide a material benefit to the public, and that losing them may, itself, prove harmful to public welfare. More importantly, exclusions protect FHCPs and the public-at-large from these *fraudulent* actors repeating their gambles in the future.[221]

2. *Publicly Held Firms*

The effects of permissive exclusions on publicly held firms are mostly parallel to their effects on closely held firms. Permissive exclusions can augment the costs of fraud to a rational actor when considering ex ante whether or not to engage in fraud.

As with the RCO Doctrine, such severe penalties for strict liability crimes do not provide the same kind of behavior improvements that negligence crimes provide because there is no hypothetical "reasonable person" to emulate.[222] This is not a concern in closely held firms where we assume the actor is rationally bad—her actions were well-calculated due to their profitability, and there was no attempt to emulate a reasonable person. However, in the publicly traded context where a health care executive is more likely to be removed from the offense, their pursuit of ideal behavior is not informed by these convictions. These executives are unsure what changes to make because there is no reasonable person standard; instead, they simply know that they must be vigilant. Thus, as previously argued, the combination of the RCO Doctrine and OIG exclusions—i.e., the RCO Doctrine "with teeth"—in the context of a publicly held firm is only appropriately applied to a culpable rational actor under the burden-lowering perspective. If prosecutors apply the RCO Doctrine under the vicarious liability perspective, OIG should withhold excluding those individuals unless there is some evidence that prosecutors' past applications of the RCO Doctrine under this perspective

220. For example, Mark Hermelin agreed to resign from KV Pharmaceutical, sold all of his shares in the company, and resigned as trustee of family accounts that had shares in KV Pharmaceutical in order to prevent OIG from excluding the company. *See* Grizzle, *supra* note 158.

221. Of course, this effect only lasts as long as the exclusion period.

222. For an in-depth discussion of this concept, see Polinsky & Shavell, *supra* note 93.

is alone ineffective in motivating future corporate officers to adopt internal monitoring and compliance programs. At the time of this writing, the RCO Doctrine has been applied in this way too infrequently to be able to determine whether or not this is the case.

If OIG nonetheless wishes to exclude individuals under a vicarious liability perspective, and because prosecutors will not announce the perspective on which they are applying the RCO Doctrine, OIG should form a clear policy of abstaining from exclusions against any individual who maintained acceptable monitoring and compliance programs. Unlike in the RCO Doctrine, OIG has set a precedent for this kind of policy in their treatment of Howard Solomon at Forest Laboratories.[223] Although the exact weight, if any, that OIG applied to his maintenance of a robust compliance program in their decision to withhold exclusion is unknown, it was likely at least considered because it represented a significant part of Solomon's appeal.[224] OIG does not specifically state in their guidance that compliance programs will be considered in their decisions; instead, Solomon's attorneys inserted the compliance defense under the second factor in OIG's guidance: the individual's role in the sanctioned entity.[225] OIG should clarify in their guidance that compliance will be considered in these decisions going forward.

Recall that, according to OIG Chief Counsel Gregory Demske, OIG's exclusions are applied to protect FHCPs and not to punish individuals.[226] As such, when applied to a culpable actor, the purpose of ex post exclusion is presumably to deter future fraudulent actors in their ex ante decision. However, when applied under a vicarious liability perspective, the purpose should be (like the RCO Doctrine under this perspective) to encourage future officers to increase the probability of fraud detection through internal monitoring and compliance programs. Given that, the presence of such programs at the

223. *See* discussion *supra* Part III.E.

224. *See* Ropes & Gray Alert, *supra* note 174, at 2-3. The compliance program maintained by Solomon at Forest Laboratories was mentioned several times throughout the summary of the defenses used in his appeal.

225. *See id.* at 2.

226. *See* Transcript, *supra* note 85.

time of the fraudulent act should be an explicit defense against exclusion.

Permissible exclusions can also distort the plea bargaining process by occurring after and separate from sentencing. For example, defendants in these cases know that, due to the use of the RCO Doctrine and the lowered bar for meeting the *actus reus* requirement, they are very likely to be convicted, so they have often entered plea agreements that admit to being "responsible corporate officers" instead of risking trial. Except for unprecedentedly harsh sentences like those found in the Synthes case, they generally know what to expect out of a plea. However, after sentencing, another federal agency—OIG—can swoop in and apply a multi-year exclusion. This result is not easily anticipated or negotiated with prosecutors because it is applied by an entirely different party that has limited, if any, collaboration with the DOJ during the plea bargaining and sentencing stages of a particular case.[227] To remedy this, OIG and prosecutors should ideally work together in forming the contours of plea agreements so defendants know what lies ahead.

VI.
CONCLUSION

The prominence of health care fraud has understandably prompted a multi-faceted approach to increasing enforcement from the DOJ and OIG. The new measures are potent, resulting in significant potential costs to both companies and individuals, which warrants their examination using optimal deterrence principles. Because of the difference in agency costs, size, and complexity between closely held and publicly held firms, it is important to treat each as a separate context with different enforcement strategies.

With regard to closely held firms, the lack of agency costs and simple employee hierarchy encourage entity liability when the companies are well-capitalized since prosecution of the entity is relatively simple (given strict liability) and innocent shareholders are not likely to be present. The presence of some minimal amount of manager-employee agency costs may

227. The FDA's Office of Criminal Investigation recommends cases to the DOJ for prosecution but, to my knowledge, ceases to be significantly involved after prosecution and is not part of sentencing or plea bargaining.

allow some room for compliance programs and internal sanctions, but it is not likely to be very beneficial. However, it is relatively easy in the closely held context to maintain a thinly capitalized firm in order to engage in a fraudulent activity with little monetary risk to the entity, so individual liability is incredibly important. When firms are thinly capitalized, federal agencies should impose increased external oversight of those companies to increase the probability of detection. The RCO Doctrine can be appropriately utilized to maximize the probability of individual liability under the burden-lowering perspective because, under that perspective, you are targeting clients that are likely culpable. However, given the relative ease of proving *actus reus* in a small company with a simple employee structure, it may not be necessary or important. In the closely held context as we have defined it, the vicarious liability perspective is not applicable. Finally, OIG's permissive exclusionary authority should be used to increase the assets at risk for the culpable defendant. It nonetheless remains important that these enforcement tools are used with caution to avoid unfair results against individuals.

In the publicly held context, the presence of agency costs makes both external and internal oversight more important, so the DOJ and federal agencies should use their authority to impose external and internal ex ante oversight at companies that are thinly capitalized or are otherwise at high risk of lucrative fraudulent activity with a low probability of detection. Similarly, the same federal authorities should impose external and internal ex post oversight against companies that have already been indicted to ensure that agency costs are sufficiently accounted for.

The RCO Doctrine is even more important against publicly held firms given the relative ease with which managers can separate themselves from the tasks of front-line employees. Against culpable corporate officers—like those we assumed existed in the closely held context—prosecutors should take advantage of the ability to impute *actus reus* by utilizing the RCO Doctrine under a burden-lowering perspective. Against corporate officers who are innocent—i.e., under the vicarious liability perspective—the RCO Doctrine should not be applied. In these cases, because there is no reasonable person standard, strict liability does not provide a benchmark for an officer's ex ante behavior, and there are insufficient judicial defenses currently in place to protect defendants from unfair results. Therefore, in order to protect these innocent officers from an indiscriminate prosecutor, there should be reform to the RCO Doctrine that adds a *Caremark*-like defense. This would judicially add a reasonable person standard as a defense to these strict liability crimes that would enable officers to police and prevent fraud in good faith without the danger of severe sanctions.

Finally, OIG should use permissive exclusions to prevent especially culpable actors from repeating their offenses at another company ex post and also to increase the ex ante expected costs for rational fraudulent actors. However, these measures must be used judiciously—by applying a narrower standard than that of the RCO Doctrine—in order to avoid unfair results. To this end, if OIG exclusions are to be used under a vicarious liability perspective, they should add an explicit defense to their guidelines for exclusion that considers the presence of an internal monitoring and compliance program as a strong mitigating factor.