

## **RESPONSIBLE CORPORATE OFFICER DOCTRINE: WHEN IS FALLING DOWN ON THE JOB A CRIME?**

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### PROLOGUE

*A federal inspection of a company whose tainted pain medicine has caused one of the worst public health drug disasters since the 1930s found greenish-yellow residue on sterilization equipment, surfaces coated with levels of mold and bacteria that exceeded the company's own environmental limits, and an air-conditioner that was shut off nightly despite the importance of controlling temperature and humidity. The findings, made public on Friday by the Food and Drug Administration, followed a report from Massachusetts regulators on Tuesday and offered disturbing new details in an emerging portrait of what went wrong inside the New England Compounding Center, the pharmacy at the heart of a national meningitis outbreak in which 25 people have died, 313 more have fallen ill and as many as 14,000 people are believed to have been exposed.*

*Instead of producing tailor-made drugs for individual patients, as the law allowed, the company turned into a major drug maker that supplied some of the most prestigious hospitals in the country, including ones affiliated with Harvard, Yale and the Mayo Clinic, all with minimal oversight from federal regulators.*

*Federal officials also drew attention to the company's proximity to a recycling plant where excavators and freight trucks heaped old mattresses, plastics and other materials, generating large amounts of dust. The plant, which is owned by one of the same people as the pharmacy, has not always complied with regulations and has drawn complaints, according to records in Framingham, Massachusetts, where the company is located.*

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\* Professor of Law, Seton Hall Law, Center for Health & Pharmaceutical Law & Policy. My colleagues Charles Sullivan and, in particular, Stephen Lubben and Jordan Paradise, were very helpful in their comments, but errors remain mine. I also benefited from the perspective of an industry executive, although we ultimately and respectfully disagree. Journal Editors Katherine Ledden and Jessica Bailey were nothing short of superb. Seton Hall Center for Health & Pharmaceutical Law & Policy receives funding from a variety of entities, including life sciences companies. Professor Boozang does not personally benefit from such funding.

And as the death toll continues to rise, the F.D.A.'s commissioner, Dr. Margaret Hamburg, who was appointed by President Obama, has stayed mostly silent.

Some observers said that weighing in loudly and publicly on a contentious issue was simply not Dr. Hamburg's style. Others said that it was because the agency was preparing a criminal case and would not want to endanger that with statements construed to be prejudicial. David Kessler, a former F.D.A. commissioner, pointed to the impending presidential election and efforts to keep the outbreak from becoming a political issue.

"Everyone is closed down right now," he said. "People are being very careful. No one wants to make a mistake."

The inspection report offered the clearest indication yet that the fungus that contaminated the company's vials of methylprednisolone acetate, an injectable pain medicine, may have gotten there because of the company's own practices.

Inspectors said that 83 out of 321 vials from one of the lots linked to the meningitis outbreak that they observed contained "greenish black foreign matter" and another 17 vials had "white filamentous material."

The report said the company had tested only one sample from that lot, and it had proved sterile. When the F.D.A. tested 50 vials from that same lot, all of them contained some microbial growth.

Experts said that perhaps the most worrisome finding was that the company's own testing between January and September found surfaces in the clean rooms contaminated with either bacteria or mold exceeding the levels at which the company's own procedures called for remedial measures. In some cases, there were so many bacteria or fungi in a sample that the whole testing dish was overrun with a so-called overgrowth.

"Think of a plant just growing out of control," said Steven Lynn, director of the Office of Manufacturing and Product Quality at the F.D.A. Yet, according to the agency, there was no evidence the company took remedial actions.

"This is pretty heinous stuff," said Lou Diorio of LDT Health Solutions, a consultant to compounding pharmacies. "This just shows a general lack of basic clean-room principles."<sup>1</sup>

People continue to fall ill and die across nineteen states from the contaminated products of the New England Compounding Company (NECC). NECC escaped punishment for repeated regulatory gaps since its opening in 1999, by a husband and wife who teamed up with a brother-in-

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1. Sabrina Tavernise & Andrew Pollack, *F.D.A. Details Contamination at Pharmacy*, N.Y. TIMES, Oct. 26, 2012, <http://www.nytimes.com/2012/10/27/health/fda-finds-unsanitary-conditions-at-new-england-compounding-center.html?pagewanted=all>.

law to grow a business whose products, until October 2012, were distributed in all fifty states.<sup>2</sup> Lawsuits have already been filed.<sup>3</sup> Bankruptcy is predicted.<sup>4</sup> All NECC products shipped in 2012 have been “voluntarily” recalled.<sup>5</sup> An FDA inspection revealed numerous conditions<sup>6</sup> that are likely violations of the Food, Drug and Cosmetic Act.<sup>7</sup> The State Board of Pharmacy has voted to revoke the licenses of the NECC, its pharmacists, and NECC’s husband-wife owners.<sup>8</sup>

These outcomes are predictable, and the minimum one would expect. The pressing question is whether the owners and/or managers should bear any criminal responsibility, and whether such criminal liability is possible if the government is unable to establish criminal intent or precise knowledge of the conditions of the laboratories by the owners and top executives. Under a recently resurrected and highly controversial doctrine called the Responsible Corporate Officer Doctrine, the answer to both questions is yes. This Article explains the RCO Doctrine, and defends its use in egregious cases such as what apparently has transpired in the NECC case.

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2. Toni Clarke & Tim McLaughlin, *New England Compounding Center, Pharmacy Tied to Meningitis Outbreak, Avoided Sanctions Several Times from Health Regulators*, HUFFINGTON POST, Oct. 23, 2012, [http://www.huffingtonpost.com/2012/10/23/meningitis-outbreak-new-england-compounding-center\\_n\\_2004234.html](http://www.huffingtonpost.com/2012/10/23/meningitis-outbreak-new-england-compounding-center_n_2004234.html).

3. Todd Wallack, *Bankruptcy Likely for Framingham Firm Linked to Meningitis Infections*, BOSTON GLOBE, Oct. 19, 2012, <http://www.boston.com/business/technology/2012/10/19/new-england-compounding-center-likely-file-bankruptcy-stop-flood-lawsuits/PuUllvr1CVFy7nubfbTbwO/story.html>.

4. *Id.*

5. *See id.*

6. The FDA’s multiple October 2012 inspection reports are available at Inspectional Observations from the U.S. Food & Drug Admin., to Barry J. Cadden, Owner, New England Compounding Pharmacy Inc. (Oct. 26, 2012), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM325980.pdf> (reporting vials of an injectable drug containing a “greenish black foreign matter” with other vials containing “what appeared to be white filamentous material” with sterility samples revealing the presence of viable microbial growth and fungal morphological features).

7. News Release, U.S. Food & Drug Admin., FDA Reports Conditions Observed at New England Compounding Center Facility (Oct. 26, 2012), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm325994.htm>.

8. Chelsea Conaboy & Kay Lazar, *New England Compounding did not Follow Sterility Procedures, Investigators Find; State Orders Regular Inspections of Similar Pharmacies*, BOSTON GLOBE, Oct. 23, 2012, <http://www.boston.com/whitecoatnotes/2012/10/23/new-england-compounding-did-not-follow-sterility-procedures-state-revokes-pharmacy-license-and-orders-regular-inspections-similar-compounders/tHluCSNUWjP1IVs5OhUHNI/story.html>.

## I. INTRODUCTION

For three decades, state and federal enforcement agencies have invested significant energy in attempted reforms of the health care industry<sup>9</sup> with particular recent focus on the manufacturers of pharmaceuticals and medical devices. As the biggest purchaser of these products in the United States,<sup>10</sup> the government has particular interest in product usage that is actually or potentially harmful to patients or is inappropriate,<sup>11</sup> thereby unnecessarily driving up the nation's healthcare bill. As such, enforcement agencies have pursued new theories borne out of fraud, waste, and abuse laws to reform, in a fundamental way, how manufacturers of drugs and devices price, promote, and sell their products.

The failure of two disparate regulatory regimes has created the environment into which the Justice Department (DOJ) and Health and Human Services Office of Inspector General (OIG) have intervened with their aggressive reform agenda. First is the perverse marketing incentive created by the relationship between the patent laws and Food and Drug Administration (FDA) approval, particularly with drugs. Second is the failure of the laws governing directors' exercise of their fiduciary duties to impel boards to pursue their company's strict adherence to the law. These failures have created what enforcement agencies believe to be an atmosphere of corporate impunity in an industry whose products are essential to the world's

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9. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created the Health Care Fraud and Abuse Control Program, which is jointly overseen by the Attorney General and the Health and Human Services Office of Inspector General. Jason Chimon et al., *Health Care Fraud*, 48 AM. CRIM. L. REV. 783, 821-22 (2011).

10. See *id.* at 785; *Insurance and Medicare/Medicaid*, ABOUT.COM (2012), <http://pharma.about.com/od/Insurance-and-Medicare/Insurance-And-Medicare-Medicaid.htm>. Referred to as the Big 4, the "four largest purchasers of pharmaceuticals within the Federal government [are] Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard. . . . [T]he Big 4 often get pricing below the [Federal Supply Schedule] on brand name drugs because these drugs are subject to a maximum statutory price called the Federal Ceiling Price." 340B Dictionary, HEALTH RES. & SERVS. ADMIN., <http://www.hrsa.gov/opa/faqs/dictionary/index.html> (last visited Oct. 12, 2012).

11. Approximately 21% of prescriptions overall in the medical office setting were off-label solely in terms of the indication or purpose for which the medication was prescribed, although some categories of medications—specifically, cardiac medications and antiasthmatics for allergies—had much higher rates, approaching or exceeding 50%. David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1025 (2006). Off-label prescribing of medications for psychiatric conditions appears to be higher than that for other medical conditions. *Id.*; Hua Chen et al., *Off-Label Use of Antidepressant, Anticonvulsant, and Antipsychotic Medications Among Georgia Medicaid Enrollees in 2001*, 67 J. CLINICAL PSYCHIATRY 972, 975 (2006) (stating 75% of antidepressant recipients and 80% of anticonvulsant recipients received at least one of these medications off label).

health and welfare. The indispensability of drugs and devices has made it almost impossible to criminally prosecute life science companies because convictions would bar them from contracting with most nations' governments, which would thereby deny their citizenry access to (potentially) essential medicines.<sup>12</sup> It is this unique set of circumstances that justifies the DOJ's use of the Responsible Corporate Officer (RCO) Doctrine against, and Department of Health and Human Services (HHS) debarment from Federal healthcare programs of, officers and directors when the legal doctrine is violated, and the facts underlying the violation and the threats to public health are clear.

Drug and device manufacturers reap huge profits on a product while it remains on patent, that is, it retains market exclusivity — thereafter, generics enter the market creating price competition and reducing the sales volume for every market participant. But they have to get the product to market, as the period of clinical trials and FDA market approval eats into the life of the patent;<sup>13</sup> the incentive, then, is to test the product in a narrow population for a limited purpose, to ensure speed and positive trial outcomes. Once the product hits the market, the incentive reverses — to promote the product for as many potential patients and uses as plausible, thereby enhancing revenue as much as possible during the period of market exclusivity.

While the FDA and OIG posit that the Food Drug and Cosmetic Act prohibits "off label marketing,"<sup>14</sup> physicians are not subject to FDA

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12. See *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)* [hereinafter *Morris Testimony*] (statement of Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health & Human Services). This applies outside of the United States as well; industrialized health care systems are government-sponsored in one form or another, and drug prices are regulated or negotiated; consequently, the government is the primary purchaser of drugs and devices. See Dennis S. Corgill, *Distributing Products Under The Nonprofit Institutions Act: Price Discrimination, Arbitrage, And Fraud In The Pharmaceutical Industry*, 2001 BYU L. REV. 1383, 1398 n.45; see James B. Roche, *Health Care In America: Why We Need Universal Health Care and Why We Need It Now*, 13 ST. THOMAS L. REV. 1013, 1028-35 (2001).

13. See Isabelle Bibet-Kalinyak, *A Critical Analysis of Sorrell v. IMS Health, Inc.: Pandora's Box at Best*, 67 FOOD & DRUG L.J. 191, 194-95 (2012). A pharmaceutical patent lasts for twenty years. 35 U.S.C. § 154(a)(2) (2006). While a portion of this time is obviously lost during to the approval process, the Hatch-Waxman Act restored some of that time, with a five year cap. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1590 (codified as amended in scattered sections of 15, 21, 35, 42 U.S.C. (2006)); see also Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033, 1038 n.20 (2012).

14. John N. Joseph et al., *Is Sorrell the Death Knell for FDA's Off-Label Marketing Restrictions?*, 5 J. HEALTH & LIFE SCI. L. 3, 4 (2012). As observed by a recent article, "there is no specific FDA regulation that expressly prohibits off-label marketing or that defines what activities qualify as off-label marketing. Rather, FDA's enforcement actions typically are

jurisdiction and may legally prescribe drugs “off label” for unapproved uses, or in populations in which the drug was not tested.<sup>15</sup> Further complicating the matter, it is frequently the case that such off-label use represents the standard of care for treatment in certain circumstances,<sup>16</sup> and the off-label use may be eligible for Medicare and/or Medicaid reimbursement.<sup>17</sup> While the FDA has jurisdiction over off-label marketing activities, it is under-funded and has been ineffective in stopping the well-funded and pervasive practices of manufacturers’ sales divisions.<sup>18</sup>

The marketing techniques that have so attracted the government’s attention also create conflicts of interest that could result in inappropriate prescribing or product selection.<sup>19</sup> These inducements to physicians to prescribe particular products have been extensively categorized elsewhere, and have included expensive meals and gifts, free trips to conferences in exotic locales, payments for sham research and attribution for ghost written articles, excessive payments for legitimate research, payments to speak about company products to peer physicians, underwriting of continuing medical education programs, and any variety of consulting arrangements that may or may not be legitimate.<sup>20</sup> An important role that drug and device sales representatives, sometimes referred to as detailers, have served as a significant resource for physicians struggling to remain current about the latest treatments available for their patients.<sup>21</sup> These detailers focus on new, and therefore the most expensive drugs (those that are on patent),<sup>22</sup> do not

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premised on the theory that a drug is illegally “misbranded” under the Food, Drug, and Cosmetic Act (FDCA) if it is marketed for a use inconsistent with the directions on its label.” *Id.*

15. 21 U.S.C. § 396 (2006) (stating that “[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”).

16. Erin E. Bennett, Comment, *Central Hudson-Plus: Why Off-Label Pharmaceutical Speech Will Find Its Voice*, 49 HOUS. L. REV. 459, 460-61 (2012).

17. Copeland, *supra* note 13, at 1043.

18. The FDA may also be limited in its efforts by the First Amendment. Joseph et al., *supra* note 14, at 7.

19. See generally TRACY MILLER ET AL., SETON HALL CTR. FOR HEALTH & PHARM. LAW & POLICY, DRUG AND DEVICE PROMOTION: CHARTING A COURSE FOR POLICY REFORM (2009), available at <http://law.shu.edu/ProgramsCenters/HealthTechIP/upload/whitepaperjan2009.pdf> (discussing conflicts of interest resulting from industry-physician financial relationships).

20. *Id.* at 1, 10-12, 14.

21. *Id.* at 1, 11-12.

22. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 46 (1st Cir. 2008), *abrogated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011). As described by the First Circuit:

“Detailing involves tailored one-on-one visits by pharmaceutical sales representatives with physicians and their staffs. This is time-consuming and expensive work, not suited to the marketing of lower-priced bioequivalent generic drugs (drugs that are

engage in a comparative effectiveness analysis of these new products with older and less costly products or alternatives, such as diet and exercise,<sup>23</sup> and have been known to liberally push the products' prescription for patient groups on whom they have not been tested, *i.e.*, children, or for uses that have not been approved by the FDA.<sup>24</sup> Manufacturers supply their sales representatives with copious amounts of information about their physicians' prescribing patterns and background to facilitate these sales pitches.<sup>25</sup>

What is objectionable about the medical device industry's relationship with physicians is more difficult to sort out, because companies have relationships with many physicians that necessarily go beyond the sales visits described above.<sup>26</sup> For many devices, physicians require manufacturer training before using the product.<sup>27</sup> Further, once trained on a particular device, inertia or company loyalty may cause a physician to resist using another product, even if better or more cost effective for patients. But, the challenges go even deeper. In many instances, the actual inventor of the device is a physician who then sells or licenses the patent to a device company, which creates a symbiotic relationship, as the inventor-physician remains a key expert regarding that device. Whether he or she is indispensable to testing that device and teaching other physicians about it remains a challenging question. Whether he or she should be deployed as an expert speaker at continuing medical education meetings is difficult — where is the line between product promotion and scientific conversation? Further, medical device companies claim that, with new or technically

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pharmacologically indistinguishable from their brand-name counterparts save for potential differences in rates of absorption). The higher profit margins associated with brand-name drugs leaves the personal solicitation field open to brand-name drug manufacturers, who in the year 2000 spent roughly \$4,000,000,000 on detailing."

*Id.*

23. See Richard S. Saver, *Health Care Reform's Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research*, 159 U. PA. L. REV. 2147, 2175, 2203-04 (2011).

24. See generally Bibet-Kalinyak, *supra* note 13. Off-label prescribing is a common practice, particularly in certain medical specialties such as oncology and neuropsychiatry. It is also commonplace in certain populations such as pediatrics, pregnant patients, and "orphan disease" patients." *Id.* at 237.

25. See Sorrell, 131 S. Ct. at 2659-60.

26. See Bruce Patsner, *Problems Associated with Direct-to-Consumer Advertising (DTCA) of Restricted, Implantable Medical Devices: Should the Current Regulatory Approach be Changed?*, 64 FOOD & DRUG L.J. 1, 2 (2009) (discussing unique relationship between physicians and the device industry, which can enable device companies to circumvent restrictions on product promotion by use of physicians as surrogates and various financial relationships).

27. See *Surgeons for Sale: Conflicts and Consultant Payment in the Medical Device Industry: Hearing Before the S. Spec. Comm. on Aging*, 110th Cong. 1 (2008) [hereinafter *Demske Testimony*] (statement of Gregory E. Demske, Assistant Inspector General for Legal Affairs, Office of Inspector General, Department of Health and Human Services).

difficult products in particular, it is essential that company representatives see patients with the physician to calibrate the device, or in the operating suite to aid the physician in choosing the correct device or otherwise dealing with technical questions that arise.<sup>28</sup> A new trend is physician-owned device distributorships.<sup>29</sup> Critics claim that the companies should be training the physicians and their staffs to use their products independently, without manufacturers' representatives hovering about or becoming part of the physician-patient relationship.<sup>30</sup> Whether these interactions comprise important collaborative product development or promotional activity continues to challenge the government.

To summarize, life science companies earn significant income on their products while they remain on patent. Initial clinical trials and the resultant FDA approved labels are generally for narrow uses and populations that frequently do not represent the full spectrum of uses, populations, modes of delivery or dosage amounts for which physicians ultimately prescribe the drug.<sup>31</sup> Companies benefit by marketing for this full spectrum of alternative uses; the government objects to such marketing because it lacks evidence supported by clinical trials.<sup>32</sup> No incentive exists for companies to engage in clinical trials for these expanded uses due to the extraordinary cost, which may not be recovered while the product remains on patent, the fact that the trial most likely will not conclude before the patent expires, and because the trials may produce adverse evidence that undermines sales.<sup>33</sup>

The ineffectiveness of the law of directors' fiduciary duties is the second regulatory failure that may explain OIG and DOJ stepping up their enforcement actions against life science companies. The standards of review courts invoke in corporate fiduciary duty cases rarely result in findings of director liability in civil suits.<sup>34</sup> While the Delaware courts have expanded the duty of loyalty, debate persists over whether the obligation of good faith subsumed by the duty of loyalty requires strict adherence to the law. Increasingly, commentators and perhaps some judges view certain

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28. David S. Hilzenrath, *Medical Sales Reps Work Alongside Doctors, Even in Operating Rooms*, WASH. POST, Dec. 27, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/24/AR2009122403368.html>.

29. *Demske Testimony*, *supra* note 27, at 2.

30. Hilzenrath, *supra* note 28.

31. See James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANNALS HEALTH L. 295, 298 (2003).

32. *Id.* at 300.

33. *Id.* at 304, 307.

34. See ROBERT W. HAMILTON ET AL., CASES AND MATERIALS ON CORPORATIONS INCLUDING PARTNERSHIPS AND LIMITED LIABILITY COMPANIES 180 (11th ed. 2010) (including the business judgment rule discussion in *Sullivan v. Hammer*, 1990 WL 114223 (Del. Ch. 1990)).



regulations not as limits or prohibitions, but rather options or taxes, especially, as is the case with life sciences marketing, when the revenue net of sanctions is significant.<sup>35</sup>

As might be expected, OIG and DOJ have an entirely different perspective. These enforcement agencies hold the view that many of the operators in the life sciences industry are corrupt. Consequently, they seek structural reform to make life science companies better corporate citizens.<sup>36</sup> At an operational level, these enforcement agencies push the boundaries of the False Claims Act<sup>37</sup> and Anti-Kickback Statute<sup>38</sup> to get inside these companies to change their culture and organization, and to address the specific practices prosecutors wish to see eliminated.<sup>39</sup>

Specifically, OIG and DOJ have imposed elaborate corporate compliance programs,<sup>40</sup> entered into onerous corporate integrity

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35. See Cynthia A. Williams, *Corporate Compliance with the Law in the Era of Efficiency*, 76 N.C. L. REV. 1265, 1279-80 (1998).

36. Miriam Hechler Baer, *Governing Corporate Compliance*, 50 B.C. L. REV. 949, 953, 965 (2009); Kathleen M. Boozang & Simone Handler-Hutchison, "Monitoring" Corporate Corruption: DOJ's Use of Deferred Prosecution Agreements in Health Care, 35 AM. J.L. & MED. 89, 89-90 (2009); Brandon L. Garrett, *Structural Reform Prosecution*, 93 VA. L. REV. 853, 890 (2007). Reforms to the Federal Sentencing Guidelines for Organizations similarly aspired to corporate compliance facilitating corporate transformation. 2011 FEDERAL SENTENCING GUIDELINES MANUAL § 8B2.1(a)(2) (2011) (describing an effective compliance and ethics program as one which "promote[s] an organizational culture that encourages ethical conduct and a commitment to compliance with the law").

37. 31 U.S.C. §§ 3729-3733 (2006).

38. 42 U.S.C. § 1320a-7b (2006).

39. Outside of the United States, the Justice Department and Securities and Exchange Commission are employing the Foreign Corrupt Practices Act to achieve many of the same ends. See Foreign Corrupt Practices Act of 1977, Pub. L. No. 95-213, 91 Stat. 1494 (1977) (codified as amended at 15 U.S.C. § 78m(b), (d)(1), (g)-(h), 78dd-1, 78dd-2, 78dd-3, 78ff (2006)). "Of note is that France recently enacted a law specifically addressing off-label promotion." Joseph Emmerich et al., *France's New Framework for Regulating Off-Label Drug Use*, 367 NEW. ENG. J. MED. 1279, 1279-1281 (2012). This Article focuses on domestic reforms and does not address the two extremely important policy questions that hover over this entire debate. First is the argument that prohibiting off-label promotion discourages off-label prescribing, which is an activity important to innovation and many patients' health. See generally Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 63, 72 (2008). The second argument revolves around whether the FDA has the constitutional power under the First Amendment to regulate the provision of truthful and non-misleading product information to physicians. Kate Greenwood, *The Ban on "Off-Label" Pharmaceutical Promotion: Constitutionally Permissible Prophylaxis Against False or Misleading Commercial Speech?*, 37 AM. J.L. & MED. 278, 280 (2011); Joseph et al., *supra* note 14, at 4-5; see, e.g., Bibet-Kalinyak, *supra* note 13, at 191-92.

40. See *Morris Testimony*, *supra* note 12, at 7.

agreements (CIA)<sup>41</sup> and deferred prosecution agreements (DPA),<sup>42</sup> and imposed fines recently exceeding the one billion dollar mark to achieve these goals.<sup>43</sup> While some business practices in the life sciences industry have unquestionably and significantly changed,<sup>44</sup> it remains an open question whether the government's efforts have accomplished the ultimate goals of transforming corporate governance.<sup>45</sup> Many hold the belief that the continuing parade of CIAs suggests that fundamental transformation has not occurred, and business continues as usual.<sup>46</sup>

Given the unremitting pressure of government enforcement, what could explain industry behavior? An appealing hypothesis is that companies treat the astounding fines assessed against them, as well as the costs of corporate compliance,<sup>47</sup> as a cost of doing business.<sup>48</sup> Specifically, during the market-exclusivity period conferred by patent law, the revenues generated so greatly exceed the fines levied that the economically rational choice is to sell product, even while risking<sup>49</sup> penalties that would be exorbitant in other

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41. See generally Thomas F. O'Neil III and T. Brendan Kennedy, *Answering to a Higher Authority: Sovereign-Mandated Oversight in the Board Room and the C-Suite*, 17 *FORDHAM J. CORP. FIN. L.* 299, 348 (2012).

42. See Boozang & Handler-Hutchinson, *supra* note 36, at 91.

43. See, e.g., Press Release, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), available at <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>.

44. The OIG's operating assumption is that "health care fraud . . . migrates." Daniel R. Levinson, Inspector Gen., Dep't of Health & Human Servs., Highlights of the Keynote Address at the Health Care Compliance Association Annual Compliance Institute 3 (April 19, 2010), available at <http://oig.hhs.gov/testimony/docs/2010/HCCAIGKeynoteSummary.pdf>. That is, when the government clamps down on a particular behavior, another one replaces it. *Id.*

45. See Baer, *supra* note 36, at 965 (suggesting that corporate compliance and other Sarbanes-Oxley reforms have failed to stem corporate crime or affect corporate norms).

46. See Copeland, *supra* note 13, at 1034.

47. Actually, the marginal cost of corporate compliance is probably minimal with each new CIA. *Id.* at 1055; *Morris Testimony*, *supra* note 12, at 6. All major companies have robust compliance programs by now. Thus, the marginal cost of adhering to the specific training dictates of a new CIA is likely inconsequential. Copeland, *supra* note 13, at 1055, 1063-64; *Morris Testimony*, *supra* note 12, at 6.

48. In testimony before the House Committee on Ways and Means, HHS OIG then-Chief Counsel Lewis Morris stated, "[w]e are concerned that the providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business." *Morris Testimony*, *supra* note 12, at 6.

49. And the point is that detection and penalty assessment is only a risk. As described by Professor Williams,

"[r]ather, part of the calculation to violate the law includes a calculation of the probability that the violation will go undetected; or if detected, that it will go unprosecuted for any one of a plethora of reasons; or if prosecuted, that liability will not be established; or if liability is established, that the penalty will be lower than the profits obtained; or that the penalty will not be upheld on appeal in any event."

contexts.<sup>50</sup> This behavior is analogous to contract law's theory of efficient breach.<sup>51</sup> Life science companies pay a tax in lieu of regulatory adherence, which appears to be a rational choice during the patent life of their products.<sup>52</sup>

So, the question becomes, if we agree that the sought after changes in corporate behavior are desirable, and all else has failed in affecting change in corporate behavior, is there anything that will capture the attention of these companies to induce change? The ultimate problem is that the U.S. pharmaceutical industry is "too big to nail."<sup>53</sup> It comprises a handful of multinational companies that produce multiple products at least some of which are essential to the life, health and well-being of patients throughout the world. The essential nature of these companies' products limits the government's ability to criminally prosecute them. Recall that mere indictment of Arthur Anderson resulted in its demise.<sup>54</sup> An additional consequence to a life sciences company convicted of a crime is exclusion

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Williams, *supra* note 35, at 1279-80.

50. Copeland, *supra* note 13, at 1034; see also, Johnson, *supra* note 39, at 114-15 (noting that Parke-Davis paid over \$455 million to both the federal and state governments for off-label prescriptions for Neurontin in 2004, while having previously earned sales up to nearly \$2.5 billion in 2003 for off-label uses).

51. As explained by Professor Humbach,

"[e]xtending the rationale of efficient breach theory to legal and regulatory contexts, the corresponding idea would be a kind of 'theory of efficient crime.' Under this theory, whenever the benefit to the corporation from legal or regulatory violations would exceed the applicable fines and penalties (presumably discounted to reflect the risk of getting caught), then the corporation should commit the violations. Forsaking the benefits of breaking the law would be inefficient and a waste. So if a board makes a rational choice to take the corporation beyond the limits of the law, that choice (it is argued) should be protected by the business judgment rule."

John A. Humbach, *Director Liability for Corporate Crimes: Lawyers as Safe Haven?*, 55 N.Y.L. SCH. L. REV. 437, 439-40 (2010-11).

52. *But see* Williams, *supra* note 35, at 1278-80 (repudiating the efficient-breach theory, claiming that "the law ought to be understood to impose a prima facie obligation to comply, even when unprofitable").

53. *Morris Testimony*, *supra* note 12, at 5-6. In testimony before the House Committee on Ways and Means, HHS OIG Chief Counsel Lewis Morris stated that

"[s]ome hospital systems, pharmaceutical manufacturers and other providers play such a critical role in the care delivery system that they may believe that they are 'too big to fire' and thus OIG would never exclude them and thereby risk compromising the welfare of our beneficiaries."

*Id.*

54. Boozang & Handler-Hutchinson, *supra* note 36, at 96; Christopher McNamara, *How the Decisions in Favor of the Stein Thirteen Will Affect the Litigation of Corporate Crime and Department of Justice Policies and Expand the Sixth Amendment Right to Counsel*, 78 FORDHAM L. REV. 933, 956 n.240 (2009).

from any Federal healthcare program,<sup>55</sup> which would make the drug unaffordable for significant portions of the population. The company would likely go out of existence, thereby threatening to deny the public the drug entirely<sup>56</sup> while the company would presumably sell or license the patent to another company, it would take significant time for the licensee to gear up to manufacture the drug, which may not be worthwhile, depending upon the remaining life on the patent.<sup>57</sup> Sale of the entire company to avoid debarment would be wholly dependent upon the OIG's consent;<sup>58</sup> given its recent compelled sale in the *Synthes* case, it seems that it would be open to such a solution.<sup>59</sup> Such a sale would not relieve the company of its fines or CIA obligations, which may make it an unappealing acquisition.<sup>60</sup> Medical device companies are much more numerous, with many bringing only one significant product to market.<sup>61</sup> While perhaps not too big to nail in a general sense, the niches such companies fill are often critical to those using their products.

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55. 42 U.S.C. § 1320a-7 (2006); 42 C.F.R. § 1001.101 (2011). Regulations provide for the exclusion of pharmaceutical and medical device manufactures, as well as others in the supply chain, even if not direct recipients of federal reimbursement. 42 C.F.R. § 1000.10.

56. See *Morris Testimony*, *supra* note 12, at 6.

57. 35 U.S.C. § 154(a)(2) (2006) (stating the term of a patent is twenty years).

58. Corporate Integrity Agreements traditionally include a Sale of Unit or Location Clause requiring the signee to notify OIG. This clause further states that the CIA will be binding on the purchaser of the business unit or location. See, e.g., OFFICE OF THE INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SYNTHES, INC. 31-32 (2010), available at [https://oig.hhs.gov/fraud/cia/agreements/synthes\\_inc\\_09232010.pdf](https://oig.hhs.gov/fraud/cia/agreements/synthes_inc_09232010.pdf) [hereinafter *Synthes CIA*]; see, e.g., OFFICE OF THE INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND GLAXOSMITHKLINE, LLC. 50-51 (2012), available at [https://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline\\_LLC\\_06282012.pdf](https://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline_LLC_06282012.pdf).

59. OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., DIVESTITURE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SYNTHES INC. 2 (2010), available at [http://www.justice.gov/usao/pae/Pharma-Device/synthes\\_divestagrmt.pdf](http://www.justice.gov/usao/pae/Pharma-Device/synthes_divestagrmt.pdf).

60. E.g., *Synthes CIA*, *supra* note 58, at 32. It may be that the offending company's assets could be sold under the Bankruptcy Code, leaving the sale proceeds to satisfy the fines and other liabilities. 11 U.S.C. § 363(f) (2006). Such a process recently was used with regard to the automakers. See generally Stephanie Ben-Shai & Stephen J. Lubben, *Involuntary Creditors and Corporate Bankruptcy*, 45 U.B.C. L. REV. 253 (2012).

61. MED. DEVICE MFRS. ASS'N & NAT'L VENTURE CAPITAL ASS'N, MEDICAL TECHNOLOGY AND VENTURE CAPITAL: A FRUITFUL YET FRAGILE ECOSYSTEM 2 (2009), available at <http://www.medicaldevices.org/node/656>; see Yair Holtzman, *The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad*, MED. DEVICE & DIAGNOSTIC INDUSTRY (July 17, 2012), <http://www.mddionline.com/article/medtech-2012-SWOT>.

Circumscribed by this reality, FDA and OIG have upped the ante and are now employing a rarely used doctrine that holds criminally responsible those corporate officials who are in a position to discover and prevent the illegal behaviors that present a threat to the public health that occur on their watch.<sup>62</sup> Following conviction, OIG may exclude the officials from the Federal healthcare programs, which ends the individual's career in healthcare.<sup>63</sup> The invocation of this doctrine with resultant exclusion from Federal healthcare programs has provoked outrage.<sup>64</sup>

This Article accepts the constraints of "too big to nail" under which enforcement agencies are laboring in their oversight of life science companies, and that the tools used thus far by enforcement agencies may be insufficient to capture the attention of the most egregious actors.<sup>65</sup> It concludes that, while the RCO Doctrine may be an appropriate tool for corporate reform, and in some rare instances should be available to prosecute and exclude directors as well, the doctrine should not be employed to address behaviors about which the government's public policy rationale is not unassailable, the law is in dispute, or about which little recent case law exists.<sup>66</sup> Specifically, while the RCO Doctrine may be appropriate to pervasive false marketing of a product which threatens patient harm, it is ill-suited to situations where the underlying legal theory is largely untested through litigation, or involves off-label marketing that represents the standard of care, or uses for patients with no or few treatment options who appear to be helped by the product.

## II. IT PAYS TO BREAK THE LAW

Why do life science companies continue to have so many legal problems, even in the face of exorbitant fines and investigations that are

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62. See discussion *infra* Part II.B.1; see also Levinson, *supra* note 44, at 5 (explaining that OIG is focused on holding corporate officials accountable for health care fraud using the "Responsible Corporate Officer" doctrine).

63. *Morris Testimony*, *supra* note 12, at 5.

64. The Washington Legal Foundation, for example, was very involved in the *Friedman* case from its inception, including the filing of briefs. Brief of the Washington Legal Foundation as Amicus Curiae in Support of Petitioners at 1, *Goldenheim*, DAB No. CR1883, 2009 WL 2912444 (H.H.S. 2009), available at <http://www.wlf.org/Upload/litigation/briefs/Goldenheimv.IG-WLFAmicus.pdf>; Brief of Amicus Curiae Washington Legal Foundation at 1, *Friedman v. Sebelius*, 672 F. Supp. 2d 54 (D.D.C. 2009), available at <http://www.wlf.org/Upload/litigation/briefs/FriedmanvSebelius-WLFAmicus.pdf>; Brief of Washington Legal Foundation as Amicus Curiae in Support of Appellants Urging Reversal at 1-2, *Friedman v. Sebelius*, No. 11-5028, 2012 WL 3055520 (D.C. 2011), available at <http://www.wlf.org/Upload/litigation/briefs/FriedmanvSebelius-WLFAmicusJune29.pdf>.

65. See *supra* Part I.

66. See *infra* Part II.B.3, II.C.

onerous? Industry would respond fairly, many of the most offensive promotional practices have been significantly reined in at many companies.<sup>67</sup> Further, the institution of Corporate Compliance programs has impacted employee behavior in many settings. The days of extravagant weekend conferences at spas or on cruises have disappeared, as have the innumerable opportunities for free meals, hard-to-get tickets, and the variety of equipment and desk accessories that used to come physicians' way for their birthdays and holidays.<sup>68</sup> Other questionable practices, however, continue. Ghost writing seems not to have been eliminated, and companies now employ medical science liaisons, generally medical doctors or Ph.D.s, to answer physicians' questions about off-label uses, which the industry claims comprises scientific communication not subject to FDA regulation.<sup>69</sup> They also continue to distribute peer-reviewed studies of off-label practices under the watchful eye of the FDA, although such personal conversations are impossible to monitor for compliance.<sup>70</sup>

Government would respond that the fundamental structural problems have not been resolved, and that true ethos reform has yet to occur.

Related somewhat to the prior response, is that it makes economic sense to ignore certain laws, even if at the risk of incurring significant fines. OIG and DOJ to the contrary, many would argue that there is nothing wrong with life science companies making this choice. That is, to choose to "pay the price" to violate certain regulations,<sup>71</sup> sometimes referred to as the "efficient breach of public law."<sup>72</sup> Professor Coffee succinctly explains the efficient breach perspective:

Legal rules that exact a "price" thus straddle the deterrent/compensatory watershed because they seek to do both; that is, they seek to make victims whole and to induce precautions that avert future injuries. Clearly, their purpose is not prohibitory in the sense of forbidding entirely the activity in

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67. See Robert Steinbrook, *Physician-Industry Relations – Will Fewer Gifts Make a Difference?*, 360 NEW ENG. J. MED. 557, 557-58 (2009).

68. *Id.*; see PHARM. RESEARCH & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (2008), available at [http://www.phrma.org/sites/default/files/108/phrma\\_marketing\\_code\\_2008.pdf](http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf).

69. *Drug Companies Float Off-Label Reg Limits; FDA Mulls Scientific Exchange*, FDA WEEK, Apr. 6, 2012, at 2; see generally MINORITY STAFF REPORT, S. COMM. ON FINANCE, 111TH CONG., GHOSTWRITING IN MEDICAL LITERATURE 2 (2010) ("Medical ghostwriting is a practice where pharmaceutical or device companies hire medical education, marketing or communications companies to draft articles that are presented to prominent physicians and scientists to sign on as authors to increase the likelihood that the article will be published in important medical journals.").

70. Adriane Fugh-Berman & Douglas Melnick, *Off-Label Promotion, On-Target Sales*, 5 PLOS MED. 1432, 1434 (2008).

71. Williams, *supra* note 35, at 1279.

72. *Id.* at 1267.

question by imposing penalties greater than the social costs created by the activity. Indeed, if the defendant's benefit from the conduct exceeds the victim's loss (adjusted to reflect the limited likelihood of apprehension), the defendant is free under optimal deterrence theory to engage in conduct that harms others at will, so long as the defendant pays all compensation.<sup>73</sup>

The concept of efficient breach in the corporate context represents a determination that it is economically preferable to violate an under-enforced law due to a calculation that the probability of enforcement occurring at all, factored by the likelihood that the particular actor will be detected factored by the probability of liability represented by the ultimate fine is less than the benefits to the corporate actor of not following the law.<sup>74</sup> Intuitively, we know that even law and economics theorists would not take the position with respect to all crimes. Rather, the consensus of the law and economics literature on the strategic decision to breach and pay is “that committing acts that are *malum in se* cannot be ethically defended with a simple willingness to pay the price.”<sup>75</sup> However, in the case of “matters that are *malum prohibitum*, a strategy of breach-and-pay not only makes sense and should be legally permitted, but is also ethically defensible.”<sup>76</sup>

On the side of enforcement, Professor Cynthia Williams posits that the law represents obligations applicable to all, including corporations.<sup>77</sup> She rejects the theory of a “private right to violate public law when it is profitable”<sup>78</sup> as a theory that over-emphasizes shareholder wealth-maximization thereby leading to ethically and politically problematic corporate behavior that threatens society and our democracy.<sup>79</sup> Williams advances a vision that is more public-regarding, affording both freedom and concomitant responsibilities to corporations — the option to buy out of adhering to health, safety and other regulations is contrary to the corporation’s obligations as a citizen, according to Williams.<sup>80</sup>

Several factors distinguish the behavior of the life sciences industry from that described in the literature on efficient breach. First, the pharmaceutical industry would argue that it is no longer operating in an environment of under-enforcement. In 2011, the Federal Government recovered \$2.4

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73. John C. Coffee, Jr., *Paradigms Lost: The Blurring of the Criminal and Civil Law Models – And What Can Be Done About It*, 101 YALE L.J. 1875, 1883 (1992).

74. See generally Daniel T. Ostas, *Legal Loopholes and Underenforced Laws: Examining the Ethical Dimensions of Corporate Legal Strategy*, 46 AM. BUS. L.J. 487 (2009) (examining arguments in favor of efficient breach).

75. *Id.* at 497.

76. *Id.*

77. Williams, *supra* note 35, at 1271-72.

78. *Id.* at 1377-78.

79. *Id.* at 1381-82.

80. See *id.* at 1385.

billion in fraud judgments and settlements — this amount does not reflect state or joint federal-state recoveries.<sup>81</sup> Notably in 2011, HHS allocated \$3.4 million in funding for a FDA Pharmaceutical Fraud Pilot Program to enhance the FDA's criminal investigatory work, with a focus on "fraudulent marketing schemes, application fraud, clinical trial fraud, and flagrant manufacturing-related violations related to biologics, drugs, and medical devices."<sup>82</sup> Further, laws that govern the healthcare sector increasingly require self-reporting of detected deviations from the law,<sup>83</sup> with an expectation of mitigation of sentencing articulated in the Federal Sentencing Guidelines, and increased fines if the behavior remains unreported by a corporate entity to the government.<sup>84</sup>

In the absence of data, there are reasons to believe that even stepped-up law enforcement remains an inadequate response to efficient breaches that continue to generate significant revenue, which likely explains the continuing and dramatic escalation of fines in the last year. First of all, CIAs last only three to five years.<sup>85</sup> Companies' repeated settlements with the government, albeit involving different subsidiaries and products, suggest that any real reform that might be limited to the period of the settlement agreement and to the particular products and corporate divisions subject to the agreement. Also unclear is whether the bad publicity attendant to government settlements adversely affects the largest life science companies — physicians are not going to stop prescribing products that patients require, and most shareholders are unaffected by such publicity, especially if the entire industry is subject to the continued disapprobation.

In the healthcare context, the government goal seems not merely to eliminate behaviors that are costly to government programs and potentially harmful to beneficiaries, but to accomplish wholesale reform of corporate norms.

#### A. *Fiduciary Duties as Aspirations*

Corporate law directly addresses expectations about individual officers' and directors' management. It too is inadequate to inspire "an ethical tone at the top" or general corporate ethos reform. In fact, the weakness of

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81. DEP'T OF HEALTH & HUMAN SERVS. & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2011, at 1 (2012), available at <http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2011.pdf>.

82. *Id.* at 73.

83. See, e.g., Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399, 58,400 (Oct. 30, 1998).

84. 2011 FEDERAL SENTENCING GUIDELINES MANUAL, *supra* note 36, § 8C2.5.

85. Sharon Finegan, *The False Claims Act and Corporate Criminal Liability: Qui Tam Actions, Corporate Integrity Agreements and the Overlap of Criminal and Civil Law*, 111 PENN. ST. L. REV. 625, 663 (2007).



corporate law is that the concepts are largely aspirational rather than mandatory: directors do not perceive they are breaking the law when they behave in a negligent but not grossly negligent fashion, or approve a transaction that is fair but not in the corporation's best interests in a conflicted transaction.<sup>86</sup> The absence of liability, it is reasoned, must mean that the directors acted within the law.<sup>87</sup> While Delaware opinions themselves attempt to distinguish between aspirational ideals and that for which fiduciaries may be liable,<sup>88</sup> the question is whether the Delaware case law stands for the proposition that directors' fiduciary duties are themselves merely aspirational ideals that are actually unattainable.<sup>89</sup>

Directors' and officers' risk of liability<sup>90</sup> for breach of their fiduciary duties of care and loyalty is low.<sup>91</sup> The duty of care requires boards to engage ordinary care in the processes by which they make decisions, and to supervise and monitor the activities of corporate managers; however, liability results only when the fiduciaries' behavior constitutes gross negligence.<sup>92</sup> Thus, while the duty of care employs a negligence standard, the standard of review in actually applying the law is one of gross

86. See Julian Velasco, *The Role of Aspiration in Corporate Fiduciary Duties*, 54 WM. & MARY L. REV. 519, 521-22 (2012).

87. See generally *id.* (summarizing the literature that suggests that the standards of conduct articulate aspirational norms, while the standards of review determine liability).

88. "But Delaware law does not – indeed, the common law cannot—hold fiduciaries liable for a failure to comply with the aspirational ideal of best practices. . ." *In re Walt Disney Co. Derivative Litig.*, 907 A.2d 693, 679 (Del. Ch. 2005).

89. See Velasco, *supra* note 86, at 534-35.

90. In a case of first impression, the Delaware Supreme Court held that corporate officers' fiduciary duties are identical to those of directors. *Gantler v. Stephens*, 965 A.2d 695, 708-09 (Del. 2009).

91. See Velasco, *supra* note 86, at 551 (asserting that directors are rarely held liable for breaching fiduciary duties of care and loyalty).

92. *In re Walt Disney Co. Derivative Litig.*, 907 A.2d 693, 749-50 (Del. Ch. 2005) ("In the duty of care context with respect to corporate fiduciaries, gross negligence has been defined as a "reckless indifference to or a deliberate disregard of the whole body of stockholders' or actions which are 'without the bounds of reason.'"); see Thomas A. Uebler, *Shareholder Police Power: Shareholders' Ability to Hold Directors Accountable for Intentional Violations of Law*, 33 DEL. J. CORP. L. 199, 203 nn. 17-18 (2008). But, even in such a case liability may not result, due to the following provision in Delaware Code Section 102(b)(7) which authorizes the inclusion in a certificate of incorporation of the following:

[A] provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for monetary damages for breach of a fiduciary duty as a director, provided that such provisions shall not eliminate or limit the liability for a director; (i) for any breach of the director's duty of loyalty to the corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a violation of law; . . .

DEL. CODE ANN. tit. 8, § 102(b)(7) (2011).

negligence.<sup>93</sup> Directors' duty of loyalty requires them to give primacy to the corporation's interests, that is, to avoid conflicts of interest.<sup>94</sup> The law's application does not preclude conflicted transactions, but requires them to be fair.<sup>95</sup> Only recently, the duty of loyalty also encompasses the directors' obligation to act in good faith.<sup>96</sup>

The business judgment rule creates the gap between the standard of conduct and standard of review applied to cases involving directors' fiduciary duties.<sup>97</sup> This rule affords corporate boards a "judicial presumption that a business decision of the board of directors was well-informed, made in good faith, and decided in the honest belief that it would benefit the corporation and its shareholders."<sup>98</sup> Delaware cases regularly reaffirm that the duty of care is not a tool for substantive second-guessing the content of board decisions.<sup>99</sup> The law seeks to avoid the mistakes that occasionally emerge from the litigation process, specifically, "the over-enforcement of fiduciary duties," which would discourage risk-taking, stifle entrepreneurialism, and risk depressing wealth generation.<sup>100</sup>

For purposes of this discussion, we will assume that life sciences companies' off-label promotional behavior falls into two categories, both of which the board is aware — that which is misleading and untruthful, and that which, while also off-label, is supported by legitimate trials and/or peer reviewed articles. In either case, the government interprets the law as precluding off-label promotions.<sup>101</sup> Presumably, few would defend false and misleading marketing. The question is whether directors violate the duty of loyalty, specifically their duty to act in good faith, by allowing or even encouraging profitable and truthful off-label promotional activities.

The literature is unresolved on the question of whether intentional violations of the law constitute a violation of the duty of loyalty. Delaware case law would suggest that "fulfilling a fiduciary duty requires obedience to other positive law."<sup>102</sup> Commentators are in disagreement about this question. As assessed by Gold, "[p]ublic policy is a leading basis for limiting the board's discretion to break the law. But viewing intentional violations of

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93. Velasco, *supra* note 86, at 521.

94. See *Disney*, 907 A.2d at 751 (citing *Guth v. Loft*, 5 A.2d 503, 510 (Del. 1939)).

95. See Melvin Aron Eisenberg, *The Divergence of Standards of Conduct and Standards of Review in Corporate Law*, 62 *FORDHAM L. REV.* 437, 454 (1993).

96. *Stone v. Ritter*, 911 A.2d 362, 369-70 (Del. 2006).

97. Velasco, *supra* note 86, at 546.

98. Andrew S. Gold, *The New Concept of Loyalty in Corporate Law*, 43 *U.C. DAVIS L. REV.* 457, 466 (2009).

99. *Id.* at 526.

100. Velasco, *supra* note 86, at 550.

101. Joseph et al., *supra* note 14, at 7-8.

102. *Disney*, 907 A.2d at 697.

positive law as socially undesirable does not provide a clear conceptual basis for treating such violations as a form of *disloyalty* to the corporation or its shareholders."<sup>103</sup>

Even if we conclude that violating the law is prohibited by the duty of loyalty, shareholders derivative suits do not provide a mechanism for sanctioning directors who permit or encourage off-label marketing that results in fines if there is no net loss to the shareholders. We, here, imagine a board that employs a weak hand in dealing with off-label promotion and the use of incentives to sell products to health care providers. On the one hand, corporate compliance training educates the sales force regarding proper sales techniques. On the other, generous sales force compensation, including bonuses, depends upon the prescribing practices of the providers assigned to the sales representative, who also has an expense account to expend appropriately to advance company sales. The corporate ethos is one that promotes how important the company's lifesaving drugs are to patients, how dependent physicians are upon sales representatives to remain current about the latest treatments, and how imperative it is that product adoption occurs before patent expiration and potentially lower quality (generic) products enter the market.

The board makes no affirmative decision to encourage violations of the law. To the contrary, corporate policy forbids such behavior. Violations of the law occur in an ethos that emphasizes sales of products that are imperative to saving lives. Evidence of such an ethos, absent some decision by the board that approves of the illegal conduct at issue, is insufficient to establish the intent required to pursue a shareholder derivative action.<sup>104</sup> The ethos created by the board is one that benefits both the company and its shareholders. More product sales increase the value of the stock.

Even if it were determined that the board acted illegally by implicitly encouraging or turning a blind eye to illegal promotional practices, thereby arguably violating the duty of loyalty, it is unlikely that damages can be proven. The directors will not have personally gained by their actions as they presumably have in self-dealing cases in which their gains are disgorged. Even with fines, the net revenues of blockbuster drugs, which likely result significantly from prohibited sales practices, result in a net benefit to the corporation.<sup>105</sup> Whether stock prices are adversely affected by the significant fines levied by enforcement agencies requires analysis, but so many life science companies have been subject to CIAs that they may not cause adverse market reactions. Only if the sanctions from particular conduct were

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103. Gold, *supra* note 98, at 475 (emphasis in original).

104. *In re Johnson & Johnson Derivative Litig.*, Civil Action No. 10-2033, 2011 WL 4526040, at \*31-32 (D.N.J. Sept. 29, 2011).

105. *Morris Testimony*, *supra* note 12, at 6.

so high as to outweigh the increased profits would there be a problem, and we have seen that this is unlikely.

Ultimately, the fact that shareholders are likely benefiting from the significant profits resulting from the complained of sales behavior, even with the significant fines being levied, suggests that a rational shareholder would desire this behavior to continue, and thereby lack any incentive to pursue the board for damages, which are speculative at best.

Even if the outcome of a shareholder derivative suit were a finding of breach of fiduciary duty, an adverse outcome is unlikely to affect directors' behavior because they are insured or indemnified against personal loss for the monetary damages attendant to an adverse outcome.<sup>106</sup> That shareholder gain is unlikely is supported by the increasing frequency with which shareholder derivative cases are resolved with damages or monetary settlements; rather, the majority of settlements involve corporate reforms and significant attorneys' fees.<sup>107</sup> An October 2012 J&J settlement of a consolidated shareholder derivative action evidences this phenomenon.<sup>108</sup> The essential shareholder complaints alleged that the J&J board insulated itself from knowledge of compliance and quality issues among its many subsidiaries through its decentralized compliance structure, thereby enabling the board to ignore "red flags" involving product recalls, deviation from good manufacturing practices, off-label marketing, and illegal kick-backs. The case was settled with J&J agreeing to more centralized oversight of quality and compliance, with upstream reporting to the J&J board. Plaintiffs' attorneys were awarded \$10 million dollars in fees in addition to costs.

There were fifteen objectors to the settlement, notable not for their number but for their arguments. All seemed to have wanted the suit dismissed in the first place, claiming that it was wasting resources in the form of attorneys' fees. More relevant to this discussion, however, is one objector's argument, with support from expert witnesses Professors Litvak and Henderson, that the plaintiffs' experts failed to produce evidence that the recommended corporate reforms would produce any benefit for the corporation or shareholders in the form of increased value.

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106. See DEL. CODE ANN. tit. 8, § 102(b)(7). A potential law reform might be to amend Delaware or securities law to preclude indemnification of breach of loyalty claims related to legal violations.

107. See generally Jessica Erickson, *Corporate Governance in the Courtroom: An Empirical Analysis*, 51 WM. & MARY L. REV. 1749 (2010) (empirical study concluding that shareholders file more derivative suits than class actions; settlements usually involve corporate reforms rather than money; corporate reforms rarely benefit the corporations or their shareholders; the real winners are the plaintiffs' attorneys who recover significant fees).

108. *In re Johnson & Johnson Derivative Litig.*, Civil Action No. 10-2033, 2012 WL 5292963 (D.N.J. Oct. 26, 2012), available at [http://newsandinsight.thomsonreuters.com/uploadedFiles/Reuters\\_Content/2012/10\\_-\\_October/jj.pdf](http://newsandinsight.thomsonreuters.com/uploadedFiles/Reuters_Content/2012/10_-_October/jj.pdf).

If indeed it is true that the primary mover of these shareholder derivative cases are plaintiffs' counsel, and the skepticism about the value of corporate governance reforms bears out, then a real question exists as to whether shareholder derivative suits have anything to contribute to corporate reform. As explained by Professor Gold, "[t]he Delaware courts have admittedly been wary about using fiduciary duties to enforce the norms of morality. This is cause to question whether the courts are truly concerned with what morality or virtue *as such* require of corporate directors."<sup>109</sup> By comparison, enforcement agencies, through their use of CIAs and DPAs, are seeking structural reforms that will result in a corporate ethos that strives toward the ethical conduct of business.<sup>110</sup>

## B. *Purdue Pharma and the Responsible Corporate Officer Doctrine*

### 1. The Emergence of the Park Doctrine

The Responsible Corporate Officer Doctrine's genesis was the Supreme Court's 1943 opinion in *United States v. Dotterweich*,<sup>111</sup> in which the Court affirmed the misdemeanor conviction under the Food, Drug and Cosmetic Act of the president and general manager of a pharmaceutical company for the introduction of adulterated or misbranded products into commerce despite the defendant's claim that he had no knowledge of the relabeling that gave rise to the conviction.<sup>112</sup> The Court rejected the argument that the conviction of an individual not involved in the actual illegal conduct was too harsh, stating that "[t]he offense is committed . . . by all who do have such a *responsible share in the furtherance of the transaction* which the statute outlaws."<sup>113</sup> Though recognizing the hardship of penalizing someone not involved in illegal conduct, the Court responded that "[b]alancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."<sup>114</sup>

*U.S. v. Park* required the Court to reconsider the Doctrine in 1975; the Court's opinion revisited the same issue: the harshness of a criminal conviction of an individual lacking knowledge of the crime in the context of protecting public health.<sup>115</sup> The facts of the case involved a shipment of

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109. Gold, *supra* note 98, at 503 (emphasis in original).

110. O'Neil & Kennedy, *supra* note 41, at 308, 323, 349.

111. 320 U.S. 277 (1943).

112. *Id.* at 281, 285.

113. *Id.* at 284 (emphasis added).

114. *Id.* at 284-85.

115. *United States v. Park*, 421 U.S. 658, 660, 670-71 (1975).

food containing rodent contamination<sup>116</sup> following multiple warnings from the FDA, about which the defendant, the CEO of a national food chain, was aware.<sup>117</sup> Defendant Park argued that as CEO, matters such as food contamination and sanitation rested with others much below him in the corporate hierarchy, and that he had delegated the matter to a Vice President, after which there really was not much more he as president could do.<sup>118</sup> On cross-examination, however, the defendant agreed there was clearly a problem in the company's sanitation system, and that ultimately, it is the CEO who is responsible for systemic problems.<sup>119</sup> The Court held that the Responsible Corporate Officer Doctrine is satisfied when the government introduces evidence that the individual defendant had "by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."<sup>120</sup>

Insufficiently satisfying to the many detractors of the Doctrine, the Court addressed culpability by stating: "The considerations which prompted the imposition of this duty, and the scope of the duty, provide the measure of culpability."<sup>121</sup> The Court was clear that guilt is not based solely on the defendant's corporate position, reiterating the *Dotterweich* quotation regarding a defendant's relationship of responsibility as well as her authority to address the situation that gave rise to liability.<sup>122</sup> Importantly, the Court explicitly recognized an affirmative defense when the defendant is "'powerless' to prevent or correct the violation."<sup>123</sup>

The Supreme Court upheld Park's conviction, concluding that "the Act imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions."<sup>124</sup> The Court described the duty as one

to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose

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116. *Id.* at 660-61.

117. *Id.* at 664.

118. *Id.* at 663-64.

119. *Id.* at 664-65.

120. *Park*, 421 U.S. at 673-74.

121. *Id.* at 674.

122. *Id.* at 672-73.

123. *Id.* at 673.

124. *Id.* at 676.

services and products affect the health and well-being of the public that supports them.<sup>125</sup>

In short, in the case of a business that affects the public's health, the Court places the burden and attendant risks of safety on corporate leadership to ensure that the highest standards of caution are taken. In the context of the *Park* facts, the Doctrine makes sense. Park knew there was a specific compliance problem with which the FDA was concerned;<sup>126</sup> he knew that it was not adequately addressed the first time it arose;<sup>127</sup> and he admitted that there was a systemic operational problem that he had not personally addressed.<sup>128</sup> In the context of public health, it seems reasonable to hold Park ultimately responsible.

## 2. Contemporary Application: Purdue Pharma

I suggest that the case of the Purdue Pharma senior executives who pled to misdemeanor violations under the Park Doctrine, resulting in their debarment from the Federal healthcare programs, was also an appropriate application of the Doctrine. Nonetheless, the case represents the most controversial use of the RCO Doctrine in the healthcare field in many years. Purdue Pharma is itself a unique entity in that it is family-owned<sup>129</sup> and not publicly traded, which is rare in the pharmaceutical industry.<sup>130</sup> Purdue Frederick, created in 1892,<sup>131</sup> was acquired in 1952 by two psychiatrist brothers — Mortimer and Raymond Sackler — with the financial help of a third brother, Arthur, known as a brilliant scientist and psychiatrist whose financial success came from innovative pharmaceutical and medical advertising.<sup>132</sup> In 1984, the brothers Sackler took an old drug used in

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125. *Park*, 421 U.S. at 672.

126. *Id.* at 664.

127. *Id.* at 664-65.

128. *Id.*

129. See Bruce Weber, *Mortimer D. Sackler, Arts Patron, Dies at 93*, N.Y. TIMES, Apr. 1, 2010, at A25. Of the trio of brothers who originally acquired Purdue Frederick in 1952, only one remains alive. *Id.*

130. *Who We Are, About Purdue Pharma L.P.*, PURDUE PHARMA (2012), <http://www.purduepharma.com/about/>. Many pharmaceutical entities are large, publicly traded companies.

131. Agreed Statement of Facts at 1, *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007).

132. Grace Gleuck, *Dr. Arthur Sackler Dies at 73; Philanthropist and Art Patron*, N.Y. TIMES, May 27, 1987, at B8; Weber, *supra* note 129, at A25. According to Sackler's biography in the Medical Advertising Hall of Fame, to which he was inducted in 1997, Sackler "helped shape pharmaceutical promotion as we know it today (he even experimented with medical radio and TV in the 1950's), as well as established the role of communications and promotional programs in pharmaceutical marketing." *Inductees, Arthur M. Sackler*, MED. ADVER. HALL OF FAME (2012), [http://www.mahf.com/index.php?Itemid=139&id=117&option=com\\_content&task=view](http://www.mahf.com/index.php?Itemid=139&id=117&option=com_content&task=view).

treating pain in cancer patients, repurposed it as MS Contin.<sup>133</sup> The product's success led to the formation of Purdue Pharma as the vehicle for promoting its pain medications, of which OxyContin would prove to be among the most financially successful.<sup>134</sup>

The FDA approved Purdue Pharma's newly formulated OxyContin (the only controlled-release version of HCl oxycodone, an opioid agonist which has been on the market for many years with addiction potential similar to morphine)<sup>135</sup> in 1995 to manage moderate to severe chronic pain when a continuous, potent narcotic is required around the clock;<sup>136</sup> the package insert included a statement that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."<sup>137</sup> Market research focus groups by Purdue with physicians in early 1995 revealed that physicians' biggest concern about OxyContin was its "abuse potential."<sup>138</sup> The focus group findings apparently resonated, because from the time of FDA approval until 2001, in some instances with their supervisors' urging or through sales training, certain Purdue employees promoted OxyContin "as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal," as subject to "fewer peak and trough blood level effects," and producing less euphoria than other pain short-action opioids.<sup>139</sup> Purdue representatives also told healthcare providers that patients could stop OxyContin abruptly with no adverse side effects, which was contradicted by Purdue's own study.<sup>140</sup> In 1997, Purdue

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133. Katherine Eban, *Painful Medicine, What the Strange Saga of Purdue Pharma – and its \$3 Billion drug, OxyContin – Tell Us About Our National Dependence on Painkillers*, FORTUNE, Sept. 21, 2011, at 143, 148, available at <http://features.blogs.fortune.cnn.com/2011/11/09/oxycontin-purdue-pharma/>.

134. *Id.* at 144, 148.

135. *Oxycontin: Balancing Risks and Benefits: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 107th Cong. 15 (2002) [hereinafter *Jenkins Statement*] (statement of John K. Jenkins, Director, Office of New Drugs, Center For Drug Evaluation and Research, Food and Drug Administration), available at <http://www.fda.gov/NewsEvents/Testimony/ucm115180.htm>.

136. *Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations for 2002, Part 10: OxyContin: Hearing Before the Subcomm. on Commerce, Justice, State, and Judiciary of the H. Comm. on Appropriations*, 107th Cong. 15 (2001) [hereinafter *Hutchinson Statement*] (statement of Asa Hutchinson, Administrator, Drug Enforcement Administration).

137. Agreed Statement of Facts, *supra* note 131, at 5.

138. *Id.*

139. *Id.* at 5-6. According to Congressional testimony, "the disproportionate abuse of OxyContin is due, in part, to aggressive marketing and promotion of OxyContin by Purdue Pharma . . . accentuated the problem by suggesting that physicians prescribe OxyContin as a substitute for a variety of less addictive existing medications." *Hutchinson Statement*, *supra* note 136, at 23.

140. Agreed Statement of Facts, *supra* note 131, at 5-6.



employees intentionally did nothing to disabuse physicians of their misperception that oxycodone was weaker than morphine.<sup>141</sup>

The FDA sent Purdue Pharma a letter in May 2000 regarding a false and misleading advertisement in the *New England Journal of Medicine*<sup>142</sup> that implied OxyContin had been studied in all types of arthritis and can be used as first-line therapy for the treatment of osteoarthritis but failed to include important limitations to the study; it also promoted OxyContin in a selected class of patients without including the attendant risks.<sup>143</sup> Purdue Pharma and the FDA agreed upon label changes in 2001 to include a “black box” warning of the potentially lethal consequences of using OxyContin other than as directed, as well as an instruction sheet for patients.<sup>144</sup> OxyContin became the most prescribed Schedule II narcotic in the United States, with 5.8 million prescriptions in 2000.<sup>145</sup> Its revenues reached approximately \$3 billion in June 2001, accounting for 80% of Purdue Pharma’s revenue.<sup>146</sup> Effective August 5, 2010,<sup>147</sup> Purdue discontinued manufacturing and distribution of the original formulation, replacing it with an FDA-approved reformulation that is much more difficult for abusers to penetrate by cutting, breaking, crushing, or dissolving.<sup>148</sup> OxyContin sales reached \$3.5 billion in 2010.<sup>149</sup>

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141. *Id.* at 9-10.

142. Letter from Spencer Salis, Regulatory Review Officer, Div. of Drug Mktg., Adver. & Commc’ns, Food & Drug Admin., to Beth Connelly, Senior Assoc., Regulatory Affairs, Purdue Pharma, L.P. (May 11, 2000) available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166015.pdf>. Apparently, the “advertisement” was actually an article published on March 27, 2000 that was authored by Purdue employees; the reprints were then provided to sales representatives for use in marketing to physicians. News Release, John L. Brownlee & Heidi Coy, U.S. Attorney’s Office, Western District of Va., The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin; Will Pay Over \$600 Million (May 10, 2007), available at [http://www.tricare.mil/fraud/News/Document/purdue\\_freder.pdf](http://www.tricare.mil/fraud/News/Document/purdue_freder.pdf).

143. *Jenkins Statement*, *supra* note 135, at 18.

144. *Id.* at 16.

145. *Hutchinson Statement*, *supra* note 136.

146. *Weber*, *supra* note 129, at A25.

147. *Purdue’s Prescription Drug Products*, PURDUE PHARMA (2012), <http://www.purduepharma.com/Products/Prescription/Pages/default.aspx>.

148. News Release, U.S. Food & Drug Admin., FDA Approves New Formulation for OxyContin (Apr. 5, 2010), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm207480.htm>. However, Purdue Pharma’s discussion of the newly reformulated pain medication emphasizes that “there is no evidence that the reformulation of OxyContin is less subject to misuse, abuse, diversion, overdose or addiction.” *Statement of Purdue Pharma, L.P. Regarding FDA’s Approval of Reformulated OxyContin (oxycodone HCl controlled-release) Tablets*, PURDUE PHARMA (April 5, 2010), available at <http://www.purdue>

OxyContin is “a very effective and efficient analgesic.”<sup>150</sup> In addition to its legitimate use, however, OxyContin became very popular as a street drug, either taken orally, injected, or crushed, which circumvented the controlled release mechanism and allowed a more rapid and intense heroin-like high.<sup>151</sup> Diversion to street use became acute in rural areas such as Appalachia before spreading to urban areas.<sup>152</sup> Emergency room visits related to ingestion of products containing oxycodone increased 89% from 1993 to 1999 and then again by 68% between 1999 and 2000.<sup>153</sup> While reports of addiction by people using OxyContin as prescribed were rare, many people with legitimate prescriptions became addicted by self-medicating.<sup>154</sup>

In 2007, the U.S. Attorney in the Western District of Virginia charged the company and three top executives with violations of the Food, Drug and Cosmetic Act.<sup>155</sup> The Purdue Frederick Company, Inc., along with the President, Chief Legal Officer, and former Chief Medical Officer of Purdue Pharma LP, entered into a global settlement whereby they pled guilty to felony charges of fraudulent misbranding of OxyContin, agreeing to pay fines totaling \$634,515,475.<sup>156</sup> Notably, Purdue Pharma was not charged, thereby enabling it to continue to submit drug applications to the FDA and allowing it to continue its relationship with Federal healthcare programs, thereby enabling its products to continue to be paid for by Medicare and

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pharma.com/news-media/2010/04/statement-of-purdue-pharma-l-p-regarding-fdas-approval-of-reformulated-oxycodone-hcl-controlled-release-tablets/.

149. *Oxycontin*, DRUG PATENT WATCH (2012), <http://drugpatentwatch.com/ultimate/preview/tradename/index.php?query=OXYCONTIN>. It is currently on the market as OxyNEO in Canada. Linda Diebel, *Critics allege OxyNeo was Introduced in Canada Because of Impending Patent Expiry*, TORONTO STAR, Apr. 24, 2012, <http://www.thestar.com/news/canada/article/1165664—critics-allege-oxynéo-was-introduced-in-canada-because-of-impending-patent-expiry>.

150. *OxyContin: Balancing Risks and Benefits: Hearing Before the S. Comm. for Health, Educ., Labor, and Pensions*, 107th Cong. 1 (2002) [hereinafter *Hanson Statement*] (statement submitted for the record by Glen R. Hanson, Acting Director, National Institute on Drug Abuse), available at <http://www.help.senate.gov/imo/media/doc/Hanson1.pdf>.

151. *Hutchinson Statement*, *supra* note 136.

152. *Id.*

153. *Hanson Statement*, *supra* note 150, at 3.

154. *Id.*

155. Agreed Statement of Facts, *supra* note 131, at 1-2, 14-15.

156. *Brownlee & Coy*, *supra* note 142, at 1. Purdue Frederick pleaded to a felony, while the individual executives each pleaded to a misdemeanor. *Id.* at 2. Purdue's payments included \$276.1 million forfeited to the United States; \$160 million paid to state and federal agencies to resolve liability for false claims to Federal healthcare programs; \$130 million set aside to resolve private civil claims; \$5.3 million paid to fund Virginia's Medicaid Fraud Unit; \$20 million to fund the Virginia Prescription Monitoring Program; and a payment of the maximum criminal fine of \$500,000. *Id.*

Medicaid.<sup>157</sup> Three top executives — President and CEO Michael Friedman, Vice President and Chief Legal Officer Howard Udell,<sup>158</sup> and Vice President and Chief Scientific Officer Paul Goldenheim — simultaneously pled guilty to the misdemeanor violation of introduction into commerce of a misbranded drug,<sup>159</sup> pursuant to the RCO Doctrine which imposed upon the defendants the “responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding . . . .”<sup>160</sup>

Attendant to their guilty pleas, the individual defendants assented to an Agreed Statement of Facts, which states that the “company supervisors . . . repeatedly misrepresented the drug’s addictiveness and potential for abuse and diversion in an effort to ‘defraud or mislead’ the medical community.”<sup>161</sup> It explicitly states that the defendants had no personal knowledge of “all of the matters” set forth in the Agreed Statement of Facts,<sup>162</sup> and that they were “responsible corporate officers” of Purdue.<sup>163</sup> In addition to fines<sup>164</sup> designed to significantly disgorge the compensation earned during the misbranding period,<sup>165</sup> but that were actually paid for by

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157. Kathleen M. Boozang, *A New Insurance Product: Responsible Corporate Officer Defense Insurance*, HEALTH REFORM WATCH (March 8, 2012), <http://www.healthreformwatch.com/2012/03/08/a-new-insurance-product-responsible-corporate-officer-defense-insurance/>. Purdue Pharma was “formed in 1991 to research, develop, produce, market, sell, distribute, and license analgesic medications and other pharmaceutical products.” *Purdue Pharma*, IPTECHEX PHARMALICENSING (2012), <http://pharmalicensing.com/public/companies/view/3061/purdue-pharma>.

158. Interestingly, Mr. Udell continues to serve as Purdue Pharma’s Chief Legal Officer. *Company Overview of Purdue Pharma, L.P.*, BLOOMBERG BUSINESSWEEK (Oct. 19, 2012), <http://investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=264625>.

159. 21 U.S.C. § 331(a) (2006).

160. Agreed Statement of Facts, *supra* note 131, at 3.

161. *Friedman v. Sebelius*, 755 F. Supp. 2d 98, 102 (D.D.C. 2010). The [Inspector General] indicated that he had increased the exclusion period from three to twenty years because of the aggravating factors that 1) the illegal behavior had occurred for a period of time exceeding one year; 2) the conduct had a significant adverse financial impact on beneficiaries and 3) the behavior had a significant “adverse physical or mental impact on one or more program beneficiaries or other individuals.” *Id.* at 103.

162. *Id.* at 102.

163. *Id.*

164. *Brownlee & Coy*, *supra* note 142, at 2. Purdue’s CEO paid \$19 million; counsel paid \$8 million; and the chief medical officer paid \$7.5 million. Each executive also paid a \$5,000 criminal fine. *Id.*

165. Plea Agreement at 1-2, *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007).

Purdue pursuant to indemnification agreements,<sup>166</sup> the executives were each sentenced to three years' probation and 400 hours of community service.<sup>167</sup>

In March 2008, Purdue Pharma's corporate officials were notified by the Inspector General of Health and Human Services that, as a result of their convictions, they were excluded from all Federal healthcare programs, including Medicare and Medicaid for twenty (later reduced by the Departmental Appeals Board to twelve) years,<sup>168</sup> under the Secretary's authority for permissive exclusions for having been convicted "of a criminal offense consisting of a misdemeanor relating to fraud . . . ."<sup>169</sup> The exclusion was upheld by the administrative law judge,<sup>170</sup> Departmental Appeals Board,<sup>171</sup> and the District of Columbia federal district court.<sup>172</sup> The OIG based the exclusion on three factors: (1) the conduct upon which the convictions were based lasted more than a year; (2) "the amount of financial loss; and (3) the significant adverse physical or mental impact upon program beneficiaries."<sup>173</sup> The executives' appeal to the Court of Appeals argued that the statute does not authorize their exclusion, and that the exclusion was unsupported by substantial evidence and was arbitrary and capricious because it lacked a reasoned explanation of the exclusions' length.<sup>174</sup> The executives were unsuccessful before the appellate court with respect to the fact of their exclusion, but prevailed on the arguments related to the length of exclusion, causing the case to be remanded to the Secretary of HHS.<sup>175</sup>

The Pharma executives argued that they could not be excluded for misdemeanor misbranding under the RCO Doctrine because the convictions were strict liability offenses which did not require any evidence of personal wrong-doing or scienter.<sup>176</sup> They unsuccessfully argued that they personally

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166. *Friedman*, 755 F. Supp. 2d at 102 n.7.

167. *Id.* at 102.

168. *Id.* at 103-04. The DAB determined that the ALJ's finding that the crimes had an adverse impact on program beneficiaries was unsupported by the evidence. *Friedman v. Sebelius*, No. 11-5028, 2012 WL 3055520, at \*2 (D.C. Cir. July 27, 2012).

169. 42 U.S.C. § 1320a-7(b)(1)(A) (2006).

170. *Goldenheim v. Inspector General*, DAB No. CR1883, at 1, 15 (Dep't of Health & Human Servs. 2009), available at <http://www.hhs.gov/dab/decisions/civildecisions/2009/CR1883.pdf>.

171. *Goldenheim v. Inspector General*, DAB No. 2268, at 1, 10 (Dep't of Health & Human Servs. 2009) (final admin. review), available at <http://www.hhs.gov/dab/decisions/dabdecisions/dab2268.pdf>.

172. *Friedman*, 755 F. Supp. 2d at 113.

173. *Friedman v. Sebelius*, No. 11-5028, 2012 WL 3055520, at \*2 (D.C. Cir. July 27, 2012).

174. *Id.* at \*3.

175. *Id.* at \*11.

176. *Id.* at \*3.

would have had to engage in the fraud or other activity that subjects one to exclusion.<sup>177</sup> The government prevailed against this argument on the basis of the statutory language, which allows exclusion of those convicted of misdemeanors “related to fraud;” there need only have been a factual connection between the criminal conduct and fraud in a government program — there need be no evidence that the defendant himself engaged in fraud.<sup>178</sup>

The appellants were more successful in challenging the length of their exclusions; twelve years is four times the statutory baseline of a three-year exclusion absent aggravating or mitigating factors.<sup>179</sup> The appellants’ suggestion of mitigating factors gained no traction with the court — that the government had no proof of harm exceeding \$5,000 to its health programs; the executives were convicted on the basis of omissions rather than specific acts, and that they lacked any awareness of wrong-doing.<sup>180</sup> The single issue on which the Pharma executives were successful on appeal was that the length of the exclusions was arbitrary and capricious because the decision was unaccompanied by an explanation of why the exclusion exceeded by eight years any previously imposed sanction under the permissive exclusion section of the law.<sup>181</sup>

### 3. A Contemporary Application: Synthes

The Synthes’ executives’ behavior and consequences were of a whole different degree than those in Purdue Pharma. Synthes is a multinational medical device manufacturer of which Norian was a subsidiary acquired in 1999.<sup>182</sup> Norian produced two FDA-approved bone cements that it desired to market for spinal infusions, despite labeling that its product could not be used for spinal indications and was “non-load bearing only.”<sup>183</sup> Because the FDA did not require other cement manufactures to include this caveat, Synthes executives believed they were at a competitive disadvantage.<sup>184</sup> The FDA was explicit in advising Synthes that spinal use of its products would require clinical trials and pre-market approval.<sup>185</sup>

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177. *Id.* at \*9.

178. *Friedman v. Sebelius*, No. 11-5028, 2012 WL 3055520, at \*8 (D.C. Cir. July 27, 2012).

179. *Id.* at \*8, \*11.

180. *Id.* at \*8-9.

181. *Id.* at \*11.

182. Superseding Information at 1-2, *United States v. Synthes Inc.*, Criminal No. 09-403-02, 2010 WL 4977512 (E.D. Pa. Dec. 10, 2010), available at [http://www.justice.gov/usao/pae/Pharma-Device/synthes\\_supersedinginformation.pdf](http://www.justice.gov/usao/pae/Pharma-Device/synthes_supersedinginformation.pdf).

183. *Id.* at 1, 12, 17.

184. *Id.* at 23.

185. *Id.* at 14-15.

Even while receiving reports from surgeons about patients suffering hypotensive episodes<sup>186</sup> believed to be attributable to an adverse interaction of the Norian cement with patients' blood following cement leaks, Synthes elected to circumvent the formal clinical trial process and notification to the FDA.<sup>187</sup> Instead, it initiated "test market" activities with an eye towards collecting data from multiple surgeons about spinal use of its product, producing a peer-reviewed article, and then marketing off-label.<sup>188</sup> To this end, Synthes trained two groups of surgeons in the use of its product for spinal surgery, who were to then train other surgeons, as part of the "test market" project.<sup>189</sup> Three patients died of hypotensive events while in surgery — Synthes' sales representatives were present in the surgical suite at the time of each death but clinical analysis has not occurred to determine whether Norian cement caused the deaths.<sup>190</sup>

The Synthes executives who ultimately plead guilty pursuant to the RCO Doctrine, who included the Synthes North American President, President of Synthes Spine Division, Senior Vice President of Operations, and the Director of Regulatory and Clinical Affairs,<sup>191</sup> received multiple warnings from surgical consultants,<sup>192</sup> employees,<sup>193</sup> and the FDA that proceeding with the off-label testing, use, and marketing of its product was illegal and

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186. A hypotensive episode is defined as a sudden unexpected drop in blood pressure. *Low Blood Pressure (Hypotension)*, MAYO CLINIC (May 19, 2011), <http://www.mayoclinic.com/health/low-blood-pressure/DS00590>.

187. *Id.* at 13, 15. One of Synthes' competitors obtained FDA permission to conduct a trial, and a Synthes employee prepared a proposal for Synthes to do the same, which Synthes executives ignored. *Id.* at 22.

188. Superseding Information, *supra* note 182, at 15, 20.

189. Press Release, U.S. Dep't of Justice, International Medical Device Maker Agrees to Plead Guilty in Connection with Shipments of Adulterated and Misbranded Bone Cement Prods. as Part of Unlawful Clinical Trials 3 (Oct. 4, 2010), available at [http://www.justice.gov/usao/pae/News/2010/Oct/synthes,norian\\_release.pdf](http://www.justice.gov/usao/pae/News/2010/Oct/synthes,norian_release.pdf).

190. Superseding Information, *supra* note 182, at 19, 21, 23.

191. David Sell, "Human Experimentation" Leads to Sentencing for Ex-Synthes Executives, PHILADELPHIA INQUIRER, Nov. 21, 2011, <http://www.philly.com/philly/blogs/phillypharma/134229168.html>.

192. Indictment at 13, *United States v. Synthes Inc.*, Criminal No. 09-403-02, 2010 WL 4977512 (E.D. Pa. Dec. 10, 2010), available at <http://www.justice.gov/usao/pae/News/2009/jun/synthesind.pdf> (discussing notification of two adverse events during off label use); *id.* at 14 (noting that spine trauma surgeon suggests cement might be interacting with blood and causing problems); *id.* at 16 (stating that surgeon also suggested clinical studies were needed); *id.* at 21-22 (noting another surgeon hypothesized that the dewatering was causing hypotension, that company was violating warning on label, and that the company had risk management and compliance problems).

193. *Id.* at 12 (warning that Norian cannot promote cement for unapproved uses); *id.* at 13 (noting that another company had received an FDA warning letter about claims for spinal use of cement); *id.* at 18-19 (stating training surgeons on off-label uses would be illegal).

unethical.<sup>194</sup> Not only did Synthes fail to recall its bone cement from the market until after the third patient death, it also made false statements to an FDA official during a 2004 inspection.<sup>195</sup>

Synthes pled guilty to a misdemeanor violation of the FDCA of introducing misbranded and adulterated medical devices into interstate commerce;<sup>196</sup> Norian pled guilty to a felony;<sup>197</sup> and the individual defendants pled guilty to misdemeanor charges of shipping adulterated and misbranded products in interstate commerce pursuant to the RCO Doctrine.<sup>198</sup> Synthes entered into an extremely onerous CIA with OIG.<sup>199</sup> The OIG agreed to waive permissive exclusion of Synthes from the Federal healthcare program on condition that it divested all of Norian's assets to an entity wholly unaffiliated with Synthes.<sup>200</sup> Norian was sold to Kensey Nash Corp.,<sup>201</sup> and Johnson & Johnson acquired Synthes in a \$21.3 billion transaction.<sup>202</sup> The individual defendants served prison sentences ranging from five to nine months, and were fined \$100,000 each, the maximum amounts allowed.<sup>203</sup>

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194. See Letter from Timothy A. Ulatowski, Director, Office of Compliance, Food & Drug Admin., to Maria L. Maccacchini, President, Synthes Biomaterials Worldwide Division, Synthes, Inc. (Nov. 5, 2004), available at [http://www.circare.org/fdawls2/synthes\\_20041105.pdf](http://www.circare.org/fdawls2/synthes_20041105.pdf).

195. Press Release, *supra* note 189, at 2.

196. Settlement Agreement at 2, United States v. Synthes Inc., Criminal No. 09-403-02, 2010 WL 4977512 (E.D. Pa. Dec. 10, 2010), available at [http://www.justice.gov/usao/pae/Pharma-Device/synthesnorian\\_settlementagreement.pdf](http://www.justice.gov/usao/pae/Pharma-Device/synthesnorian_settlementagreement.pdf). The companies explicitly denied the allegations of wrongdoing contained in the Settlement Agreement. *Id.* at 3.

197. *Id.* at 2.

198. Peter Loftus, *Ex-Synthes Executive Huggins Gets 9 Months in Jail*, WALL ST. J. MARKET WATCH, Nov. 21, 2011, <http://www.marketwatch.com/Story/story/print?guid=12B5B2FD-9993-4691-A0C2-9929F16B287C>.

199. Corporate Integrity Agreement, United States v. Synthes Inc., Criminal No. 09-403-02, 2010 WL 4977512 (E.D. Pa. Dec. 10, 2010), available at [http://oig.hhs.gov/fraud/cia/agreements/synthes\\_inc\\_09232010.pdf](http://oig.hhs.gov/fraud/cia/agreements/synthes_inc_09232010.pdf).

200. Divestiture Agreement at 2, United States v. Synthes Inc., Criminal No. 09-403-02, 2010 WL 4977512 (E.D. Pa. Dec. 10, 2010), available at [http://www.justice.gov/usao/pae/Pharma-Device/synthes\\_divestagrmt.pdf](http://www.justice.gov/usao/pae/Pharma-Device/synthes_divestagrmt.pdf).

201. Loftus, *supra* note 198.

202. Johnson & Johnson and Synthes Announce Definitive Merger Agreement to Create World's Most Innovative and Comprehensive Orthopaedics Business, JOHNSON & JOHNSON (Apr. 27, 2011), <http://www.jnj.com/connect/news/all/johnson-and-johnson-synthes-medical-device>.

203. 18 U.S.C. § 1371(b)(5) (2006) (fines for individuals found guilty of a Class A misdemeanor may not be exceed \$100,000); Press Release, U.S. Dep't of Justice, Former Executives of International Medical Device Maker Sentenced to Prison in Unlawful Clinical Trials Case 1, 2 (Nov. 21, 2011), available at [http://www.justice.gov/usao/pae/News/2011/Nov/synthesexecs\\_release.pdf](http://www.justice.gov/usao/pae/News/2011/Nov/synthesexecs_release.pdf).

If the facts recounted in the government's Information accurately reflect the involvement of Synthes corporate executives in its patient trials, they were personally and deeply involved in the companies' transgressions, thereby eliminating the complaint about the RCO Doctrine that executives unaware of corporate illegalities should not be subject to criminal penalties.

While the known facts of Purdue Pharma do not directly and personally implicate the corporate officers, they do represent a scenario for which application of the RCO Doctrine is appropriate. What the corporate executives knew, if anything, is beside the point for purposes of the RCO Doctrine. The point is that they managed companies where employees were engaged in clearly illegal behavior — misrepresenting the attributes of products to physicians — that presented extreme risk to the public. The occurrence of this behavior suggests management failures directly attributable to leadership. While no one would expect a corporation's officers to know or control everything that happens within its operations, the activities in both of these instances were sufficiently significant that the consequences, if not the actual behaviors, should have been detected by managerial oversight and/or corporate compliance efforts. That employees, including those at the highest levels of the corporation in the case of Synthes, participated in the illegal conduct implicates the corporate ethos and suggests either that the toleration level for unethical and risky behavior was extremely permissive, or that the focus on sales at all costs was so extreme that it trumped all other principles and values throughout the company. The problems of Purdue Pharma and Synthes were ultimately about leadership and responsibility, which is what the Park Doctrine addresses.

#### 4. FDA Announces Criteria for Park Doctrine Prosecutions

On the heels of this success, the FDA announced that it was implementing a Government Accountability Office (GAO) suggestion that it increase its use of misdemeanor prosecutions against responsible corporate officials.<sup>204</sup> The agency released its internal agency guidance for determining when to forward a case to the DOJ for a "Park Doctrine Prosecution."<sup>205</sup> The guidance provides that a first time conviction for a violation of the FDCA will be a misdemeanor, with the second resulting in a

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204. Letter from Margaret A. Hamburg, Comm'r of Food & Drugs, Food & Drug Admin., to Senator Charles E. Grassley, Senate Comm. on Fin. (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>.

205. FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., REGULATORY PROCEDURES MANUAL 6-49 (2011) [hereinafter FDA REGULATORY PROCEDURES MANUAL], available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>.



felony.<sup>206</sup> Further, in some cases, a misdemeanor conviction can result in debarment by the FDA.<sup>207</sup> The guidance enumerates the following criteria:

- The individual's position in the company; relationship to the violation; whether the official had the authority to correct or prevent the violation
- Knowledge of and actual participation in the violation
- Actual or potential harm to the public
- Obviousness of the violation
- Existence of a pattern of illegal behavior and/or failure to heed prior warnings
- Whether the violation is widespread
- Seriousness of the violation
- Quality of the legal and factual support for the proposed prosecution
- Whether prosecution is a prudent use of agency resources<sup>208</sup>

Within the same week, Lewis Morris, then-Chief Counsel to the Inspector General of Health & Human Services, testified before the House Ways and Means Committee that the OIG would consider any individual convicted pursuant to the RCO Doctrine for exclusion from participation in Federal healthcare programs.<sup>209</sup> This, Mr. Morris testified, will overcome the barriers presented by corporations' attitude that they are too important to the healthcare system to criminally prosecute and that fines are simply a cost of doing business.<sup>210</sup> Mr. Morris assured the House Committee that the OIG would use this tool judiciously, employing a presumption in favor of exclusion only "when there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization."<sup>211</sup>

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206. *Id.*

207. 21 U.S.C. § 333(a)(1) (2006); FDA REGULATORY PROCEDURES MANUAL, *supra* note 205, at 6-49.

208. FDA REGULATORY PROCEDURES MANUAL, *supra* note 205, at 6-49.

209. *Morris Testimony*, *supra* note 12, at 6. Section 1128(b)(15)(A)(ii) of the Social Security Act authorizes "permissive exclusions" by the OIG in situations of health care fraud that does not involve Medicare or Medicaid, and that which involves the unlawful manufacture, distribution, prescription or dispensing of controlled substances; submission of false or fraudulent claims to a Federal healthcare program; and engaging in unlawful kickback arrangements. 42 U.S.C. § 1320a-7(b) (2006). The individuals subject to this permissive exclusion authority include an individual owner, "officer, director, agent, or managing employee" of a sanctioned entity if he knew or should have known of the conduct underlying the sanctioned entity's violation, as well as an "officer or managing employee" of a sanctioned entity. *Id.* § 1320a-7(b)(8), (15). See also Levinson, *supra* note 44, at 5 (stating that the "OIG is focused on holding Responsible Corporate Officials accountable for healthcare fraud").

210. *Morris Testimony*, *supra* note 12, at 6.

211. *Id.*

The OIG's published (non-exclusive) criteria for permissive exclusions<sup>212</sup> from Federal healthcare programs includes a consideration of the entity's misconduct, including whether it is part of a pattern of conduct and whether it caused harm to beneficiaries; the individual's role in the sanctioned entity with a focus on degree of managerial control or authority and the position's relation to the underlying misconduct and whether the misconduct occurred in the individual's chain of command; and finally, detailed information about the nature of the sanctioned entity including its size, revenues, organization and structure.<sup>213</sup> It seems that the criteria focus on corporate ethos and organization as it relates to the ability of top management to have access to information about the ethos of the corporation, and the tone of compliance that pervades the organization.

C. *When the Application of the Park Doctrine Makes Sense*

Unquestionably, more facts about NECC are required prior to determining who might be considered appropriate targets for conviction under the RCO Doctrine. The case epitomizes the situation contemplated by the Supreme Court, however, when it referred to imposing responsibility upon those best able to avoid harms to innocent consumers. We can only wait to see what prosecutorial decisions the government makes.<sup>214</sup>

Questions abound about the application of the RCO Doctrine — a few of which are addressed here. The first question addresses the actual scope of the Doctrine, which should extend to both officers and directors. The situations in which criminal responsibility for corporate misbehavior should adhere to individuals implicate fiduciary responsibility.<sup>215</sup> Because these duties do not depend upon one's status as a director or officer,<sup>216</sup> the Doctrine should encompass both, although any particular circumstance may

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212. OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT (2010), available at [http://oig.hhs.gov/fraud/exclusions/files/permissive\\_excl\\_under\\_1128b15\\_10192010.pdf](http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf).

213. *Id.* at 3-4.

214. The Responsible Corporate Office Doctrine has never, to my pervasive knowledge been applied to executives of a compounder, which is not subject to pervasive FDA jurisdiction. However, section 351(a)(2)(B), which relates to products determined to be adulterated due to the failure to adhere to good manufacturing practices, applies to a compounded drug that fails to meet the criteria of section 353(a), which would thereby seem to encompass NECC.

215. Amy J. Sepinwall, *Guilty by Proxy: Expanding the Boundaries of Responsibility in the Face of Corporate Crime*, 63 HASTINGS L.J. 411, 439-40 (2012).

216. See, e.g., *Gantler v. Stephens*, 965 A.2d 695, 708-09 (Del. 2009); see, e.g., *Friedman v. Sebelius*, No. 11-5028, 2012 WL 3055520 at \*1 (D.C. 2012); see also Sepinwall, *supra* note 215, at 417 n.26 (stating officers and directors owe the corporation the same fiduciary duties).

not justify punishing directors as well as officers. Corporate officers and directors must own the culture of their organizations. Every conversation about corporate ethics and compliance rests on the foundation principle that the “tone is set at the top.”<sup>217</sup> This should translate into a system that incentivizes, rewards, and sanctions those at the top, who are the entity’s directors. As suggested earlier, corporate law jurisprudence does not aspire to encourage corporate morality.<sup>218</sup> Neither is it particularly effective at addressing corporate illegalities if those legal breaches are highly profitable. The law of fiduciary duties wishes to give breadth for risk-taking, which results in over-breadth, as it can also protect law breaking. Enforcement agencies charged in particular with protecting public health and safety require another tool in their armament. The ability to impose the RCO Doctrine on both officers and directors could prove to be such a tool.

The RCO Doctrine should be used sparingly. *Dotterweich, Park, Purdue Pharma* and *Synthes* were egregious situations that epitomize the appropriate application of the Park Doctrine. It should be employed against responsible executives and/or directors of New England Compounding. Enforcement agencies seek structural reform of corrupt organizations. When it is the culture, as opposed to the more frequent situation where it is an individual or a segment of the organization, that is corrupt, the responsibility for this failure must lie at the feet of the organization’s corporate leadership, and there should be tools for accountability. The determination of whether an organization is truly corrupt should be hard and complex, with a consideration of how long current leadership has been at the helm, the complexity and size of the organization, whether an effective corporate compliance program exists, the pervasiveness of illegal conduct throughout the organization such that it can be said to be encouraged or approved, the values and incentives used in hiring and rewarding those who exercise discretionary authority throughout the organization.

This justification of the RCO Doctrine is not dissimilar to the rationale presented by Professor Sepinwall for corporate criminal liability, with the twist that while the liability would be that of the corporation, she wishes to see individual corporate officers singled out for punishment as surrogates of a sort for the corporate entity.<sup>219</sup> As conceived by Sepinwall, “when the corporation commits a crime, its senior officers and directors are necessarily blameworthy, *whether or not they participated in the crime, recklessly tolerated it, or negligently allowed it to occur.*”<sup>220</sup> Specifically, she believes,

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217. Mark S. Schwartz et al., *Tone at the Top: An Ethics Code for Directors?*, 58 J. BUS. ETHICS 79, 82 (2005).

218. See *supra* Part II.A.

219. Sepinwall, *supra* note 215, at 438-40.

220. *Id.* at 415 (emphasis in original).

as do I, that there are cases of corporate criminal liability where the corporate officials are morally responsible for the crime,<sup>221</sup> and should be held to some account. This position is not intended to suggest that the corporation is not also a moral agent with responsibility.<sup>222</sup> In the situation that frames this article, however, that is neither here nor there, as we have already concluded that we seek to avoid the great harms that would result from corporate prosecution.

The most significant objection to the RCO Doctrine is that it requires no evidence of knowledge of wrongdoing by the corporate officer.<sup>223</sup> The absence of the specific knowledge requirement goes to the heart of the goals being pursued in seeking a reform of ethos or norms. Rogue behavior by an isolated individual is much more credible in entities with a zero tolerance policy with respect to certain kinds of behavior. If such a corporate climate exists, rogue behavior by a single individual or a particular unit of a company is more likely to be reported or discovered and dealt with. If instead the problem is that the performance expectations to which employees are held require violations of the law to be met, the problem is actually one of ethos set by management and the board, not the rogue employee who is morally incapable of following the rules.<sup>224</sup> And this is the ultimate point of the RCO doctrine — it is about creating a corporate atmosphere about expectations, and clear consequences when such expectations are not met.<sup>225</sup> Creating this ethos is the responsibility of the board in the first instance, to be executed by the corporation's officers. The operating assumption accepts that it is impossible for corporate leadership to know everything that occurs ostensibly in the corporation's name or on its behalf. However, leadership can also insulate itself from knowledge — giving themselves "plausible deniability" — which is an option that should not be available.<sup>226</sup>

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221. *Id.* at 447.

222. *Id.* at 422.

223. FDA REGULATORY PROCEDURES MANUAL, *supra* note 205, at 6-49.

224. As explained by Professor Baer:

[N]oncompliance often comes about not because an employee has some burning desire to violate the law, but because he needs noncompliance to substitute for some performance goal that has been previously set within the firm. Because he lacks sufficient voice to challenge the performance goal as unrealistic *ex ante*, he violates the law *ex post* in order to meet previously set expectations.

Baer, *supra* note 36, at 1008-09.

225. See Sepinwall, *supra* note 215, at 440.

226. Donald C. Langevoort, *Internal Controls After Sarbanes-Oxley: Revisiting Corporate Law's "Duty of Care as Responsibility for Systems"*, 31 J. CORP. L. 949, 958 (2006).