

A CALL TO PROSECUTE DRUG COMPANY FRAUD AS ORGANIZED CRIME

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INTRODUCTION

In 2011, Merck Pharmaceuticals (“Merck”) admitted to illegally misbranding its prescription painkiller Vioxx.¹ Researchers and executives concealed evidence that Vioxx caused an alarming number of heart attacks during clinical trials.² Rather than disclose these results, Merck hired ghostwriters to draft deceptive journal articles touting

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1. Press Release, U.S. Dep’t of Justice, U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx® (Nov. 22, 2011) [hereinafter Merck Press Release], <https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion>.

2. Deanna Minasi, Note, *Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters*, 86 FORDHAM L. REV. 299, 310 (2017). See generally Stephanie M. Greene, *After Caronia: First Amendment Concerns in Off Label Promotion*, 51 SAN DIEGO L. REV. 645 (2014) (discussing various concerns about off-label prescription drug use including undisclosed side effects).

Vioxx's safety and efficacy.³ To lend credibility to these articles in the medical community, Merck paid doctors to add their names as article co-authors.⁴ Despite knowledge that patients taking Vioxx were six times more likely to have heart attacks than patients not taking the drug, Merck executives aggressively marketed Vioxx to the public.⁵ Company sales representatives persuaded doctors—via material false statements and illegal kickbacks—to prescribe the drug to patients.⁶ Merck made approximately eleven billion dollars from Vioxx sales before voluntarily pulling the drug from the market.⁷ Regulators estimate that Vioxx killed at least 60,000 people.⁸ The government did not charge any Merck executives, employees, researchers, or doctors with a crime.⁹ Instead, Merck paid a fine and pled guilty to one count of violating the Food Drug and Cosmetic Act related to its marketing of Vioxx.¹⁰ Merck paid its CEO Raymond Gilmartin—who oversaw the Vioxx regime—nearly forty million dollars during his final year of employment.¹¹ After departing from Merck, Gilmartin proceeded not to jail, but to Harvard Business School to teach courses in corporate social responsibility.¹²

Similar stories are unfortunately common in the pharmaceutical industry. Indeed, the pharmaceutical industry is beset with fraud, yet the U.S. government is doing little to protect the American people from this dangerous criminal activity. Prescription drug fraud like Merck's

3. Minasi, *supra* note 2, at 310.

4. *Id.*

5. David R. Culp & Isobel Berry, *Merck and the Vioxx Debacle*, 22 ST. JOHN'S J.L. COMM. 1, 18 n.98, 19 (2007).

6. *Id.* at 25; Carrie Johnson, *Merck to Pay \$650 Million in Medicaid Settlement*, WASH. POST (Feb. 8, 2008), <http://www.washingtonpost.com/wp-dyn/content/article/2008/02/07/AR2008020701336.html>.

7. Linda A. Johnson, *Merck to Start Writing Vioxx Checks in August*, CHARLOTTE OBSERVER (Jul. 18, 2008), <https://www.charlotteobserver.com/news/business/article8993681.html>.

8. See Matthew Herper, *David Graham on the Vioxx Verdict*, FORBES (Aug. 19, 2005) (estimating 60,000 people), https://www.forbes.com/2005/08/19/merck-vioxx-graham_cx_mh_0819graham.html#2b3ed9175698. But see Alexander Cockburn, *When Half a Million Americans Died and Nobody Noticed*, WEEK U.K. (Apr. 27, 2012) (estimating 500,000 people), <http://www.theweek.co.uk/us/46535/when-half-million-americans-died-and-nobody-noticed>.

9. See Cockburn, *supra* note 8.

10. See Merck Press Release, *supra* note 1.

11. TOM NESI, POISON PILLS: THE UNTOLD STORY OF THE VIOXX DRUG SCANDAL 251 (2008).

12. See generally Raymond Gilmartin, *CEOs Need a New Set of Beliefs*, HARVARD BUS. REV. (Sep. 26, 2011), <https://hbr.org/2011/09/ceos-need-a-new-set-of-beliefs.html> (sharing thoughts on the path that CEOs should take, using his own experiences as the CEO of Merck to a professor of Harvard Business School).

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contributes to more than 100,000 American fatalities every year.¹³ However, few (if any) drug company executives or other complicit parties face criminal charges for fraudulently developing and marketing these drugs. The legal framework that governs the pharmaceutical industry is broken and the time has come for the government to change its enforcement strategy.¹⁴

This Article proposes that the government should prosecute drug company fraud as organized crime under the Racketeering Influenced and Corrupt Organizations Act of 1970 (RICO).¹⁵ The government faced similar prosecutorial barriers while combating the Mafia in the 1960s,¹⁶ which is why it enacted RICO. Instead of focusing on individual crimes, RICO allows the government to prosecute an entire criminal enterprise and its constituent members at once—it “paint[s] with a broad brush” to unite individual criminal acts into an organized pattern of crime.¹⁷ Prior to RICO, high-ranking Mafia members avoided prosecution simply by delegating crimes to underlings who would take the fall for the larger organization.¹⁸ With RICO at its disposal, the government instead holds each member of the criminal enterprise—whether the “boss” or a “soldier”—accountable for the conduct of the other members of the crime syndicate.¹⁹ RICO aggregates the crimes of all enterprise members into the single offense of *participating* in the criminal enterprise and imposes the same punishment on all participants regardless of their rank in—or illegal contribution to—the organization.²⁰ The government can present evidence, which would otherwise be inadmissible, about a defendant’s

13. See Robert Parker Tricarico, Note, *A Nation in the Throes of Addiction: Why a National Prescription Drug Monitoring Program Is Needed Before It Is Too Late*, 37 WHITTIER L. REV. 117, 123 (2015); Barbara Starfield, *Is US Health Really the Best in the World?*, J. AM. MED. ASS’N. (Jul. 26, 2000), <https://jamanetwork.com/journals/jama/fullarticle/192908>.

14. See Eugene McCarthy, *The Pharma Barons: Corporate Law’s Dangerous New “Race to the Bottom” in the Pharmaceutical Industry*, 8 MICH. BUS. & ENTREP. L. REV. 29, 30–31 (2018).

15. See 18 U.S.C. §§ 1961–1968 (2012).

16. See Organized Crime Control Act of 1970, Pub. L. No. 91-452, 84 Stat. 922 (codified at scattered sections of 18 U.S.C.).

17. Peter J. Henning, *RICO Charge in Pharmaceutical Case May Signal Tougher Tactics*, N.Y. TIMES (Dec. 12, 2016), <https://www.nytimes.com/2016/12/12/business/dealbook/rico-charge-in-pharmaceutical-case-may-signal-tougher-tactics.html>.

18. Benjamin Scotti, Comment, *Rico vs. 416-bis: A Comparison of U.S. and Italian Anti-Organized Crime Legislation*, 25 LOY. L.A. INT’L & COMP. L. REV. 143, 147–48 (2002).

19. Henning, *supra* note 17.

20. See 18 U.S.C. § 1962(c); Brian Goodwin, *Civil Versus Criminal RICO and the “Eradication” of La Cosa Nostra*, 28 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 279, 287 (2002).

criminal associations and past crimes related to the enterprise.²¹ If convicted of violating RICO, each enterprise member is subject to a maximum twenty-year prison sentence and a mandatory forfeiture of assets.²² As such, RICO “has been instrumental in the government’s mission of eradicating organized crime and has proven to be a most effective means of dismantling organized criminal entities such as the Mafia.”²³

Many drug companies engage in Mafia-like criminal behavior and the government should therefore punish them accordingly. Drug companies and other complicit profiteers from the scientific, medical, legal, and political spheres function as organized criminal enterprises. These criminal enterprises routinely engage in patterns of fraud related to the testing, marketing, and distribution of dangerous pharmaceutical drugs.²⁴ However, because of each enterprises’ complex organizational structure, the government has made little headway in curtailing widespread industry corruption.²⁵ Deploying RICO against drug company fraud will help the government dismantle pharmaceutical industry criminal enterprises that kill hundreds of innocent Americans every day for the sake of profit.²⁶

This argument has three key components. Part I examines the nature and extent of pharmaceutical industry fraud. As a matter of course, many drug companies engage in fraud related to the testing and marketing of their prescription drugs.²⁷ Researchers and executives routinely hide a drug’s dangerous side effects and then persuade doctors—often through lies, bribes, and kickbacks—to prescribe it to patients.²⁸ At the same time, executives insulate themselves from meaningful punishment through extensive lobbying efforts and by erecting a revolving door between the

21. Lesley Suzanne Bonney, Comment, *The Prosecution of Sophisticated Urban Street Gangs: A Proper Application of RICO*, 42 CATH. U.L. REV. 579, 595 (1993); Michael Goldsmith, *Resurrecting Rico: Removing Immunity for White-Collar Crime*, 41 HARV. J. ON LEGIS. 281, 286–87 (2004).

22. 18 U.S.C. § 1963(a) (2012); *see also* United States v. Corrado, 227 F.3d 543, 552 (6th Cir. 2000) (first citing United States v. Defries, 129 F.3d 1293, 1313 (D.D.C. 1997); and then citing United States v. Russello, 464 U.S. 16, 26–27 (1983)) (establishing mandatory forfeiture in accordance with the language of 18 U.S.C. § 1963(a)).

23. Bonney, *supra* note 21, at 612.

24. *See, e.g.*, Merck Press Release, *supra* note 1.

25. *See* Michael Goldsmith, *RICO and Enterprise Criminality: A Response to Gerard E. Lynch*, 88 COLUM. L. REV. 774, 775 (1988) (discussing the difficulties the government had in curtailing organized crime activity which is similar in nature to fraudulent drug companies).

26. *See* Starfield, *supra* note 13.

27. *See* Tricarico, *supra* note 13, at 120–22.

28. *See* JEROME P. KASSIRER, ON THE TAKE: HOW AMERICA’S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH ch. 2 (2005) (discussing the different incentives by pharmaceutical companies to persuade doctors to prescribe to patients).

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industry and government.²⁹ Part II explains how RICO targets this sort of “organized crime” and enables prosecutors to demonstrate how various individuals constitute a single criminal enterprise.³⁰ This section explains how Congress anticipated using RICO against precisely this type of drug company fraud when it enacted the statute, despite corporate insiders’ claims to the contrary. In fact, the similarities between “traditional” organized crime syndicates like the Mafia and the pharmaceutical industry are uncanny. Both the Mafia and drug companies engage in violent crime for profit while relying on strict hierarchical structures and a delegation of criminal authority to insulate high-ranking officials from punishment.³¹ Part III applies RICO to pharmaceutical industry criminal enterprises. RICO would aggregate and punish the illicit acts of executives, salespersons, corrupt doctors, advisory lawyers, and the politicians who participate in a related pattern of fraud to profit through the sale of harmful prescription drugs.

I. THE FRAUD EPIDEMIC IN THE PHARMACEUTICAL INDUSTRY

Pharmaceutical companies engage in a sophisticated system of fraud with regard to prescription drug research, marketing, and distribution. These companies face few, if any, repercussions for their fraudulent behavior. As this Part demonstrates, Merck’s Vioxx scandal is but one of many instances of pharmaceutical industry fraud that harms Americans while leaving criminals unpunished.³² Drug companies routinely profit from misleading the U.S. Food and Drug Administration (FDA) and persuading the public to consume large quantities of unnecessary, ineffective, and often deadly prescription drugs.³³ Typical pharmaceutical industry fraud involves culpable behavior from not only the drug company executives, but also researchers, sales representatives, medical doctors, and even lawyers and politicians who are associated with and receive payments from these companies.³⁴ To demonstrate the nature and extent of drug company fraud, Section I.A maps out the ineffective legal framework that governs the pharmaceutical industry and

29. See Minasi, *supra* note 2, at 313 (discussing the various governmental entities engaged in punishing the behavior of Merck in particular).

30. Goldsmith, *supra* note 25, at 774.

31. See Goodwin, *supra* note 20, at 301; see also James B. Jacobs & Lauryn P. Gouldin, *Cosa Nostra: The Final Chapter?*, 25 CRIME & JUST. 129, 140 (1999).

32. See, e.g., Cockburn, *supra* note 8.

33. See generally JOSEPH DUMIT, DRUGS FOR LIFE: HOW PHARMACEUTICAL COMPANIES DEFINE OUR HEALTH (Duke Univ. Press 2012); DAVID HEALY, PHARMAGEDDON (Univ. Cal. Press 2012) (demonstrating how drug companies aim to persuade American to take unnecessary and often dangerous prescription drugs for the sole purpose of corporate profit).

34. See KASSIRER, *supra* note 28, at 31.

offers several case studies to demonstrate this industry fraud in action.

A. The Legal Framework for Fraud in the Pharmaceutical Industry

The root of pharmaceutical industry fraud lies, paradoxically, in legislation that was designed to eliminate dangerous drug company misrepresentations. Congress passed the Kefauver-Harris Amendments to the Food and Drug Cosmetic Act in 1962.³⁵ This legislation responded to public outrage over severe birth defects caused by Thalidomide, an anti-anxiety drug that doctors prescribed to pregnant women.³⁶ The Kefauver-Harris Amendments established new protocols that required drug companies to conduct clinical trials to prove a new drug was safe and effective—these protocols also required full disclosure of a drug’s adverse side effects.³⁷ The goal was to achieve a system of “evidence-based medicine,” whereby hard scientific proof would establish a new drug’s utility.³⁸ The safety protocols—which are still in effect today—require drug companies to first identify a potential therapeutic use for the drug and to begin testing it on animals.³⁹ If the drug proves safe and effective relative to existing treatments, the drug company initiates three phases of human testing.⁴⁰ The first phase involves tests on a small group of human subjects, usually fewer than eighty patients.⁴¹ If the drug still appears safe and effective, drug companies begin phase two clinical trials and expand the testing to a larger group of several hundred patients.⁴² If trial results remain positive, the company begins phase three testing, which includes controlled clinical trials with thousands of patients.⁴³ These clinical trials compare patients taking the experimental drug with a control group.⁴⁴ The control group takes either a placebo or a standard therapy that the FDA has already approved.⁴⁵ If the drug company conducts two successful phase three clinical trials that demonstrate “statistically significant” positive results in comparison to the control group, they may petition the FDA for approval to market the drug.⁴⁶ After

35. See Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified in scattered sections of 21 U.S.C.).

36. Marc A. Rodwin, *Independent Clinical Trials to Test Drugs: The Neglected Reform*, 6 ST. LOUIS UNIV. J. HEALTH L. & POL’Y 113, 123 (2012).

37. See 21 U.S.C. §§ 321 (p)(1), 355(d) (2012).

38. See Rodwin, *supra* note 36, at 124.

39. 21 C.F.R. § 312.23(a)(8) (2018).

40. 21 C.F.R. § 312.21 (2018).

41. *Id.* § 312.21(a).

42. *Id.* § 312.21(b).

43. *Id.* § 312.21(c).

44. Rodwin, *supra* note 36, at 125.

45. *Id.*

46. HEALY, *supra* note 33, at 77.

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the FDA approves the drug, the company is free to market the drug to the public for all approved FDA uses—but *only* FDA approved uses.⁴⁷

Clinical trials are expensive to conduct. Drug companies claim that securing FDA approval for a new drug costs approximately \$800 million.⁴⁸ These high costs raise the stakes for clinical trials and tempt drug companies to engage in “clinical bias.”⁴⁹ Clinical bias is the process through which drug companies rig the clinical trial to ensure that the drug appears safe and effective.⁵⁰ A drug company engages in this fraud by encouraging its paid—and therefore financially dependent—researchers to break from scientific protocol, hide data, misreport data, or even invent the data that they gather during the clinical trial.⁵¹ Drummond Rennie, an editor of the highly respected *Journal of the American Medical Association*, decries the industry’s reliance on clinical bias in the following terms:

[I]t is very much in the interest of the drug’s sponsor, or manufacturer, to make everyone in the process its dependent, fostering as many conflicts of interest as possible. Before the approval process, the sponsor sets up the clinical trial—the drug selected, and the dose and route of administration of the comparison drug (or placebo). Since the trial is designed to have one outcome, is it surprising that the comparison drug may be hobbled—given in the wrong dose, by the wrong method? The sponsor pays those who collect the evidence, doctors, and nurses, so is it surprising that in a dozen ways they influence results? All the results flow in to the sponsor, who analyses the evidence, *drops what is inconvenient, and keeps it all secret*—even from the trial physicians. . . . If the drug seems no good or harmful, the trial is buried and everyone reminded of their confidentiality agreements. . . . In short, we have a system where defendant, developers of evidence, police, judge, jury, and even court reporters are all induced to arrive at one conclusion in favor of the new drug.⁵²

Perhaps even more problematic is the fact that a drug company is not required to report a failed clinical trial—for all intents and purposes, the FDA ignores negative clinical trial results.⁵³ A drug company could in theory conduct twenty (or even 100) clinical trials in which a new drug proves dangerous and ineffective, but then rig two biased clinical trials

47. Rodwin, *supra* note 36, at 114.

48. Drummond Rennie, *When Evidence Isn’t: Trials, Drug Companies and the FDA*, 15 J.L. & POL’Y 991, 1008 (2007).

49. Rodwin, *supra* note 36, at 131.

50. *See id.* at 129–30.

51. *Id.*

52. Rennie, *supra* note 48, at 1007–08 (emphasis added) (internal footnotes omitted).

53. DUMIT, *supra* note 33, at 100.

that show the new drug outperforming a placebo in order to successfully secure FDA approval to market its drug.⁵⁴ Clinical bias allows drug companies to engage in fraud that transforms a drug that a clinical trial has proven unsafe or ineffective into what appears to be a “wonder drug.”⁵⁵ Medical experts call clinical bias “profoundly corrupting” and note that “those who have the most to gain by finding positive results in clinical trials are often the only source of information about their drugs.”⁵⁶ Doctors and the general public have no way to know whether the “evidence” from a clinical trial is the byproduct of fraud.⁵⁷

The fraud inherent in the regime of “evidence-based medicine” extends also to the dissemination of clinical trial results.⁵⁸ Engaging in the practice known as “publication bias,” drug companies only publish—and *pay* to have published—the positive results from their clinical trials.⁵⁹ It is standard operating procedure for a drug company—or a professional ghostwriter the company hires—to draft an article that inaccurately describes the safety and efficacy of its new drug, and then to pay “thought leaders” (respected doctors) to sign their names to the article as authors.⁶⁰ The drug company “manages” the “evidence” during the entire publication process from the article’s first draft through its paid placement in respected medical journals.⁶¹ Drug companies also refuse to publish negative clinical trial results and have threatened the careers of researchers who contravene the accuracy of their purported clinical trials and subsequent publications.⁶² Recent court orders requiring drug companies to disclose all of their clinical trial data have proven ineffective due to industry-wide noncompliance with disclosure protocols.⁶³ In short, not only is the information that emerges from clinical trials fraudulently skewed in the company’s favor, but so too is the information that companies disseminate throughout the medical community. A drug that clinical trials proved to be dangerous or ineffective will once again appear—after the company “manages” its

54. HEALY, *supra* note 33, at 77.

55. *See id.*

56. Rennie, *supra* note 48, 1009–10.

57. *See id.* at 1001–02.

58. *See* Rodwin, *supra* note 36, at 129.

59. *Id.*

60. KASSIRER, *supra* note 28, at 31.

61. *See* Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 PLOS MED. 1429, 1429 (2007), <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.0040286&type=printable>.

62. *See, e.g.,* Culp & Berry, *supra* note 5, at 27.

63. *See* Minasi, *supra* note 2, at 306–07.

“evidence”—to be a safe and effective treatment.⁶⁴

The next step in the process of pharmaceutical industry fraud is the recrafting of “evidence” from biased clinical trials and ghostwritten publications into marketing materials fit for public consumption.⁶⁵ Drug companies try to persuade consumers (via materially misleading commercial advertisements) to purchase and use their prescription drugs.⁶⁶ The pharmaceutical industry achieved a major marketing breakthrough as a result of legal changes that arose from the Food and Drug Modernization Act of 1997 (FDAMA).⁶⁷ FDAMA lifted the long-standing restriction on direct-to-consumer (DTC) prescription drug advertising.⁶⁸ The United States is the only nation that affirmatively authorizes drug companies to advertise prescription drugs directly to the public.⁶⁹ Other nations ban DTC prescription drug advertising because they fear such practices will result in fraudulent “disease mongering,” or a drug company’s attempt to create “awareness” of a “disease” that they actually invented—or overstated the prevalence of—for the sole purpose of selling a treatment for profit.⁷⁰ Critics point to examples such as the increased occurrence of restless-leg syndrome and fibromyalgia in the wake of advertising campaigns as pharmaceutical industry for-profit constructions of disease.⁷¹ Drug companies justify DTC prescription drug advertising under the auspices of “educating” the public; however, “the primary purpose of DTC advertising is not to educate consumers, but instead is to encourage them to actively seek out medication that their physician would not otherwise prescribe.”⁷² Indeed, these “educational” advertisements earn drug companies more than four dollars in profit for

64. *See id.* at 303.

65. *See* Chung-Lin Chen, *Assessing Potential Legal Responses to Medical Ghostwriting: Effectiveness and Constitutionality*, 5 J.L. & BIOSCIENCES 84, 88 (2018).

66. *See* Amanda L. Connors, Note, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 ALB. L. REV. 243, 244 (2009).

67. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 421, 111 Stat. 2296, 2380 (codified at 21 U.S.C. § 331(*l*)) (2012)); Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171, 43,172 (Aug. 12, 1997).

68. *See* 21 U.S.C. § 331(*l*); Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. at 43,172.

69. *See* Connors, *supra* note 66, at 267. New Zealand also allows drug companies to engage in DTC prescription drug advertising, but in New Zealand this legal outcome appears to be the result of a legislative oversight. *See* Susanna Every-Palmer et al., *Direct-to-Consumer Advertising of Prescription Medication in New Zealand*, 127 N.Z. MED. J. 102, 103 (2014).

70. *See* HEALY, *supra* note 33, at 38.

71. *See id.*

72. David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 286 (2007).

every one dollar they invest in DTC prescription drug advertising.⁷³ This profit margin exists because doctors prescribe the drug a patient requests approximately seventy-five percent of the time.⁷⁴ As a result, drug companies now spend twice as much money on marketing than they do on research and development.⁷⁵ This marketing saturation means that the average American actually spends more time each year viewing DTC prescription drug advertisements than they do with their primary care physician.⁷⁶ Note, importantly, that these DTC prescription drug advertisements are seldom (if ever) for “cures,” but instead seek to sell so-called blockbuster “lifestyle drugs” that require once-a-day treatment for life so as to maximize the drug company’s market share and profit margins.⁷⁷ DTC advertisements further compound industry fraud, since these misleading marketing campaigns simply relay the fabricated evidence that companies obtain through both clinical bias and publication bias.⁷⁸

FDAMA also instituted changes that allow drug company representatives to engage in new forms of off-label “detailing” of doctors.⁷⁹ Detailing is the practice through which pharmaceutical sales representatives meet privately with a doctor in an attempt to persuade her to prescribe drugs to patients for uses that the FDA has not approved.⁸⁰ Doctors retain the right to prescribe any drug they deem medically

73. See Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. TECH. L. REV. 1, 27 (2015).

74. See Vladeck, *supra* note 72, at 270.

75. Greene, *supra* note 2, at 696.

76. See Vladeck, *supra* note 72, at 270.

77. Joseph Dumit describes this industry logic with regard to DTC advertising in the following terms:

Once you take the perspective that what matters is not return to health but the growth of prescription sales, it is obvious that patients are valuable only to the extent they can afford to purchase treatments (or have treatments purchased for them). Often, research is directed . . . at me-too drugs, tiny variations on existing drugs with very little difference in efficacy that can nonetheless be patented and used to take over existing markets.

DUMIT, *supra* note 33, at 94–95.

78. See Sismondo, *supra* note 61, at 1429.

79. See U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES 3–4 (2008).

80. See Puneet Manchanda & Elisabeth Honka, *Pharmaceutical Innovation and Cost: An American Dilemma: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL’Y L. & ETHICS 785, 785 (2005).

necessary, even if the FDA has not approved that drug to treat a particular condition.⁸¹ In an effort to persuade doctors to supersede FDA approval, sales representatives present them with journal articles—the same ones that the drug company has written—about a drug’s effectiveness to treat a particular ailment for which it is not approved.⁸² Ghostwriters who draft these journal articles on behalf of the drug companies describe them as “marketing masquerading as science.”⁸³ If the company-prepared “proof” remains unpersuasive, some drug representatives—at the behest of corporate executives—illegally bribe the doctor or offer her a kickback to prescribe the drug for an off-label (or unapproved) use.⁸⁴ These bribes and kickbacks come in the form of honoraria payments, bogus speaker’s fees (doctors often give the “speeches” while out to dinner at a restaurant with friends), or trips to exotic locales.⁸⁵

Detailing is a very effective marketing tactic, as twenty percent of all prescriptions that doctors write are for off-label uses.⁸⁶ In many patient populations, off-label prescriptions constitute the bulk of treatment, as up to seventy-five percent of cancer drugs, eighty percent of pediatric drugs, and ninety percent of prescription drugs for rare diseases are off-label.⁸⁷ Drug companies earn hundreds of billions of dollars each year from the sale of off-label prescription drugs.⁸⁸ These numbers are all the more staggering when one considers that “more than 70 percent of off-label uses lack significant scientific support.”⁸⁹ At best, the vast majority of off-label treatments are experimental; at worst, the drug companies often know that these off-label treatments are ineffective or harmful.⁹⁰ Off-

81. Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*, 41 J.L. MED. & ETHICS 654, 654 (2013).

82. *Id.* at 657.

83. KASSIRER, *supra* note 28, at 33.

84. See Press Release, U.S. Att’y’s Office for the Dist. of Mass., Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017) [hereinafter Insys Press Release], <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

85. Minasi, *supra* note 2, at 310; Tricarico, *supra* note 13, at 121; Janelle Lawrence & Jef Feeley, *Ivy League Doctor Gets 4 Years in Prison for Insys Opioid Kickbacks*, BLOOMBERG (Mar. 9, 2018), <https://www.bloomberg.com/news/articles/2018-03-09/ivy-league-doctor-gets-4-years-prison-for-insys-opioid-kickbacks>.

86. Stephanie M. Greene & Lars Noah, Debate, *Off-Label Drug Promotion and the First Amendment*, 162 U. PA. L. REV. ONLINE 239, 241 (2014).

87. Rodwin, *supra* note 81, at 656.

88. *Id.* at 658. This calculation is based on the estimate that 2017 global pharmaceutical sales are expected to top \$1.2 trillion. See Craig W. Lindsley, *New 2016 Data and Statistics for Global Pharmaceutical Products and Projections through 2017*, 8 ACS CHEM. NEUROSCI. 1635, 1635 (2017). Twenty percent—the percentage of off-label prescription sales—would amount to \$240 billion. See *id.*

89. Rodwin, *supra* note 81, at 656.

90. See Greene, *supra* note 2, at 656–57.

label detailing adds still another opportunity for drug companies to commit prescription drug fraud and corruption.

The government's response—or, more accurately, *lack* of response—to this systemic fraud is perhaps more disturbing than the pharmaceutical industry's illegal behavior. Except in very rare situations, the government does not hold individual drug company executives or representatives accountable for their criminal acts of fraud related to clinical bias, publication bias, and misleading advertising campaigns.⁹¹ Rather than charging individual executives with a crime, the government enters into deferred-prosecution agreements (DPAs) or non-prosecution agreements (NPAs) with the corporate entity.⁹² Under a DPA,

the prosecutor and the corporation agree that although the prosecutor will charge the corporation in federal court, the prosecutor will defer the continued prosecution of the charges until the end of a certain period of time agreed upon by both parties. If, at the end of the term of the agreement, the corporation has followed through on its obligations [under a corporate integrity agreement], the prosecutor will dismiss the charges.⁹³

An NPA functions in a similar manner, only the government does not even take the step of filing charges in federal court so as to defer them to a later date.⁹⁴ As part of the DPA or NPA, a drug company will typically pay a criminal fine out of the corporate treasury and agree to implement internal reforms to prevent future criminal fraud.⁹⁵ Professor Brandon Garrett believes that the government resorts to DPAs rather than individual criminal prosecutions of executives because proving intentional fraud is difficult given the organizational complexity and diffuse responsibilities of corporate decision making.⁹⁶ He also points to the fact the corporate executives are “sophisticated actors” who can “point fingers at each other, or their lawyers, or their accountants, or their risk managers, or others” in escaping culpability for their decisions.⁹⁷ As such, the government conducts a cost-benefit analysis and determines that

91. Henning, *supra* note 17. The government has charged six executives from Insys for engaging in bribery to persuade doctors to prescribe a highly addictive fentanyl spray; it is not yet clear whether the government will settle charges with these defendants. *See id.*

92. *See* Cindy R. Alexander & Mark A. Cohen, *The Evolution of Corporate Criminal Settlements: An Empirical Perspective on Non-Prosecution, Deferred Prosecution, and Plea Agreements*, 52 AM. CRIM. L. REV. 537, 537 (2015).

93. *Id.* at 545.

94. *Id.*

95. *See* Brandon L. Garrett, *The Corporate Criminal as Scapegoat*, 101 VA. L. REV. 1789, 1848 (2015).

96. *Id.* at 1825–26.

97. *Id.* at 1836.

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the DPA is the safer bet for ensuring at least some corporate accountability.⁹⁸ A more cynical explanation for the government's failed prosecution of pharmaceutical industry fraud is that "large companies can buy their way out of criminal prosecution."⁹⁹ Unfortunately, the empirical evidence supports this cynical conclusion that the government shows preferential prosecutorial treatment to large domestic corporations like the pharmaceutical companies discussed herein.¹⁰⁰ But why does the government show such favoritism?

In the past twenty years, the pharmaceutical industry has spent over four billion dollars lobbying government officials, which is over *one billion dollars* more than any other special interest group or industrial sector.¹⁰¹ Since 1999, the pharmaceutical industry has ranked first in U.S. lobbying expenditures every year without exception.¹⁰² Drug companies likewise have the dubious honor of having spent more money lobbying in a single year (\$272 million in 2009) than any other industry.¹⁰³

In addition to lobbying, drug companies insulate themselves from legal regulation by erecting a revolving door between the government and the pharmaceutical industry. In 2017, a total of sixty-seven percent (995 of 1488) of registered pharmaceutical industry lobbyists disclosed that they were once federal officials.¹⁰⁴ Senior FDA officials are typically industry insiders or have strong financial ties to drug companies.¹⁰⁵ Many government regulators are merely biding their time before departing for more lucrative opportunities in the pharmaceutical industry, which experts agree compromises their regulatory decisions.¹⁰⁶

The case of Daniel Troy is illustrative.¹⁰⁷ Troy was a partner at the

98. David M. Uhlmann, *Too Big to Jail: Overcoming the Roadblocks to Regulatory Enforcement: Deferred Prosecution and Non-Prosecution Agreements and the Erosion of Corporate Criminal Liability*, 72 MD. L. REV. 1295, 1324 (2013).

99. *Id.* at 1301.

100. *Id.* at 1326–27.

101. *Top Industries: All Years (1998–2018)*, CTR. FOR RESPONSIVE POLITICS, <https://www.opensecrets.org/lobby/top.php?indexType=i> (last visited Apr. 22, 2019).

102. *See, e.g., Top Industries: 2018*, CTR. FOR RESPONSIVE POLITICS, <https://www.opensecrets.org/lobby/top.php?indexType=i&showYear=2018> (last visited Apr. 22, 2019).

103. Dana Taschner, *PLIVA Shields Big Pharma from Billions, Cuts Consumers' Rights*, 49 SAN DIEGO L. REV. 879, 902 (2012).

104. *Industry: Pharm/Health Prod. 2017*, CTR. FOR RESPONSIVE POLITICS, https://www.opensecrets.org/lobby/indusclient_lob.php?id=h04&year=2017 (last visited Apr. 22, 2019).

105. McCarthy, *supra* note 14, at 59.

106. *See* FRAN HAWTHORNE, *INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT* 150 (2005).

107. *See GlaxoSmithKline GC Dan Troy Preparing to Step Down After 10 Years*, CORP. COUNS. (Jan. 25, 2018, 4:50 PM), <https://www.law.com/corpcounsel/sites/corpcounsel/2018/>

law firm Wiley, Rein & Fielding (and then later at Sidley Austin LLP)—where he represented drug companies against the government—before President George W. Bush appointed him as Chief Counsel of the FDA.¹⁰⁸ As Chief Counsel, Troy implemented several key changes to FDA policies that favored the pharmaceutical industry.¹⁰⁹ Shortly after initiating these changes, Troy left his government position and returned to the pharmaceutical industry to serve as General Counsel and Senior Vice President of GlaxoSmithKline (GSK), one of the largest drug companies in the world.¹¹⁰

These facts and statistics may explain why federal legislation appears to facilitate pharmaceutical industry fraud. They might also help explain why, at least in part, the government fails to prosecute individual drug company executives after it uncovers their fraud.

B. Case Studies of Pharmaceutical Industry Fraud

As the following case studies demonstrate, major drug companies like Merck, GSK, Purdue Pharmaceuticals (“Purdue”), and Pfizer use the legal framework described in the previous section to engage in identical patterns of fraud regarding the development, marketing, and distribution of their prescription drugs.¹¹¹ Recall that Merck lied about their clinical trial data, which revealed that Vioxx greatly increased the risk of heart attack deaths in patients.¹¹² It then hired ghostwriters to draft articles touting the painkiller’s safety and paid doctors to sign their names to these articles.¹¹³ It rolled out a sophisticated DTC advertising campaign starring Olympic figure skater Dorothy Hamill and decathlete Bruce Jenner (now Caitlyn Jenner) that turned “hype into hope” for Americans suffering from arthritis and other chronic pain.¹¹⁴ In the end, Vioxx killed, at best, more Americans (60,000) than the Vietnam conflict and, at worst,

01/25/glaxosmithkline-gc-dan-troy-preparing-to-step-down-after-10-years/ [hereinafter *GlaxoSmithKline*]; see also Daniel Troy, LINKEDIN, <https://www.linkedin.com/in/dan-troy-701868b> (last visited Apr. 25, 2019).

108. *GlaxoSmithKline*, *supra* note 107.

109. See Vladeck, *supra* note 72, at 273–74.

110. *Human Genome Sciences, Inc. Executive Profile: Daniel E. Troy*, BLOOMBERG, <https://www.bloomberg.com/research/stocks/private/person.asp?personId=22278770&privcapId=29617> (last visited Apr. 22, 2019).

111. See Paul J. Zwier & Reuben Guttman, *A Failure of Remedies the Case of Big Pharma*, 3 EMORY CORP. GOVERNANCE ACCOUNTABILITY REV. 41, 53–54 (2016).

112. Walter T. Champion, *The Vioxx Litigation Paradigm: The Search for Smoking Guns*, 31 T. MARSHALL L. REV. 157, 173 (2006).

113. Stephanie Saul, *Ghostwriters Used in Vioxx Studies, Article Says*, N.Y. TIMES (Apr. 15, 2008), <https://www.nytimes.com/2008/04/15/business/15cnd-vioxx.html>.

114. See Darren Rovell, *The Burden of Pitching Pills*, ESPN (Nov. 19, 2004), <http://www.espn.com/espn/sportsbusiness/news/story?id=1927023>.

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more Americans (500,000) than World War II.¹¹⁵ The company admitted to the crimes of introducing a misbranded drug into interstate commerce, conducting illegal off-label promotion, and making false statements about “Vioxx’s cardiovascular safety in order to increase sales of the drug.”¹¹⁶ Merck entered into an NPA with the government and one of its subsidiaries agreed to plead guilty to one misdemeanor charge of illegal promotional activity and to pay a fine of \$950 million.¹¹⁷ No executives faced criminal charges.¹¹⁸ Merck’s story is, unfortunately, typical in the pharmaceutical industry.¹¹⁹

GSK engaged in a nearly identical pattern of fraud with regard to the development and marketing of Paxil, its well-known antidepressant drug.¹²⁰ GSK needed to conduct sixteen separate clinical trials for Paxil in order to achieve the two successful outcomes required to secure FDA approval.¹²¹ During the failed trials, GSK found that Paxil almost tripled the risk of suicide in adolescents.¹²² Nonetheless, GSK engaged in clinical and publication bias to actively conceal this information from both the FDA and the public.¹²³ Worse yet, the company embarked on an off-label detailing campaign specifically designed to persuade doctors to prescribe the drug *to adolescents*.¹²⁴ Despite this knowledge that Paxil caused children to attempt suicide, the company instructed sales representatives to inform doctors that Paxil demonstrated “remarkable efficacy and safety” in the treatment of childhood depression.¹²⁵ Thousands of children and teens ultimately attempted or committed

115. McCarthy, *supra* note 14, at 44. This large discrepancy in fatalities results from the FDA’s conservative estimate in contrast with private investigators’ less politically accountable (and presumably motivated) estimates.

116. Merck Press Release, *supra* note 1.

117. Press Release, Gibson Dunn, 2011 Year-End Update on Corporate Deferred Prosecution and Non-Prosecution Agreements (Jan. 4, 2012), <https://www.gibsondunn.com/2011-year-end-update-on-corporate-deferred-prosecution-and-non-prosecution-agreements/>.

118. McCarthy, *supra* note 14, at 64.

119. *Id.* at 50.

120. 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 (Jul. 2, 2012) [hereinafter GSK Press Release], <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

121. Jonathan J. Darrow, Note, *Pharmaceutical Efficacy: The Illusory Legal Standard*, 70 WASH. & LEE L. REV. 2073, 2098–99 (2013).

122. Timothy J. Hixson, Note, *Anti-depressants and Children: Suicidality, Off-label Use, and Trial Publication*, 3 IND. HEALTH L. REV. 201, 209 (2006).

123. *Id.* at 226.

124. GSK Press Release, *supra* note 120.

125. Press Release, N.Y. State Office of the Att’y Gen., Major Pharmaceutical Firm Concealed Drug Information (Jun. 2, 2004), <https://ag.ny.gov/press-release/major-pharmaceutical-firm-concealed-drug-information>.

suicide while on Paxil.¹²⁶ After the government discovered the Paxil-related fraud, it entered into an NPA with GSK and imposed a three billion dollar fine.¹²⁷ This fine, incidentally, amounts to roughly one-quarter of the nearly twelve billion dollars in profits GSK secured through the sale of Paxil.¹²⁸ The government did not charge any GSK executives, employees, or doctors with a crime,¹²⁹ and the company paid its chief executive approximately fourteen million dollars in the year it settled the criminal charges related to this fraud.¹³⁰

Purdue, the manufacturer of the opioid painkiller OxyContin, likewise utilized this blueprint for profit-via-deadly fraud.¹³¹ Opioid painkillers, like OxyContin, are not effective at treating long-term or chronic pain.¹³² In a tragic case of irony, one of the primary side effects of the long-term use of opioid pain killers is, in fact, *chronic pain*.¹³³ As such, drug companies have yet to conduct successful clinical trials that prove the safety and efficacy of their opioids for treating chronic pain.¹³⁴ Instead, Purdue and other opioid manufacturers lobbied for a new kind of clinical trial that utilizes so-called “enriched enrollment” protocols.¹³⁵ Enriched enrollment protocols allow opioid manufacturers to engage in clinical bias without resorting to the subterfuge required in traditional clinical trials.¹³⁶ These protocols allow researchers who are conducting the clinical trial to actually remove patients from the study who are not responding well to the opioid treatment.¹³⁷ In other words, if the drug is *failing* the clinical trial the researchers remove the subjects who *prove*

126. David Dobbs, *The Human Cost of a Misleading Drug-Safety Study*, ATLANTIC (Sept. 18, 2015), <https://www.theatlantic.com/health/archive/2015/09/paxil-safety-bmj-depression-suicide/406105/>.

127. GSK Press Release, *supra* note 120.

128. Darrow, *supra* note 121, at 2103–04.

129. Katie Thomas & Michael S. Schmidt, *Glaxo Agrees to Pay \$3 Billion in Fraud Settlement*, N.Y. TIMES (July 2, 2012), <https://www.nytimes.com/2012/07/03/business/glaxo-smithkline-agrees-to-pay-3-billion-in-fraud-settlement.html>.

130. Jill Treanor, *GlaxoSmithKline Chief's Pay Package More than Doubles to £6.7m*, GUARDIAN (Mar. 12, 2012), <https://www.theguardian.com/business/2012/mar/12/glaxosmithkline-chief-pay-andrew-witty>.

131. See Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 223 (2009).

132. See ANNA LEMBKE, DRUG DEALER, M.D.: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT'S SO HARD TO STOP 68–69 (2016).

133. *Id.* at 59.

134. Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 562–63 (2015).

135. Martha Rosenberg, *What Big Pharma Doesn't Want You to Know about the Opioid Epidemic*, SALON (Jun. 3, 2016), https://www.salon.com/2016/06/03/what_big_pharma_doesnt_want_you_to_know_about_the_opioid_epidemic_partner/.

136. *Id.*

137. See LEMBKE, *supra* note 132, at 69.

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that it is failing and simply continue the trial without them.¹³⁸ As Dr. Anna Lembke of Stanford Medical School puts it, “The enriched enrollment protocol does appear to be a way for drug companies to cheat, getting approval for opioid painkillers that don’t really work.”¹³⁹

Opioid painkillers are also highly addictive: about twelve percent of patients treated with opioids for chronic pain become addicted, and many of these individuals go on to become heroin addicts.¹⁴⁰ Like Merck and GSK, Purdue employed a ghostwriting campaign to produce false and misleading evidence about OxyContin and actively lied to doctors and the public about how addictive and subject to abuse the company knew the drug to be.¹⁴¹

With these biased results in hand, Purdue launched an aggressive pain “awareness” marketing campaign through which they encouraged doctors to prescribe OxyContin to treat all sorts of pain-related symptoms.¹⁴² Throughout this campaign, they downplayed and lied about OxyContin’s dependency rates.¹⁴³ As part of this marketing campaign, Purdue generously sponsored forty pain management conferences where “more than 5000 physicians, pharmacists, and nurses attended these all-expense-paid symposia” at which Purdue persuaded them to prescribe OxyContin to their patients.¹⁴⁴ Purdue also provided free thirty-day samples of the highly addictive drug to patients across the nation.¹⁴⁵

Opioids including OxyContin kill approximately 130 Americans every day—and killed more than 47,000 Americans in 2017 alone.¹⁴⁶ Experts agree that Purdue deserves the “lion’s share” of blame for these deaths and more generally for the American opioid crisis.¹⁴⁷ OxyContin also causes indirect social harm, as one Virginia county estimates that OxyContin was the root cause of eighty to ninety-five percent of all the

138. *See id.*

139. *Id.* at 68.

140. *Opioid Overdose Crisis*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last revised Jan. 2019).

141. Paul D. Frederickson, *Criminal Marketing: Corporate and Managerial Liability in the Prescription Drug Industry*, 22 *MIDWEST L.J.* 115, 137 (2008).

142. Kolodny et al., *supra* note 134, at 562.

143. *Id.*

144. Van Zee, *supra* note 131, at 221.

145. *Id.* at 222.

146. *The Opioid Epidemic by the Numbers*, U.S. DEP’T. HEALTH & HUM. SERVS., <https://www.hhs.gov/opioids/about-the-epidemic/index.html> (last visited Apr. 25, 2019).

147. Patrick Radden Keefe, *The Family That Built an Empire of Pain*, *NEW YORKER* (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

crimes committed in its jurisdiction.¹⁴⁸

The government eventually addressed Purdue's criminal fraud.¹⁴⁹ In what should now be an unsurprising outcome, Purdue entered into an NPA with the government and a subsidiary pled guilty to "misbranding OxyContin by claiming that it was less addictive and less subject to abuse and diversion than other opioids," while also paying a \$634 million fine.¹⁵⁰ The Sackler family, who owns and controls Purdue,¹⁵¹ enjoys a cumulative net worth of thirteen billion dollars, derived mostly from OxyContin sales.¹⁵²

Finally, Pfizer serves as the poster child for pharmaceutical industry fraud. Pfizer repeatedly (and blatantly) engages in this pattern of prescription drug fraud. In the first instance, the FDA approved Pfizer's drug Neurontin to treat epilepsy.¹⁵³ Not satisfied with the profits derived from this limited approval, Pfizer initiated a "strategic swerve" in marketing and began promoting Neurontin to treat a host of unapproved ailments, such as bipolar disorder and chronic pain.¹⁵⁴ The company was aware that the drug was either unsafe or ineffective for these off-label purposes and was also aware that it caused depression and suicidal tendencies in patients.¹⁵⁵ Indeed, in an internal memo "one [Pfizer] employee referred to Neurontin as 'the snake oil' of the twentieth century."¹⁵⁶ Pfizer's new "strategic swerve" involved a process

whereby academics were solicited with various grants and speaking opportunities to publish and promote Neurontin. Additional marketing tactics involved publishing Neurontin research while disguising its

148. Frederickson, *supra* note 141, at 136.

149. *Id.*

150. Van Zee, *supra* note 131; *see also* Friedman v. Sebelius, 755 F. Supp. 2d 98, 102 n.7 (D.D.C. 2010) (explaining that the government did fine three company executives \$5000 a piece for perpetuating this deadly fraud, but Purdue indemnified them for these and other costs related to criminal charges).

151. *Sackler Family*, FORBES (June 29, 2016), <https://www.forbes.com/profile/sackler/#65eb95535d63>.

152. *See* Chase Peterson-Withorn, *Fortune of Family Behind OxyContin Drops Amid Declining Prescriptions*, FORBES (June 29, 2016), <https://www.forbes.com/sites/chasewithorn/2016/06/29/fortune-of-family-behind-oxycontin-drops-amid-declining-prescriptions/#36a064096341>.

153. Greene, *supra* note 2, at 651–52. Pfizer did not initially develop Neurontin, but acquired Warner-Lambert and that company's patent to Neurontin in 2000. *See Pfizer and Warner-Lambert Merger Creates Industry's Largest R&D Budget*, THE PHARMA LETTER (Oct. 2, 2000), <https://www.thepharmalletter.com/article/pfizer-and-warner-lambert-merger-creates-industry-s-largest-r-d-budget>.

154. Greene, *supra* note 2, at 652.

155. *Id.*; *see In re Neurontin Mktg. & Sales Practices Litig.*, No. 04-CV-10739, 2011 U.S. Dist. LEXIS 99593, at *37–38 (D. Mass. Aug. 31, 2011), *aff'd*, 712 F.3d 21 (1st Cir. 2013).

156. Greene, *supra* note 2, at 652.

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promotional purpose and conducting teleconferences with prescribing physicians that were moderated by well-remunerated contracted physicians involved in the marketing scheme.¹⁵⁷

The fraudulent advertising scheme involving executives, sales representatives, and doctors proved successful.¹⁵⁸ Eventually ninety percent of all Neurontin prescriptions were off-label and sales rose sharply from \$97.5 million in 1995 to \$2.7 billion in 2003.¹⁵⁹ Pfizer likewise bolstered sales by rewarding doctors with kickbacks for prescribing large quantities of Neurontin.¹⁶⁰ The government eventually caught Pfizer and accused the company of engaging in an “illegal and fraudulent promotion scheme [that] corrupted the information process relied upon by doctors in their medical decision making, thereby putting patients at risk.”¹⁶¹ In 2004, Pfizer paid a \$430 million fine and—like the drug companies in each of the previous case studies—entered into an NPA with the government through which they promised to stop this kind of off-label marketing.¹⁶² No individuals were charged with a crime.¹⁶³

In 2007, Pfizer again found itself in trouble after engaging in a nearly identical pattern of fraud regarding its drug Genotropin.¹⁶⁴ Through a subsidiary, Pfizer settled the criminal charges by entering into a DPA with the government and paying a thirty-four million dollar fine.¹⁶⁵

In 2009, the government caught Pfizer executives and sales representatives once again engaging in an identical pattern of fraud with regard to the illegal marketing of the prescription drugs Bextra, Geodon, Zyvox, and Lyrica.¹⁶⁶ The company, it turns out, formulated this new fraudulent scheme while negotiating its first NPA with the government to settle the 2004 Neurontin fraud charges.¹⁶⁷ Even though the

157. Mona Ghogomu, Comment, *When Does the Chain Break? Prescribing Around Drug Manufacturer Fraud*, 67 DEPAUL L. REV. 557, 572 (2018) (internal footnotes omitted).

158. Frederickson, *supra* note 141, at 128.

159. Greene, *supra* note 2, at 653.

160. Frederickson, *supra* note 141, at 128.

161. Press Release, U.S. Dep’t of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004) [hereinafter Warner-Lambert Press Release], https://www.justice.gov/archive/opa/pr/2004/May/04_civ_322.htm.

162. *Id.*

163. *See id.*

164. *See* Robert G. Evans, *Tough on Crime? Pfizer and the CIHR*, 5 HEALTHCARE POL’Y, May 2010, at 19.

165. *Id.*

166. Gardiner Harris, *Pfizer Pays \$2.3 Billion to Settle Marketing Case*, N.Y. TIMES (Sept. 2, 2009), <https://www.nytimes.com/2009/09/03/business/03health.html>.

167. *Id.*

government recognized Pfizer's recidivism in its press release, it entered into another DPA with the company and fined Pfizer \$2.3 billion, which amounts to fewer than three weeks of the company's sales.¹⁶⁸ After reaching an agreement with the government, Pfizer's general counsel Amy Schulman issued a public statement promising that *this time* the company would really stop committing prescription drug fraud.¹⁶⁹ Despite this public promise to behave, the government and Pfizer settled another fraud charge in 2016.¹⁷⁰

In 2018, Pfizer entered into still another DPA with the government and paid \$23.85 million to settle an additional case of fraud.¹⁷¹ At no point did the government charge any individuals for participating in these repeated fraudulent schemes.¹⁷² Pfizer earns approximately fifty billion dollars in annual revenue.¹⁷³ Pfizer is also the pharmaceutical industry's leading contributor to U.S. political campaigns.¹⁷⁴

As these case studies demonstrate, the pharmaceutical industry engages in a pattern of systemic fraud that endangers U.S. public health and safety. The government's current legal response of imposing criminal fines and entering into DPAs and NPAs with drug companies clearly has little to no deterrent value. Pfizer's recidivism is indicative of the industry-wide disregard of the government's enforcement strategy. In just a four-year span, the FDA sent 170 warning notices to companies for engaging in false and misleading advertising or concealing (and misreporting) negative clinical trial results that exposed patients to "considerable risk of harm."¹⁷⁵ Drug companies consistently ignored

168. *Id.*

169. *Id.* Schulman noted: "The reasons to trust Pfizer are because, as I have walked the halls at Pfizer, you would see that the vast majority of our employees spend their lives dedicated to bringing truly important medications to patients and physicians in an appropriate manner." *Id.*

170. Press Release, U.S. Att'y's Office for the Dist. of Mass., Wyeth and Pfizer Agree to Pay \$784.6 Million to Resolve Lawsuit Alleging that Wyeth Underpaid Drug Rebates to Medicaid (Apr. 27, 2016) [hereinafter Wyeth & Pfizer Press Release], <https://www.justice.gov/usao-ma/pr/wyeth-and-pfizer-agree-pay-7846-million-resolve-lawsuit-alleging-wyeth-underpaid-drug>.

171. Press Release, U.S. Att'y's Office for the Dist. of Mass., Pfizer Agrees to Pay \$23.85 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation (May 24, 2018) [hereinafter Pfizer Press Release], <https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay>.

172. *See id.*

173. Niamh Marriott, *The Top 21 . . . Wealthiest Pharma Companies*, EUR. PHARM. REV. (Feb. 6, 2017), <https://www.europeanpharmaceuticalreview.com/article/47001/top-21-wealthiest-pharma-companies/>.

174. *Pharmaceuticals/Health Products: Summary*, CTR. FOR RESPONSIVE POLITICS, <https://www.opensecrets.org/industries/indus.php?ind=H04> (last visited Mar. 21, 2019).

175. Ghogomu, *supra* note 157, at 571.

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these warnings because they faced no meaningful repercussions for doing so.¹⁷⁶ The deferred prosecutions are toothless and the companies write off criminal fines as “a cost of doing business.”¹⁷⁷ What then is the government to do about this fraud? How can it stem the tide of corruption in the pharmaceutical industry? As Part II demonstrates, the government should turn to RICO, the legal tool it devised to respond to other sophisticated criminal enterprises that likewise flouted attempts at government prosecution.

II. RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (RICO) ACT AND PROSECUTING ENTERPRISE CRIMINALITY

The government has a history of confronting dangerous criminal enterprises that have managed to avoid meaningful punishment despite posing a significant threat to public safety.¹⁷⁸ The Mafia, or La Cosa Nostra, frustrated government justice from the Prohibition Era through the early 1980s.¹⁷⁹ The Mafia successfully avoided government sanction because it was “entrepreneurial, opportunistic, and adaptable”; organized crime simply evolved faster than the legal tools the government used against it.¹⁸⁰ Mafia families thrived by employing a hierarchical control structure, limiting membership, securing protection through political bribery, and by enforcing discipline with a rigid set of internal rules.¹⁸¹ As a result, Mafia leaders insulated themselves from government prosecution by delegating crime and decision-making authority down the hierarchical chain.¹⁸² Before RICO, the successful prosecution of high-ranking Mafia members was inconceivable.¹⁸³ The government’s organized crime prosecutions were necessarily piecemeal and targeted only the behavior of low-level individuals engaged in singular criminal acts.¹⁸⁴ The rules of criminal evidence also insulated organized crime syndicates from meaningful prosecution. Normal evidentiary rules prevent the government from introducing at trial evidence about a

176. *See id.*

177. Minasi, *supra* note 2, at 313.

178. *See generally* ROBERT J. KELLY, *ENCYCLOPEDIA OF ORGANIZED CRIME IN THE UNITED STATES: FROM CAPONE’S CHICAGO TO THE NEW URBAN UNDERWORLD* (2000) (providing an in-depth analysis on traditional crime families and organizations, including their escape from criminal liability).

179. *See id.*

180. Goodwin, *supra* note 20, at 286.

181. *Id.*

182. Bonney, *supra* note 21, at 584, 585 n.44.

183. Goodwin, *supra* note 20, at 281.

184. *Id.* at 292.

defendant's associational affiliations and past criminal offenses.¹⁸⁵ These rules provided ideal protection for the Mafia, exposing only individual members of the organization to criminal liability while keeping the larger criminal enterprise a necessary secret from the jury.¹⁸⁶

The government recognized that organized criminal activity posed a greater threat to society than individual crimes and began devising a way to distinguish organized crime from other criminal behavior.¹⁸⁷ Congress sought a statutory scheme to criminalize any *pattern of acts* that contributed to an organized crime syndicate's larger objectives.¹⁸⁸ Allowing law enforcement to focus on the criminal enterprise as opposed to individual crimes would revolutionize the rules of evidence and courtroom procedure. The government needed a tool that would allow it to submit to a jury the "entire history of a criminal organization's illegal acts, including multiple acts committed by a wide range of persons, rather than perpetuating the practice of separately prosecuting individual crimes within a pattern of activity."¹⁸⁹ In other words, prosecutors needed a way to put the entire criminal enterprise on trial at once.

The government enacted RICO to be its new legal weapon to combat organized crime and enterprise criminality.¹⁹⁰ This weapon proved powerful, and since 1980, the government has brought almost every significant organized criminal prosecution under RICO.¹⁹¹ The enterprise-approach to prosecuting crime has largely dismantled the Mafia.¹⁹² This Part explains in detail RICO's legal elements and demonstrates how the government successfully shifted its focus from individual crimes to the larger criminal enterprise in its battle against organized crime.¹⁹³ This Part also demonstrates that the government specifically designed RICO to combat not only organized crime syndicates like the Mafia, but also entities like the drug companies that likewise engage in dangerous and highly profitable enterprise criminality.¹⁹⁴

185. Goldsmith, *supra* note 21, at 286.

186. *Id.* at 286–87.

187. Goodwin, *supra* note 20, at 292.

188. See 18 U.S.C. § 1962 (2012).

189. Bonney, *supra* note 21, at 594.

190. *Id.*

191. Jacobs & Gouldin, *supra* note 31, at 170.

192. Goodwin, *supra* note 20, at 281.

193. See discussion *infra* Section II.A.

194. See discussion *infra* Sections II.B–C.

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The government and the American public came to realize that the nation had a problem with the Mafia in the 1950s.¹⁹⁵ The government's efforts to comprehend the power and reach of organized crime in the United States began with the Kefauver Committee in 1951, continued with the McClellan Committee in 1963, and culminated with the President's Task Force on Organized Crime in 1967.¹⁹⁶ Ironically, the head of the Kefauver Committee, Senator Estes Kefauver (D-Tennessee), also led the charge to enact the regime of "evidence-based medicine" that helped transform drug companies into organized criminal enterprises.¹⁹⁷ These related committees were tasked with "investigating the degree to which organized crime had permeated interstate commerce, identifying the structure and possible members of the criminal underground, and determining whether interstate criminal organizations were violating any state or federal laws."¹⁹⁸

These investigations revealed a complex and organized criminal underworld that—though largely invisible in day-to-day life—had seeped into the fabric of American society.¹⁹⁹ After several years of debate, Congress enacted RICO on September 23, 1970.²⁰⁰ However, because law enforcement did not immediately grasp RICO's investigative and prosecutorial advantages, it took over a decade before various government officials began to utilize it.²⁰¹ Change came when G. Robert Blakey, one of RICO's primary drafters (and a law professor), "invited FBI agents, assistant U.S. attorneys, and state prosecutors to Cornell University for a summer law enforcement training institute" in 1979.²⁰² During the training, Blakey explained how traditional law enforcement methods created a futile "merry-go-round" effect that only put low-level organized crime members in prison for short stints while leaving the larger enterprise intact.²⁰³ He asked law enforcement officials to focus not on individual acts, but on crimes and associations connected to the larger criminal enterprise; he explained that government officials needed to re-conceptualize their approach with RICO's new legal tools in

195. Goodwin, *supra* note 20, at 290.

196. Bonney, *supra* note 21, at 588.

197. See HEALY, *supra* note 33, at 13, 41–42.

198. Bonney, *supra* note 21, at 588.

199. See KELLY, *supra* note 178, at ix.

200. Organized Crime Control Act of 1970, Pub. L. No. 91-452, § 901(a), 84 Stat. 922, 941–47 (codified as amended at 18 U.S.C. §§ 1961–1968 (2012)); Bonney, *supra* note 21, at 592.

201. Bonney, *supra* note 21, at 583.

202. Jacobs & Gouldin, *supra* note 31, at 169.

203. See *id.* at 169–70.

mind.²⁰⁴

Title 18, section 1962(c) of the U.S. Code enumerates RICO's most commonly invoked substantive elements.²⁰⁵ It states that

[i]t shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.²⁰⁶

Breaking this down into simpler terms, to convict a defendant under RICO the government must prove that a "person": (1) *conducted or participated in an enterprise*, and (2) that she did so by committing *two or more predicate offenses* that together constitute a *pattern of racketeering activity*.²⁰⁷ The government can also convict a person under RICO for conspiring to participate in a criminal enterprise.²⁰⁸ Under the statute, a "person" includes "any individual or entity capable of holding a legal or beneficial interest in property."²⁰⁹ Notably, under this broad definition a corporation is a "person" and both the corporation and its employees can be separate "persons" participating in the same enterprise.²¹⁰

Establishing the existence of an enterprise is the government's primary hurdle in any RICO prosecution.²¹¹ Proving that the enterprise exists at first appears to create a substantial burden for the government. However, this burden is illusory since the process of proving the existence of the enterprise constitutes the core of RICO's prosecutorial power.²¹² This "requirement" allows prosecutors to introduce to the jury

204. *Id.* at 170.

205. *See* 18 U.S.C. § 1962(c).

206. *Id.*

207. *See* Devika Singh et al., *Racketeer Influenced and Corrupt Organizations*, 54 AM. CRIM. L. REV. 1727, 1730 (2017). The government must also prove that "the activities of which affected interstate or foreign commerce" in order to invoke RICO. *Id.*

208. *See* 18 U.S.C. § 1962(d). Unlike traditional conspiracy laws, the defendant need not commit an overt act or take a substantial step toward pursuing the goal of the criminal agreement. *See* *Salinas v. United States*, 522 U.S. 52, 63 (1997) (stating that a jury can also convict a defendant for RICO conspiracy if she simply agrees with a partner in a criminal plan to pursue the same criminal objective).

209. *See* 18 U.S.C. § 1961(3) (2012).

210. *See* *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 163 (2001) (citing 18 U.S.C. § 1961(3), (4)) (holding that the illegal acts of an employee conducting a corporation's affairs, even if acting within the scope of her authority, is covered by RICO's provisions forbidding any "person" to unlawfully conduct an enterprise).

211. Randy D. Gordon, *Of Gangs and Gaggles: Can a Corporation be Part of an Association-in-Fact RICO Enterprise? Linguistic, Historical, and Rhetorical Perspectives*, 16 U. PA. J. BUS. L. 973, 980 (2014).

212. *Id.* at 981.

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previously inadmissible evidence about the “history, structure, and operations” of the crime syndicate.²¹³ This element allows the government to present a persuasive narrative that describes the danger and extent of the criminal enterprise using details normally barred by the rules of evidence. According to the statute, an “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”²¹⁴ Importantly, the defendant “need not have a stake in the operation of the enterprise but instead may be an individual outside of the enterprise who assists the enterprise in attaining its illegal goals.”²¹⁵ The enterprise must have continuity of structure (or personnel), a shared purpose or goal amongst its constituents, and some system in place for coordinating the group’s affairs.²¹⁶

Constituent members may have an informal relationship and still constitute an “association-in-fact” enterprise so long as they are “associated together for a common purpose of engaging in a course of conduct.”²¹⁷ That is, any group of individuals that associates with one another for the purpose of pursuing an illegal pattern of racketeering activity is an “association-in-fact” criminal enterprise and can face RICO charges.²¹⁸ This very broad “association-in-fact” standard affords the government great discretion in establishing a RICO enterprise.²¹⁹ Courts have upheld a diverse array of associational enterprise theories.²²⁰ For example, courts have determined that a loosely affiliated group of pro-life activists constituted a RICO enterprise,²²¹ a marriage consummated for financial gain was an enterprise,²²² and even the state of Illinois satisfied the requirement of an association-in-fact RICO enterprise.²²³

213. Jacobs & Gouldin, *supra* note 31, at 170.

214. 18 U.S.C. § 1961(4).

215. Singh et al., *supra* note 207, at 1738.

216. See *United States v. Olson*, 450 F.3d 655, 665–68 (7th Cir. 2006) (considering the hierarchical structure, admission and membership requirements, and collective actions of the Latin Kings as indicative of the structure, personnel, and system of an enterprise).

217. *United States v. Turkette*, 452 U.S. 576, 583 (1981).

218. Paul Edgar Harold, Note, *Quo Vadis, Association in Fact? The Growing Disparity Between How Federal Courts Interpret RICO’s Enterprise Provision in Criminal and Civil Cases (With a Little Statutory Background to Explain Why)*, 80 NOTRE DAME L. REV. 781, 789 (2005).

219. *Id.* at 790.

220. *Boyle v. United States*, 556 U.S. 938, 944 (2009) (citing *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 218–19 (2008)).

221. *Nat’l Org. for Women v. Scheidler*, 510 U.S. 249, 262 (1994) (indicating it was possible for this organization to qualify as an enterprise, but that question was not before the Court).

222. *Am. Mfrs. Mut. Ins. Co. v. Townson*, 912 F. Supp. 291, 295 (E.D. Tenn. 1995).

223. *United States v. Warner*, 498 F.3d 666, 696 (7th Cir. 2007).

Essentially, any group of two or more “persons” that works together to engage in a pattern of organized criminal acts constitutes a RICO enterprise.²²⁴ Courts grant this broad construction because of the “fluid nature of criminal association” which allows criminal enterprises to adapt to changing socio-legal circumstances.²²⁵ This open-ended concept of association-in-fact enterprises is also in keeping with the statute’s so-called “liberal construction clause,” which mandates that courts construe RICO liberally to “effectuate its remedial purpose[]” of preventing organized crime from harming society.²²⁶

After establishing the existence of the RICO enterprise, the government must also prove that a defendant *conducted* the affairs of or *participated in* that criminal enterprise.²²⁷ In *Reves v. Ernst & Young*, the Court established the “operation-or-management” test for determining whether a defendant conducted or participated in the affairs of the enterprise.²²⁸ In essence, the government must show that the enterprise has a leader—or hierarchical chain of leaders—who operates or manages the enterprise.²²⁹ Mid- or low-level members of the enterprise who follow orders from superiors in the chain of command are likewise deemed to have participated in the enterprise.²³⁰ As such, the RICO net “is woven tightly to trap even the smallest fish” who participated in the organized crime syndicate, while likewise ensnaring the leaders who direct the enterprise.²³¹ The “operation-or-management” test has its greatest effect on outside professionals who provide a service to the criminal enterprise but who sit outside of the chain of command.²³² Unless those professionals “managed” or “operated” the criminal enterprise by exerting some degree of control over it, the government cannot generally catch them in RICO’s net.²³³ As such, in *Reves* an outside accounting firm that provided a fraudulent company audit did not exert control over the enterprise’s decision-making process and the Court deemed that the auditors were therefore immune from RICO prosecution.²³⁴ The circuit courts have extended the *Reves* holding to excuse from RICO liability

224. See Harold, *supra* note 218, at 781.

225. Singh et al., *supra* note 207, at 1739.

226. Organized Crime Control Act of 1970, Pub. L. No. 91-452, § 904(a), 84 Stat. 947 (1970) (codified as amended at 18 U.S.C. §§ 1961–1968 (2012)).

227. See *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993).

228. See *id.*

229. See *id.*

230. Christopher W. Madel, *The Modern RICO Enterprise: The Inoperation and Mismanagement of Reves v. Ernst & Young*, 71 TUL. L. REV. 1133, 1173 (1997).

231. *United States v. Elliott*, 571 F.2d 880, 903 (5th Cir. 1978).

232. See *Reves*, 507 U.S. at 185.

233. See *id.*

234. *Id.* at 186.

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most outside professionals who provide “traditional” professional services to the criminal enterprise.²³⁵

After establishing that a defendant conducted or participated in the enterprise, the government must next prove that she did so by committing at least two “predicate offenses” that together constitute a pattern of racketeering activity.²³⁶ Among the commonly cited “predicate offenses” (or predicate acts) of racketeering activity that can trigger RICO are “murder, kidnapping, gambling, arson, robbery, bribery, extortion, dealing in obscene matter, [and] dealing in a controlled substance.”²³⁷ Also included in the predicate offenses are mail fraud, wire fraud, insurance fraud, false claims, and honest services fraud.²³⁸ In practice, virtually any federal felony and most state felonies can also serve as a RICO predicate offense.²³⁹ Moreover, the government can use crimes for which the defendant has not yet been convicted as well as prior convictions as predicate offenses in a RICO case.²⁴⁰

The “pattern of racketeering activity” must involve at least two of these predicate offenses that have occurred within ten years of each other—the ten-year clock does not toll during any period of incarceration between the two acts.²⁴¹ In *Sedima v. Imrex Co.*, the Supreme Court held that two “isolated acts” of racketeering activity are by themselves insufficient for establishing a “pattern.”²⁴² Later, in *H.J. Inc. v. Northwestern Bell Telephone Co.*, the Court established the “continuity-plus-relationship” test for establishing when two predicate acts can establish a pattern of racketeering activity.²⁴³ To prove a relationship between the predicate acts, the government must show that the acts were somehow, in any way, related to each other.²⁴⁴ To prove continuity

235. See Jeffrey N. Shapiro, Comment, *Attorney Liability under RICO § 1962(c) after Reves v. Ernst & Young*, 61 UNIV. CHI. L. REV. 1153, 1161 (1994).

236. *Elliott*, 571 F.2d at 903.

237. 18 U.S.C. § 1961(1)(A) (2012).

238. Rebecca Pyne, *Combating the Organized Crime Threat to the Healthcare System: Learned from Eurasian Organized Crime Prosecutions*, 60 U.S. ATT’YS’ BULL., Nov. 2012, at 41. For the uses of honest services fraud as a RICO predicate offense, see Robert Radick, *Down the RICO Rabbit Hole: John Reynolds and the Hospital for Special Surgery*, FORBES (Feb. 13, 2013), <http://www.forbes.com/sites/insider/2013/02/13/down-the-rico-rabbit-hole-john-reynolds-and-the-hospital-for-special-surgery/>.

239. JAMES B. JACOBS ET AL., *BUSTING THE MOB: UNITED STATES V. COSTA NOSTRA* 10 (1994).

240. See *Sedima v. Imrex Co.*, 473 U.S. 479, 488 (1985); see also *United States v. Persico*, 832 F.2d 705, 711 (2d Cir. 1987) (citing *United States v. Persico*, 774 F.2d 30, 32 (2d Cir. 1985)).

241. 18 U.S.C. § 1961(5) (excluding any period of imprisonment between the two acts).

242. 473 U.S. at 496 n.14.

243. 492 U.S. 229, 250 (1989).

244. See *id.* at 239.

between the predicate acts, the government must demonstrate that a series of related acts extended over a “substantial period” of time or that there is an “open-ended” threat that the racketeering activity will continue in the future.²⁴⁵ According to the Court, the government can use the same evidence to prove that the predicate acts of racketeering activity were both continuous and related to one another.²⁴⁶ Courts generally find that even tangentially related predicate acts constitute a pattern of criminal activity in the context of a criminal RICO proceeding.²⁴⁷ In practice, the “continuity-plus-relationship” test is only meaningful in the context of civil RICO cases,²⁴⁸ which are discussed briefly below.

The government must also prove that the pattern of racketeering activity affected interstate commerce.²⁴⁹ To prove this, the government needs to demonstrate that the enterprise itself somehow (and in any way) affects interstate commerce or that a predicate offense has some de minimis impact on interstate commerce.²⁵⁰ As students of U.S. law know, courts find that essentially any economic behavior—or, for that matter, noneconomic behavior—no matter how indirect, insubstantial, or inconsequential, has an effect or impact on interstate commerce.²⁵¹ As such, this final “burden” amounts to a perfunctory legal requirement.

If the government proves each of these elements, RICO’s criminal penalties are substantial. If convicted of violating RICO (or conspiring to do so), a defendant faces up to a twenty-year prison sentence.²⁵² However, if any of the predicate offenses carry a life sentence, the RICO sentencing guidelines permit the court to hand down a sentence of life in prison.²⁵³ The defendant can also be convicted separately for RICO

245. *Id.* at 241–42 (citing *Barticheck v. Fidelity Union Bank/First Nat’l State*, 832 F.2d 36, 39 (3d Cir. 1987)).

246. *Id.* at 239 (“For analytic purposes these two constituents of RICO’s pattern requirement must be stated separately, though in practice their proof will often overlap.”). Despite the Court’s clear guidance with regard to relationship and continuity, the federal circuit courts are fractured with regard to applying the “continuity-plus-relationship” test. *See generally* Harold, *supra* note 218 (concluding that the circuit courts apply this test in civil RICO cases to clear their dockets of strike suits but apply a toothless version of the test in the criminal context whereby essentially any criminal organization’s two criminal acts constitute a pattern of racketeering activity).

247. Harold, *supra* note 218, at 805–06.

248. *Id.*

249. 18 U.S.C. § 1962(c) (2012).

250. *See* *United States v. Farmer*, 924 F.2d 647, 651 (7th Cir. 1991) (first citing 18 U.S.C. § 1962(c); and then citing *United States v. Alvarez*, 860 F.2d 801, 820 (7th Cir. 1988)).

251. *See* *Gonzales v. Raich*, 545 U.S. 1, 11–19 (2005) (holding that even the act of growing cannabis on your own property for your own in-house medical treatment affects interstate commerce).

252. 18 U.S.C. § 1963(a) (2012).

253. *Id.*

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conspiracy—also a twenty-year sentence—*and* for each of the predicate offenses that the government includes to prove the pattern of racketeering activity.²⁵⁴ In addition, the defendant’s assets are subject to mandatory forfeiture and this forfeiture “relates back” to the occurrence of the criminal enterprise’s first predicate offense and covers all real, tangible, and intangible property that the government can connect to the racketeering activity.²⁵⁵

RICO also has civil applications.²⁵⁶ If a private party feels that a RICO enterprise caused harm to her business or property, she may file a civil RICO claim against the enterprise for treble damages and legal fees.²⁵⁷ Most critics and courts agree that civil RICO, as applied, is “organized-crime law run amok.”²⁵⁸ These criticisms exist because the majority of civil RICO lawsuits amount to “strike suits” against corporations for engaging in “garden-variety” fraud with regard to user fees, annual fees, and other boilerplate provisions in their day-to-day commercial activities.²⁵⁹ Indeed, courts routinely attempt to limit civil RICO’s reach—via the aforementioned “continuity-plus-relationship” test—to prevent an overcrowding of their dockets.²⁶⁰ It is not readily apparent why corporations engaging in “garden-variety” fraud should be exempt from civil RICO liability, but that is an argument for another time and venue.

B. Government Applications of RICO Against the Mafia

The government served the criminal underground notice of RICO’s power in *United States v. Salerno*, or what is more commonly known as the “Mafia Commission” case.²⁶¹ The “Commission” was the governing body of New York’s five Mafia families—the Gambino, Genovese, Colombo, Lucchese, and Bonanno crime families—that was responsible for directing the Mafia’s various criminal schemes.²⁶² Using RICO, the

254. Jacobs & Gouldin, *supra* note 31, at 169.

255. 18 U.S.C. § 1963(a)(3), (b)(1)–(2).

256. *See* 18 U.S.C. § 1964 (2012).

257. *Id.* § 1964(c).

258. Goldsmith, *supra* note 21, at 288.

259. *See* Caroline N. Mitchell et al., *Returning RICO to Racketeers: Corporations Cannot Constitute an Associated-In-Fact Enterprise Under 18 U.S.C. § 1961(4)*, 13 *FORDHAM J. CORP. & FIN. L.* 1, 11 (2008); Justin D. Weitz, *A Necessary Supplement: Reinigorating Civil RICO’s Securities Fraud Predicate*, 21 *WIDENER L. REV.* 27, 41 (2015).

260. *See* Mitchell et al., *supra* note 259, at 3; *see also* H.J. Inc. v. Nw. Bell Tel. Co., 492 U.S. 229, 243 (1989).

261. *See generally* 868 F.2d 524 (2d Cir. 1989) (upholding 100-year sentences imposed by the trial judge for seven defendants convicted of RICO conspiracy and substantive RICO violations).

262. *See id.* at 528.

government switched from its previous tactic of prosecuting individual criminal acts and instead targeted the larger crime families themselves.²⁶³ The government's new theory was that the "[C]ommission constituted a criminal enterprise; that each defendant was a member or functionary of the commission; and that each defendant had committed two or more racketeering acts in furtherance of the commission's goals."²⁶⁴ And since RICO not only allows, but also *requires*, the prosecution to submit evidence to prove the existence of the larger criminal enterprise, the government was able to provide the jury with the lurid details and violent history of the five Mafia families.²⁶⁵ These details, recall, would be inadmissible in a non-RICO criminal prosecution.²⁶⁶ Proving the existence of the enterprise provided prosecutors with

an excellent opportunity to introduce extensive evidence, complete with charts and tables of organization, depicting the structure of an organized-crime family. In the Commission case and other organized-crime prosecutions, the government has been able to introduce testimony about the history of organized crime in order to establish the enterprise's existence over time.²⁶⁷

RICO's new evidentiary rules allowed prosecutors to show not only that each individual defendant engaged in loansharking or shakedowns, but also that a larger enterprise existed that orchestrated these violent crimes in an effort to corrupt entire industries for profit.²⁶⁸ In other words, RICO allowed "the government to present a complete picture of what the defendant was doing and why—instead of the artificially fragmented picture that traditional criminal law demands."²⁶⁹

The Commission case also demonstrates how RICO allows the prosecution to join all members of the enterprise as defendants in a single trial and under the same charge.²⁷⁰ That is, even if each defendant committed radically different predicate offenses—either in degree or kind—they all committed the same crime of *participating* in the criminal enterprise. As such, the government indicted the Mafia family bosses—and their subordinates—under the same charge of participating in the mob's "board of directors" through a pattern of racketeering activity.²⁷¹

263. JACOBS ET AL., *supra* note 239, at 10–11.

264. *Id.* at 81.

265. Goodwin, *supra* note 20, at 307.

266. *See* Goldsmith, *supra* note 21, at 286–87; *see also* Jacobs & Gouldin, *supra* note 31, at 170.

267. JACOBS ET AL., *supra* note 239, at 10.

268. *Id.* at 11.

269. *Id.*

270. *Id.*

271. *United States v. Salerno*, 868 F.2d 524, 528–29 (2d Cir. 1989); JACOBS ET AL., *supra*

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The government joined as defendants under the same RICO charge and in a single trial Anthony “Fat Tony” Salerno (Genovese boss), Paul Castellano (Gambino boss), Aniello Dellacroce (Gambino underboss), Anthony Corallo (Luchesse boss), Salvatore Santoro (Luchesse underboss), Christopher Furnari (Luchesse *consigliere*), Carmine Persico (Colombo boss), Gennaro Langella (Colombo underboss), Ralph Scopo (Colombo soldier), and Anthony Indelicato (Bonanno captain).²⁷² During the trial, the government “painted organized crime as a sprawling criminal conglomerate whose activities ranged from garden-variety vice rackets to murder, labor racketeering, bid rigging, and unfair competition in the construction industry.”²⁷³ The jury found all *Salerno* defendants guilty of violating RICO by participating in the criminal enterprise (and twenty related predicate offenses); the court sentenced all but one of the defendants to 100 years in prison.²⁷⁴ Given this novel prosecutorial approach and its stunning outcome, experts have compared *Salerno* to some of the most meaningful statutory prosecutions in U.S. legal history.²⁷⁵

The next major RICO success came in *United States v. Badalamenti*, or the “Pizza Connection” case.²⁷⁶ This case exposed the Mafia’s role in an international heroin-trafficking conspiracy whereby the defendants used U.S. pizzerias as fronts for drug distribution.²⁷⁷ The indictment charged thirty-one defendants with engaging in a RICO conspiracy.²⁷⁸ It joined together as defendants “senior Mafia figures, including Gaetano Badalamenti and Salvatore Catalano, along with lower-level participants in the drug traffic, such as investors, drug couriers, and messengers responsible for coordinating the conspiracy’s far-flung factions.”²⁷⁹ The case is notable not only for the large number of defendants successfully joined together in one RICO conspiracy charge, but also because it revealed a new willingness in low-level members of the criminal enterprise to cooperate with the government to avoid harsh RICO penalties. Mafia underlings began, as they put it, to do “the arithmetic” and provided evidence against their bosses rather than taking the fall for

note 239, at 79.

272. *Salerno*, 868 F.2d at 527–28; JACOBS ET AL., *supra* note 239, at 81.

273. JACOBS ET AL., *supra* note 239, at 82; *see Salerno*, 868 F.2d at 529.

274. *Salerno*, 868 F.2d at 527–29; JACOBS ET AL., *supra* note 239, at 86.

275. M. A. Farber, *U.S.-Italian Teamwork Bringing Organized Crime Chiefs to Trial*, N.Y. TIMES (Oct. 18, 1985), <https://www.nytimes.com/1985/10/18/world/us-italian-teamwork-bringing-organized-crime-chiefs-to-trial.html>.

276. 663 F. Supp. 1542, 1544 (S.D.N.Y. 1987).

277. *Id.*; JACOBS ET AL., *supra* note 239, at 129.

278. JACOBS ET AL., *supra* note 239, at 130; *see Badalamenti*, 663 F. Supp. at 1544–45.

279. JACOBS ET AL., *supra* note 239, at 130; *see Badalamenti*, 663 F. Supp. at 1544–45.

the organization as they had in the past.²⁸⁰ This new calculus made sense because RICO was likely to send the bosses to prison anyway, thereby reducing threats of retribution and undermining any guarantees of financial support for continued loyalty.²⁸¹ As such, the testimony of two low-level defendants, Salvatore Contorno and Luigi Ronsisvalle, proved pivotal in securing the remaining defendants' RICO convictions.²⁸² The Pizza Connection case established that the government, armed with RICO, finally represented a formidable threat to organized crime at both high and low levels and on a global scale.

RICO's power to convert witnesses and bring previously untouchable defendants to justice caught the public's attention again in 1992 during the government's prosecution of Gambino crime family boss John Gotti.²⁸³ Gotti, originally known as the "Dapper Don" for his flamboyance, later earned the moniker "Teflon Don" for escaping three separate government prosecutions.²⁸⁴ Even as he was taken into custody for the fourth time, Gotti quipped to the arresting officers that "I'll lay you three to one, I beat it."²⁸⁵ Gotti lost the wager, as RICO ensured that he would not beat the rap for a fourth time. Using RICO's stiff penalties as a "rubber hose," the government convinced one of the defendants, Salvatore "Sammy the Bull" Gravano, to testify against Gotti.²⁸⁶ Gravano—one of the Mafia's most notorious hitmen—admitted to carrying out nineteen murders at Gotti's behest and proved highly effective on the witness stand.²⁸⁷ Indeed,

[h]is nine days of testimony covered the nature, organization, and goals of the Gambino crime family and the roles that he and the defendants had played in perpetrating crimes to further the interests of the enterprise, and he gave an account of his and Gotti's on-the-scene orchestration of Paul Castellano's [(Gotti's predecessor as boss of the Gambino family)] assassination.²⁸⁸

The government also used the larger RICO enterprise to disqualify Gotti's long-time attorney, Bruce Cutler, from the case on the grounds that he was the criminal enterprise's "house counsel" and therefore had

280. Goodwin, *supra* note 20, at 304.

281. *See id.*

282. JACOBS ET AL., *supra* note 239, at 136.

283. *See* United States v. Locascio, 6 F.3d 924, 929 (2d Cir. 1993).

284. Goodwin, *supra* note 20, at 303; *see also* Robert J. Anello & Miriam L. Glaser, *White Collar Crime*, 85 *FORDHAM L. REV.* 39, 49 (2016).

285. GENE MUSTAIN & JERRY CAPECI, *MOB STAR: THE STORY OF JOHN GOTTI* 305 (2d ed. 2002).

286. *Locascio*, 6 F.3d at 929; JACOBS ET AL., *supra* note 239, at 213.

287. *See* JACOBS ET AL., *supra* note 239, at 213; Jacobs & Gouldin, *supra* note 31, at 168.

288. JACOBS ET AL., *supra* note 239, at 217.

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an irreconcilable conflict of interest.²⁸⁹ As a result of Gravano's "big picture" testimony and the absence of Cutler, the jury convicted Gotti of violating RICO and the judge sentenced him to concurrent life sentences in prison.²⁹⁰ Gotti died in prison of throat cancer in 2002.²⁹¹ Gotti's conviction symbolized both the twilight of the New York City Mafia and RICO's ultimate ascendancy as the primary tool for fighting organized criminal enterprises.

C. RICO and White-Collar Crime

Congress enacted RICO *primarily* to combat traditional organized crime syndicates like the Mafia.²⁹² However, it also purposefully drafted the statute to target white-collar corporate crime.²⁹³ The government made this legislative decision in large part because it recognized the fundamental similarities between Mafia hierarchies and corporate structures.²⁹⁴ Accordingly, both RICO's statutory text and legislative history reveal the congressional intent that the law should apply to corporate crime.²⁹⁵ Original versions of the RICO statute did not include white-collar offenses,²⁹⁶ but Congress specifically revised RICO to include white-collar predicate acts such as securities fraud, wire fraud, and mail fraud.²⁹⁷ Moreover, the statute's primary drafter, G. Robert Blakey, stated of RICO that "[w]e don't want one set of rules for people whose collars are blue or whose names end in vowels, and another set for those whose collars are white and have Ivy League diplomas."²⁹⁸ Given this evidence, it is not surprising that courts have summarily dismissed each attempt—usually led by corporate counsel—to contest RICO's applicability to corporate crime.²⁹⁹ Private industry has lobbied heavily to amend RICO to remove white-collar predicate acts such as securities

289. *Locascio*, 6 F.3d at 931–32; Goodwin, *supra* note 20, at 303.

290. *Locascio*, 6 F.3d at 929; JACOBS ET AL., *supra* note 239, at 218.

291. Selwyn Raab, *John Gotti Is Dead at 61; Ex-Mafia Boss Courted Limelight*, N.Y. TIMES (June 10, 2002), <https://www.nytimes.com/2002/06/10/national/john-gotti-is-dead-at-61-exmafia-boss-courted-limelight.html>.

292. Goldsmith, *supra* note 21, at 284.

293. *Id.* at 284–85.

294. See THE PRESIDENT'S COMM'N ON LAW ENF'T & ADMIN. OF JUSTICE, TASK FORCE REPORT: ORGANIZED CRIME 16–24 (2d ed. 1967) [hereinafter THE REPORT].

295. Goldsmith, *supra* note 25, at 786; see S. 1861, 91st Cong. (1969); S. 1623, 91st Cong. (1969); S. 2187, 89th Cong. § 2(a) (1965).

296. See S. 1861; S. 1623; S. 2187; Goldsmith, *supra* note 25, at 787.

297. See S. 30, 91st Cong. (1969); 116 Cong. Rec. 581 (1970); Goldsmith, *supra* note 25, at 787.

298. Lee E. Berlik, *RICO: Not Just for Gangsters Anymore*, VA. BUS. LITIG. BLOG (Feb. 9, 2015), <https://www.virginiabusinesslitigationlawyer.com/2015/02/rico-not-just-for-gangsters-an.html>.

299. Goldsmith, *supra* note 25, at 775.

fraud, but these attempts to amend the statute only reinforce the fact that it applies to white-collar crime.³⁰⁰ These concerted lobbying efforts to disqualify corporate crime from RICO began in earnest after the government turned it against the investment banking firm Drexel Burnham Lambert for engaging in securities fraud in the 1980s—sparking financial industry fears that RICO would “maul Wall Street.”³⁰¹ These fears arose because industry insiders recognized the undeniable similarities between the Mafia and the modern business corporation.³⁰² And if RICO summarily dismantled the Mafia and put its leaders in prison for life, it could do the same to corporate criminals—a daunting outcome for less hardened but equally culpable white-collar offenders.

Prior to drafting RICO, Congress identified the stark similarities between the Mafia and the corporation. In fact, the President’s 1967 *U.S. Task Force on Organized Crime Report* (the “Report”) describes the Mafia exclusively in terms of the business corporation.³⁰³ As the Report states, Mafia “organization is rationally designed with an integrated set of positions geared to maximize profits. Like any large corporation, the organization functions regardless of personnel changes, and no individual—not even the leader—is indispensable. If he dies or goes to jail, business goes on.”³⁰⁴ The Report describes the “commission,” or the Mafia’s governing body, as a corporate “board of directors” that dictates the Mafia’s long-term business strategy.³⁰⁵ The “boss” or “don” is akin to the chief executive officer, tasked with “maintaining order and maximizing profits.”³⁰⁶ Beneath the boss is the so-called “underboss,” who is the “vice president or deputy director of the family” and who serves as a conduit between the boss and various classes of underlings.³⁰⁷ On the same level of the underboss is the “*consigliere*,” who serves as general counsel and advises the family’s chief executive.³⁰⁸ Next come the “*caporegime*” (captains).³⁰⁹ These members play the role that is “from a business standpoint . . . analogous to plant supervisor or sales

300. Goldsmith, *supra* note 21, at 302; *see also* Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, § 107, 109 Stat. 737, 758 (codified at 18 U.S.C. § 1964(c) (2012)).

301. L. Gordon Crovitz, *How the RICO Monster Mauled Wall Street*, 65 NOTRE DAME L. REV. 1050, 1050 (1990).

302. *See* Shayna A. Hutchins, Comment, *Flip That Prosecution Strategy: An Argument for Using RICO to Prosecute Large-Scale Mortgage Fraud*, 59 BUFF. L. REV. 293, 312 (2011).

303. *See* THE REPORT, *supra* note 294, at 16–24.

304. *Id.* at 7.

305. *Id.* at 8.

306. *Id.* at 7.

307. *Id.*

308. THE REPORT, *supra* note 294, at 7.

309. *Id.*

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manager.”³¹⁰ They also “serve as buffers between the top members of the family and the lower-echelon *personnel*. To maintain their insulation from the police, the leaders of the hierarchy (particularly the boss) avoid direct communication with the *workers*.”³¹¹ The lowest-ranked internal members of the organization, according to the Report, are the “soldiers.”³¹² Each soldier operates a single division or franchise of the criminal enterprise on a “commission basis,” such that they funnel all profits beyond their own cut back to higher ranking officials.³¹³ The corporate structure of organized crime led “many family members to send their sons to universities to learn business administration skills” so that they could accordingly run the family’s financial enterprise.³¹⁴

The analogy between the Mafia and the business corporation extends beyond the level of personnel. The Mafia, like a business corporation, notoriously sought “protection” from individuals outside of the organization. The Report notes that “[t]o secure political power organized crime tries by bribes or political contributions to corrupt” various political leaders to whom “judges, mayors, prosecuting attorneys, and correctional officials may be responsive.”³¹⁵ The mob had a “pervasive presence” in politics, through which “mobsters and city officials were in business together.”³¹⁶ As former federal prosecutor Rudy Giuliani later observed: “We’re beginning to find that many of the companies linked to organized crime have openly contributed to political campaigns”³¹⁷ Giuliani added that “[t]he arrangements are made through middle-men and aides, people who have forged friendships in childhood, in campaigns, in various business deals.”³¹⁸ In other words, the Mafia routinely engaged in corporate-style political lobbying. Lawyers, too, provide “protection” to organized crime syndicates.³¹⁹ According to the government, it was this sort of legal protection that insulated top-level organized criminals from effective criminal prosecution and made organized crime a legitimate threat to society.³²⁰

310. *Id.* at 8.

311. *Id.* at 7 (emphasis added).

312. *Id.* at 8.

313. THE REPORT, *supra* note 294, at 8.

314. *Id.*

315. *Id.* at 6.

316. Nicholas Pileggi, *The Mob and the Machine*, N.Y. MAG (May 5, 1986), <http://nymag.com/news/features/crime/46610/>.

317. *Id.*

318. *Id.*

319. Ronald Goldstock & Steven Chananie, *Criminal Lawyers: The Use of Electronic Surveillance and Search Warrants in the Investigation and Prosecution of Attorneys Suspected of Criminal Wrongdoing*, 136 U. PA. L. REV. 1855, 1857 (1988).

320. *Id.*

Recall the government's efforts to disqualify John Gotti's attorney and the subsequent conviction that disqualification enabled.³²¹ Attorneys who serve criminal enterprises "act as unassailable black knights for organized crime, doing its bidding in furtherance of its illegal schemes."³²²

The Mafia-corporation analogy is an apt one: the Mafia structure and tactics the Report describes are nearly identical to those that the contemporary pharmaceutical corporations like Merck, GSK, Purdue, and Pfizer utilize. A board of directors—like the Commission—dictates the company's overall strategy regarding drug development and marketing. Drug company CEOs, the bosses, execute the board's initiatives and organize the corporation in order to maximize profit. Top executives, or underbosses, relay orders to engage in clinical and publication bias to the captains. These sales representatives, researchers, marketers, and ghostwriters then implement the company's strategic swerves in marketing prescription drugs. Doctors, or soldiers, ultimately prescribe the drugs on a commission (kickback) basis, with the primary profits beyond their own cut returning to the drug company. Like the Mafia, the pharmaceutical industry's unrivaled lobbying efforts afford these individuals the protection required to avoid meaningful criminal sanction. However, and in a very real sense, the pharmaceutical industry is engaged in a version of organized crime that is far more socially destructive—and, frankly, more profitable—than any Mafia criminal enterprise to date. "Sammy the Bull" Gravano (the Mafia's most notorious killer) murdered nineteen people during the course of his entire criminal career before going to prison.³²³ Yet, executives at companies like Purdue engage in fraud to sell prescription opioid drugs that contribute to the death of nearly 130 Americans *every single day*.³²⁴

It is estimated that John Gotti earned approximately ten million dollars each year from his Gambino Mafia enterprise before going to prison for life.³²⁵ Raymond Gilmartin, Merck's CEO when the company fraudulently marketed Vioxx and killed at least 60,000 Americans, earned forty million dollars in a single year and was never charged with a crime.³²⁶

Government estimates suggest that the *entire* Mafia, at the height of its powers immediately prior to the Mafia Commission case, earned about

321. Goodwin, *supra* note 20, at 303.

322. Goldstock & Chananie, *supra* note 319, at 1877.

323. Jacobs & Gouldin, *supra* note 31, at 168.

324. *The Opioid Epidemic by the Numbers*, *supra* note 146.

325. Raab, *supra* note 291.

326. See NESI, *supra* note 11, at 255.

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fifty billion dollars a year.³²⁷ The global pharmaceutical market approaches *one trillion dollars* a year.³²⁸ This, despite the fact that prescription drugs remain the leading cause of accidental death in the United States—recently surpassing car accidents.³²⁹ Since these companies mirror (and magnify) the Mafia’s enterprise criminality, the government should accordingly apply RICO to pharmaceutical industry fraud.³³⁰

Part III demonstrates precisely how RICO should apply to drug company executives, sales representatives, doctors, and the lawyers and politicians who work to protect them.

III. APPLYING RICO TO PHARMACEUTICAL INDUSTRY FRAUD

Merck, recall, engaged in a brazen pattern of criminal fraud that killed at least 60,000 Americans.³³¹ No executives were charged with a crime, the company paid a fine, and its CEO walked away with millions.³³² Purdue lied about the safety and efficacy of its drug OxyContin and bribed doctors to prescribe it, which triggered the opioid epidemic that experts believe will take a *million* American lives by 2020.³³³ No executives went to prison, the company paid a fine, and its owners are now worth thirteen billion dollars.³³⁴ GSK fraudulently marketed to children a drug that they knew triggered adolescent suicides.³³⁵ No executives were charged with a crime and the British government actually knighted the company’s CEO for his “services . . .

327. Roy Rowan & Andrew Kupfer, *The 50 Biggest Mafia Bosses*, FORTUNE (Nov. 10, 1986), http://archive.fortune.com/magazines/fortune/fortune_archive/1986/11/10/68275/index.htm.

328. HEALY, *supra* note 33, at 10.

329. Tricarico, *supra* note 13, at 123.

330. Peter Gotzsche makes a connection between the pharmaceutical industry and organized crime, but leaves his analysis at the level of brief comparison. See PETER R. GOTZSCHE, *DEADLY MEDICINES AND ORGANISED CRIME: HOW BIG PHARMA HAS CORRUPTED HEALTHCARE* ch. 3 (2013). Gotzsche, a physician, examines medical solutions such as nationalizing the pharmaceutical industry. *Id.* As a lawyer, I believe we need to take the analogy several steps farther, and actually apply the legal apparatus designed to prevent organized crime to the industry itself. This more basic solution, I propose, will have more immediate and lasting effects.

331. See Herper, *supra* note 8.

332. See Cockburn, *supra* note 8.

333. Van Zee, *supra* note 131; see Jerry Mitchell, *With 175 Americans Dying a Day, What Are the Solutions to the Opioid Epidemic?*, USA TODAY (Jan. 29, 2018), <https://www.usatoday.com/story/news/nation-now/2018/01/29/175-americans-dying-day-what-solutions-opioid-epidemic/1074336001/>.

334. Van Zee, *supra* note 131; Peterson-Withorn, *supra* note 152.

335. See Thomas & Schmidt, *supra* note 129.

to the pharmaceutical industry.”³³⁶ Pfizer engages in a seemingly perpetual cycle of prescription drug fraud: executives illegally market a drug, settle charges with the government, and then immediately embark on a new fraudulent prescription drug scheme.³³⁷ These drug companies and other complicit parties routinely engage in this pattern of prescription drug fraud because they face no meaningful repercussions for their actions. This final Part demonstrates how the government should apply RICO to pharmaceutical industry fraud in order to dismantle these dangerous enterprises as it previously (and successfully) accomplished with the Mafia. This Part provides viable legal theories for applying RICO to prosecute complicit executives, sales representatives, doctors, lawyers, and politicians for participating in association-in-fact criminal enterprises through a pattern of deadly criminal fraud.³³⁸

As a reminder, for RICO purposes an association-in-fact enterprise is any formal or informal group of persons and entities that work “together for a common purpose of engaging in a course of conduct.”³³⁹ Executives, sales representatives, doctors, lawyers, and politicians undeniably work toward the common purpose of helping drug companies sell prescription drugs for profit.

The government must also show that each person conducted or participated in the enterprise.³⁴⁰ That is, prosecutors must show that a pharmaceutical industry defendant either gave a directive to engage in fraud, followed a directive to do so, or exerted some sort of influence or control over the enterprise in its pursuit of profit from the sale of prescription drugs through fraud.³⁴¹

The government must also show that a defendant engaged in two predicate acts of mail fraud, wire fraud, honest services fraud, bribery, or some other applicable federal or state felony in order to advance the enterprise’s purpose of profiting from the sale of prescription drugs.³⁴²

Finally, the government must show that the sale of these prescription drugs had at least a de minimis impact on interstate commerce, an inquiry that warrants little discussion given the judiciary’s broad definition of

336. Louisa Peacock, *Glaxo’s Andrew Witty Gets New Year Knighthood*, TELEGRAPH (Dec. 31, 2011), <http://www.telegraph.co.uk/finance/newsbysector/pharmaceuticalsandchemicals/8985213/Glaxos-Andrew-Witty-gets-New-Year-knighthood.html>.

337. See discussion *supra* Part I.

338. See discussion *infra* Sections III.A–E.

339. *United States v. Turkette*, 452 U.S. 576, 583 (1981).

340. 18 U.S.C. § 1962(c) (2012).

341. See Bonney, *supra* note 21, at 595.

342. See *id.* Since this inquiry relates to the criminal application of RICO, the “continuity-and-relationship” test is satisfied as a matter of course and any two predicate acts will constitute a pattern of racketeering activity. *Id.*

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interstate commerce and the pharmaceutical industry's unrivaled levels of profitability.³⁴³

A. Executives

Drug company executives are the easiest and least controversial individuals to connect to the drug company association-in-fact RICO enterprises. Executives are analogous to the Mafia bosses and underbosses. Indeed, the government recently applied RICO to a small network of corporate executives at Insys Therapeutics.³⁴⁴ Despite its great precedential value, the government's action against Insys Therapeutics seems to be a symbolic gesture to scapegoat a few individuals at a single opioid manufacturer and to demonstrate a government "crackdown" on opioid manufacturers.³⁴⁵ The government's prosecution of Drexel Burnham Lambert banking executives also serves as precedent for RICO charges against corporate executives who engage in fraud.³⁴⁶ As such, executives like those at Merck who authorized press releases similar to the one titled "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx," despite being aware of the drug's adverse heart attack risks, would undoubtedly have committed the predicate RICO offense of wire fraud.³⁴⁷ Indeed, the FDA went on the record calling this press release "simply incomprehensible" and demanded that Merck executives retract the statement.³⁴⁸ The same goes for Merck executives who designed and then mandated the use of the company's "Cardiovascular Card," which was promotional material that Merck delivered to doctors to assure them that Vioxx was *protecting* the heart, not harming it.³⁴⁹ These specific items of proof are, of course, gratuitous given that Merck admitted in its settlement with the government to routinely making "false statements to state Medicaid agencies about the cardiovascular safety of Vioxx, and that those agencies relied on Merck's false claims in making payment decisions about the drug."³⁵⁰ The company likewise settled charges

343. 18 U.S.C. § 1962(c); *see also* Liyan Chen, *The Most Profitable Industries in 2016*, FORBES (Dec. 21, 2015), <https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#11c2eb585716>.

344. Henning, *supra* note 17.

345. *See* Insys Press Release, *supra* note 84. The press release only mentions the government's commitment to fighting the opioid epidemic and never implicates the larger structures of widespread prescription drug fraud. *See id.*

346. *See generally* Crovitz, *supra* note 301 (discussing the use of RICO to prosecute white-collar crimes such as mail fraud and securities fraud).

347. *See* Snigdha Prakash, *Merck Rests Its Defense in Federal Vioxx Trial*, NAT'L PUB. RADIO (Dec. 7, 2005), <https://www.npr.org/templates/story/story.php?storyId=5043658>.

348. Culp & Berry, *supra* note 5, at 26.

349. *Id.* at 25.

350. Merck Press Release, *supra* note 1.

related to executives paying kickbacks to doctors to prescribe Vioxx, each occurrence of which would serve as a predicate offense for RICO.³⁵¹ Any drug company executives privy to similar false claims, kickback schemes, and acts of clinical and publication bias are likewise prime candidates for the government to include as defendants who participated in the association-in-fact RICO enterprise.

B. Drug Representatives

Drug representatives are akin to the Mafia captains that the government has successfully prosecuted with RICO. These are the individuals who participate in the RICO enterprise by following orders from within the hierarchical structure to engage in predicate acts of fraud. Among medical industry insiders, drug representatives lying to doctors about prescription drugs is “so common among drug and device makers that it’s often dismissed as the equivalent of driving slightly over the speed limit.”³⁵² For instance, Merck actually *trained* its sales representatives to lie in response to a doctor’s questions about the oft-rumored cardiovascular risks of Vioxx.³⁵³ These drug representatives were aware that the company was asking them to engage in fraud and to make false statements, since

[t]o market Vioxx, Merck prepared an in-house training game for Vioxx sales representatives dubbed “Dodge Ball.” Sales trainees could only move on to the next round of the card game if they gave Merck-approved answers to doctors’ questions raising Vioxx safety concerns, or dodged such questions altogether.³⁵⁴

Executives motivate drug representatives to participate in prescription drug fraud by paying them large bonuses related to the sale of specific drugs.³⁵⁵ With regard to its highly addictive prescription opioid painkiller, Purdue instituted “[a] lucrative bonus system [that] encouraged sales representatives to increase sales of OxyContin in their territories” using any means necessary.³⁵⁶ In conjunction with these bonuses, Purdue executives “instructed [drug representatives] to downplay the threat of addiction with OxyContin.”³⁵⁷

351. See *Merck to Pay \$650M to Settle Fraud Case*, ABC7NEWS (Feb. 7, 2008), <https://abc7news.com/archive/5942426/>.

352. Greene, *supra* note 2, at 648.

353. Culp & Berry, *supra* note 5, at 25.

354. *Id.*

355. Marc A. Rodwin, *Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform*, 40 J.L. MED. & ETHICS 511, 516 (2012).

356. Van Zee, *supra* note 131, at 222.

357. David Armstrong, *Secret Trove Reveals Bold ‘Crusade’ to Make OxyContin a Blockbuster*, STAT (Sept. 22, 2016), <https://www.statnews.com/2016/09/22/abbott->

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It has recently come to light that drug companies even give their sales representatives crash courses on how to commit prescription drug fraud. Take former Pfizer drug representative Dr. David Franklin, who revealed that in the course of his corporate training he was

instructed to make exaggerated or false claims about [the] safety and efficacy of off-label uses [of Neurontin] and to misrepresent his scientific credentials. Franklin also alleged doctors were rewarded with kickbacks for prescribing large quantities of Parke-Davis [(a Pfizer subsidiary)] drugs. When doctors questioned the availability of government reimbursement for off-label uses, Franklin alleged he was instructed to coach doctors on how to conceal the off-label nature of the prescription.³⁵⁸

Franklin and other drug representatives who participate in these types of fraud and kickback schemes at the behest of their managers are also participating in the criminal enterprise through a pattern of racketeering activity. So, too, would drug representatives like Michelle Breitenbach, who recently admitted to routinely bribing doctors to prescribe specific drugs to patients, an illegal tactic that many critics believe is ubiquitous in the industry.³⁵⁹ Drug representatives who knowingly misrepresent material facts about a drug's safety or bribe doctors to prescribe drugs are also participating in the association-in-fact RICO enterprise and the government could reasonably join them as defendants in a RICO prosecution together with complicit drug company executives.³⁶⁰

C. Doctors

The government should likewise consider doctors who accept kickbacks or bribes in exchange for prescribing specific drugs to their patients as participating in the association-in-fact RICO enterprise. The recent case of John Reynolds, the former head of the prestigious Hospital for Special Surgery in New York City, provides relevant precedent for using RICO to prosecute members of the medical community for participating in kickback schemes.³⁶¹ The government's indictment against Reynolds accuses him of using

his high-level position at the hospital to conduct three separate kickback schemes between 1996 and 2007—one involving hospital vendors that

oxycontin-crusade/.

358. Frederickson, *supra* note 141, at 128.

359. *Former Insys Sales Rep Pleads Guilty to Paying Kickbacks to Doctors*, FDANEWS (June 4, 2018), <https://www.fdanews.com/articles/187041-former-insys-sales-rep-pleads-guilty-to-paying-kickbacks-to-doctors>.

360. *See* Greene, *supra* note 2, at 651 n.38.

361. Singh et al., *supra* note 207, at 1784.

wanted to secure future business, one involving kickbacks that were allegedly demanded and obtained from an employee in return for having arranged the payment of that employee's annual bonus, and a last that involved the alleged receipt of payment as a condition for forming a partnership with a British-based healthcare organization.³⁶²

In this case, Reynolds and the Hospital of Special Surgery comprised the two-"person" RICO enterprise.³⁶³ For its RICO case, the government used these medical kickback schemes to claim that Reynolds engaged in honest services fraud, which served as the predicate acts for the pattern of racketeering activity.³⁶⁴ Honest services fraud includes any scheme that aims to "deprive another of the intangible right of honest services."³⁶⁵ That is, a doctor (or a high-ranking medical administrator) owes a duty to provide honest services to her patients; in accepting a kickback to make a particular recommendation, a medical professional deprives her patient of the intangible right to receive honest and uncorrupted medical services.³⁶⁶ Facing up to twenty-five years in prison in large part due to the RICO charge, Reynolds pled guilty and forfeited the kickback-related assets in return for a lighter sentence.³⁶⁷

In connection with Vioxx, Merck settled claims that it likewise paid physicians kickbacks to prescribe the drug.³⁶⁸ Pfizer, too, settled claims with the government that it "paid kickbacks to health care providers to induce them to prescribe [Neurontin]."³⁶⁹ GSK also "illegally marketed [Paxil] for use in children and teens, offering kickbacks to doctors and sales representatives to push the drug."³⁷⁰ These kickback schemes are commonplace, so much so that a former high-ranking Drug Enforcement Administration official described doctors as "drug dealers in lab

362. Radick, *supra* note 238.

363. *Id.*

364. *Id.*

365. 18 U.S.C. § 1346 (2012); *see also* Brian H. Connor, Comment, *The Quid Pro Quo Quark: Unstable Elementary Particle of Honest Services Fraud*, 65 CATH. U.L. REV. 335, 338 (2015).

366. *See* 18 U.S.C. § 1346; Connor, *supra* note 365, at 338.

367. Barbara Benson, *Ex-Hospital CEO Sentenced to 18 Months in Prison*, CRAIN'S N.Y. BUS. (Nov. 6, 2013), http://www.crainsnewyork.com/article/20131107/health_care/131109911/ex-hospital-ceo-sentenced-to-18-months-in-prison.

368. *Merck to Pay \$650M to Settle Fraud Case*, *supra* note 351.

369. Press Release, U.S. Dep't of Justice, Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay \$2.3 Billion for Fraudulent Marketing (Sept. 2, 2009), <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>.

370. Alexandra Sifferlin, *Breaking Down GlaxoSmithKline's Billion-Dollar Wrongdoing*, TIME (July 5, 2012), <http://healthland.time.com/2012/07/05/breaking-down-glaxosmithklines-billion-dollar-wrongdoing/>.

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coats.”³⁷¹ The government would have little difficulty accumulating evidence about which doctors are accepting bribes and kickbacks. If executives and drug representatives were facing RICO charges, it stands to reason that they would, like similarly situated underlings in Mafia RICO cases, “do the arithmetic” and cooperate with the government by providing evidence about other complicit parties in exchange for leniency. In this case, those details would relate to which doctors were accepting kickbacks and therefore engaging in the predicate act of honest services fraud. This prediction that drug representatives would cooperate with the government is not idle speculation. Drug representatives are already rolling over on doctors to whom they paid kickbacks in order to avoid more serious criminal charges.³⁷² Doctors who get caught accepting kickbacks to prescribe a drug, such as Jerrold Rosenberg of Rhode Island—a former Brown University professor—generally face only short prison sentences for engaging in prescription drug fraud even though judges recognize that this sort of behavior “represent[s] a grave betrayal of the duty every physician owes to his or her patients.”³⁷³ If the government instead charged them under RICO, doctors who accept kickbacks to prescribe a drug would face up to twenty years in prison and would forfeit their assets to the government.³⁷⁴ Under such a scenario, I anticipate that we would hear fewer judges merely castigating doctors, like the judge in Rosenberg’s case, for selling “your medical license to a pharmaceutical company.”³⁷⁵ Instead, judges would be sentencing doctors who accept these bribes to hard time in federal prison.

D. Lawyers

The law firms that advise drug companies present a more difficult—but still very interesting—case from a RICO perspective. It is generally accepted that attorneys serving as outside counsel in sensitive business matters find themselves at the “fulcrum of corporate decision making.”³⁷⁶ However, under the *Reves* “management-and-operation” test, courts have

371. Scott Higham & Lenny Bernstein, *The Drug Industry’s Triumph over the DEA*, WASH. POST (Oct. 15, 2017), https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.22295bc3efcc.

372. See, e.g., Andy Marso, *Drug Rep for Doctor Sued over Fentanyl Spray Prescriptions Revealed as Whistleblower*, KAN. CITY STAR (May 31, 2018), <https://www.kansascity.com/news/business/health-care/article212260139.html>.

373. Lawrence & Feely, *supra* note 85.

374. See *id.*; see also ADAM OVERSTREET, BURR & FORMAN LLP, BURR ALERT: WHITE COLLAR COURIER: DELIVERING NEWS AND PROVIDING GUIDANCE IN WHITE COLLAR MATTERS 3 (2017), http://www.burr.com/wp-content/uploads/2017/11/ALERT_White-Collar-Courier-Part2_Delivering-News-and-Providing-Guidance-in-White-Collar-Matters_AO.pdf.

375. Lawrence & Feely, *supra* note 85.

376. Shapiro, *supra* note 235, at 1172.

mostly “excused attorneys from [RICO] liability through application of a crude ‘legal services’ standard.”³⁷⁷ Under this standard, lawyers who provide traditional legal services do not “exert control” over the RICO enterprise and therefore do not participate in or conduct the enterprise.³⁷⁸ However, there is precedent for attaching lawyers to the RICO enterprise when they go beyond providing “traditional” legal services. The government charged attorney Thomas Lee, who represented members of New York’s Bonanno crime family, with racketeering.³⁷⁹ The government claimed that Lee participated too closely in the enterprise by carrying messages between members of the crime family.³⁸⁰ In implicating Lee, the U.S. Attorney stated that “[w]hat he has shown himself to be is an associate of organized crime who happens to also have a law degree.”³⁸¹ The government likewise charged Salvatore Avena, the lawyer for the Bruno crime family, under RICO for participating in the criminal enterprise by providing specific legal advice regarding ongoing criminal activity.³⁸² Notably, both of these RICO indictments arose after *Reves*, and demonstrate that the legal services standard does not preclude RICO liability for attorneys.³⁸³ Indeed, it is possible to imagine lawyers from a top corporate law firm exerting control over a board of directors that they advise. Consider, for instance, that

[a]n attorney’s professional role, however, is often to suggest how a company might change its course of conduct to avoid legal liability or to engage in a profitable commercial transaction. An attorney’s legal advice will inevitably shape the course of a corporation’s actions and is likely to have a concrete effect on a company’s future plans. Moreover, a lawyer’s client may systematically “rubber stamp” her recommendations, invariably heeding whatever advice the attorney gives. Generally, it seems more likely that an attorney’s conduct, rather than an auditor’s, will be deemed operation or management of an enterprise. Put another way, an attorney may be able to exert control over a client’s enterprise without going beyond traditional roles.³⁸⁴

377. *Id.* at 1161.

378. *Id.*

379. Robert F. Worth, *Mob Boss’s Lawyer Charged With Aiding Murder Plot*, N.Y. TIMES (June 25, 2005), <https://www.nytimes.com/2005/06/25/nyregion/mob-bosss-lawyer-charged-with-aiding-murder-plot.html>.

380. *Id.*

381. *Id.*

382. Michael Decourcy Hinds, *F.B.I. Arrests Reputed Leader of Philadelphia Mob and 23 Others*, N.Y. TIMES (Mar. 18, 1994), <https://www.nytimes.com/1994/03/18/us/fbi-arrests-reputed-leader-of-philadelphia-mob-and-23-others.html>.

383. Singh et al., *supra* note 207, at 1750; *see also* *Reves v. Ernst & Young*, 507 U.S. 170, 186 (1993).

384. Shapiro, *supra* note 235, at 1162–63.

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Lawyers often have a tremendous amount of influence over corporate clients. In some cases, corporate executives can even avoid liability by demonstrating that they were heeding the advice of counsel when they engaged in corporate malfeasance.³⁸⁵ For RICO purposes, the government should therefore examine the precise role that an attorney plays in advising a drug company with regard to the sale of prescription drugs.

Corporate law firms like Skadden, Arps, Slate, Meagher & Flom LLP (“Skadden”) are often staunch corporate advocates.³⁸⁶ For example, some even decry corporate DPAs—like those that Merck, Purdue, GSK, and Pfizer routinely ignore without consequence—as “formidable” government sanctions.³⁸⁷ As part of its corporate advocacy, Skadden holds an annual pharmaceutical and medical device seminar for pharmaceutical industry executives, where

[p]anel of Skadden attorneys and in-house counsel discuss[] litigation challenges and shared practical strategies. Discussions include[] “DOJ Enforcement Update,” “Prosecution of Individuals: New DOJ Memo and Recent Developments,” “State Attorney General Enforcement Actions and Defense Strategies,” and “Taking on the Government: Lessons Learned From Companies That Have Litigated Against DOJ”. . . . Guest speakers included Robin Abrams of Purdue Pharma L.P., Daniel Dovdavyan of Sanofi US, Timothy Howard of Merck & Co., Inc., Joseph Kennedy of Amarin Corp plc and Dr. William Polvino of Veloxis Pharmaceuticals.³⁸⁸

The seminar description is candid (indeed, so candid that it brings to mind mafia commission meetings of years past).³⁸⁹ Note, as well, that the participants include several of the major corporate actors in the prescription drug fraud schemes described herein. The description states

385. See, e.g., Thoma J. Widor & Peter S. Privack, *Advice of Counsel Defense in U.S. v. Lauren Stevens: Dismissal of Indictment is Not Necessarily Good News for Companies*, LEXOLOGY (Mar. 25, 2011), <https://www.lexology.com/library/detail.aspx?g=dcec9bb1-b186-4bf6-8dcf-58c8080f10af>.

386. See *About the Firm*, SKADDEN, <https://www.skadden.com/about/overview> (last visited Apr. 22, 2019).

387. Allen L. Lanstra & Kevin J. Minnick, *The Collateral Effects of Deferred Prosecution Agreements to Corporations in Subsequent Civil and Regulatory Actions*, SKADDEN (June 26, 2014), <https://www.skadden.com/insights/publications/2014/06/the-collateral-effects-of-deferred-prosecution-agr>.

388. John H. Beisner et al., *A Dialogue with Corporate Counsel: Skadden’s Fifth Annual Pharmaceutical and Medical Device Seminar—Enforcement and Litigation Strategies*, SKADDEN (Nov. 17, 2015), <https://www.skadden.com/insights/events/2015/11/a-dialogue-with-corporate-counsel-skaddens-fifth-a>.

389. See SELWYN RAAB, *FIVE FAMILIES: THE RISE, DECLINE, AND RESURGENCE OF AMERICA’S MOST POWERFUL MAFIA EMPIRES* at xv, xix–xx (2005) (describing the Commission, its leaders, some of its duties, and its aim to evade law enforcement action).

that executives from Purdue and Merck worked with corporate attorneys on “practical strategies” for “taking on the government.”³⁹⁰ These large corporate law firms like Skadden also represent drug companies on a regular basis.³⁹¹ *The American Lawyer* recognized Skadden for representing Purdue “in lawsuits brought by various state and local governments in the United States, accusing the company of deceptively marketing opioid painkillers.”³⁹² Skadden likewise represented Merck in connection with its Vioxx fraud.³⁹³ The firm has successfully represented Pfizer in matters related to its prescription drug fraud.³⁹⁴ Rounding out the list, Skadden previously served in an advisory role in transactions involving GSK.³⁹⁵ If drug companies like Purdue, Merck, GSK, and Pfizer are indeed RICO criminal enterprises, it stands to reason that perhaps some corporate lawyers who advise them are likewise participating in the criminal enterprise. Like Lee and Avena before them, the government might determine that certain corporate lawyers exert sufficient control over the criminal enterprise and therefore act as *consigliere* in the organized criminal hierarchy.

E. Politicians

The *Washington Post* recently ran an exposé on the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (the “Enforcement Act”).³⁹⁶ With the Enforcement Act, “Congress effectively stripped the Drug Enforcement Administration [(DEA)] of its most potent weapon against large drug companies suspected of spilling prescription narcotics

390. Beisner et al., *supra* note 388.

391. See, e.g., *Litigation*, SKADDEN, <https://www.skadden.com/capabilities/practices/litigationcontroversy/cc/litigation> (last visited Apr. 22, 2019).

392. Scott Flaherty, *Global Enforcer: Skadden, Arps, Slate, Meagher & Flom, Winner, White Collar/Regulatory Litigation Department of the Year*, AM. LAW. (Dec. 20, 2017), <https://www.law.com/americanlawyer/2017/12/20/global-enforcer-skadden-arps-slate-meagher-flom-winner-white-collarregulatory-litigation-department-of-the-year/?sreturn=20180529170835>.

393. *Merck Resolves Previously Disclosed Missouri Consumer Class Action Lawsuit Related to Vioxx*, FIERCEPHARMA (Nov. 6, 2012), <https://www.fiercepharma.com/pharma/merck-resolves-previously-disclosed-missouri-consumer-class-action-lawsuit-related-to-vioxx>.

394. See, e.g., Press Release, Skadden, Arps, Slate, Meagher, & Flom LLP, Pfizer Defeats Stockholder Demand to Inspect Records (Sept. 1, 2016), <https://www.skadden.com/about/news-and-rankings/news/2016/09/pfizer-defeats-stockholder-demand-to-inspect-recor>.

395. See, e.g., *Partner Bio: Jennifer L. Bragg*, SKADDEN, <https://www.skadden.com/professionals/b/bragg-jennifer-l> (last visited Apr. 22, 2019).

396. See Higham & Bernstein, *supra* note 371; see also Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2(a), 130 Stat. 354, 354–56 (codified as amended at 21 U.S.C. §§ 823(j), 824(c)–(d) (Supp. V 2017)).

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onto the nation's streets."³⁹⁷ The Enforcement Act makes it harder for the DEA to sanction prescription drug distributors who send suspiciously large opioid shipments to pharmacies, which in turn illegally dispense the pills to fuel the opioid epidemic.³⁹⁸ So unhappy with this piece of legislation, sitting DEA Chief Administrative Law Judge John J. Mulrooney wrote a law review article condemning the Enforcement Act.³⁹⁹ Critics like Judge Mulrooney claim that the legislation manifestly serves the pharmaceutical industry and point to the fact that the drug companies spent \$102 million lobbying Congress to pass the bill.⁴⁰⁰ The Enforcement Act, which had stalled in congressional committees for years, ultimately passed after Senator Orrin Hatch (R-Utah) personally negotiated a final version of the bill with the DEA.⁴⁰¹ Senator Hatch, incidentally, has received \$2,750,722 in campaign contributions from the pharmaceutical industry over the course of his political career.⁴⁰² Industry observers routinely accuse Senator Hatch of being beholden to the pharmaceutical industry because of these substantial campaign contributions.⁴⁰³ Senator Hatch is not alone, of course, as politicians from both parties accept hefty campaign contributions from drug companies; indeed, Senator Hatch ranks only third in all-time pharmaceutical industry campaign contributions, trailing by a substantial margin both Barack Obama (D-Illinois) and Hillary Rodham Clinton (D-New York).⁴⁰⁴ These industry campaign contributions spurred a former high-ranking DEA official to state publicly that "[t]he drug industry, the manufacturers, wholesalers, distributors and chain drugstores, have an influence over Congress that has never been seen before."⁴⁰⁵ RICO could help curtail this influence. If the Department of Justice (DOJ) were to consider drug companies to be association-in-fact RICO enterprises, at

397. Higham & Bernstein, *supra* note 371.

398. 21 U.S.C. §§ 823(j), 824(c)–(d); *see* Higham & Bernstein, *supra* note 371.

399. *See generally* John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 MARQ. L. REV. 333 (2017) (criticizing the effects of Congress passing the Enforcement Act as a means of completely eliminating the DEA's ability to ever impose suspensions on distributors and manufacturers).

400. *See id.* at 340; Higham & Bernstein, *supra* note 371.

401. Higham & Bernstein, *supra* note 371.

402. *Pharmaceuticals/Health Products: Money to Congress*, CTR. FOR RESPONSIVE POLITICS, <https://www.opensecrets.org/industries/summary.php?ind=H04&cycle=All&recipdetail=S&mem=Y> (last visited Apr. 15, 2018) [hereinafter *Money to Congress*].

403. *See generally* Greg Price, *Senate Healthcare Bill: Big Pharma, Insurance Lobbies Responsible For Secrecy?*, NEWSWEEK (June 21, 2017), <http://www.newsweek.com/healthcare-republicans-bill-campaign-628110> (comparing the contributions of pharmaceutical industry lobbying money to decisions made by senators).

404. *Money to Congress*, *supra* note 402.

405. Higham & Bernstein, *supra* note 371.

some point campaign contributions given as quid-pro-quo payments for political favors would ensnare politicians as RICO defendants.

Two cases set a clear precedent for attaching RICO liability to politicians who solicit campaign contributions in exchange for preferential treatment and favorable legislation. In *United States v. Cianci*, the government charged and convicted Vincent “Buddy” Cianci—then Mayor of Providence, Rhode Island—of conspiracy to violate RICO.⁴⁰⁶ Cianci and his co-conspirators (the association-in-fact enterprise was Cianci, other city officials, and the city of Providence itself) engaged in a pattern of racketeering activity whereby they would “award and dispense job contracts in exchange for bribes and political contributions.”⁴⁰⁷ The court sentenced Cianci to five years in prison for violating RICO by accepting campaign contributions in exchange for political favors.⁴⁰⁸ Former Illinois Governor George Ryan also went to prison as a result of a RICO conviction related to the receipt of corrupt campaign contributions.⁴⁰⁹

The second case, *McDonnell v. United States*, sets a clear standard for when a campaign contribution constitutes bribery, which is a predicate RICO offense.⁴¹⁰ Bob McDonnell, the former governor of Virginia, appealed his conviction under the Hobbs Act for public corruption in connection with allegedly taking bribes from a corporate executive in the form of gifts and campaign contributions.⁴¹¹ In the lower courts, McDonnell was convicted for his involvement in a “scheme to sell the office of governor for \$177,000 in gifts and cash from a dietary supplements executive.”⁴¹² The Supreme Court later vacated his conviction, noting that the contributions were not a bribe under federal bribery law since McDonnell never committed an “official act” for his

406. 378 F.3d 71, 78 (1st Cir. 2004); see Janelle G. Koren, *Criminal Law—RICO Enterprise Present Even If Enterprise Members Do Not Share an Express Common Purpose—United States v. Cianci*, 378 F.3d 71 (1st Cir. 2004), 39 SUFFOLK U.L. REV. 325, 325 (2005).

407. Koren, *supra* note 406, at 326; see *Cianci*, 378 F.3d at 78.

408. *Cianci*, 378 F.3d at 77–78; Elizabeth Mehren, *Providence Mayor Gets Prison Sentence for Corruption*, L.A. TIMES (Sept. 7, 2002), <http://articles.latimes.com/2002/sep/07/nation/na-buddy7>.

409. Monica Davey & John O’Neil, *Ex-Governor of Illinois Is Convicted on All Charges*, N.Y. TIMES (Apr. 17, 2006), <https://www.nytimes.com/2006/04/17/us/exgovernor-of-illinois-is-convicted-on-all-charges.html>.

410. See generally 136 S. Ct. 2355 (2016) (implementing a more limited interpretation of the word “act” in relation to the federal bribery statute).

411. *Id.* at 2361.

412. Trip Gabriel, *Former Governor in Virginia Guilty in Bribery Case*, N.Y. TIMES (Sept. 4, 2014), <https://www.nytimes.com/2014/09/05/us/bob-mcdonnell-maureen-mcdonnell-virginia-verdict.html>; see *McDonnell*, 136 S. Ct. at 2357.

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benefactor.⁴¹³ McDonnell made phone calls and arranged meetings on the executive's behalf, but never tried to influence other public officials or used his political office to advance his benefactor's goals.⁴¹⁴

Pundits have too quickly suggested that the Court's ruling in *McDonnell* opens the door to increased public corruption.⁴¹⁵ The case actually sets a very clear (and relatively low) standard for when a politician or public official violates federal bribery laws by accepting campaign contributions, which probably makes future bribery convictions more likely.⁴¹⁶ As Daniel Tokaji explains:

McDonnell clarifies that making phone calls and arranging meetings aren't themselves official acts, but pressure or advice as to other public officials could be, so long as there's an agreement to exchange such acts for something of value. The legal standard crafted by the Court thus puts public officials on notice of when their conduct may cross the line separating everyday politics from criminal corruption, while also providing guidance for federal prosecutors on what they'll have to prove in future bribery cases. Although the Court vacated McDonnell's convictions, the ruling is hardly a disaster for the government. To the contrary, it offers a reasonable standard that prosecutors should have little trouble meeting in future cases where something of value—like a campaign contribution—is exchanged for tangible government action.⁴¹⁷

After *McDonnell*, it seems clear that politicians who accept campaign contributions from drug companies with even an implicit understanding that they will exert pressure or offer advice to other public officials on behalf of the drug company have engaged in bribery.⁴¹⁸ As one observer of the *McDonnell* case puts it, "Public officials would thus be well-advised to act with caution when they receive contributions from someone with an interest in a pending decision or action."⁴¹⁹ Politicians like Senator Hatch, then, who steer legislation through Congress on behalf of companies who have contributed massive sums to their political careers would be prime candidates for RICO charges if, or when, the government recognizes drug company fraud as organized crime.⁴²⁰

413. *McDonnell*, 136 S. Ct. at 2373.

414. *See id.* at 2365–66.

415. *See, e.g.,* David Voreacos & Neil Weinberg, *Menendez Judge Suggests He May Dismiss Senator's Bribe Counts*, BLOOMBERG (Oct. 11, 2017), <https://www.bloomberg.com/news/articles/2017-10-11/menendez-prosecutors-finish-case-as-senator-opens-defense>.

416. Daniel P. Tokaji, *Bribery and Campaign Finance: McDonnell's Double-Edged Sword*, 14 OHIO STATE J. CRIM. L. AMICI BRIEFS 15, 15 (2017).

417. *Id.*

418. *Id.* at 17.

419. *Id.*

420. *See Price, supra* note 403; *see also Money to Congress, supra* note 402.

CONCLUSION

The Enforcement Act that Senator Hatch helped push through Congress exacerbated the opioid epidemic and “neutered” the DEA, such that the DOJ recently asked Congress to rewrite or repeal the legislation.⁴²¹ In response, the U.S. House Committee on Energy and Commerce held hearings concerning the pharmaceutical industry’s distribution of prescription opioid painkillers under the Enforcement Act.⁴²² In a room “packed with attorneys, lobbyists, and staffers for the drug companies,” the hearings digressed into a game of finger pointing.⁴²³ John Gray, the drug distributors’ chief lobbyist, noted that prescription opioid abuse “was not caused by distributors who neither prescribe, manufacture, nor dispense medicines.”⁴²⁴ The distributors blamed doctors for overprescribing opioids who, in turn, faulted pharmacists for over-dispensing them.⁴²⁵ Congresswoman Anna Eshoo (D-California) glibly contributed to the hearings by observing that the government needs a solution to the problem that simply has “more teeth.”⁴²⁶ Congresswoman Eshoo, it should be noted, leads all U.S. representatives in pharmaceutical industry campaign contributions at the lofty sum of \$1.6 million.⁴²⁷ Each faction at the hearings—politicians, lawyers, executives, doctors, distributors, manufacturers, etc.—blamed somebody else for the problem and, ironically, each party was ultimately correct in their assessment.⁴²⁸ They are *all* to blame for drug company fraud. It is now time to hold each of them accountable.

Drug company executives, lobbyists, sales representatives, doctors, lawyers, and politicians worked together to create and exacerbate the

421. See Scott Higham & Sari Horwitz, *Justice Dept. Urges Congress to Rewrite Law that Handcuffed DEA’s Opioid Enforcement*, WASH. POST (Mar. 2, 2018), https://www.washingtonpost.com/world/national-security/justice-dept-urges-congress-to-rewrite-law-that-handcuffed-deas-opioid-enforcement/2018/03/02/29582944-1e45-11e8-9de1-147dd2df3829_story.html?noredirect=on&utm_term=.cba9cbd6d05a.

422. See *Hearing on Combating the Opioid Crisis: Prevention and Public Health Solutions*, H. COMM. ON ENERGY & COM. (Mar. 21, 2018), <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-prevention-and-public-health> [hereinafter *Opioid Crisis Hearing*].

423. Katie Zezima & Scott Higham, *Drug Executives Express Regret over Opioid Crisis, One Tells Congress His Company Contributed to the Epidemic*, WASH. POST (May 8, 2018), https://www.washingtonpost.com/national/drug-executives-to-testify-before-congress-about-role-in-opioid-crisis-one-is-deeply-sorry/2018/05/08/f4d91536-5259-11e8-a551-5b648abe29ef_story.html?noredirect=on&utm_term=.1900d89fe7af&wpisrc=nl_daily202&wpm=1.

424. *Id.*

425. *Id.*

426. *Opioid Crisis Hearing*, *supra* note 422.

427. *Money to Congress*, *supra* note 402.

428. See Zezima & Higman, *supra* note 423.

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systemic problem of prescription drug fraud. The legal framework that governs the industry is broken.⁴²⁹ RICO can fix the problem. RICO will allow the government to combat pharmaceutical industry fraud as a form of enterprise criminality. Any individual who commits two predicate acts that contribute to the pattern of prescription drug fraud will face the prospect of twenty years in prison and a forfeiture of assets.⁴³⁰ These stiff penalties will not only dissuade acts of fraud, but will incentivize defendants to cooperate with government investigations in order to hold all complicit parties accountable. The time has come to recognize that the pharmaceutical industry and its enablers who together kill more than 100 Americans every day are engaging in organized crime.⁴³¹ The drug companies and their networks of fraud are reminiscent of the Mafia, only *worse*. RICO dismantled the Mafia, and as this article demonstrates, it can do the same to the criminal enterprises that have corrupted the pharmaceutical industry.

429. See McCarthy, *supra* note 14.

430. See discussion *supra* Part II.

431. See Keefe, *supra* note 147.