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# A CALL TO PROSECUTE DRUG COMPANY FRAUD AS ORGANIZED CRIME

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## INTRODUCTION

In 2011, Merck Pharmaceuticals 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 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 $11 billion from Vioxx sales before voluntarily pulling the drug from the market.[7] Regulators estimate that Vioxx killed more than 60,000 people.[8] The government did not charge any Merck executives, employees, researchers, or doctors with a crime. Instead, a Merck subsidiary paid a

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[1] Department of Justice, Press Release, *U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx*® (Nov. 22, 2011), https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion.

[2] Stephanie M. Greene, *After Caronia: First Amendment Concerns in Off-Label Promotion*, 51 SAN DIEGO L. REV. 645, 753 (2014).

[3] Deanna Minasi. *Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters*, 86 FORDHAM L. REV. 299, 310 (2017).

[4] Id.

[5] David R. Culp & Isobel Berry, *Merck and the Vioxx Debacle: Deadly Loyalty*, 22 ST. JOHN'S J.L. COMM. 1, 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*, THE CHARLOTTE OBSERVER (Jul. 18, 2008), https://www.charlotteobserver.com/news/business/article8993681.html.

[8] Matthew Herper, *David Graham On The Vioxx Verdict*, FORBES (Aug. 19, 2005), https://www.forbes.com/2005/08/19/merck-vioxx-graham_cx_mh_0819graham.html#2b3ed9175698; Alexander Cockburn, *When half a million Americans died and nobody noticed*, THE WEEK (Apr. 27, 2012), http://www.theweek.co.uk/us/46535/when-half-million-americans-died-and-nobody-noticed.

fine and entered into a deferred-prosecution agreement with the government to settle the criminal charges.[9] Merck paid its CEO Raymond Gilmartin (who oversaw the Vioxx regime) nearly $40 million during his final year of employment.[10] After departing from Merck, Gilmartin proceeded not to jail but to Harvard Business School to teach courses in corporate social responsibility.[11] Similar stories are alarmingly 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 contributes to more than 100,000 American fatalities every year.[12] 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 it is time for the government to change its enforcement strategy.[13]

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).[14] The government faced similar prosecutorial barriers while combating the Mafia in the 1960s, which is why it enacted RICO.[15] Instead of focusing on individual crimes, RICO allows the government to prosecute an entire criminal enterprise and its constituent members at once—it



[9] Department of Justice, Press Release, *U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx®*, (Nov. 22, 2011), https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion.
[10] Tom Nesi, *POISON PILLS: THE UNTOLD STORY OF THE VIOXX DRUG SCANDAL* 255 (2008).
[11] 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.
[12] Robert Parker Tricarico, *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. OF THE AM. MED. ASS. (Jul. 26, 2000), https://jamanetwork.com/journals/jama/fullarticle/192908 (last visited on July 4, 2018).
[13] See generally Eugene McCarthy, *The Pharma Barons: Corporate Law's Dangerous New "Race to the Bottom" in the Pharmaceutical Industry* 8 MICH. BUS. AND ENTREP. L. REV. __ (2018).
[14] 18 U.S.C. §§ 1961-1968 (2012).
[15] Pub. L. No. 91-452, 84 Stat. 922 (1970) (codified as amended in various sections of 18 U.S.C. §§ 1961-1968).

"paints with a broad brush" to unite individual criminal acts into an organized pattern of crime.[16] Prior to RICO, high ranking Mafia members avoided prosecution by simply delegating crimes to underlings who would take the fall for the larger organization. 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.[17] 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.[18] The government can present evidence, which would otherwise be inadmissible, about a defendant's criminal associations and past crimes related to the enterprise. If convicted of violating RICO, each enterprise member is subject to a 20-year prison sentence and a mandatory forfeiture of assets.[19] 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."[20]

This article argues that many drug companies engage in criminal behavior akin to the that of the Mafia and that the government should begin to 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. However, because of each enterprise's complex organizational structure, the government has made little

[16] 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.
[17] Id.
[18] 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).
[19] 18 U.S.C. § 1963(a) (2012); see *United States v. Corrado*, 227 F.3d 543, 552 (6th Cir. 2000) (establishing mandatory forfeiture in accordance with the language of 18 U.S.C. § 1963(a)).
[20] Lesley Suzanne Bonney, *The Prosecution of Sophisticated Urban Street Ganges: A Proper Application of RICO*, 42 CATH. U. L. Rev. 579, 612 (1993).

headway in curtailing widespread industry corruption. Deploying RICO against drug company fraud will assist the government in dismantling criminal enterprises in the pharmaceutical industry that fraudulently test and market prescription drugs that kill hundreds of innocent Americans every day for the sake of profit.[21]

This argument has three key components. Part I examines the nature and extent of pharmaceutical industry crime. As a matter of course, many drug companies engage in fraud related to the testing and marketing of their prescription drugs.[22] Researchers and executives routinely hide a drugs' dangerous side effects and then persuade doctors—often through lies, bribes, and kickbacks—to prescribe it to patients.[23] At the same time, they insulate themselves from meaningful punishment through extensive lobbying efforts and by erecting a revolving door between the industry and government.[24] Part II describes precisely how RICO targets this sort of "organized crime" by enabling prosecutors to demonstrate how a group of individuals constitute a single criminal enterprise engaging in a dangerous pattern of for-profit criminal conduct.[25] 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 and the larger enterprise from punishment.[26] Part III

[21] Starfield, *supra* note 12, at 123.
[22] See *supra* note 13.
[23] Id.
[24] Minasi, *supra* note 3, at 313.
[25] Michael Goldsmith, *RICO and Enterprise Criminality: A Response to Gerard E. Lynch*, 88 COLUM. L. REV. 774, 774 (1988).
[26] Goodwin, *supra* note 18, at 301; James B. Jacobs and Lauryn P. Gouldin. *Cosa Nostra: The Final Chapter?*, 25 CRIME & JUST. 129, 140 (1999).

demonstrates precisely how RICO should apply 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 as organized criminal enterprises through the sale of harmful prescription drugs.

## PART 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 section demonstrates, Merck's Vioxx scandal is but one of many instances of pharmaceutical industry fraud that harms Americans while leaving criminals unpunished. Drug companies routinely profit from misleading the FDA and persuading the public to consume large quantities of unnecessary, ineffective, and often deadly prescription drugs.[27] 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.[28] To demonstrate the nature and extent of drug company fraud, this section maps out the ineffective legal framework that governs the pharmaceutical industry and offers several case studies to demonstrate this industry fraud in action.

### *The Legal Framework for Fraud in the Pharmaceutical Industry*

The root of pharmaceutical industry fraud lies, paradoxically, in legislation that was supposed to eliminate dangerous drug company misrepresentations. Congress passed the

[27] See, generally, Joseph Dumit, DRUGS FOR LIFE: HOW PHARMACEUTICAL COMPANIES DEFINE OUR HEALTH (2012); see also David Healy, PHARMAGEDDON 6 (2012) (both book-length studies demonstrating how drug companies aim to persuade American to take unnecessary and often dangerous prescription drugs for the sole purpose of corporate profit).
[28] Jerome P. Kassirer, ON THE TAKE: HOW AMERICA'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH 31 (2005).

*Kefauver-Harris Amendments* to the *Food and Drug Cosmetic Act* in 1962.[29] This legislation was in response to public outrage over severe birth defects caused by Thalidomide, an anti-anxiety drug that doctors prescribed to pregnant women.[30] The *Kefauver-Harris Amendments* established new protocols that required drug companies to conduct clinical trials to prove that a new drug was safe and effective (these protocols also required full disclosure of a drug's adverse side effects).[31] The goal was to achieve a system of "evidence-based medicine," whereby hard scientific evidence would prove a new drug's utility. 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 in animals.[32] If the drug proves safe and effective relative to existing treatments, the drug company initiates three phases of human testing.[33] The first phase involves tests on a small group of human subjects, usually fewer than 80 patients.[34] If the drug still appears safe and effective, drug companies begin phase two of their clinical trial and expand the testing to a larger group of several hundred patients.[35] If trial results remain positive, the company begins phase three testing, which includes controlled clinical trials with thousands of patients.[36] These clinical trials compare patients taking the experimental drug with a control group. The control group takes either a placebo or a standard therapy that the FDA has already approved.[37] If the drug company conducts two successful phase three clinical trials that demonstrate "statistically significant" positive results in comparison to the control group, they

[29] *Federal Food, Drug, and Cosmetic Act*, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938); *Drug Amendments of 1962*, Pub. L. No. 87-781, § 102(a), 76 Stat. 780, 784
[30] Marc A. Rodwin, *Independent Clinical Trials to Test Drugs: The Neglected Reform*, 6 ST. LOUIS UNIV. J. OF HEALTH LAW & POL. 113, 123 (2012).
[31] *Drug Amendments of 1962*, Pub. L. No. 87-781, § 102(a), 76 Stat. 780, 784; Drug Amendments of 1962, Pub. L. No. 87-781, § 131(a), 76 Stat. 780, 784.
[32] *Investigational New Drug Application*, 21 C.F.R. § 312.23.
[33] *Investigational New Drug Application*, 21 C.F.R. § 312.21(a)
[34] *Investigational New Drug Application*, 21 C.F.R. § 312.21(a)
[35] *Investigational New Drug Application*, 21 C.F.R. § 312.21(b)
[36] *Investigational New Drug Application*, 21 C.F.R. § 312.21(c)
[37] Rodwin, *supra* note 32, at 125.

may petition the FDA for approval to market the drug.[38] After 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.

Clinical trials are expensive to conduct. Drug companies claim that securing FDA approval for a new drug costs approximately $800 million.[39] These high costs raise the stakes for clinical trials and tempt drug companies to engage in "clinical bias." Clinical bias is the process through which drug companies rig the clinical trial to ensure that the drug appears safe and effective. 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.[40] 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.[41]

[38] Healy, *supra* note 27, at 77.
[39] Drummond Rennie, *When Evidence Isn't: Trials, Drug Companies and the FDA*, 15 J. L. & POL'Y, 991, 1008 (2007).
[40] Rodwin, *supra* note 32, at 129-30.
[41] Rennie, *supra* note 41, at 1007-8. (My emphasis.)

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.[42] A drug company could in theory conduct 20 (or even 100) clinical trials in which a new drug proves dangerous and ineffective, but then rig two biased clinical trials that show the new drug outperforming a placebo in order to successfully secure FDA approval to market its drug.[43] Clinical bias allows drug companies to engage in fraud to transform a drug that a clinical trial has proven unsafe and ineffective into what seems to be a "wonder drug." 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."[44] Doctors and the general public have no way to know whether or not the "evidence" from a clinical trial is the byproduct of fraud.

The fraud inherent in the regime of "evidence-based medicine" extends also to the dissemination of clinical trial results. Engaging in the practice known as "publication bias," drug companies only publish—and *pay* to have published—the positive results from their clinical trials. 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.[45] The drug company "manages" the "evidence" during the entire publication process from the article's first draft through its paid placement in some of the most respected medical journals.[46] Drug companies also refuse to publish negative clinical trial results and have

[42] Dumit, *supra* note 27, at 100.
[43] Healy, *supra* note 27, at 77.
[44] Rennie, *supra* note 41, 1010.
[45] Kassirer, *supra* note 28, at 31.
[46] 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).

threatened the careers of researchers who contravene the accuracy of their purported clinical trials and subsequent publications.[47] 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.[48] 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 now appear—after the company "manages" its "evidence"—to be a safe and effective treatment.

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. Drug companies try to persuade consumers—via materially misleading commercial advertisements—to purchase and use their prescription drugs. The pharmaceutical industry achieved a major marketing breakthrough as a result legal changes that arose from the *Food and Drug Modernization Act of 1997* (FDAMA).[49] FDAMA lifted the long-standing restriction on direct-to-consumer (DTC) prescription drug advertising.[50] The U.S. is the only nation that affirmatively allows drug companies to advertise prescription drugs directly to the public.[51] 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

[47] Culp & Berry, *supra* note 6, at 27.
[48] Minasi, *supra* note 4, at 306-7.
[49] *Food and Drug Administration Modernization Act of 1997*, Pub. L. No. 105-115, 111 Stat. 2296 (1997); Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 FED. REG. 43171, 43172 (Aug. 12, 1997).
[50] Id.
[51] Amanda L. Connors, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 ALB. L. REV. 243, 267 (2009). New Zealand also allows drug companies to engage in direct-to-consumer prescription drug advertising, but in New Zealand this legal outcome appears to be the result of a legislative oversight, see Susanna Every-Palmer, Rishi Duggal, and David B Menkes, *Direct-to-consumer advertising of prescription medication in New Zealand*, 127 THE NEW ZEALAND MED. JOURNAL 102, 103 (2014).

selling a treatment for profit.[52] 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.[53] 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."[54] Indeed, these "educational" advertisements earn drug companies more than $4 in profit for every $1 they invest in DTC prescription drug advertising.[55] (This profit margin exists because doctors prescribe the drug a patient requests from them 75% of the time.)[56] As a result, drug companies now spend twice as much money on marketing than they do on research and development.[57] This marketing saturation means that the average American actually spends more time each year viewing DTC prescription drug advertisements on television than they do with their primary care physician.[58] 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.[59] DTC advertisements further compound industry fraud, since these misleading marketing campaigns



[52] Healy, *supra* note 27, at 38.
[53] Id.
[54] David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 276 (2007).
[55] Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. TECH. L. REV. 1, 27 (2015).
[56] Vladeck, *supra* note 56, at 270.
[57] Greene, *supra* note 3, at 696.
[58] Vladeck, *supra* note 56, at 270.
[59] 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 27, at 95.

often relay the fabricated evidence that companies obtain through both clinical bias and publication bias.

FDAMA also instituted changes that allow drug company representatives to engage in new forms of off-label "detailing" of doctors.[60] 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. Doctors retain the right to prescribe any drug they deem medically necessary, even if the FDA has not approved that drug to treat a particular condition.[61] In an effort to persuade the doctors to supersede FDA approval and to negate safety protocols, 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.[62] Ghostwriters who draft these journal articles on behalf of the drug companies describe them as "marketing masquerading as science."[63] 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.[64] These bribes and kickbacks come in the form of honoraria payments, bogus speaker's fees (doctors often give the "speeches" out to dinner at a restaurant with friends), or trips to exotic locales.[65] Detailing is a very effective marketing tactic, as 20% of

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[60] *FDA 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*. Docket No. FDA-2008-D-0053, OC 2007268, February 15, 2008.
[61] Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*, 41 J.L. MED. & ETHICS 654, 656 (2013).
[62] *Food and Drug Administration Modernization Act of 1997*, Pub. L. No. 105-115, 111 Stat. 2296, Section 401 (1997).
[63] Kassirer, *supra* note 27, at 33.
[64] Department of Justice, U.S. Attorney's Office, District of Massachusetts. "Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering" (October 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering (last retrieved on July 4, 2018).
[65] Minasi, supra note 4, at 310; see also, Tricarico, *supra* note 1, at 121; see also, Staff. *Ivy League Doctor Gets 4 Years in Prison for Insys Opioid Kickbacks*, BLOOMBERG (March 10, 2018), http://fortune.com/2018/03/10/jerrold-rosenberg-opioid-kickbacks/

all prescriptions that doctors write are for off-label uses.[66] In many patient populations, off-label prescriptions make up the bulk of treatment, as up to 75% of cancer drugs, 80% of pediatric drugs, and 90% of prescription drugs for rare diseases are off label.[67] Drug companies earn hundreds of billions of dollars each year from the sale of off-label prescription drugs.[68] These numbers are all the more staggering when one considers that "more than 70 percent of off-label uses lack significant scientific support."[69] At best, the vast majority of off-label treatments are experimental; at worst, the drug companies often know them to be ineffective or harmful at treating the condition for which they detail them to doctors.[70] Off-label detailing adds still another opportunity for drug company 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.[71] Rather than charging an individual executives with a crime, the government enters into deferred-prosecution agreements (DPAs) or non-prosecution agreements (NPAs) with the corporate entity. 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

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[66] Stephanie M. Greene and Lars Noah, *Off-Label Drug Promotion and the First Amendment*, 162 U. PA. L. REV. ONLINE 239, 241 (2014).
[67] Rodwin, *Institutional Corruption*, *supra* note 63, at 656.
[68] Id. at 658. This calculation is based on the fact the estimated 2017 global pharmaceutical sales are excepted to top $1.2 trillion. 20% (the percentage of off-label prescription sales) would amount to $240 billion. Craig W. Lindsley, *New 2016 Data and Statistics for Global Pharmaceutical Products and Projections through 2017*, 8 ACS CHEM. NEUROSCIENCE 1635, 1635 (2017).
[69] Rodwin, *Institutional Corruption*, *supra* note 63, at 656.
[70] Greene, *supra* note 3, at 675.
[71] 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 (the government has charged 6 executives from Insys for engaging in bribery to persuade doctors to prescribe a highly addictive fentanyl spray; it is not yet clear whether or not the government will settle charges with these defendants).

> 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.[72]

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 at a later date. 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.[73] 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.[74] 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.[75] As such, the government conducts a cost-benefit analysis and determines that the DPA is the safer bet for ensuring at least some corporate accountability.[76] Of course, a more cynical explanation for the government's failed prosecutions of pharmaceutical industry fraud is that "large companies can buy their way out of criminal prosecution."[77] Unfortunately, the empirical evidence supports the conclusion that the government shows preferential prosecutorial treatment to large domestic corporations like the pharmaceutical companies discussed herein.[78] But why does the government show such favoritism?

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[72] 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, 545 (2015).
[73] Brandon L. Garrett, *The Corporate Criminal Scapegoat*, 101 VA. L. REV. 1789, 1848 (2015).
[74] Id. at 1825.
[75] Id. at 1836.
[76] 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).
[77] Uhlmann, *supra*, at 1301-02.
[78] Id. at 1327.

In the past twenty years, the pharmaceutical industry has spent over $3.7 billion lobbying government officials—which is $1 billion more than any other special interest group or industrial sector.[79] Since 1999, the pharmaceutical industry has ranked first in U.S. lobbying expenditures *every single year*.[80] 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.[81]

In addition to lobbying, drug companies further insulated themselves from legal regulation by erecting a revolving door between the government and the pharmaceutical industry. A total of 66% (926 of 1403) of pharmaceutical industry lobbyists were once federal officials.[82] Senior FDA officials are typically industry insiders or have strong financial ties to drug companies.[83] Many government regulators are merely biding their time before departing for more lucrative opportunities in the pharmaceutical industry, which experts agree frequently compromises their regulatory decisions.[84] The case of Daniel Troy is illustrative. Troy was a partner at the law firm Sidley Austin LLP—where he represented drug companies against the government—before President George W. Bush appointed him as Chief Counsel of the FDA.[85] As Chief Counsel, Troy implemented several key changes to FDA policies that favored the pharmaceutical industry.[86] Shortly after initiating these changes, Troy left his government position and returned to the pharmaceutical industry to serve as General Counsel and Senior Vice

[79] OpenSecrets.Org: Center for Responsive Politics, https://www.opensecrets.org/lobby/top.php?indexType=i (last retrieved on July 4, 2018).
[80] OpenSecrets.Org: Center for Responsive Politics, https://www.opensecrets.org/lobby/top.php?showYear=2017&indexType=i (last retrieved on July 4, 2018).
[81] Dana Taschner, *PLIVA Shields Big Pharma from Billions, Cuts Consumers' Rights*. 49 SAN DIEGO L. REV. 879, 903 (2012).
[82] OpenSecrets.Org: Center for Responsive Politics, https://www.opensecrets.org/lobby/indusclient_lobs.php?id=h04&year=2017
[83] McCarthy, *supra* note 13, at __
[84] Fran Hawthorne, INSIDE THE FDA: THE BUSINESS OF POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 150 (2005).
[85] GlaxoSmithKline Corporate Website, https://www.gsk.com/en-gb/about-us/corporate-executive-team/dan-troy/ (last retrieved July 4, 2018).
[86] Vladeck, *supra* note 56, at 273-74.

President of GlaxoSmithKline, one of the largest drug companies in the world.[87] Cynical observers use these facts and statistics to explain why federal legislation appears to facilitate pharmaceutical industry fraud. These facts might also help explain why, at least in part, the government fails to prosecute individual drug company executives after industry fraud is exposed.

*Case Studies of Pharmaceutical Industry Fraud*

As the following case studies demonstrate, major drug companies like Merck Pharmaceuticals, GlaxoSmithKline, Purdue Pharmaceuticals, and Pfizer use the legal framework described in the previous section to engage in a nearly identical pattern of fraud regarding the development, marketing, and distribution of their prescription drugs. Recall that Merck lied about their clinical trial data, which revealed that Vioxx greatly increased the risk of heart attack deaths in patients. They then hired ghostwriters to draft articles touting the painkiller's safety and paid doctors to sign their names to these articles. They 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.[88] In the end, Vioxx killed, at best, more Americans (60,000) that the Vietnam conflict and, at worst, more Americans (500,000) than World War II.[89] 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."[90] Merck entered into an NPA with the government and one of its

[87] GlaxoSmithKline Corporate Website, https://www.gsk.com/en-gb/about-us/corporate-executive-team/dan-troy/ (last retrieved July 4, 2018).
[88] Vladeck, *supra* note 56, at 276.
[89] McCarthy, *supra* note 13, at __. This large discrepancy in fatalities results from the FDA's conservative estimate in contrast with private investigators' less politically accountable (and presumably motivated) estimates.
[90] U.S. Department of Justice Press Release, *U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx: Merck to Pay $950 Million for Illegal Marketing*, (Nov. 22, 2011),

subsidiaries agreed to plead guilty to one misdemeanor charge of illegal promotional activity and to pay a fine of $950 million.[91] No executives faced criminal charges. Merck's story is, unfortunately, typical in the pharmaceutical industry.

GlaxoSmithKline (GSK) engaged in a nearly identical pattern of fraud with regard to the development and marketing of Paxil, their well-known antidepressant drug. GSK needed to conduct 16 separate clinical trials for Paxil in order to achieve the two successful outcomes required to secure FDA approval.[92] During the failed trials, GSK found that Paxil tripled the risk of suicide in adolescents.[93] Nonetheless, GSK engaged in clinical and publication bias to actively conceal this information from both the FDA and the public.[94] Worse yet, the company embarked on an off-label detailing campaign specifically designed to persuade doctors to prescribe the drug *to adolescents*.[95] Despite this knowledge that Paxil caused children to attempt suicide, the company instructed sales representatives to inform doctors that Paxil demonstrated "remarkable safety" in the treatment of childhood depression.[96] Thousands of children and teens ultimately committed suicide while on Paxil.[97] After the government discovered the Paxil-related fraud, it entered into an NPA with GSK and imposed a $3 billion fine.[98] (This fine, incidentally, amounts



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https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion.

[91] Gibson Dunn Memo, *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/.

[92] Jonathan J. Darrow, *Pharmaceutical Efficacy: The Illusory Legal Standard*, 70 WASH & LEE L. REV. 2073, 2099 (2013).

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

[94] Id. at 222.

[95] Department of Justice Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

[96] Scott Tillett, *Off-Label Prescribing of SSRIs to Children: Should Pediatric Testing be Required, or are there Other Means to a Safer End for Children?*, 19 S. CAL. REV. L. & SOCIAL JUSTICE 447, 477 (2010).

[97] David Dobbs, *The Human Cost of a Misleading Drug-Safety Study*, THE ATLANTIC (Sep. 8, 2015), https://www.theatlantic.com/health/archive/2015/09/paxil-safety-bmj-depression-suicide/406105/.

[98] Department of Justice Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

to roughly one-quarter of the nearly $12 billion in profits GSK secured through the sale of Paxil.)[99] The government did not charge any GSK executives, employees, or doctors with a crime, and the company paid its chief executive approximately $14 million in the year it settled the criminal charges related to this fraud.[100]

Purdue Pharmaceuticals (Purdue), the manufacturer of the opioid painkiller OxyContin, likewise utilized this blueprint for profit-via-deadly fraud. Opioid painkillers, like OxyContin, are not effective at treating long-term or chronic pain.[101] 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*.[102] As such, drug companies have yet to conduct successful clinical trials that prove the safety and efficacy of their opioids for treating chronic pain.[103] Instead, Purdue and other opioid manufacturers lobbied for a new kind of clinical trial that utilizes so-called "enriched enrollment protocols."[104] Enriched enrollment protocols allow opioid manufacturers to engage in clinical bias without resorting to the subterfuge required in traditional clinical trials. These protocols allow researches who are conducting the clinical trial to actually remove patients from the study if they are not responding well to the opioid treatment.[105] In other words, if the drug is *failing* the trial the researchers remove the subjects who *prove* that it is failing and simply continue the trial without them. As Dr. Anna Lembke of Stanford Medical School puts it, "the enriched enrollment

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[99] Darrow, *supra* note 94, at 2104.
[100] Katie Thomas and Michael S. Schmidt, *Glaxo Agrees to Pay $3 Billion in Fraud Settlement*, N.Y. TIMES (Jul. 2, 2012), http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html; Jill Treanor, *GlaxoSmithKline chief's pay package more than doubles to £6.7m: Drug company insists Andrew Witty remains underpaid and plans rise to £10.4m to close 'competitiveness gap'*, THE GUARDIAN (UK) (Mar. 12, 2012), https://www.theguardian.com/business/2012/mar/12/glaxosmithkline-chief-pay-andrew-witty
[101] Anna Lembke, DRUG DEALER, M.D.: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT'S SO HARD TO STOP 69 (2016).
[102] Id. at 59.
[103] 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, 562-3 (2015).
[104] 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/
[105] Lembke, *supra* note 102, at 69.

protocol does appear to be a way for drug companies to cheat, getting approval for opioid painkillers that don't really work."[106] Opioid painkillers are also highly addictive: about 12% of patients treated with opioids for chronic pain become addicted and many of these individuals go on to become heroin addicts.[107] 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.[108]

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.[109] Throughout this campaign they lied about and downplayed OxyContin's dependency rates.[110] As part of this marketing campaign, Purdue generously sponsored 40 pain management conferences where "more than 5,000 physicians, pharmacists, and nurses attended these all-expense-paid symposia" at which Purdue persuaded them to prescribe OxyContin to their patients.[111] Purdue also provided free 30-day samples of the highly addictive drug to patients across the nation.[112] Opioids like OxyContin kill approximately 90 Americans every day (and killed about 32,445 Americans in 2016 alone).[113] Experts agree that Purdue deserves the "lion's share" of blame for these deaths and for the American opioid crisis more generally.[114] OxyContin also causes indirect social harm, as one Virginia county estimates

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[106] Id. at 68.
[107] Id. at 64-65.
[108] Paul E. Frederickson, *Criminal Marketing: Corporate and Managerial Liability in the Prescription Drug Industry*, 22 MIDWEST L.J. 115, 137 (2008).
[109] Kolodny et al., *supra* note 104, at 562.
[110] Id.
[111] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. JOURNAL OF PUB. HEALTH 221, 221 (2009).
[112] Id. at 222.
[113] Centers for Disease Control and Prevention. Opioid Data Analysis. https://www.cdc.gov/drugoverdose/data/analysis.html (last retrieved on July 4, 2018).
[114] Patrick Radden Keefe, *The Family That Built an Empire of Pain: The Sackler dynasty's ruthless marketing of painkillers has generated billions of dollars—and millions of addicts*, NEW YORKER (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

that OxyContin was the root cause of 95% of all the crimes committed in its jurisdiction.[115] The government eventually addressed Purdue's criminal fraud. 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.[116] The Sackler family, who own and control Purdue,[117] enjoy a cumulative net worth of $13 billion, derived mostly from OxyContin sales.[118]

Finally, Pfizer serves as the poster child for pharmaceutical industry fraud. Indeed, Pfizer repeatedly engages in this pattern of prescription drug fraud. In the first instance, the FDA approved Pfizer's drug Neurontin to treat epilepsy.[119] Not satisfied with the profits derived from this limited approval, Pfizer proposed a "strategic swerve" in marketing and began promoting Neurontin to treat a host of unapproved ailments, such as bipolar disorder and chronic pain.[120] The company was aware that the drug was either unsafe or ineffective for these off-label purposes and also that it caused depression and suicidal tendencies in patients.[121] Indeed, in an internal memo one Pfizer employee referred to Neurontin as the "snake oil" of the twentieth century.[122] 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 promotional purpose and conducting teleconferences with prescribing

[115] Frederickson, *supra* note 109, at 136.
[116] Van Zee, *supra* note 112, at 223. The government did fine three company executives $5,000 a piece for perpetuating this deadly fraud, but Purdue indemnified them for these and other costs related to criminal charges (*Friedman v. Sebelius*, 755 F. Supp. 2d 98, 102 n.7 (D.D.C. 2010))
[117] Sackler Family Profile, Forbes.com, https://www.forbes.com/profile/sackler/
[118] 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
[119] Greene, *supra* note 3, at 651-2.
[120] Id. at 652.
[121] Id.
[122] Id.

> physicians that were moderated by well-remunerated contracted physicians involved in the marketing scheme.[123]

The fraudulent advertising scheme involving executives, sales representatives, and doctors proved successful. Eventually, 90% of all Neurontin prescriptions were off-label and sales rose sharply from $98 million in 1995 to $2.7 billion in 2003.[124] Pfizer likewise bolstered sales by rewarding doctors with kickbacks for prescribing large quantities of Neurontin.[125] 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."[126] 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.[127] No individuals were charged with a crime.

In 2007, Pfizer again found itself in trouble after engaging in a nearly identical pattern of fraud regarding its drug Genotropin.[128] Through a subsidiary, Pfizer settled the criminal charges by entering into a DPA with the government and paying a $34 million fine.[129] 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.[130] The company, it turns out, formulated this new fraudulent

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[123] Mona Ghogomu, *When does the Chain Break? Prescribing Around Drug Manufacturer Fraud*, 67 DEPAUL L. REV. 557, 572 (2018).
[124] Frederickson, *supra* note 109, at 128; Greene, *supra* note 3, at 653.
[125] Frederickson, *supra* note 109, at 128.
[126] Press Release, Department of Justice, Warner-Lambert to Pay $ 430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), available at http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm.]
[127] Id.
[128] Robert G. Evans, *Tough on Crime? Pfizer and the CIHR*, 5 HEALTH POLICY 16, 19 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2875889/
[129] Id.
[130] Gardiner Harrissept. *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

scheme while negotiating its first NPA with the government to settle the 2004 Neurontin fraud charges.[131] Even though the 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.[132] 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.[133] Despite this public promise to behave, the government and Pfizer settled another fraud charge in 2016.[134] In 2018, Pfizer entered into still another DPA with the government and paid $24 million to settle an additional case of fraud. At no point did the government charge any individuals for participating in these repeated fraudulent schemes.[135] Pfizer earns approximately $50 billion in annual revenue.[136] Pfizer is also the pharmaceutical industry's leading contributor to U.S. political campaigns.[137]

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

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[131] Id.
[132] Id.
[133] Schulman noted that "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.
[134] Press Release, Department of Justice, *Wyeth and Pfizer Agree to Pay $784.6 Million to Resolve Lawsuit Alleging that Wyeth Underpaid Drug Rebates to Medicaid* (April 27, 2016), available at https://www.justice.gov/usao-ma/pr/wyeth-and-pfizer-agree-pay-7846-million-resolve-lawsuit-alleging-wyeth-underpaid-drug
[135] Press Release, Department of Justice, *Pfizer Agrees to Pay $23.85 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation* (May 24, 2018), available at https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay.
[136] Niamh Marriott, *The top 21 wealthiest pharma companie*s, EUROPEAN PHARM. REV (Feb. 6, 2017), https://www.europeanpharmaceuticalreview.com/article/47001/top-21-wealthiest-pharma-companies/
[137] Opensecrets.org. Center for Responsive Politics, https://www.opensecrets.org/industries/indus.php?ind=H04

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."[138] Drug companies consistently ignore these warnings because they face no meaningful repercussions for doing so. The deferred prosecutions are toothless and the companies write off criminal fines as "a cost of doing business."[139] What then is the government to do about this fraud? How can it stem the tide of corruption in the pharmaceutical industry? As the next section of this article 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.

## PART II: RICO 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.[140] The Mafia, or La Cosa Nostra, frustrated government justice from the Prohibition Era through the early 1980s.[141] The Mafia successfully avoided government sanction because it was "entrepreneurial, opportunistic, and adaptable"; the Mafia simply evolved faster than the legal tools the government used against it.[142] 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.[143] As a result, Mafia leaders insulated themselves from government prosecution by delegating crime and decision-making authority down the hierarchical chain. Before RICO, the successful prosecution of high-ranking Mafia

[138] Ghogomu, *supra* note 124, at 571.
[139] Minasi, *supra* note 4, at 313.
[140] See, generally, Robert J. Kelly, ENCYCLOPEDIA OF ORGANIZED CRIME IN THE UNITED STATES: FROM CAPONE'S CHICAGO TO THE NEW URBAN UNDERWORLD (2000).
[141] Id.
[142] Goodwin, *supra* note 18, at 286.
[143] Id.

members was inconceivable.[144] The government's organized crime prosecutions were necessarily piecemeal and targeted only the behavior of low-level individuals engaged in singular criminal acts.[145] 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 defendant's associational affiliations and past criminal offenses.[146] These rules provided ideal protection for the Mafia, exposing only individual members of the organization to criminal liability while keepting the larger criminal enterprise a necessary secret from the jury.

However, 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.[147] Congress sought a statutory scheme to criminalize any *pattern of acts* that contributed to an organized crime syndicate's larger objectives.[148] 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 prosecuting individual crimes within a pattern of activity."[149] In other words, prosecutors needed a way to put the entire criminal enterprise on trial.

The government enacted RICO to be its new legal weapon to combat organized crime and enterprise criminality. This weapon proved powerful, and since 1980 the government has

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[144] Id. at 281.
[145] Id. at 292.
[146] Michael Goldsmith, *Resurrecting Rico: Removing Immunity for White-Collar Crime*, 41 HARV. J. ON LEGIS. 281, 286 (2004).
[147] Goodwin, *supra* note 18, at 292.
[148] RICO Crim. Penalties: 209. 18 U.S.C. § 1963 (1994).
[149] Bonney, *supra* note 20, at 594.

brought almost every significant organized criminal prosecution under RICO.[150] The enterprise-approach to prosecuting crime has largely dismantled the Mafia.[151] This section 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. This section 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.

*RICO's Criminal Elements and Penalties*

The government and the American public came to realize that the nation had a problem with the Mafia in the 1950s. The government's efforts to comprehend the power and reach of organized crime in the U.S. began with the Kefauver Committee in 1951, continued with the McClellan Committee in 1957, and culminated with the President's Task Force on Organized Crime in 1967.[152] (Ironically, the head of the Kefauver Committee, Senator Estes Kefauver, also led the charge to enact the regime of "evidence based medicine" that helped transform drug companies into organized criminal enterprises.)[153] 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.[154]

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.[155] After

[150] Jacobs and Gouldin, *supra* note 26, at 170.
[151] Godwin, *supra* note 18, at 281.
[152] Bonney, *supra* note 20, at 588.
[153] Healy, *supra* note 27, at 49.
[154] Id.
[155] Kelly, *supra* note 141, at x.

several years of debate, Congress enacted RICO on September 23, 1970.[156] 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. Change came only after G. Robert Blakey, one of RICO's primary drafters (and a law professor), invited FBI agents, U.S. attorneys, and state prosecutors to Cornell University for a summer law enforcement training institute in 1979.[157] 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.[158] 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 mind.[159]

18 U.S.C. § 1962(c) enumerates RICO's most commonly invoked substantive elements. It states that

> It 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.[160]

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*.[161] The government can also convict a person under RICO for conspiring to participate in

[156] Bonney, *supra* note 20, at 592.
[157] Jacobs and Gouldin, *supra* note 26, at 169.
[158] Id.
[159] Id.
[160] 18 U.S.C. § 1962(c).
[161] Devika Singh et al, *Racketeer Influenced and Corrupt Organizations*, 54 AM. CRIM. L. REV. 1727, 1730 (2017).

a criminal enterprise.[162] Under the statute, a "person" includes "any individual or entity capable of holding a legal or beneficial interest in property."[163] 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.[164]

Establishing the existence of an enterprise is the government's primary hurdle in any RICO prosecution.[165] 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. This "requirement" allows prosecutors to introduce previously inadmissible evidence about the "history, structure, and operations" of the crime syndicate to the jury.[166] 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."[167] 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



[162] 18 U.S.C. § 1962(d) (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); 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, 61-66 (1997).
[163] 18 U.S.C. § 1961(3) (2012).
[164] See *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 163 (2001) (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).
[165] 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).
[166] Jacobs and Gouldin, *supra* note 26, at 170.
[167] 18 U.S.C. § 1961(4) (2012).

goals."[168] 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.[169]

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."[170] 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.[171] This very broad "association-in-fact" standard affords the government great discretion in establishing a RICO enterprise. Courts have upheld a diverse array of associational enterprise theories.[172] For example, courts have determined that a loosely banded group of pro-life activists constituted a RICO enterprise,[173] a marriage consummated for financial gain was an enterprise,[174] and even the state of Illinois satisfied the requirement of an association-in-fact RICO enterprise.[175] Essentially, any group of two or more "persons" that works together to engage in a pattern of organized criminal acts constitutes a RICO enterprise. Courts grant this broad construction because of the "fluid nature of criminal enterprises," which allows them to adapt to changing socio-legal circumstances.[176] 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.[177]

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[168] Singh et al., *supra* note 162, at 1738.
[169] *United States v. Olson*, 450 F.3d 655, 665-68 (7th Cir. 2006).
[170] *United States v. Turkette*, 452 U.S. 576, 583 (1981).
[171] Paul Edgar Harold, *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).
[172] *Boyle v. United States*, 556 U.S. 938, 944 (2009).
[173] 510 U.S. 249 (1994).
[174] *Am. Mfrs. Mut. Ins. Co. v. Townson*, 912 F. Supp. 291, 295 (E.D. Tenn. 1995).
[175] *United States v. Warner*, 498 F.3d 666, 696 (7th Cir. 2007).
[176] Singh, et al., *supra* note 162, at 1739.
[177] Organized Crime Control Act § 904(a), 84 Stat. at 947.

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. 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.[178] In essence, the government must show that the enterprise has a leader (or hierarchical chain of leaders) who operates or manages the enterprise. 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.[179] As such, the RICO net "is woven tightly to catch even the smallest fish" who participated in the organized crime syndicate, while likewise ensnaring the individuals who direct the enterprise.[180] 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. 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. 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.[181] The circuit courts have generally extended the *Reves* holding to excuse from RICO liability most outside professionals who provide "traditional" professional services to the criminal enterprise.[182]

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

[178] *Reves v. Ernst & Young*, 507 U.S. 170 (1993).
[179] Christopher W. Madel, *The Modern RICO Enterprise: The Inoperation and Mismanagement of Reves v. Ernst & Young*, 71 TUL. L. REV. 1133, 1173 (1997).
[180] *United States v. Elliott*, 571 F.2d 880, 903 (5th Cir. 1978).
[181] *Reves*, 507 U.S. at 178-79.
[182] Jeffrey N. Shapiro, *Attorney Liability under RICO § 1962(c) after Reves v. Ernst & Young*, 61 UNIV. OF CHICAGO L. REV. 1153, 1161 (1994).

together constitute a "pattern of racketeering activity." 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.[183] Also included in the predicate offenses are mail fraud, wire fraud, insurance fraud, false claims, and honest services fraud.[184] In practice, virtually any federal felony and most state felonies can also serve as a RICO predicate offense.[185] 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.[186]

The "pattern of racketeering activity" must involve at least two of these predicate offenses that have occurred within 10 years of each other (the 10-year clock does not tick during any period of incarceration between the two acts).[187] In *Sedima, S.P.R.L. v. Imrex Co*. (1985), the Supreme Court held that two "isolated acts" of racketeering activity are by themselves insufficient for establishing a "pattern."[188] Later, in *H.J. Inc. v. Northwestern Bell Telephone Co.* (1989), the Court established the "continuity-plus-relationship" test for establishing when two predicate acts can establish a pattern of racketeering activity.[189] To prove a relationship between the predicate acts, the government must show that the acts were somehow, in any way, related to each other.[190] To prove continuity 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-

[183] 18 U.S.C. § 1961(1)(A).
[184] Rebecca Pyne, *Combating the Organized Crime Threat to the Healthcare System: Lessons Learned from Eurasian Organized Crime Prosecutions*, U.S. ATTY'S BULL. 37 (Nov. 2012); 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/.
[185] James B. Jacobs et al, BUSTING THE MOB: UNITED STATES V. COSTA NOSTRA, 10 (1994).
[186] see *Sedima, S.P.R.L. v. Imrex Co*., 473 U.S. 479, 488 (1985); see also *U.S. v. Persico*, 832 F.2d 705 (2d Cir. 1987).
[187] 18 U.S.C. § 1961(5) (2012) (this excludes any period of imprisonment between the two acts).
[188] *Sedima*, 473 U.S. at 496 n.14.
[189] *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 250 (1989).
[190] See generally *H.J., Inc*., 492 U.S. at 239-43.

ended" threat that the racketeering activity will continue in the future.[191] 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.[192] Courts generally find that even tangentially related predicate acts constitute a pattern of criminal activity in the context of any criminal RICO proceeding. (In practice, the "continuity-plus-relationship" test is only meaningful in the context of civil RICO cases, which are discussed briefly below.)

The government must also prove that the pattern of racketeering activity affected interstate commerce.[193] 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.[194] 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 some affect or impact on interstate commerce.[195] 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.[196] 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.[197] The

[191] *H.J., Inc*., 492 U.S. at 242.
[192] See *H.J. Inc*., 492 U.S. at 239 (with the Court stating that "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 175, concluding that the circuit courts apply this test in the civil RICO case 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.
[193] 18 U.S.C. § 1962(c)
[194] *United States v. Farmer*, 924 F.2d 647, 651 (7th Cir. 1991)
[195] *Gonzales v. Raich*, 545 U.S. 1 (2005) (holding that even the act of growing cannabis on your own property and for your own in-house medical treatment affects interstate commerce).
[196] 18 U.S.C. § 1963(a) (2012).
[197] Id.

defendant can also be convicted separately for RICO conspiracy (also a 20-year sentence) *and* for each of the predicate offenses that the government includes to prove the pattern of racketeering activity.[198] 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.[199]

RICO also has civil applications.[200] 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.[201] Most critics and courts agree that civil RICO, as applied, is "organized-crime law run amok."[202] 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 users fees, annual fees, and other boilerplate provisions in their day-to-day commercial activities.[203] Indeed, courts routinely attempt to limit civil RICO's reach (via the aforementioned "continuity-plus-relationship" test) to prevent an overcrowding of their respective dockets.[204] It is not readily apparent why corporations engaging in "garden-variety" fraud should be exempt from civil RICO charges, but that is an argument for another time and venue.



[198] Jacobs and Gouldin, *supra* note 26, at 169.
[199] 18 U.S.C. § 1963(b).
[200] 18 U.S. Code § 1964(c).
[201] Id.
[202] Goldsmith, *Resurrecting RICO*, *supra* note 147, at 288.
[203] Justin D. Weitz, *A Necessary Supplement: Reinvigorating Civil RICO's Securities Fraud Predicated*, 21 WIDENER L. REV. 27, 41 (2015). See also Caroline N. Mitchell, and Jordan Cunningham, and Mark R. Lentz, *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).
[204] Mitchell et al, *supra* note 205, at 3.

*Government Applications of RICO against the Mafia*

The government served the criminal underground notice of RICO's power in *United States v. Salerno* (1986), or what is more commonly known as the "Mafia Commission" case.[205] 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.[206] Using RICO, the government switched from its previous tactic of prosecuting individual criminal acts and instead targeted the larger crime families themselves. The government's new theory was that the "Commission 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."[207] 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.[208] (These details, recall, would be inadmissible in a non-RICO criminal prosecution.) 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.[209]

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. In other

[205] 868 F.2d 524 (2d Cir. 1989).
[206] Selwyn Raab, THE RISE, DECLINE, AND RESURGENCE OF AMERICA'S MOST POWERFUL MAFIA EMPIRES 732-4 (2006).
[207] Jacobs et al., *supra* note 189, at 81.
[208] Goodwin, *supra* note 18, at 307.
[209] Jacobs et al., *supra* note 189, at 10.

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."[210]

The Commission Case also displays how RICO allows the prosecution to join all members of the enterprise as defendants in a single trial and under the same charge. 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.[211] The government joined as defendants in a single trial—and under the same RICO charge of participating in the criminal enterprise—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).[212] 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."[213] The jury found all the *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.[214] Given this

[210] Id. at 11.
[211] Id. at 79.
[212] Id. at 81.
[213] Id. at 82.
[214] Id. at 86.

novel prosecutorial approach and its stunning outcome, experts have compared *Salerno* to some of the most meaningful statutory prosecutions in U.S. history.[215]

The next major RICO success came in *United States v. Badalamenti* (1987), or the "Pizza Connection" case.[216] 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.[217] The indictment charged thirty-one defendants with engaging in a RICO conspiracy.[218] 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."[219] 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. Smaller fish began, as they put it, to "do the arithmetic" and provided evidence against their bosses rather than taking the fall for the organization as they had in the past.[220] 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.[221] As such, the testimony of two low-level defendants, Salvatore Contorno and Luigi Ronsisvalle, proved pivotal in securing the remaining defendants' RICO convictions.[222] The Pizza Connection

[215] 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
[216] 84 CR 236 (S.D.N.Y. 1987)
[217] Jacobs et al, *supra* note 189, at 129.
[218] Id. at 130.
[219] Id.
[220] Goodwin, *supra* note 18, at 304.
[221] Id.
[222] Jacobs et al, *supra* note 189, at 140.

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.[223] Gotti, originally known as the "Dapper Don" for his flamboyance, later earned the moniker "Teflon Don" for escaping three separate government prosecutions.[224] Even as he was taken into custody for the fourth time, Gotti quipped to the arresting officers that "I bet ya three-to-one I beat this."[225] 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.[226] 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.[227] Indeed,

> His 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.[228]

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 an irreconcilable conflict of interest.[229] As a result of Gravano's "big picture" testimony and the absence of Cutler, the jury convicted Gotti of violating RICO and the judge

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[223] *United States v. Locascio*, 6 F.3d 924, 929 (2d Cir. 1993).
[224] Robert J. Anello and Miriam L. Glaser, *White Collar Crime*, 85 FORDHAM L. REV. 39, 49 (2016).
[225] Gene Mustain and Jerry Capeci. MOB STAR: THE STORY OF JOHN GOTTI 376 (1996).
[226] Jacobs et al, *supra* note 189, at 213.
[227] Jacobs and Gouldin, *supra* note 26, at 167.
[228] Jacobs et al, *supra* note 189, at 217.
[229] Goodwin, *supra* note 18, at 303.

sentenced him to concurrent life sentences in prison.[230] Gotti died in prison of throat cancer in 2002.[231] 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.

*RICO and White-Collar Crime*

Congress enacted RICO *primarily* to combat traditional organized crime syndicates like the Mafia. However, it also purposefully drafted the statute to target white-collar corporate crime.[232] The government made this legislative decision in large part because it recognized the fundamental similarities between Mafia hierarchies and corporate structures.[233] Accordingly, both RICO's statutory text and legislative history reveal the congressional intent that it should apply to corporate crime.[234] Original versions of the RICO statute did not include white-collar offenses, but Congress specifically revised RICO to include white-collar predicate acts such as securities fraud, wire fraud, and mail fraud.[235] Moreover, the statute's primary drafter, G. Robert Blakey, stated of RICO that "We 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."[236] 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.[237] Private industry has lobbied heavily to amend RICO to remove white-collar predicate acts such as securities fraud, but these attempts to amend the statute only reinforce the

[230] Jacobs et al, *supra* note 189, at 218.
[231] Selwyn Raab, *John Gotti Is Dead at 61; Ex-Mafia Boss Courted Limelight*, N.Y. TIMES (Jun. 10, 2002), https://www.nytimes.com/2002/06/10/national/john-gotti-is-dead-at-61-exmafia-boss-courted-limelight.html
[232] Goldsmith, *Resurrecting RICO*, *supra* note 147, at 284.
[233] The President's Comm'n on Law Enforcement and Admin. of Justice, Task Force Report: Organized Crime 2, 16-24 (1967).
[234] Goldsmith, *Enterprise Criminality*, *supra* note 24, at 786.
[235] Id. at 787.
[236] Lee E. Berlik. *RICO: Not Just For Gangsters Anymore*, VIRGINIA BUS. LITIGATION BLOG (Feb. 9, 2015), https://www.virginiabusinesslitigationlawyer.com/2015/02/rico-not-just-for-gangsters-an.html
[237] Goldsmith, *Enterprise Criminality*, *supra* note 24, at 775.

fact that it applies to white-collar crime.[238] 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."[239] These fears arose because industry insiders recognized the undeniable similarities between the Mafia and the modern business corporation.[240] 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 white-collar criminals.

Prior to drafting RICO, Congress identified the stark similarities between the Mafia and the corporation. In fact, the *President's 1967 Task Force on Organized Crime Report* (the Report) describes the Mafia exclusively in terms of the business corporation.[241] 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.[242]

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.[243] The "boss" or "don" is akin to the chief executive officer, tasked with "maintaining order and maximizing profits."[244] Beneath the boss is the so-called "underboss," who is the "vice president or deputy director of

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[238] Goldsmith, *Resurrecting RICO*, *supra* note 147, at 302; Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, § 107, 109 Stat. 737, 758 (1995) (codified at 18 U.S.C. § 1964(c) (2000)).
[239] See, generally, L. Gordon Crovitz, *How the RICO Monster Mauled Wall Street*, 65 NOTRE DAME L. REV. 1050 (1990).
[240] See, generally, Shayna A. Hutchins, *Flip That Prosecution Strategy: An Argument for Using RICO to Prosecute Large-Scale Mortgage Fraud*, 59 BUFFALO L. REV. 293 (2011).
[241] The President's Comm'n on Law Enforcement and Admin. of Justice, Task Force Report: Organized Crime 2, 16-24 (1967).
[242] Id. at 7.
[243] Id. at 8.
[244] Id. at 7.

the family" and who serves as a conduit between the boss and various classes of underlings. On the same level of the underboss is the "*consigliere,"* who serves as general counsel and advises the family's chief executive.[245] Next come the "caporegime" (captains). These members play the role that is "from a business standpoint…analogous to plant supervisor or sales manager."[246] They also "serve as buffers between the top members of the family and the lower-echelon *personnel*. To maintain insulation from the police, the leaders of the hierarchy (particularly the boss) avoid direct communication with the *workers*."[247] The lowest-ranked internal members of the organization, according to the Report, are the "soldiers." 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.[248] 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 run the family's financial enterprise accordingly.[249]

The analogy between the Mafia and the business corporation extends beyond the level of personnel. The Mafia, like a business corporation, seeks "protection" from individuals outside of the organization. The Report notes that "to seek 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."[250] The mob had a "pervasive presence" in politics, through which "mobsters and city officials were in business together."[251] 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

[245] Id.
[246] Id. at 8.
[247] Id. at 7-8. My emphasis.
[248] Id. at 8.
[249] Id. at 8.
[250] Id. at 6.
[251] Nicholas Pileggi, *The Mob and the Machine*, N.Y. MAG (May 5, 1986), http://nymag.com/news/features/crime/46610/

campaigns," and that "the arrangements are made through middle-men and aides, people who have forged friendships in childhood, in campaigns, in various business deals."[252] In other words, the Mafia engaged in corporate-style political lobbying. Lawyers, too, provide "protection" to organized crime syndicates. 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.[253] Recall the government's efforts to disqualify John Gotti's attorney and the subsequent conviction that disqualification enabled.[254] Attorneys who serve criminal enterprises "act as unassailable black knights for organized crime, doing its bidding in furtherance of its illegal schemes."[255]

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

[252] Id.
[253] 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).
[254] Jacobs et al, *supra* note 189, at 218.
[255] Goldstock and Chananie, *supra* note 254, at 1877.

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 19 people during the course of his entire criminal career before going to prison.[256] Yet, executives at companies like Purdue engage in fraud to sell prescription opioid drugs that kill nearly 90 Americans *every single day*.[257] It is estimated that John Gotti earned approximately $10 million each year from his Gambino Mafia enterprise before going to prison for life.[258] Raymond Gilmartin, Merck's CEO when the company fraudulently marketed Vioxx and killed at least 60,000 Americans, earned $40 million in a single year and was never charged with a crime.[259] Government estimates suggest that the *entire* Mafia, at the height of its powers immediately prior to the Mafia Commission case, earned about $60 billion a year.[260] The global pharmaceutical market exceeds $1 *trillion* a year.[261] This, despite the fact that prescription drugs remain the leading cause of accidental death in the U.S.—recently surpassing car accidents.[262] Since these companies mirror (and magnify) the Mafia's enterprise criminality, the government should accordingly apply RICO to pharmaceutical industry fraud.[263] The next section demonstrates precisely how RICO should apply to drug company executives, sales representatives, doctors, and the lawyers and politicians who work to protect them.



[256] Jacobs and Gouldin, supra, at 167.
[257] Centers for Disease Control and Prevention. Opioid Data Analysis. https://www.cdc.gov/drugoverdose/data/analysis.html (last retrieved on July 4, 2018).
[258] Raab, *Gotti is Dead*, *supra* note 233.
[259] Nesi, *supra* note 11, at 255.
[260] Roy Rowan and 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 (amounts adjusted for inflation).
[261] Healy, *supra* note 27, at 10.
[262] Tricarico, *supra* note 1, at 123.
[263] Peter Gotzsche makes a connection between the pharmaceutical industry and organized crime, but leaves his analysis at the level of brief comparison. Gotzsche, a physician, examines medical solution such as nationalizing the pharmaceutical industry. 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. See Peter R. Gotzsche, DEADLY MEDICINES AND ORGANISED CRIME 22-39 (2013).

## PART III: APPLYING RICO TO PHARMACEUTICAL INDUSTRY FRAUD

Merck, recall, engaged in a brazen pattern of criminal fraud that killed at least 60,000 Americans.[264] No executives were charged with a crime, the company paid a fine, and its CEO walked away with millions.[265] 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.[266] No executives went to prison, the company paid a fine, and its owners are now worth $13 billion.[267] GlaxoSmithKline engaged in fraud to market to children a drug that they knew triggered adolescent suicides.[268] No executives were charged with a crime and the British government actually knighted the company's CEO for his "contributions to the pharmaceutical industry."[269] 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.[270] These drug companies and other complicit parties routinely engage in this pattern of fraud because they face no meaningful repercussions for their actions. This final section demonstrates how the government should apply RICO to pharmaceutical industry fraud in order to dismantle these dangerous enterprises as it previously (and successfully) did with the Mafia. This section provides viable legal theories for applying RICO to prosecute complicit executives, sales representatives,



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[264] See *supra* note 9.
[265] See *supra* note 11.
[266] 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/
[267] See *supra* note 119.
[268] See *supra* note 95.
[269] Louisa Peacock, *Glaxo's Andrew Witty gets New Year knighthood*, THE TELEGRAPH (Dec. 31, 2011), http://www.telegraph.co.uk/finance/newsbysector/pharmaceuticalsandchemicals/8985213/Glaxos-Andrew-Witty-gets-New-Year-knighthood.html
[270] See discussion *supra* pp. 17-20.

doctors, lawyers, and politicians for participating in association-in-fact criminal enterprises through a pattern of deadly criminal fraud.

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."[271] 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.[272] 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 profiting from the sale of prescription drugs through fraud.[273] 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.[274] 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 interstate commerce and the pharmaceutical industry's unrivaled levels of profitability.[275]

*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

[271] *United States v. Turkette*, 452 U.S. 576, 583 (1981)
[272] 18 U.S.C. § 1962(c).
[273] See *supra* note 183.
[274] See *supra* note 188. 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.
[275] 18 U.S.C. § 1962(c); 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

bosses and underbosses. Indeed, the government recently applied RICO to a small network of corporate executives at Insys Pharmaceuticals.[276] (Despite its great precedential value, the government's action against Insys seems to be a symbolic gesture to scapegoat a few individuals at a single opioid manufacturer and to serve as evidence of a government "crackdown" on the opioid crisis.)[277] The government's prosecution of Drexel Burnham Lambert banking executives also serves as precedent for RICO charges against corporate executives who engage in fraud.[278] As such, executives like those at Merck who authorized press releases similar to the one that stated that "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.[279] Indeed, the FDA went on the record calling this press release "simply incomprehensible" and demanded Merck executives retract the statement.[280] 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.[281] 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

[276] Henning, *supra* note 16.
[277] Department of Justice, U.S. Attorney's Office, District of Massachusetts. "Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering" (October 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering (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).
[278] See, generally, Crovitz, *supra* note 240.
[279] Snigdha Prakash, *Merck Rests Its Defense in Federal Vioxx Trial*, NATIONALPUBLICRADIO.ORG (Dec. 7, 2005), https://www.npr.org/templates/story/story.php?storyId=5043658
[280] Culp & Berry, *supra* note 6, at 26.
[281] Id. at 25.

about the drug."[282] The company likewise settled charges related to executives paying kickbacks to doctors to prescribe Vioxx, each occurrence of which would serve as a predicate offense for RICO.[283] 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 RICO enterprise.

*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."[284] 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.[285] The drug representatives were aware that the company was asking them to engage in fraud and to make false statements, since

> To 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.[286]

Executives motivate drug representatives to participate in prescription drug fraud by paying them large bonuses related to the sale of specific drugs. With regard to its highly addictive prescription

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[282] Department of Justice. Press Release, *U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx*® (Nov. 22, 2011), https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion.
[283] *Merck to pay $650M to settle fraud case.* ABCNews.com (Feb. 7, 2008), http://abc7news.com/archive/5942426/.
[284] Greene, *supra* note 3, at 648.
[285] Culp & Berry, *supra* note 6, at 25.
[286] Id.

opioid painkiller, Purdue instituted "A lucrative bonus system [that] encouraged sales representatives to increase sales of OxyContin in their territories" using any means necessary.[287] In conjunction with these bonuses, Purdue executives "instructed [drug representatives] to downplay the threat of addiction with OxyContin."[288]

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.[289]

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 the 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.[290] 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.

*Doctors*

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[287] Van Zee, *supra* note 112, at 222.
[288] David Armstrong, *Secret trove reveals bold 'crusade' to make OxyContin a blockbuster*, STATNEWS.COM (Sep. 22, 2016), https://www.statnews.com/2016/09/22/abbott-oxycontin-crusade/
[289] Frederickson, *supra* note 109, at 128.
[290] Staff, *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

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.[291] 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 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.[292]

In this case, Reynolds and the Hospital of Special Surgery comprised the two "person" RICO enterprise.[293] 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 offenses for the pattern of racketeering activity.[294] Honest services fraud includes any scheme that aims to "deprive another of the intangible right of honest services."[295] 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. Facing up to

[291] Singh et al, *supra* note 162, at 1784.
[292] See *supra* note 188.
[293] Id.
[294] Id.
[295] 18 U.S.C. § 1341; see also, Brian H. Connor, *The Quid Pro Quo Quark: Unstable Elementary Particle of Honest Services Fraud*, 65 CATH. U.L. REV. 335, 338 (2015).

25 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.[296]

In connection with Vioxx, Merck settled claims that it paid physicians kickbacks to prescribe the drug.[297] Pfizer, too, settled claims with the government that it "paid kickbacks to health care providers to induce them to prescribe [Neurontin].[298] GlaxoSmithKline also "illegally marketed [Paxil] for use in children and teens, offering kickbacks to doctors and sales representatives to push the drug."[299] These kickback schemes and widespread and commonplace, so much so that a former high-ranking Drug Enforcement Administration described doctors as "drug dealers in lab coats."[300] 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 defendants 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.[301] Doctors

[296] Barbara Benson, *Ex-hospital CEO sentenced to 18 months in prison*, CRAIN'S N.Y. BUSINESS (Nov. 7, 2013). http://www.crainsnewyork.com/article/20131107/health_care/131109911/ex-hospital-ceo-sentenced-to-18-months-in-prison

[297] *Merck to pay $650M to settle fraud case*, ABCNEWS.COM (Feb. 7, 2008), http://abc7news.com/archive/5942426/

[298] Department of Justice. Press Release, *Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay $2.3 Billion for Fraudulent Marketing*, DOJ.GOV (Sep. 2, 2009), https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history

[299] Alexandra Sifferlin, *Breaking Down GlaxoSmithKline's Billion-Dollar Wrongdoing*, TIME MAG. (Jul. 5, 2012), http://healthland.time.com/2012/07/05/breaking-down-glaxosmithklines-billion-dollar-wrongdoing/

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

[301] Andy Marso, *Drug rep for doctor sued over fentanyl spray prescriptions revealed as whistleblower*, KANSAS CITY STAR (May 31, 2018), https://www.kansascity.com/news/business/health-care/article212260139.html.

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."[302] If the government charged them under RICO instead, doctors who accept kickbacks to prescribe a drug would face up to 20 years in prison and would forfeit their assets to the government. Under such a scenario, I anticipate we would hear fewer judges merely castigating doctors, like the judge in Rosenberg's case, for selling "your medical license to a pharmaceutical company."[303] Instead, judges would be sentencing doctors who accept these bribes and endanger their patients' lives to hard time in federal prison.

*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 matters find themselves at the "fulcrum of corporate decision making."[304] However, under the *Reves* "management-and-operation" test, courts have mostly "excused attorneys from [RICO] liability through application of a crude 'legal services' standard."[305] 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.[306] 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

[302] *Ivy League Doctor Gets 4 Years in Prison for Insys Opioid Kickbacks*, BLOOMBERG (March 10, 2018) http://fortune.com/2018/03/10/jerrold-rosenberg-opioid-kickbacks/.
[303] Id.
[304] Shapiro, *supra* note 186, at 1172.
[305] Id. at 1161.
[306] Id.

represented members of New York's Bonanno crime family, with racketeering.[307] The government claimed that Lee participated too closely in the enterprise by carrying messages between members of the crime family.[308] In implicating Lee, The U.S. Attorney stated that "What he has shown himself to be is an associate of organized crime who happens to also have a law degree."[309] 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.[310] Notably, both of these RICO indictments arose after *Reves* and demonstrate that the legal services standard does not preclude RICO liability for attorneys.[311] Indeed, it is difficult to imagine lawyers from a top corporate law firm not exerting some sort of control over a board of directors that they advise. Consider, for instance, that

> An 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.[312]

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.[313] For RICO purposes, the government

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[307] Robert F. Worth, *Mob Boss's Lawyer Charged With Aiding Murder Plot*, N.Y. TIMES (Jun. 25, 2005), https://www.nytimes.com/2005/06/25/nyregion/mob-bosss-lawyer-charged-with-aiding-murder-plot.html
[308] Id.
[309] Id.
[310] Michael Decourcy Hinds, *F.B.I. Arrests Reputed Leader of Philadelphia Mob and 23 Others*, N.Y. TIMES (March 18, 1994), https://www.nytimes.com/1994/03/18/us/fbi-arrests-reputed-leader-of-philadelphia-mob-and-23-others.html
[311] *Reves v. Ernst & Young*, 494 U.S. 56 (1990); Singh et al, *supra* note 162, at 1750.
[312] Shapiro, *supra* note 186, at 1162-63.
[313] See supra note 74.

should therefore examine the precise role that an attorney plays in advising a drug company with regard to the sale of prescription drugs.

Take, for instance, the law firm Skadden, Arps, Slate, Meagher & Flom LLP (Skadden). This illustrious Wall Street firm is a staunch advocate for corporate freedom. For example, the firm has publicly decried corporate DPAs—like those that Merck, Purdue, Glaxo, and Pfizer routinely enter into *and routinely ignore without consequence*—as "formidable" government sanctions.[314] Skadden holds an annual pharmaceutical and medical device seminar for pharmaceutical industry executives, where

> Panels of Skadden attorneys and in-house counsel discussed litigation challenges and shared practical strategies. Discussions included "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 Dovdavany of Sanofi US, Timothy Howard of Merck & Co., Inc., Joseph Kennedy of Amarin Corp plc and Dr. William Polvino of Veloxis Pharmaceuticals.[315]

The seminar description reads like the minutes from a Mafia commission board meeting, only with leading drug company executives in attendance as opposed to New York's five major crime bosses. Skadden's newsletter states that these executives from Purdue and Merck worked with Skadden attorneys on "practical strategies" for "taking on the government." Skadden represents these drug companies on a routine basis. *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" in 39 different

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[314] Allen L. Lanstra and Kevin J. Minnick, *The Collateral Effects of Deferred Prosecution Agreements to Corporations in Subsequent Civil and Regulatory Actions*, SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP INSIGHTS (June 26, 2014), https://www.skadden.com/insights/publications/2014/06/the-collateral-effects-of-deferred-prosecution-agr

[315] Skadden Newsletter, *A Dialogue With Corporate Counsel: Skadden's Fifth Annual Pharmaceutical and Medical Device Seminar — Enforcement and Litigation Strategies*, SKADDEN.COM (November 17, 2015), https://www.skadden.com/insights/events/2015/11/a-dialogue-with-corporate-counsel-skaddens-fifth-a

cases.[316] Skadden likewise represented Merck in connection with its Vioxx fraud.[317] The firm has successfully represented Pfizer in connection with fraud cases.[318] Rounding out the list of usual suspects, Skadden has previously served in an advisory role in transactions involving GlaxoSmithKline.[319] If this is Skadden's *public* disclosure of the advice they offer drug companies, it is difficult to imagine that the firm's attorneys do not exert some form of control over drug company decision making in private. If drug companies like Purdue and Merck are indeed RICO criminal enterprises, it is not a difficult step to claim that corporate lawyers who advise them how to "take on the government" in prescription drug matters are also participating in the criminal enterprise. Like Lee and Avena before them, these corporate attorneys appear to be serving the role of *consigliere* in the organized criminal hierarchy.

*Politicians*

The *Washington Post* recently ran an exposé on the *Ensuring Patient Access and Effective Drug Enforcement Act of 2016* (Enforcement Act)[320] 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 onto the nation's streets."[321] The Enforcement Act makes it harder for the DEA to sanction prescription drug distributors who



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[316] Scott Flaherty, *Global Enforcer: Skadden, Arps, Slate, Meagher & Flom, Winner, White Collar/Regulatory Litigation Department of the Year: Skadden's white-collar and regulatory work has benefited major clients facing crises and tough problems around the world*, THE AMERICAN LAWYER (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/?slreturn=20180529170835; See also LAW360, https://www.law360.com/companies/purdue-pharma-lp/outside_counsel

[317] Staff, *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

[318] *Pfizer Defeats Stockholder Demand to Inspect Records* (September 1, 2016), https://www.skadden.com/about/news-and-rankings/news/2016/09/pfizer-defeats-stockholder-demand-to-inspect-recor.

[319] Jennifer L. Bragg, Partner Bio, Skadden.com, https://www.skadden.com/professionals/b/bragg-jennifer-l (last retrieved on July 9, 2018).

[320] *Ensuring Patient Access and Effective Drug Enforcement Act of 2016*, Pub. L. No. 114-145, 130 Stat. 353 (codified as amended at 21 U.S.C.§§823(j), 824(c), (d)).

[321] See *supra* note 300.

send suspiciously large opioid shipments to pharmacies, which in turn illegally dispense the pills to fuel the opioid epidemic.[322] 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.[323] 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.[324] 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 it with the DEA.[325] Hatch, incidentally, has received $2,863,750 in campaign contributions from the pharmaceutical industry over the course of his political career.[326] Industry observers routinely accuse Hatch of being beholden to the pharmaceutical industry because of these substantial campaign contributions.[327] Hatch is not alone, of course, as politicians from both parties accept hefty campaign contributions from drug companies (indeed, 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)).[328] These industry campaign contributions spurred a former high-ranking DEA official to state publicly that "The drug industry, the manufacturers, wholesalers, distributors and chain drugstores, have an influence over Congress that has never been seen before."[329] RICO could help lessen this

[322] See *supra* note 300.
[323] 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).
[324] Id.
[325] Id.
[326] OpenSecrets.org. Pharmaceuticals / Health Products: Money to Congress, https://www.opensecrets.org/industries/summary.php?ind=H04&cycle=2018&recipdetail=M&sortorder=U (last retrieved on July 4, 2018).
[327] 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
[328] OpenSecrets.org. Pharmaceuticals / Health Products: Money to Congress, https://www.opensecrets.org/industries/summary.php?ind=H04&cycle=All&recipdetail=M&sortorder=U (last retrieved on July 4, 2018).
[329] See *supra* note 300.

influence. If the Department of Justice were to consider drug companies to be association-in-fact RICO enterprises, at 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 friendly legislation. In *United States v. Cianci* (2004), the government charged and convicted Vincent "Buddy" Cianci (then Mayor of Providence, Rhode Island) of conspiracy to violate RICO.[330] 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."[331] The court sentenced Cianci to five years in prison for violating RICO by accepting campaign contributions in exchange for political favors.[332] (Former Illinois Governor George Ryan also went to prison as a result of a RICO conviction related to the receipt of corrupt campaign contributions.)[333] The second case, *McDonnell v. United States* (2016), sets a clear standard for when a campaign contribution constitutes bribery, which is of course a predicate RICO offense.[334] 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.[335] 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

[330] *United States v. Cianci*, 378 F.3d 71 (1st Cir. 2004); 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)
[331] Id. at 326.
[332] Elizabeth Mehren, *Providence Mayor Gets Prison Sentence for Corruption*, L.A. TIMES (Sep. 7, 2002), http://articles.latimes.com/2002/sep/07/nation/na-buddy7
[333] Monica Davey and John O'Neil, *Ex-Governor of Illinois Is Convicted on All Charges*, N.Y. TIMES (April 17, 2006), https://www.nytimes.com/2006/04/17/us/exgovernor-of-illinois-is-convicted-on-all-charges.html
[334] *McDonnell v. United States*, 579 U.S. ___ (2016)
[335] 18 U.S.C. § 1951.

dietary supplements executive."[336] 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 benefactor.[337] 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.[338]

Pundits have too quickly suggested that the Court's ruling in *McDonnell* opens the door to increased public corruption.[339] The case actually sets a very clear standard for when a politician or public official violates federal bribery rules by accepting campaign contributions and actually makes future bribery convictions much more likely.[340] 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.[341]

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.[342] As one observer of the *McDonnell* case puts it, "Public officials would thus be well-advised to act with caution

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[336] Trip Gabriel, *Former Governor in Virginia Guilty in Bribery Case*, N.Y. TIMES (Sep. 4, 2014), https://www.nytimes.com/2014/09/05/us/bob-mcdonnell-maureen-mcdonnell-virginia-verdict.html
[337] Daniel P. Tokaji, *Bribery and Campaign Finance: McDonnell's Double-Edged Sword*, 14 OHIO STATE JOURNAL OF CRIM. LAW AMICI BRIEFS 15, 15 (2017).
[338] Id.
[339] David Voreacos and 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
[340] Tokaji, *supra* note 334, at 15.
[341] Id.
[342] Tokaji, *supra* note 334, at 17.

when they receive contributions from someone with an interest in a pending decision or action." Politicians like Orrin 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.

## CONCLUSION

The Enforcement Act that Senator Hatch helped push through congress exacerbated the opioid epidemic and "neutered" the DEA, such that the Department of Justice recently asked congress to rewrite or repeal the legislation.[343] 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.[344] The committee's chairman, Greg Walden (R-Oregon), hinted at criminal charges against drug company executives and promised immediate legislative change in advance of the hearings.[345] As of yet, the government has filed no charges and instituted no binding legislative reform. Chairman Walden has received close to $1 million in campaign contributions from the pharmaceutical industry.[346] In a room "packed with attorneys, lobbyists, and staffers for the drug companies," the hearings digressed into a game of finger pointing.[347] John Gray, the drug distributors' chief lobbyist, noted that prescription opioid abuse "was not caused by distributors who neither prescribe, manufacture,

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[343] Scott Higham and Sari Horwitz, *Justice Dept. urges Congress to rewrite law that handcuffed DEA's opioid enforcement*, WASH. POST (March 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.

[344] U.S. House Energy and Commerce Committee, *Combating the Opioid Crisis: Investigation*, https://energycommerce.house.gov/opioids-pilldumping/ (last retrieved on July 4, 2018).

[345] Id.

[346] OpenSecrets.org, at https://www.opensecrets.org/industries/summary.php?ind=H04&cycle=All&recipdetail=H&sortorder=N&mem=Y&page=11 (last retrieved on July 4, 2018).

[347] Katie Zezima and 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?utm_term=.9f101fb04ff2&wpisrc=nl_daily202&wpmm=1.

nor dispense medicines."[348] The distributors blamed doctors for overprescribing opioids who, in turn, faulted pharmacists for over-dispensing them.[349] Congresswoman Anna Eshoo (D-California) glibly contributed to the hearings by noting that the government needs a solution to the problem that simply has "more teeth."[350] Eshoo, it should be noted, leads all U.S. representatives in pharmaceutical industry campaign contributions at the lofty sum of $1.5 million.[351] 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. They are *all* to blame for drug company fraud. It is now time to hold them accountable through a proposal that indeed has "more teeth."

Drug company executives, lobbyists, sales representatives, doctors, lawyers, and politicians worked together to create and exacerbate the systemic problem of pharmaceutical industry fraud. The legal framework that governs the industry is unquestionably broken.[352] 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 drug company fraud will face the prospect of 20 years in prison and a forfeiture of assets. These stiff penalties will not only dissuade acts of fraud, but will serve as an incentive for 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

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[348] Id.
[349] Id.
[350] House of Representatives Subcommittee on Health Committee on Energy and Commerce, Combating the Opioid Crisis: Prevention and Public Health Solutions 1293-1295 (March 22, 2018), transcript available at https://docs.house.gov/meetings/IF/IF14/20180321/108049/HHRG-115-IF14-Transcript-20180321.pdf
[351] OpenSecrets.org. https://www.opensecrets.org/industries/summary.php?ind=H04&cycle=All&recipdetail=H&sortorder=A&mem=Y
[352] See generally McCarthy, *supra* note 13.

crime.[353] 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.



[353] See *supra* note 114.