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Corporate Misconduct in the Pharmaceutical Industry

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CORPORATE MISCONDUCT IN THE PHARMACEUTICAL INDUSTRY

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Introduction

Sadly, many pharmaceutical companies have engaged in unethical or illegal behavior.[2] The current opioid crisis is the most recent example of misconduct by pharmaceutical companies.[3] Moreover, this pattern of conduct is neither rare, nor recent. Instead, it is long-standing and pervasive in nature.[4] Furthermore, unlike wrongdoing by other businesses that cause primarily economic or environmental harm, wrongdoing by pharmaceutical companies, like that of asbestos or tobacco companies, may cause personal injuries and death on a large scale.[5]

Part I of this Article discusses corporate misconduct in general and provides a number of examples of prominent corporate wrongdoing over the past three decades. Part II of this Article focuses on unethical practices by pharmaceutical companies. This includes manipulation of the results of clinical trials and fraud in connection with the marketing and promotion of prescription drugs, including dissemination of false information to doctors and patients, targeting vulnerable groups, secretly financing key opinion leaders and front groups, as well as engaging in kickbacks and bribery.

Part III provides a sample of case studies illustrating misconduct by drug companies over the past sixty years. Among the products discussed are MER/29, the Dalkon Shield intrauterine device (IUD), Botulinum Toxin (Botox), Neurontin, Lupron, Vioxx, and Paxil. This sets the stage for a discussion of OxyContin and its contribution to the

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2. *See infra* Part II.

3. *See infra* Part II. Misconduct includes such actions as compromising clinical trials, participating in fraudulent marketing practices, and engaging in kickbacks and bribery.

4. *See infra* Part III (describing misconduct from 1957 to 2017).

5. For example, it is estimated that Vioxx killed at least 60,000 people. Eugene McCarthy, *A Call to Prosecute Drug Company Fraud as Organized Crime*, 69 Syracuse L. Rev. 439, 440 (2019).

current opioid crisis. It shows that the OxyContin experience is not a "one off" but rather that it reflects a widely accepted business model that has existed for more than sixty years.

Part IV examines some of the factors that influence corporate behavior and encourage drug company executives to engage in unethical and illegal behavior. These factors include weak regulation by the federal government, internal and external economic pressure, and cultural influences within the company.

Part V offers some potential solutions to the problem of drug company behavior. First, stricter regulation and oversight by the federal Food and Drug Administration (FDA) is needed. Second, economic sanctions should be increased. This includes greater criminal liability for violators and greater civil liability as well. Finally, measures need to be taken to encourage a more responsible corporate culture.

I. Examples of Corporate Misconduct

The past half-century has produced its share of business scandals. Corporate scofflaws have included such companies as Johns-Manville,[6] American International Group (AIG),[7] American Tobacco Co. and other cigarette manufacturers,[8] Ford Motor Co.,[9] Volkswagen (VW),[10] Enron Corporation (Enron),[11] Wells Fargo,[12] Exxon,[13] Brit-

6. Cynthia R. Mabry, *Warning! The Manufacturers of This Product May Have Engaged in Cover-Ups, Lies, and Concealment: Making the Case for Limitless Punitive Awards in Products Liability Lawsuits,* 73 Ind. L.J. 187, 219 (1997).

7. William K. Sjostrom, Jr., *The AIG Bailout*, 66 Wash. & Lee L. Rev. 943, 959–63 (2009).

8. Richard C. Ausness, *Conspiracy Theories: Is There a Place for Civil Conspiracy in Products Liability Litigation?*, 74 Tenn. L. Rev. 383, 384–85 (2007).

9. Gary T. Schwartz, *The Myth of the Ford Pinto Case*, 43 Rutgers L. Rev. 1013, 1015–19 (1991).

10. John C. Cruden et al., *Dieselgate: How Investigation, Prosecution, and Settlement of Volkswagen's Emissions Cheating Scandal Illustrates the Need for Robust Environmental Enforcement*, 36 Va. Envtl. L.J. 118, 123–25 (2018).

11. *See generally* Enron Corp. Sec. Derivative & Erisa Litig. v. Enron. Corp., 235 F. Supp. 2d 549 (S.D. Tex. 2002).

12. Julia E. Class, Note, *Together We'll Go Far . . . Away From Court: The Wells Fargo Scandal and the Limits of Its Mandatory Arbitration Agreements*, 37 Rev. Banking & Fin. L. 927, 930 (2018).

13. Jeff Kerr, Comment, Exxon Shipping Co. v. Baker*: The Perils of Judicial Punitive Damage Reform*, 59 Emory L.J. 727, 729–32 (2010).

ish Petroleum (BP),[14] Fannie Mae and Freddie Mac,[15] HealthSouth,[16] Lehman Brothers,[17] and WorldCom.[18]

A. Johns-Manville's Concealment of Asbestos Exposure Risks

One of the most notorious cases of corporate misconduct involved Johns-Manville and other asbestos manufacturers.[19] As early as 1936, corporate officers attended a secret meeting and agreed to finance a project to accumulate data to use to rebut claims that exposure to asbestos posed serious health risks to workers and consumers.[20] In addition, one executive at Raybestos intervened on several occasions to prevent the publication of articles about the occupational health risks of asbestos.[21] Finally, an asbestos trade association suppressed a study of textile factories that found evidence of asbestosis among workers.[22] In other words, asbestos companies knew that their products were dangerous and did their best to conceal this fact from the public and government regulators.

Litigation against asbestos manufacturers began in earnest with a 1973 decision by a federal appeals court in *Borel v. Fibreboard Paper Products Corp.*[23] By 1991, an estimated 715,000 personal injury claims had been filed against asbestos companies.[24] Ultimately, these companies were overwhelmed with lawsuits and most went bankrupt.[25]

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14. Zygmunt J.B. Plater, *The Exxon Valdez Resurfaces in the Gulf of Mexico . . . and the Hazards of "Megasystem Centripetal Di-Polarity,"* 38 Bos. C. Envtl. Aff. L. Rev. 391, 400–01 (2011); Marc R. Stanley, *When Bad Companies Happen to Good People*, 56 Drake L. Rev. 517, 522–23 (2008).

15. David Reiss, *Fannie Mae and Freddie Mac and the Future of Federal Housing Finance Policy: A Study of Regulatory Privilege*, 61 Ala. L. Rev. 907, 913–14 (2010).

16. Ken Randall & Hunter Hill, *Corporate Governance and the HealthSouth Derivative Litigation*, 71 Ala. Law. 128, 129 (2010).

17. Edward J. Estrada, *The Immediate and Lasting Impacts of the 2008 Economic Collapse—Lehman Brothers, General Motors, and the Secured Credit Markets*, 45 U. Rich. L. Rev. 1111, 1113–25 (2011).

18. J. Gregory Sidak, *The Failure of Good Intentions: The WorldCom Fraud and the Collapse of American Telecommunications After Deregulation*, 20 Yale J. on Reg. 207, 227–31 (2003).

19. Mabry, *supra* note 6, at 219.

20. Ronald L. Motley & Anne McGinnis Kearse, *Decades of Deception: Secrets of Lead, Asbestos, and Tobacco*, Trial, Oct. 1999, at 47, 47.

21. Jackson v. Johns-Manville Sales Corp., 750 F.2d 1314, 1317–18 (5th Cir. 1985).

22. Motley & Kearse, *supra* note 20, at 47–48.

23. *See generally* Borel v. Fibreboard Paper Products Corp., 493 F.2d 1076 (5th Cir. 1973).

24. Ortiz v. Fibreboard Corp., 527 U.S. 815, 821 (1999).

25. Note, *The Manville Bankruptcy: Treating Mass Tort Claims in Chapter 11 Proceedings*, 96 Harv. L. Rev. 1121, 1121–22 (1983).

B. Concealment of Smoking Risks by Tobacco Companies

Tobacco companies engaged in a similar campaign of deception and concealment regarding the health effects of smoking.[26] As early as the 1950s, tobacco company executives knew that cigarette smoking could cause lung cancer and other serious health problems.[27] In 1953, they met to develop a plan to protect the market for cigarettes by issuing misleading press releases, disseminating false information in magazine articles, concealing evidence of the health risks of smoking from the public, and by targeting their advertising and promotional efforts at underage consumers.[28] Tobacco companies also falsely assured smokers that "light," "low tar," or "low nicotine" cigarettes were less dangerous when they knew that these products did not significantly reduce the health risks of smoking.[29]

Although lawsuits by individual consumers usually failed, the tide began to turn against the tobacco companies in the 1990s as various states, led by Mississippi, brought suits against cigarette manufacturers, invoking public nuisance, fraud, conspiracy, and other liability theories.[30] Eventually, more than forty states sued the tobacco industry.[31] Meanwhile, evidence of corporate fraud and wrongdoing began to mount,[32] and the tobacco companies reached multi-billion dollar settlements with Mississippi, Florida, Texas, and Minnesota.[33] In 1998, the tobacco companies threw in the towel and agreed to a Master Settlement Agreement (MSA) with the remaining forty-six states.[34] The MSA resolved all of the states' claims for the costs of treating sick smokers.[35] In return, the tobacco companies agreed to make annual payments to the states in perpetuity.[36]

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26. United States v. Philip Morris, Inc., 116 F. Supp. 2d 131, 136 (D.D.C. 2000).

27. *Id.*

28. *Id.*

29. *Id.* at 137–38.

30. Hanoch Dagan & James J. White, *Governments, Citizens and Injurious Industries*, 75 N.Y.U. L. REV. 354, 370 (2000).

31. Marie Gabriele Bianchi, *The Tobacco Agreement That Went Up in Smoke: Defining the Limits of Congressional Intervention into Ongoing Mass Tort Litigation*, 87 CAL. L. REV. 703, 712 (1999).

32. Tucker S. Player, Note, *After the Fall: The Cigarette Papers, the Global Settlement, and the Future of Tobacco Litigation*, 49 S.C. L. REV. 311, 322 (1998) (discussing the impact of the "cigarette papers," which documented thirty years of fraud and concealment by Brown & Williamson Tobacco Corp.).

33. Ryan D. Dreveskracht, *Forfeiting Federalism: The Faustian Pact with Big Tobacco*, 18 RICH. J.L. & PUB. INT. 291, 295 (2015).

34. Dagan & White, *supra* note 30, at 371.

35. *Id.* at 371–72.

36. Andrew J. Haile & Matthew W. Kreuger-Andes, *Landmark Settlements and Unintended Consequences*, 44 U. TOL. L. REV. 145, 145–46 (2012).

C. Ford Pinto and Mustang's Exploding Gas Tanks

One of the most notorious cases of corporate misconduct involved the Ford Pinto.[37] Ford developed the Pinto to compete in the subcompact market.[38] While the product design was being evaluated, crash tests revealed that rear-end collisions could impair the fuel system's integrity.[39] Although Ford could have easily and inexpensively fixed this problem, it decided to retain the existing design.[40] The company justified this decision by relying on a cost-benefit analysis that concluded that the cost of redesigning the Pinto's fuel system would exceed the monetized costs of the expected deaths and injuries.[41] During the early years of production, the Pinto was a commercial success, but numerous consumers reported accidents involving exploding gas tanks in rear-end collisions.[42] Nevertheless, for more than five years, Ford refused to fix the problem.[43]

Retribution finally came in 1981 when a California appeals court upheld a large punitive damage award against the company.[44] In *Grimshaw,* the jury, outraged at Ford's conduct, awarded Grimshaw $2.5 million in compensatory damages and $125 million in punitive damages.[45] Upholding the punitive damage award, the appeals court found that Ford's management had acted in an extremely reprehensible manner and exhibited a "conscious and callous disregard of public safety in order to maximize profits."[46]

A similar pattern occurred with the Ford Mustang.[47] In *Wangen v. Ford Motor Co*., the occupants of a 1967 Mustang were either killed or severely injured when the car's fuel tank burst into flames after being rear-ended by another vehicle.[48] As in *Grimshaw*, the appellate court determined that punitive damages were permissible if the facts

37. Maria Guadalupe Martinez Alles, *Moral Outrage and Betrayal Aversion: The Psychology of Punitive Damages*, 11 J. TORT L. 245, 289 (2018).

38. Arthur Acevedo, *Responsible Profitability? Not On My Balance Sheet!*, 61 CATH. U. L. REV. 651, 675 (2012).

39. Grimshaw v. Ford Motor Co., 174 Cal. Rptr. 348, 360 (Ct. App. 1981).

40. Richard C. Ausness, *Retribution and Deterrence: The Role of Punitive Damages in Products Liability Litigation*, 74 KY. L.J. 1, 21 (1985).

41. Acevedo, *supra* note 38, at 676.

42. *Id.*

43. *Id.*

44. *Grimshaw*, 174 Cal. Rptr. at 389 (Ct. App. 1981).

45. *Id.* at 358. The trial court later reduced this to $3.5 million. *Id.* at 391.

46. *Id.* at 388.

47. Craig K. Hemphill, Note, *Smoke Screens and Mirrors; Don't Be Fooled Get the Economic Facts Behind Tort Reform and Punitive Damages Limitations*, 23 T. MARSHALL L. REV. 143, 165 (1997).

48. Wangen v. Ford Motor Co., 294 N.W.2d 437, 440 (Wis. 1980).

alleged in the complaint were found to be true.[49] The facts alleged that Ford knew of the fire hazard as early as 1964.[50] Furthermore, years before the plaintiffs' accident, Ford was aware that the fuel tank design was causing burn injuries but failed to recall its vehicles or warn about the danger because it wanted to avoid the cost of repairs and the bad publicity that might be caused by warnings.[51]

D. Volkswagen's Diesel Emissions Fraud

Although VW's fraudulent manipulation of emissions level testing did not directly endanger occupants of its vehicles, it did amount to a deliberate and flagrant violation of the law.[52] The scandal began in 2014 when the Center for Alternative Fuels, Engines, and Emissions (CAFEE) published an emissions road testing report that it had done on several VW diesel automobiles.[53] The study revealed that the VW vehicles emitted nitrogen oxides at levels that were far above permissible Environmental Protection Agency (EPA) levels.[54] VW's cover-up began soon after CAFEE engineers reported their findings to the EPA and the California Air Resources Board.[55]

E. Enron Corporation's Financial Fraud

Enron engaged in phony transactions with illusory special purpose entities, such as Joint Energy Development Incorporated and Chewco, in order to improve its financial statements.[56] Enron's attorneys, accountants, investment banks, and other financial service providers created these affiliated corporations and made them appear to be independent entities.[57] This scheme ultimately collapsed in 2001 when Enron was forced to revise its earlier financial statements for 1997 through 2000.[58] As a result of these disclosures, the price of En-

49. *Id.* at 462.

50. *Id.*

51. *Id.*

52. Cruden et al., *supra* note 10, at 125.

53. *Id.* at 124.

54. *Id.* at 123–24. *See also* GREGORY J. THOMPSON, IN-USE EMISSIONS TESTING OF LIGHT-DUTY DIESEL VEHICLES IN THE UNITED STATES 62–63 (2014).

55. Cruden et al., *supra* note 10, at 123–24.

56. Enron's scheme is set forth in more detail in *Enron Corp. Sec. Derivative & Erisa Litig.*, 235 F. Supp. 2d 549 (S.D. Tex. 2002).

57. *Id.* at 637–85. According to the complaint, the banks involved in Enron's fraudulent scheme included J.P. Morgan Chase & Co., CitiGroup, Credit Suisse, First Boston, CIBC, Merrill Lynch & Co., Lehman Brothers Holding, Inc., Bank of America Corp., and Deutsche Bank AG. *Id.* at 637–56. Vinson & Elkins LLP was Enron's principal law firm and Arthur Anderson was its principal accountant and auditor. *Id.* at 656–85.

58. Gary J. Aguirre, *The Enron Decision: Closing the Fraud-Free Zone on Errant Gatekeepers*, 40 TEX. J. BUS. L. 107, 114 (2004).

ron's stock dropped precipitously, thereby forcing the company to declare bankruptcy.[59]

F. Wells Fargo Bank's Consumer Fraud

In 2016, it was revealed that Wells Fargo Bank's employees, pressured by the company's sales targets and compensation incentives, opened approximately 3.5 million unauthorized accounts and funded them by transferring funds from customers' accounts without their knowledge or consent, thereby generating millions of dollars in charges and fees for the bank.[60] Employees also applied for 565,000 credit cards in the name of bank customers, resulting in unauthorized annual fees and interest charges.[61] When aggrieved customers filed lawsuits against Wells Fargo Bank, the bank attempted to force them to accept mandatory arbitration, claiming that "[t]he arbitration clauses included in the legitimate contracts customers signed to open bank accounts also cover[ed] disputes related to the [unauthorized accounts]."[62]

In December 2018, the Attorney General announced a fifty-state settlement by which Wells Fargo Bank agreed to pay $575 million to resolve claims that the bank violated state consumer protection laws.[63] Wells Fargo Bank also entered into consent orders with federal authorities related to this conduct and agreed to provide restitution to consumers.[64]

G. The Exxon Valdez Oil Spill

Misconduct by employees of Exxon and BP caused oil spills that did incalculable harm to the environment.[65] One of the worst of these environmental disasters was the Exxon Valdez oil spill.[66] The incident occurred shortly after midnight on March 24, 1989, when the Exxon Valdez, whose captain had consumed a considerable amount of alco-

59. *Id.*

60. Class, *supra* note 12, at 930.

61. *Id.* at 930–31.

62. Michael Corkery & Stacey Cowley, *Wells Fargo Killing Sham Account Suits by Using Arbitration,* N.Y. TIMES (Dec. 6, 2016), https://www.nytimes.com/2016/12/06/business/dealbook/wells-fargo-killing-sham-account-suits-by-using-arbitration.html.

63. Sam Burgess, *"Learning from the Past, Transforming for the Future": The December 2018 Wells Fargo Settlement and Its Implications for the Future of the Bank*, *in Developments in Banking and Financial Law: 2019,* 38 REV. BANKING & FIN L. 482, 482 (2019).

64. *Id.* at 488.

65. Ruwantissa Abeyratne, *The Deepwater Horizon Disaster—Some Liability Issues*, 35 TUL. MAR. L.J. 125, 125–26 (2010).

66. *In re* Exxon Valdez, 296 F. Supp. 2d 1071, 1076–77 (D. Alaska 2004) (describing the environmental effects of the oil spill).

hol that evening, ran aground on Bligh Reef in Prince William Sound.[67] The Exxon Valdez released 20% of its total freight of 964,000 barrels of oil; it is estimated that by April 1989, the oil spill polluted more than 1,400 square miles of water.[68] The spillage also contaminated much of the coastline, killing thousands of animals, including some of Alaska's rarest species.[69] Furthermore, the oil spill caused severe economic damage to fishermen and other residents who worked in the affected area.[70]

In addition to spending more than $2.1 billion to remove oil from the waters and beaches of Prince William Sound, both the U.S. government and the State of Alaska sued Exxon civilly and criminally for environmental damage.[71] These lawsuits were eventually settled by a consent decree under which Exxon agreed to pay the government plaintiffs $900 million over a period of ten years.[72] Exxon was also prosecuted by the federal government for violating the Clean Water Act,[73] the Refuse Act,[74] the Migratory Bird Treaty Act,[75] the Ports and Waterways Safety Act,[76] and the Dangerous Cargo Act.[77] Exxon and Exxon Shipping were jointly fined $25 million and were ordered to pay restitution in the amount of $100 million.[78]

H. The BP Oil Spill

On April 20, 2010, the Deepwater Horizon, a movable drilling rig, exploded, killing eleven men and causing oil to spill out and spread through the Gulf of Mexico toward the southern coast of the United States.[79] "The *Deepwater Horizon* was a $350,000,000 offshore oil rig that measured 378 feet from top to bottom and had a crew of 126. The rig was operating in 5000 feet of water when an explosion occurred. . . ."[80] The rig sank after burning for thirty-six hours, leaving the well it drilled in the Gulf of Mexico gushing at the ocean bed for

67. *Id.* at 1076–77.
68. Abeyratne, *supra* note 65, at 125.
69. *Id.*
70. In re *Exxon Valdez*, 296 F. Supp. 2d at 1078.
71. *Id.* at 1078.
72. *Id.* at 1078–79.
73. 33 U.S.C. §§ 1311(a), 1319(c)(1) (2019).
74. 33 U.S.C. § 407 (2021); 33 U.S.C. § 411 (1996).
75. 16 U.S.C. § 703(a) (2004); 16 U.S.C. § 707(a) (1998).
76. 33 U.S.C. § 1232b(b)(1) (repealed 2018).
77. 46 U.S.C. § 3718(b) (2006).
78. *In re* Exxon Valdez, 296 F. Supp. 2d 1071, 1079 (D. Alaska 2004).
79. Linda S. Mullenix, *Prometheus Unbound: The Gulf Coast Claims Facility as a Means for Resolving Mass Tort Claims—A Fund Too Far*, 71 La. L. Rev. 819, 819 (2011).
80. Abeyratne, *supra* note 65, at 126.

eighty-seven days and causing the largest offshore oil spill in U.S. history.[81] The ensuing disaster in the Gulf of Mexico resulted in death, injury, environmental devastation, and economic loss to individuals, businesses, and governmental entities.[82] It was the greatest oil pollution field disaster since the Exxon Valdez oil spill off the coast of Alaska.[83]

In order to forestall the inevitable avalanche of lawsuits that were certain to follow in the wake of this disaster, BP agreed to set up a $20 billion fund to compensate potential plaintiffs and shortly thereafter selected Kenneth Feinberg to oversee the compensation fund and claims process.[84]

I. Crime and Punishment in the Corporate World

It may be possible to draw some tentative conclusions from the foregoing sampling of corporate wickedness. First, a wide range of businesses engage in unethical conduct. For example, product manufacturers produce dangerously designed products and conceal these safety flaws from government regulators and consumers; financial institutions make risky investments and then try to hide the resulting losses from stockholders and the public; and oil companies risk environmental catastrophes by using shoddy equipment and engaging in negligent operational practices.[85] Not all companies behave in this way, but a distressingly high number of them do.

Second, not surprisingly, most of this corporate misbehavior is motivated by the relentless pursuit of profits.[86] This pressure begins with investors and trickles down to various levels of corporate management, ultimately leading to a corporate culture where other social values are marginalized.[87]

Finally, the consequences of getting caught can be devastating. Depending on the conduct involved, a corporation and its officers may face serious criminal liability if any statutes are violated.[88] Further-

81. *Id.* at 126–27.

82. Thomas C. Galligan, Jr., *Death at Sea: A Sad Tale of Disaster, Injustice, and Unnecessary Risk*, 71 La. L. Rev. 787, 790 (2011).

83. *Id.* at 790–91.

84. Mullenix, *supra* note 79, at 819.

85. These businesses included product manufactures, energy producers, and financial institutions. *See supra* Part I.

86. Kimberly D. Krawiec, *Organizational Misconduct Beyond the Principal-Agreement Model*, 32 Fla. St. U. L. Rev. 571, 599–600 (2005).

87. *Id.*

88. *See, e.g.*, Fed. Food Drug & Cosm. Act, 21 U.S.C. § 331(b) (2018) (prohibiting misbranding); Prescription Drug Marketing Act, 21 U.S.C. § 331(t) (2018) (prohibiting the promotion of

more, those who suffer personal injuries, property damage, or economic losses may bring lawsuits against the company, thereby threatening huge litigation or settlement costs. Even though crime does not pay in the long run, corporate managers seem to think that it works in the short run. Unfortunately, they are often right.

II. An Overview of Big Pharma's Dirty Tricks

Misconduct by pharmaceutical companies falls into a number of categories, including: (1) manipulation of clinical trial design and findings, as well as misrepresentation of such findings in medical and scientific journals; (2) fraudulent and illegal marketing and promotion of pharmaceutical products; (3) overproduction of dangerous drugs, such as opioid manufacturers' failure to oversee and monitor the distributors of these drugs; and (4) attempts to weaken the power of regulatory agencies, such as the FDA and the Drug Enforcement Agency (DEA), by aggressive lobbying of government officials and legislators.[89]

A. Clinical Trials

The sponsor of a new drug must conduct clinical trials before seeking approval of the drug by the FDA.[90] Additional clinical trials are often conducted after initial FDA-approval to identify other uses or populations for which the drug might be beneficial.[91] Drug companies and other sponsors conduct about 10,000 of these clinical trials in the United States each year.[92]

The approval process usually begins with animal testing to determine the drug's toxicity.[93] The drug then undergoes various types of clinical trials on human subjects.[94] Phase I trials determine whether a small number of test subjects can tolerate various levels of exposure to the drug.[95] Phase II trials evaluate the safety and effectiveness of the

off-label uses); Medicare & Medicaid Anti-Kickback Stat., 42 U.S.C. § 1320a–7b(a) (2018) (prohibiting bribes and kickbacks to healthcare providers).

89. *See infra* II.A, II.B.

90. Clinical trials are also required for FDA approval of new biologics and medical devices. Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 Miss. L.J. 705, 707 n.5 (2009).

91. *Id.* at 707.

92. *Id.* at 706.

93. Ryan Sila, Note, *Incentivizing Pharmaceutical Testing in an Age of Off-Label Promotion*, 93 N.Y.U. L. Rev. 941, 944 (2018).

94. *Id.* at 945.

95. *Id.*

drug on a larger group of people for whom the drug is intended.[96] Phase III trials carry out further tests to determine the drug's safety and efficacy.[97] They are usually the principal studies upon which the FDA relies in the evaluation process.[98]

However, one weakness in this scheme is that drug manufacturers, not the FDA, design the testing protocols and determine who will conduct the trials.[99] Because the drug companies decide who will design and conduct the trials, these researchers have a strong incentive to produce positive results.[100] One technique for influencing the outcome of a clinical trial is to use "enriched enrollment protocols," which enables researchers to admit only patients who have responded well to an earlier trial and exclude those who suffered an adverse reaction in that trial.[101] Drug companies also "hobble" the standard treatment against which they are testing the new drug.[102] In such cases, the researcher either administers the standard treatment in the wrong dose or they administer it by the wrong route.[103] In other words, they administer the standard treatment in a way that ensures that it will be less effective than the new drug that they are testing.[104]

Although drug companies are required to disclose the results of clinical trials to the FDA, they generally do not have to disclose these results to the scientific community or the general public since the data produced are protected as trade secrets.[105] Thus, if a drug company chooses to disclose such information, it may selectively edit it to make the results look more favorable or fail to disclose information about unfavorable outcomes.[106]

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96. Richard A. Epstein, *Regulatory Paternalism the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL'Y L. & ETHICS 741, 756 (2005).

97. *Id.*

98. Galbraith, *supra* note 90, at 716.

99. Marc A. Rodwin, *Independent Drug Testing to Ensure Drug Safety and Efficacy*, 18 J. HEALTH CARE L. & POL'Y 45, 47 (2015).

100. *Id.*

101. Eugene McCarthy, *The Pharma Barons: Corporate Law's Dangerous New Race to the Bottom in the Pharmaceutical Industry*, 8 MICH. BUS. & ENTREPRENEURIAL L. REV. 29, 47 (2018).

102. *Id.* at 48.

103. *Id.*

104. *Id.*

105. Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 631–32 (2007).

106. For example, GSK released the results of one study involving Paxil but failed to release eight other less favorable studies. J. Tori Evans, *Clinical Trial Data Bank: The Missing Link in the Dissemination of Information to the Medical Community*, 9 QUINNIPIAC HEALTH L. J. 69, 70 (2005).

Another questionable technique is to sponsor ghost-written research and medical education pieces before clinical trials are complete in order to create a market for a drug prior to FDA approval.[107] One study revealed that drug companies were paying scientists to publish the results of the same trials in different journals under different authors' names to give the impression that there was more scientific support for the results of the study than was actually the case.[108] There was also evidence that drug companies sometimes bribed prominent researchers to add their names to favorable reviews of a drug's efficacy.[109] Finally, drug companies also engage in "publication bias" by requiring contractual agreements that allow them to delete damaging information from published results or to delay their publication.[110]

B. Marketing and Promotion

Drug companies currently spend twice as much on marketing and promoting existing products than they do on developing new ones.[111] Most of the misconduct discussed below involves some aspect of promotion or marketing after a pharmaceutical has been approved. These activities include: (1) disseminating false or fraudulent information to doctors or patients, (2) targeting vulnerable groups, (3) financing front groups, (4) promoting off-label uses, as well as (5) giving kickback payments and bribes.[112]

1. Dissemination of False Information

Materials about prescription drugs that are distributed to healthcare providers and the general public are supposed to be consistent with FDA-approved labeling.[113] A product will be deemed "misbranded" by the FDA if promotional statements do not conform to FDA requirements.[114] However, in order to boost sales, drug companies may be tempted to minimize a product's risks or overstate its therapeutic benefits. For example, the makers of the Dalkon Shield IUD steadfastly maintained that the pregnancy rate for users of their product

107. John Alan Cohan, *Psychiatric Ethics and Emerging Issues of Psychopharmacology in the Treatment of Depression*, 20 J. CONTEMP. HEALTH L. & POL'Y 115, 161 (2003).

108. Drummond Rennie, *When Evidence Isn't: Trials, Drug Companies and the FDA*, 15 J.L. & POL'Y 991, 997 (2007).

109. McCarthy, *supra* note 101, at 47; Deanna Minasi, Note, *Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters*, 86 FORDHAM L. REV. 299, 308 (2017).

110. McCarthy, *supra* note 101, at 50.

111. McCarthy, *supra* note 5, at 448.

112. *See infra* III.B.

113. *See* 21 U.S.C. § 333 (2019).

114. 21 U.S.C. § 331(k) (2018).

was only 1.1%, after other testing indicated that the failure rate was at least five times greater.[115] The manufacturer also continued to assure doctors that the IUD was safe when it knew that the product's design allowed bacteria to enter a woman's uterus.[116]

Another case of misrepresentation involved the pain medicine Vioxx.[117] Although Vioxx was an effective painkiller, testing revealed that it significantly increased the risk of heart attacks and strokes.[118] Merck, the manufacturer of Vioxx, knew of this risk, but distributed a brochure to its salespeople that claimed, based on short-term studies, that Vioxx was safer than competing products for long-term use.[119]

More recently, the U.S. Attorney for the Western District of Virginia charged Purdue Pharma, the maker of OxyContin, with misbranding the drug with intent to defraud and mislead.[120] The basis of this criminal charge was that Purdue sales representatives falsely claimed that OxyContin was less addictive than other oxycodone products.[121] Purdue and three of its officers pled guilty to this charge and paid more than $600 million in fines and monetary penalties.[122]

2. Targeting Vulnerable Groups

Taking a page out of Big Tobacco's playbook, pharmaceutical companies have targeted certain classes of doctors and patients.[123] While some targeting is legitimate, some is not. For example, Purdue directed much of its promotional efforts for OxyContin at general practitioners who were likely to be less familiar with the addictive qualities of opioids than specialists would be.[124] Purdue also targeted vulnerable patient groups such as veterans and the elderly.[125]

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115. Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1217 (Kan. 1987).

116. *Id.* at 1222.

117. David R. Culp & Isobel Berry, Comment, *Merck and the Vioxx Debacle: Deadly Loyalty*, 22 ST. JOHN'S J. LEGAL COMMENT. 1, 2 (2007).

118. Ronald M. Green, *Direct-to-Consumer Advertising and Pharmaceutical Ethics: The Case of Vioxx*, 35 HOFSTRA L. REV. 749, 756 (2006).

119. Howard M. Erichson & Benjamin C. Zipursky, *Consent Versus Closure*, 96 CORNELL L. REV. 265, 276–77 (2011).

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

121. *Id.* at 571.

122. *Id.* at 572.

123. Caitlyn Edgell, Comment, *It's Time to Finish What They Started: How Purdue Pharma and the Sackler Family Can Help End the Opioid Epidemic*, 125 PENN ST. L. REV. 255, 267 (2020).

124. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 222 (2009).

125. Edgell, *supra* note 123, at 263, 268.

3. Secretly Supporting Key Opinion Leaders and Front Groups

Another deceptive practice is secretly exercising control over seemingly independent organizations and "key opinion leaders" (KOLs).[126] For example, in order to create a market for its anti-depressant Paxil, GlaxoSmithKline supported a group of non-profit organizations for the purpose of increasing public awareness about social anxiety disorder (SAD).[127] More recently, Purdue Pharma utilized both front groups and KOLs to promote the use of OxyContin for the treatment of chronic pain.[128]

4. Kickbacks and Bribery

Sometimes, gifts to prescribing physicians go beyond free dinners, paid vacations, and compensated speaking engagements, crossing into outright bribery. A subtle form of bribery involves "seeding trials," in which physicians are paid to recruit patients to participate in a clinical trial sponsored or conducted by the manufacturer of the drug in question.[129] This encourages participating physicians to prescribe the drug to their other patients.[130] In one case, the manufacturer of the epilepsy drug Neurontin paid more than 700 doctors $300 per patient to test the drug at higher than approved dosages.[131]

A particularly blatant instance of bribery involved the drug Subsys.[132] In 2017, the founder of Insys Therapeutics and a number of corporate officers were charged with conspiring to commit racketeering offenses, mail fraud, wire fraud, and payments of kickbacks and bribes in connection with the prescribing of Subsys.[133] The company began marketing Subsys—a highly-addictive, fentanyl-based sublingual spray—in 2012.[134] The drug was approved by the FDA for the treatment of opioid-tolerant adult patients who experience break-

126. Sergio Sismondo, *Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won't Cast Light On*, 41 J.L. MED. & ETHICS 635, 636 (2013).

127. Johnathan Fish, *Overcrowding on the Ship of Fools: Health Care Reform, Psychiatry, and the Uncertain Future of Normality*, 11 HOUS. J. HEALTH L. & POL'Y 181, 235–36 (2011). "SAD" is an acronym for "Social Anxiety Disorder." Erin Lenhardt, Note, *Why So Glum? Toward a Fair Balance of Competitive Interests in Direct-to-Consumer Advertising and the Well-Being of the Mentally Ill Consumers It Targets*, 15 HEALTH MATRIX: J. L.-MED. 165, 197 (2005).

128. SAM QUINONES, DREAMLAND 136–37 (2015).

129. Lars Noah, *Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Subscribers*, 66 BUFF. L. REV. 855, 877 (2018).

130. *Id.* at 877–78

131. *Id.* at 877.

132. Stacey A. Tovino, *Fraud, Abuse, and Opioids*, 67 U. KAN. L. REV. 901, 909 (2019).

133. Andrew E. Lelling, *Corporate Accountability for the Opioid Epidemic*, 66 DOJ J. FED. L. & PRAC. 159, 164 (2018).

134. *Id.*

through cancer pain.[135] However, according to the federal indictment, the defendants sought to increase sales of Subsys by paying doctors to prescribe it for off-label uses such as back pain and migraines.[136] A number of doctors were convicted of receiving hundreds of thousands of dollars in kickbacks, disguised as speaking fees.[137] In May 2019, John Kapoor and four other Insys employees were convicted of racketeering conspiracy after a lengthy trial.[138]

III. Case Studies

This Part will examine a number of cases involving such pharmaceutical products as MER/29, the Dalkon Shield IUD, Botox, Neurontin, Lupron, Vioxx, Paxil, and OxyContin.[139] This list is by no means exhaustive; other problematic pharmaceutical products include: American Home Product's Fenfluramine, a component of the diet drugs fenphen and Redux;[140] Eli Lilly's antipsychotic medication, Zyprexa;[141] Warner-Lambert's diabetes drug, Rezulin;[142] Forest Laboratories' antidepressant, Celexa;[143] Pfizer's painkiller, Bextra;[144] Johnson & Johnson's acne medicine, Tretinoin (Retin-A);[145] AstraZeneca's cancer treatment, Zoladex;[146] and Janssen Pharmaceuticals' contraceptive patch, Ortho Evra.[147] In each case, the producers of these products

135. Tovino, *supra* note 132, at 909.

136. Ty McCoy, *The Need for Higher Punishment: Lock Up the Real Drug Dealers*, 54 Gonz. L. Rev. 47, 63 (2018/19).

137. Tovino, *supra* note 132, at 909. For example, Dr. Jerrold Rosenberg received $188,000, Dr. Gavin Awerburch received $138,435, Dr. John Couch received at least $100,000, and Dr. Xiulu Ruan received $170,000. *Id.* at 909–12.

138. Gabrielle Manuel, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case*, WBEZ Chicago (May 2, 2019, 2:37 PM), https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-in-landmark-bribery-case.

139. *See infra* Part III.

140. Paul D. Rheingold, *Fen-Phen and Redux: A Tale of Three Drugs*, 34 Trial, Jan. 1998, at 78, 78; Jaime A. Wilsker, Note, *One-Half Phen in the Morning/One Fen Before Dinner: A Proposal for FDA Regulation of Off-Label Uses of Drugs*, 6 J.L. & Pol'y 795, 824 n.133 (1998).

141. Teresa Curtin & Ellen Relkin, *Preamble Preemption and the Challenged Role of Failure to Warn and Defective Design Pharmaceutical Cases in Revealing Scientific Fraud, Marketing Mischief, and Conflicts of Interest*, 35 Hofstra L. Rev. 1773, 1783 (2007).

142. Robert K. Jenner, *Rezulin: Fast Track to Failure*, 36 Trial, July 2000, at 39, 45.

143. Van Cates et al., *Recent Developments in Business Litigation*, 55 Tort Trial & Ins. Prac. L.J. 193, 201–02 (2020).

144. Cynthia M. Ho, *A Dangerous Concoction: Pharmaceutical Marketing, Cognitive Biases, and First Amendment Overprotection*, 94 Ind. L.J. 773, 795 (2019).

145. Ameet Sarpatwari et al., *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 Harv. L. & Pol'y Rev. 463, 472 (2017).

146. Phuong D. Nguyen, *A Review of Average Wholesale Price Litigation and Comments on the Medicare Modernization Act*, 9 Quinnipiac Health L.J. 249, 255, 257–58 (2006).

147. Curtin & Relkin, *supra* note 141, at 1783.

have been accused of engaging in various unsavory practices.[148] The purpose of this analysis is not to rake up old scandals; rather, its purpose is to illustrate the pattern of misconduct that many pharmaceutical companies have engaged in from the 1950s to present day.

A. MER/29

One of the most notorious cases of fraudulent conduct during drug testing involved MER/29, a prescription drug that was developed by the Richardson-Merrell Company in the late 1950s to treat arteriosclerosis (hardening of the arteries) by reducing the level of cholesterol in the blood.[149] The drug's active ingredient was triparanol.[150] Before the drug was first marketed, Richardson-Merrell and others conducted 246 experiments involving 3,907 animals and more than 2,000 human subjects.[151] However, some of this testing was falsified to hide the drug's harmful side effects.[152]

Richardson-Merrell's Toxicology Department, headed by Knox Smith, began testing MER/29 on laboratory rats in 1957.[153] During the first six-week test in which very high dosages of the drug were administered, all of the female rats died and all of them suffered abnormal blood changes.[154] A second test, using a lower dosage, also produced abnormal blood changes in the rats; this information was sent to Dr. Harold Werner, who was the company's vice-president and director of research.[155] In 1958, William King, who replaced Smith as head of the Toxicology Department, reviewed these blood change results.[156]

During 1958 and early 1959, the company conducted a test of MER/29 on monkeys, which also produced abnormal blood changes.[157] However, Dr. Van Maanen, head of the Biological Science Division, which included the Toxicology Department, ordered a laboratory

148. Rheingold, *supra* note 140, at 78; Wilsker, *supra* note 140, at 824–25 (Fen-Phen); Curtin & Relkin, *supra* note 141, at 1783 (Zyprexa); Jenner, *supra* note 142, at 45 (Rezulin); Van Cates et al., *supra* note 143, at 201–02 (Celexa); Ho, *supra* note 144, at 795 (Bextra); Sarpatwari et al., *supra* note 145, at 472 (Tretinoin); Nguyen, *supra* note 146, at 257–58 (Zoladex); Curtin & Relkin, *supra* note 141, at 1783 (Ortho Evra).

149. Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 835 (2d Cir. 1967). Arteriosclerosis, or hardening of the arteries, may cause heart attacks or strokes. *See* Toole v. Richardson-Merrell, Inc., 60 Cal. Rptr. 398, 403 (App. Ct. 1968).

150. Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640, 644 (Tex. App. 1965).

151. *Roginsky,* 378 F.2d at 835.

152. *Toole*, 60 Cal. Rptr. at 403–05.

153. *Id.* at 404.

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

technician to falsify these test results in a chart.[158] This was done by recording false body weights and extending the test records beyond the dates after the monkeys had been killed and adding data for an imaginary monkey that had never been part of the test.[159] King later revised a brochure prepared by Smith on the rat experiments that removed any mention of the abnormal blood results.[160] These deletions were approved by Dr. McMaster, who worked in the Medical Science Division and who was in charge of all medical research on MER/29.[161]

In July 1959, Richardson-Merrell filed a new drug application (NDA) with the FDA in order to secure permission to market the drug.[162] However, the application contained a number of false statements.[163] Furthermore, although the drug was intended for long-term use, at the time the NDA was submitted, only 116 human subjects had taken MER/29 and none had used it for more than six months.[164] When the FDA questioned the adequacy of this test data and demanded that additional studies be undertaken, Dr. Joseph Murray, the company's liaison officer, falsely stated that no blood changes had occurred in the tests on rats or monkeys, and that these tests had demonstrated the safety of MER/29.[165]

Meanwhile, in January 1960, the company completed another rat study in which "nine out of ten rats in the study developed eye opacities."[166] Once again, the company failed to tell the FDA about these adverse results and instead reported that only eight out of twenty rats had merely developed mild eye inflammations.[167] In February 1960, Richardson-Merrell informed the FDA of the results of MER/29 tests on dogs but did not tell the agency that one of the dogs developed eye opacities and blindness.[168] The company also reported the results of another test that it conducted on rats but failed to disclose that

158. *Toole*, 60 Cal. Rptr. at 404.

159. *Id.* When the technician, Beulah Jordan, objected to King, she was told that because Van Maanen was higher up, "[y]ou do as he tells you and be quiet." *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.* For example, the application claimed that only four out of eight rats had died in one study when all of them had died. The application relied on wholly fictitious body weights and organ weights. Also, blood tests were fabricated for dead rats to prove that they had continued to live and take MER/29. In addition, the application failed to reveal the abnormal blood changes that occurred in the experiments. False data was included on the monkey tests. Finally, the false chart prepared by Ms. Jordan was included in the application. *Id.*

164. *Toole*, 60 Cal. Rptr. at 405.

165. *Id.*

166. *Id.*

167. *Id.*

168. *Id.*

twenty-five of the thirty-six rats in the test had also developed eye opacities.[169]

Two months later, the company received a report from Dr. Loretta Fox who had conducted experiments on rats with MER/29 and had observed lenticular and corneal eye opacities in the animals.[170] When the FDA asked the company to review Dr. Fox's findings, William King, the head of the Toxicology Department, replied that the drug had been used on thousands of rats and only one group of animals had experienced eye problems.[171] King assured the FDA that they had "no evidence from [their] experience or from the literature that MER/29 would in itself produce such changes."[172]

In April 1961, Richardson-Merrell began another testing program to determine the long-term effects of MER/29 on rats and dogs.[173] By June, some of the rats began to develop opacities in their eyes, and by August, thirty-five out of forty-six rats had developed eye opacities.[174] Notwithstanding the increasing evidence that MER/29 caused serious eye problems in test animals, the company failed to provide the FDA or medical professionals with this information and instead continued to promote the drug aggressively.[175] By October 1961, five of the seven dogs in the test had developed opacities in their eyes.[176] However, the company did not reveal this information to the FDA.[177]

Finally, in November 1961, the FDA asked the company to withdraw MER/29 from the market.[178] In April 1962, the FDA made an unannounced visit to the company's laboratories and seized all records of its animal experiments involving MER/29.[179] Based on these documents, the Justice Department obtained indictments against Richardson-Merrell and three of its employees.[180] All of the defendants entered a plea of *nolo contendere* and paid a fine of $80,000, the maximum fine allowed at that time.[181]

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169. *Id.*
170. *Toole*, 60 Cal. Rptr. at 405.
171. *Id.* at 405–06.
172. *Id.*
173. *Id.* at 406.
174. *Id.*
175. *Id.*
176. *Toole*, 60 Cal. Rptr. at 407.
177. *Id.*
178. *Id.*
179. *Id.* at 408.
180. Paul D. Rheingold, *Looking Back at the First Mass Drug Case*, 50 TRIAL, Aug. 2014, at 26, 26.
181. *Id.*

While the NDA for MER/29 was pending, Richardson-Merrell also misled the medical profession by withholding information about the risk of eye damage to patients.[182] For example, Richardson-Merrell invited a group of medical researchers to a conference in Princeton, New Jersey to discuss MER/29.[183] At this conference, King presented a paper on the toxicology of MER/29[184] but failed to mention that abnormal blood changes had occurred in test animals, and he repeated the false statements about the weights and dosages of MER/29 that had been given to the monkeys in 1959.[185]

The president of Richardson-Merrell, Frank Getman, was aware of this conference and later described it as "the most terrific selling tool that Merrell has ever had."[186] When MER/29 was approved by the FDA in April 1960, the company initiated "the greatest promotional and advertising effort ever made [by it] in support of a product."[187] Notwithstanding adverse results from animal testing, one advertising brochure declared that the drug was "virtually nontoxic and remarkably free from side effects even on prolonged clinical use."[188]

Early in 1961, as reports of adverse reactions to MER/29 began to reach Richardson-Merrell from researchers, doctors, and sales representatives, the company continued to claim that the drug was safe.[189] Eventually, under pressure from the FDA, Richardson-Merrell withdrew MER/29 from the market.[190] During the short time that MER/29 was on the market, it was administered to about 400,000 persons.[191] At least 400 of them developed cataracts and other adverse conditions.[192] Numerous lawsuits were brought against the company in the aftermath of the MER/29 disaster and at least one of them resulted in a substantial punitive damage award.[193]

182. Toole v. Richardson-Merrell, Inc., 60 Cal. Rptr. 398, 405 (App. Ct. 1968).
183. *Id.*
184. *Id.*
185. *Id.*
186. *Id.*
187. *Id.*
188. *Toole*, 60 Cal. Rptr. at 405.
189. *Id.* at 406.
190. Rheingold, *supra* note 180, at 26.
191. *Toole*, 60 Cal. Rptr at 408.
192. *Id.*
193. *Id.* at 418.

B. The Dalkon Shield IUD

The Dalkon Shield was an IUD invented by Dr. Hugh Davis and Irwin Lerner.[194] It consisted of a small piece of plastic[195] which contained four phalanges on each side.[196] It also contained a black string that could be used to remove the device from the patient's uterus.[197] In 1968, Davis and Lerner established the Dalkon Corporation in order to produce and market Dalkon Shields.[198] In February 1970, Dr. Davis published the result of a study that he had conducted between 1968 and 1969 on 640 patients which concluded that the Dalkon Shield's pregnancy rate was only 1.1% per year.[199] However, the study's methodology was deeply flawed.[200] Moreover, no further testing was done on the product prior to its introduction into the market because the FDA did not require such testing at that time.[201]

In June 1970, an employee of Robins informed the company that the pregnancy rate of the Dalkon Shield was five times greater than the rate claimed by Davis in his article.[202] Nevertheless, Robins bought the Dalkon Corporation and immediately began to market the Dalkon Shield aggressively.[203] To support its claim that the Dalkon Shield was superior to other IUDs, Robins distributed hundreds of thousands of reprints of the Davis article to physicians.[204] The company also distributed Patient Information sheets which claimed that the Dalkon Shield was a safe and effective method of birth control.[205] In addition, Robins placed advertisements in newspapers and magazines such as *Family Circle, Mademoiselle, Ladies' Home Jour-*

194. Jon M. Van Dyke, *The Dalkon Shield: A "Primer" in IUD Liability*, 6 W. ST. U. L. REV. 1, 6 (1978).

195. *Id.* at 2 n.2.

196. Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1216 (Kan. 1987).

197. *Id.*

198. Van Dyke, *supra* note 194, at 6.

199. *Tetuan*, 738 P.2d at 1216.

200. For example, although the study claimed that the Dalkon Shield's pregnancy rate was superior to that of other IUDs, Dr. Davis never actually tested any other IUDs. *Id.* at 1217. Also, no control group was used in this test. *Id.* Furthermore, Dr. Davis did not disclose that he had a substantial financial interest in the Dalkon corporation. *See id.* at 1216–17. Finally, Dr. Davis failed to mention that the Dalkon Shields that were used in his study had been modified by the time the study was published. *See* Palmer v. A.H. Robins Co., 684 P.2d 187, 195 (Colo. 1984).

201. Sylvia A. Law, *Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States*, 23 N.Y.U. REV. L. & SOC. CHANGE 339, 364 (1997).

202. *Tetuan*, 738 P.2d at 1217.

203. C. Gavin Shepherd, *Transvaginal Mesh Litigation: A New Opportunity to Resolve Mass Medical Device Failure Claims*, 80 TENN. L. REV. 477, 485–86 (2013).

204. The reprint did not include the designation "Current Investigation," which originally appeared in the article, and which would have warned readers that the Davis study was preliminary and had not been proven to be scientifically valid. *Tetuan*, 738 P.2d at 1218.

205. *Id.*

nal, Time, Glamour, Parade, and *Cosmopolitan*.[206] This campaign was very effective and by September 1972, the Dalkon Shield had captured 80% of the IUD market.[207]

However, reports of problems with the Dalkon Shield soon began to emerge. For example, in December 1972, a Canadian doctor informed Robins that the failure rate for the Dalkon Shield was between 7% and 8%.[208] That same month, a doctor at a military hospital reported a pregnancy rate of 10%, which was far greater than the 1.1% claimed by Robins in its promotional materials.[209]

Not only were there reports that the Dalkon Shield was not as effective as claimed, but reports of serious medical problems also began to pour in.[210] These included reports of septic abortions, spontaneous abortions, tubal pregnancies, perforations of the uterine wall, severe pelvic infections, and even some deaths.[211] Many of these injuries were caused by the tendency of the tail string to transport bacterial fluid by capillary action from the vagina to the uterus.[212] Unlike other IUDs, the Dalkon Shield's tail string was a nylon-encased monofilament line which was not sealed at either end.[213] Robins was aware of this risk before it acquired the Dalkon Corporation, but it ignored the concerns of its quality control personnel in order to save money.[214] Instead of informing doctors about the danger of wicking, or trying to correct it, Robins sought to assure doctors and consumers that the IUD was safe.[215]

Eventually, in February 1974, Robins issued a "Dear Doctor" letter which advised doctors to remove Dalkon Shields from any woman who became pregnant.[216] Later, at the request of the FDA, Robins suspended future sales of the Dalkon Shield, while declaring in a press release that "neither A.H. Robins nor the FDA has any reason at this time to believe that women now using the Dalkon Shield successfully should have the device removed."[217] However, even after Robins sus-

206. *Id.* at 1219.
207. *Id.*
208. *Id.*
209. *Id.*
210. Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1220 (Kan. 1987).
211. Trevor K. Scheetz, Note, *Say What You Mean: The Discoverability of Medical Device Adverse Event Reports*, 2011 U. ILL. L. REV. 1095, 1096 (2011).
212. Gerald F. Tietz, *Strict Products Liability, Design Defects and Corporate Decision-Making: Greater Deterrence Through Strict Liability*, 38 VILL. L. REV. 1361, 1385 (1993).
213. *Tetuan*, 738 P.2d at 1221.
214. *Id.*
215. *Id.*
216. *Id.* at 1220.
217. *Id.*

pended sales in the United States, it continued to sell the Dalkon Shield overseas.[218]

Finally, company officers ordered the destruction of many documents relating to the Dalkon Shield's wicking problem.[219] In 1975, Roger Tuttle, a member of Robins' legal department, was ordered to collect and destroy these documents and was told that the order came from the company's president, W.L. Zimmer.[220] According to Tuttle, hundreds of documents were burned in a furnace, although Tuttle secretly saved some copies.[221]

Not surprisingly, Robins was soon faced with a wave of lawsuits by injured Dalkon Shield users.[222] Although Robins won some of these early lawsuits,[223] the tide began to turn in 1985 when a Kansas jury awarded a plaintiff $1.75 million in compensatory damages and $7.5 million in punitive damages.[224] This verdict was later upheld on appeal.[225] By this time, Robins and its liability insurer had paid almost $530 million to injured consumers, and 5,000 additional claims were still pending.[226] As a result, Robins was eventually forced to file for bankruptcy.[227]

C. Botox

Botox was approved by the FDA for adults to treat migraine headaches, muscle stiffness in the elbow, wrist and finger muscles, neck pain associated with cervical dystonia, strabismus or blepharospasm, severe underarm sweating, and severe lines between the eyebrows.[228] However, Allergan, the manufacturer of Botox, decided to market the product for the off-label treatment of pain and headaches even though it was illegal for a drug company to promote off-label uses of its prod-

218. Law, *supra* note 201, at 365. Robins refused to pay for the cost of removing the Dalkon Shield from existing users until October 1984. *Id.*

219. Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1224 (Kan. 1987).

220. *Id.* at 1223–24.

221. Mabry, *supra* note 6, at 219.

222. Douglas G. Smith, *Resolution of Mass Tort Claims in the Bankruptcy System*, 41 U.C. DAVIS L. REV. 1613, 1636 (2008).

223. Part of Robins' defense strategy was to make the trial as unpleasant and expensive as possible for the plaintiffs. Law, *supra* note 201, at 366. For example, company attorneys would question victims about their sexual and hygienic habits. *Id.* They also asked them to identify their sex partners so that they could question them about their medical histories. *Id.*

224. Shepherd, *supra* note 203, at 486.

225. Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1210 (Kan. 1987).

226. Georgene Vairo, *Mass Torts Bankruptcies: The Who, The Why and The How*, 78 AM BANKR. L.J. 93, 112 (2004).

227. Shepherd, *supra* note 203, at 486.

228. James A. Robertson & Walter F. Timpone, *Compliance Issues for Pharmaceutical and Medical Device Manufacturers*, ASPATORE, June 2014, at 14, 2014 WL 2355619.

ucts.[229] As part of its "CD/HA Initiative," Allergan urged physicians to diagnose cervical dystonia in their patients based on the existence of pain or headache symptoms, even when no evidence of cervical dystonia was present, so that they could prescribe Botox as treatment.[230]

Allergan doubled the size of its reimbursement team to assist physicians in obtaining payment for off-label Botox injections and held workshops to teach doctors how to bill for off-label uses to advise them on how they could make money by injecting Botox.[231] The company also operated a Botox Reimbursement Hotline which provided an array of free on-demand services to physicians to encourage them to prescribe Botox for off-label uses of the drug.[232] In addition, Allergan held physician workshops and dinners that focused on off-label uses and paid physicians to attend "advisory boards" that promoted off-label uses.[233] Finally, the company created an online neurotoxin education organization to encourage the increased use of Botox for off-label uses.[234] Eventually, the federal government filed a criminal information against Allergan for misbranding Botox.[235] In 2010, the company agreed to plead guilty and pay $600 million to resolve criminal and civil liability for off-label promotion of Botox.[236]

D. Neurontin

Neurontin was originally approved by the FDA for the adjunctive treatment of epilepsy in doses ranging from 900 milligrams (mg) to 1800 mg per day.[237] However, Parke-Davis, the drug's manufacturer, sought to increase the sales of this product by promoting it for off-label uses, such as the treatment of bipolar disorder, migraines, and neuropathic pain at dosages that exceeded the FDA-approved level of

229. *Id.*

230. 230. *Id.*

231. *Id.*

232. *Id.* at 15.

233. *Id.*

234. *Id.* at 15.

235. *Id.*

236. Natasha Singer, *Maker of Botox Settles Inquiry*, N.Y. TIMES (Sept. 1, 2010), https://www.nytimes.com/2010/09/02/business/02allergan.html.

237. United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 45 (D. Mass. 2001). This means that the drug was only to be used as a second-line defense for patients who were already taking other anti-seizure medication. Neurontin was later also approved for the treatment of shingles. Edward P. Lansdale, Note, *Used as Directed? How Prosecutors Are Expanding the False Claims Act to Police Off-Label Marketing*, 41 NEW. ENG. L. REV. 159, 159 (2006).

1800 mg per day, despite the fact that there was no evidence that these unauthorized treatments were safe.[238]

According to the realtor,[239] Parke-Davis allegedly used a number of illegal tactics to promote off-label prescribing of the drug.[240] For example, the company instructed its sales personnel to discuss off-label uses in conversations with doctors when making sales calls.[241] Parke-Davis also paired medical liaisons with sales representatives, misleading doctors into believing that these individuals were not salespeople, but rather were there to provide objective scientific information.[242] Parke-Davis also encouraged medical liaisons to instruct doctors on how to conceal the fact that their prescriptions were for off-label purposes so that they would be eligible for reimbursement under Medicare. Parke-Davis paid doctors to travel to posh resorts to attend "consultant" or "advisory" meetings that exclusively discussed off-label uses of Neurontin.[243]

Furthermore, the company subsidized the production and dissemination of reports that touted off-label uses but were of no scientific value.[244] In some cases, the company also edited the results of clinical studies.[245] Finally, Parke-Davis hosted a number of seminars and conferences that were supposed to deliver independent information regarding off-label uses of Neurontin.[246] However, the company closely controlled the organization of these seminars by determining their content and choosing the speakers.[247]

These practices were very effective as shown by the fact that off-label sales rose from 15% of total sales to 90% of sales after Parke-

238. Stephanie M. Greene, *After Caronia: First Amendment Concerns in Off-Label Promotion*, 51 SAN DIEGO L. REV. 645, 652 (2014).

239. This case started out as a *qui tam* action brought under the False Claims Act of 1863, 31 U.S.C. §§ 3729–33, by the relator, Dr. David Franklin, private citizen. *Franklin*, 147 F. Supp. 2d at 43.

240. *Franklin*, 147 F. Supp. 2d at 45–46.

241. George S. Craft, Jr., Note, *Promoting Off-Label in Pursuit of Profit: An Examination of a Fraudulent Business Model*, 8 HOUS. J. HEALTH & POL'Y 103, 115 (2007).

242. Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J.L. REF. 281, 322 (2007).

243. *Id.*

244. Howard L. Dorfman & Linda Pissott Reig, *Avoiding Legal and Ethical Pitfalls of Industry-Sponsored Research: The Co-Existence of Research, Scholarship, and Marketing in the Pharmaceutical Industry*, 59 FOOD & DRUG L.J. 595, 598 (2004).

245. Jenny White & Lisa Bero, *Corporate Manipulation of Research: Strategies Are Similar Across Five Industries*, 21 STAN. L. & POL'Y REV. 105, 128 (2010) (discussing company's editing of the Gorson Study).

246. Craft, *supra* note 241, at 116.

247. Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 113 (2008).

Davis initiated its off-label use campaign.[248] In dollar terms, sales of Neurontin increased from $97.5 million in 1995 to approximately $2.7 billion in 2003.[249]

Eventually, the chickens came home to roost when federal regulators discovered the company's fraudulent practices. In 2004, Warner-Lambert, a division of Pfizer, which had acquired Parke-Davis, pled guilty to charges of introducing a misbranded drug into interstate commerce by providing inadequate labeling and introducing an unapproved drug into interstate commerce.[250] Warner-Lambert settled the case by agreeing to pay a $240 million criminal fine as well as $190 million in civil penalties.[251] The company was also forced to implement a mandatory corporate compliance program.[252]

E. Lupron

Leuprolide acetate (Lupron) acts to suppress testosterone.[253] It was approved by the FDA in 1985 as a treatment for advanced prostate cancer and was also prescribed to treat central precocious puberty.[254] Lupron was marketed in the United States by TAP Pharmaceutical Products, a joint venture between Abbott Laboratories and Takeda Pharmaceutical Company.[255]

Because Lupron was designed to be administered by intramuscular injection in daily or monthly doses, it was sold directly to doctors rather than distributed to pharmacies.[256] Furthermore, because Lupron was intended to be administered under medical supervision, much of the cost was paid by Medicare.[257]

TAP engaged in a number of questionable marketing practices to encourage doctors to prescribe the drug. For example, the company violated the Anti-Kickback Statute by offering physicians free drug samples, volume discounts, free consulting services, and trips to ex-

248. Lansdale, *supra* note 237, at 186–87.

249. Greene, *supra* note 238, at 653.

250. Craft, *supra* note 241, at 116.

251. *Id.*

252. Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 FOOD & DRUG L.J. 1, 9 (2005).

253. *In re* Lupron Marketing and Sales Practices Litig., 245 F. Supp. 2d 280, 284 (D. Mass. 2003).

254. Erika Lietzan, *Paper Promises for Drug Innovation*, 26 GEO. MASON L. REV. 168, 176–77 (2018).

255. Lansdale, *supra* note 237, at 178–79.

256. In re *Lupron*, 245 F. Supp. 2d at 284.

257. Paul D. Frederickson, *Criminal Marketing: Corporate and Managerial Liability in the Prescription Drug Industry*, 22 MIDWEST L.J. 115, 125 (2009).

pensive golf clubs and ski resorts.[258] They also provided physicians with "educational grants" to pay for cocktail parties, medical equipment, and travel expenses.[259] In one case, when the Tufts Health Maintenance Organization decided to treat cancer patients with Zoldex, a cheaper competitor drug, TAP's national accounts manager offered to provide Tufts with unrestricted educational grants of up to $25,000 per year for continuing to prescribe Lupron.[260]

Finally, the company also distributed thousands of free samples of Lupron and encouraged physicians to bill Medicare for them.[261] TAP fraudulently reported Lupron's average wholesale price, which was the price upon which Medicare reimbursement was based, as much higher than the price that physicians and others actually paid for the drug.[262] This enabled TAP to "spread the market," the difference between the price the doctors paid for the drug and the amount of reimbursement that Medicare would provide.[263]

In 2001, TAP and eight of its executives were indicted for violating the Prescription Drug Marketing Act and the Anti-Kickback Statute.[264] TAP eventually pleaded guilty and agreed to pay $875 million in criminal and civil penalties.[265] It also agreed to implement a comprehensive seven-year corporate integrity agreement.[266] The agreement required TAP to develop new marketing policies and procedures to provide four hours of compliance training for marketing and sales personnel and to obtain independent reviews of its sales and marketing practices.[267] In addition, in 2005, TAP paid another $150 million to settle a number of civil suits arising out of its marketing of Lupron.[268]

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258. Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation-Through-Litigation*, 39 J. HEALTH L. 235, 255 (2006).

259. John R. Washlick & Sidney Summers Welch, *Physician-Vendor Marketing and Financial Relationships Under Attack*, 2 J. HEALTH & LIFE SCI. L. 151, 201 (2008).

260. In re *Lupron*, 245 F. Supp. 2d at 286. Ironically, AstraZeneca, the manufacturer of Zoldex, was also charged with marketing violations. Nguyen, *supra* note 146, at 255.

261. Nguyen, *supra* note 146, at 253.

262. Scheineson & Klinger, *supra* note 252, at 8.

263. Lansdale, *supra* note 237, at 178.

264. Scheineson & Klinger, *supra* note 252, at 7–8.

265. Joan H. Krause, *Following the Money in Health Care Fraud: Reflections on a Modern-Day Yellow Brick Road*, 36 AM. J.L. & MED. 343, 359–60 (2010).

266. Scheineson & Klinger, *supra* note 252, at 8.

267. Washlick & Welch, *supra* note 259, at 202.

268. *In re* Lupron Marketing & Sales Practices Litigation, MDL No. 1430, 2005 WL 1140553, *settlement approved* (D. Mass. May 12, 2005).

F. Vioxx

Merck began marketing Vioxx in 1999 to treat acute pain in adults, including women suffering from menstrual pain.[269] Vioxx belonged to a class of substances known as COX-2 inhibitors.[270] COX-2 inhibitors impede the production of the enzyme cyclooxygenase-2, which can cause pain and inflammation.[271] At the same time, Vioxx did not inhibit the production of COX-1, an enzyme which helps to protect the stomach lining.[272] Therefore, Vioxx reduced pain but did not cause some of the gastrointestinal problems that occurred with ibuprofen or naproxen (Aleve).[273] Although Vioxx was a prescription drug, Merck relied heavily on direct-to-consumer advertising to promote it.[274] The drug was an immediate success.[275]

Prior to FDA approval of Vioxx in 1999, Merck funded a study by independent researchers known as the Vioxx Gastrointestinal Outcomes Research (VIGOR) Study Group.[276] Although the study was to be a double-blind randomized trial to compare the occurrence of gastrointestinal toxicity of Vioxx and naproxen, it was actually designed by the company's marketing department to boost sales.[277] Over 8,000 patients participated in the study.[278] On one hand, the VIGOR Study showed that while Vioxx and naproxen were both effective painkillers, Vioxx caused only about half the number of serious gastrointestinal problems as naproxen.[279] On the other hand, the VIGOR Study also found that that the incidence of myocardial infarction (MI), irreversible heart damage typically resulting from blockage of a coronary ar-

269. Walter T. Champion, *A Tale of Two Cities: A Commentary on the Media's Response to Personal Injury "Feeding Frenzies" as a Result of the Vioxx and Silicosis Litigation*, 31 WHITTIER L. REV. 47, 50 (2009).

270. Green, *supra* note 118, at 751.

271. *Id.*

272. *Id.*

273. Walter T. Champion, *The Vioxx Litigation Paradigm: The Search for Smoking Guns*, 31 THURGOOD MARSHALL L. REV. 157, 158 n. 7 (2006); *Richard A. Epstein, Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 741, 766 (2005).

274. *See generally* Marshall H. Chin, *The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 771, 772 (2005).

275. Champion, *supra* note 269, at 50.

276. Green, *supra* note 118, at 752.

277. Mona Ghogomu, Comment, *When Does the Chain Break? Prescribing Around Drug Manufacturer Fraud*, 67 DEPAUL L. REV. 557, 572–73 (2018).

278. Green, *supra* note 118, at 752.

279. *Id.* at 753.

tery, was five times higher among patients in the Vioxx group than the naproxen group.[280]

Although Merck knew that Vioxx was a dangerous drug, the company downplayed these risks and marketed the drug aggressively.[281] One of the items that was distributed to its salespeople was a tri-fold brochure known as a "Cardiovascular Card," which featured data from several earlier studies that supported the claim that Vioxx was safer than competing products.[282] However, these were short-term pre-approval studies that were based on very limited populations and were not always concerned with identifying cardiovascular effects.[283] Consequently, they were of limited scientific value.[284]

Merck was also accused of trying to suppress or edit adverse studies about Vioxx.[285] For example, FDA scientist Dr. David Graham was forced to withdraw an article which was to be published by the English medical journal, *The Lancet*.[286] The Graham study of 1.4 million patients indicated that low doses of Vioxx increased the risk of heart disease by about 5%, while higher doses increased the risk by 35%.[287] Graham later testified that he was ordered to withdraw the paper or face "severe consequences."[288]

In another case, Merck hid an unpublished study that showed an increased risk of cardiovascular problems with the use of Vioxx.[289] In addition, editors of the *New England Journal of Medicine* accused Merck of deleting data about three heart attacks observed in the VIGOR Study before submitting its results to the journal.[290] Furthermore, Merck threatened that a Stanford University researcher would "flame out" unless he stopped giving anti-Merck lectures.[291] Finally, Merck urged Cleveland Clinic's Medical College to demote Dr. Eric Topol, a prominent cardiologist, for questioning Vioxx's safety.[292]

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280. *Id.* However, the group within the study population that was most affected by MI was largely confined to the 4% of the study population for whom low-dose aspirin had been prescribed. *Id.* Aspirin was withheld during the study to prevent its influencing the results. *Id.*

281. Culp & Berry, *supra* note 117, at 3.

282. Green, *supra* note 118, at 756.

283. *Id.*

284. *Id.*

285. Culp & Berry, *supra* note 117, at 27.

286. Champion, *supra* note 273, at 165.

287. *Id.*

288. *Id.*

289. *Id.*

290. *Id.* at 166.

291. *Id.* at 170.

292. Champion, *supra* note 273, at 171.

In 2000, Merck sponsored another large long-term clinical trial involving 2,600 subjects.[293] This study, known as the Adenomatous Polyp Prevention on Vioxx (APPROVE) trial, was designed to evaluate the ability of Vioxx to prevent the recurrence of colorectal polyps in patients with a history of colorectal adenomas.[294] However, the trial was abruptly terminated in September 2004, when researchers found that there was a significantly increased risk of heart attacks and strokes after eighteen months of treatment for patients taking Vioxx compared with those taking a placebo.[295] The results of this study eventually led Merck to take Vioxx off the market.[296] In addition, one of Merck's subsidiaries paid a $950 million fine to the federal government.[297]

More than 80 million persons worldwide took Vioxx for pain relief during the five-year period between 1999 and 2004.[298] Dr. Graham estimates that Vioxx may have caused 140,000 heart attacks or strokes and 55,000 deaths in the United States alone.[299] After Merck withdrew Vioxx from the market, a large number of plaintiffs brought civil suits against the company in federal and states courts; most of the federal cases were eventually transferred to the Eastern District of Louisiana for consolidation under the federal multidistrict litigation statute.[300] Eventually, the parties settled in most of these cases under which Merck agreed to place $4.85 billion into a fund for heart attack and stroke victims.[301]

G. Paxil

Paxil is a form of antidepressant known as a selective serotonin reuptake inhibitor (SSRI) or serotonin blocker drug.[302] It was developed to treat SAD, or social phobia, which was characterized by a marked and persistent fear of social or performance situations.[303] At first, doctors assumed that SAD was relatively rare, but in the 1990s, a

293. *Id.* at 186.

294. *Id.*

295. *Id.*

296. Culp & Berry, *supra* note 117, at 2.

297. McCarthy, *supra* note 5, at 453.

298. Culp & Berry, *supra* note 117, at 4.

299. *Id.*

300. *In re* Vioxx Prods. Liab. Litig., 239 F.D.R. 450, 452 (E.D. La. 2006).

301. Howard M. Erichson & Benjamin C. Zipursky, *Consent Versus Closure*, 96 CORNELL L. REV. 265, 279 (2011).

302. Cohan, *supra* note 107, at 117.

303. Fish, *supra* note 127, at 235.

study estimated that this condition was massively underdiagnosed and might be as common as depression.[304]

In order to introduce Paxil, GlaxoSmithKline (GSK), the product's manufacturer, put together a group of several nonprofit organizations that launched a sophisticated campaign to increase public awareness about SAD.[305] "Hundreds of stories about SAD appeared in the public media."[306] Although no drugs were mentioned by name, this effort persuaded doctors and the public that SAD could be successfully treated by drug therapy.[307] After the FDA approved Paxil for SAD in 1999, GSK sponsored a series of ads that promoted Paxil in social situations that predictably evoked fear in many people, such as dinner parties and speaking engagements.[308] According to one commentator, "Paxil became one of the ten most prescribed pharmaceuticals, supplanting Zoloft as the second best-selling SSRI."[309]

In June 2003, a British researcher reported that teenagers and children were 3.2 times as likely to have suicidal thoughts or attempt suicide when given Paxil as compared with those test subjects who were given a placebo.[310] However, only one of these trial results was made available to the medical community.[311] That study concluded that Paxil was generally well-tolerated and was effective for major depression in adolescents.[312]

On June 2, 2004, the New York Attorney General filed suit in state court alleging that GSK promoted the use of Paxil in adolescents and children despite the fact that the drug was not approved by the FDA for this class of patients.[313] The suit also declared that GSK suppressed four studies that failed to confirm that Paxil was effective in treating children and adolescents for depression and also implied that it might cause an increase in suicidal ideation.[314] The Attorney General relied heavily on a report by GSK that two studies had cast doubts about Paxil's effectiveness.[315] As a result, the company de-

304. *Id.*

305. *Id.* at 235–36.

306. *Id.* at 236.

307. *Id.*

308. *Id.*

309. Fish, *supra* note 127, at 236.

310. Cohan, *supra* note 107, at 144; Evans, *supra* note 106, at 70.

311. Evans, *supra* note 106, at 70.

312. *Id.*

313. Dorfman & Reig, *supra* note 244, at 595.

314. Aisling V. O'Sullivan, Comment, *Walking a Fine Line: Are SSRIs Really Depression Wonder Drugs or Threats to Patient Safety?*, 26 PACE L. REV. 549, 568–69 (2006).

315. Dorfman & Reig, *supra* note 244, at 597.

cided to effectively manage the dissemination of this information in order to minimize any potential negative commercial impact.[316]

GSK eventually agreed to a scheduled release of negative data on the safety and effectiveness of Paxil and agreed to pay $2.5 million to the state.[317] GSK also pled guilty to a three-count criminal indictment in federal court for introducing misbranded drugs, including Paxil, and agreed to pay a $3 billion fine for engaging in kickbacks and fraudulent marketing of the drug.[318]

The FDA conducted a study on suicidal ideation, known as the Columbia Study, which combined data from twenty-four smaller studies on adolescents and children.[319] This study showed that about 4% of test subjects who took antidepressants became suicidal, compared with 2% of those who took a placebo.[320] This led the FDA to require that all SSRI drugs be labeled with a black box warning.[321]

H. OxyContin

The current opioid epidemic is a serious public health problem.[322] Since 1999, opioids, including illegal street drugs, have killed about 400,000 people in the United States.[323] According to one source, between 2013 and 2017, about 2.1 million Americans were addicted to opioids and over 4 million persons misused opioids each month.[324] Furthermore, prescription drug abuse often leads to the use of heroin and other illegal street drugs.[325] Although opioid addiction is particularly acute in economically depressed areas such as Appalachia, it is a nationwide problem.[326] The opioid epidemic also has severe economic consequences. For example, the Council of Economic Advisors has

316. *Id.*

317. Scheineson & Klinger, *supra* note 252, at 11; O'Sullivan, *supra* note 314, at 569.

318. McCarthy, *supra* note 101, at 45.

319. Timothy J. Hixson, Note, *Anti-Depressants and Children: Suicidality, Off-Label Use, and Trial Publication*, 3 IND. HEALTH L. REV. 201, 207–08 (2006).

320. *Id.* at 208–09.

321. O'Sullivan, *supra* note 314, at 567; Hixson, *supra* note 319, at 209.

322. Wellesley Anna DuBois, *Healthcare's Biggest Little Lie: Rampant Hospital Drug Diversion Hidden Behind Stethoscopes and White Coats*, 18 RUTGERS J.L. & PUB. POL'Y at 2, 4 (2020).

323. Nora Freeman Engstrom & Robert L. Rabin, *Pursuing Public Health Through Litigation: Lessons from Tobacco and Opioids*, 73 STAN. L. REV. 285, 287 (2021).

324. LAWRENCE SCHOLL ET AL., *Drug and Opioid Involved Overdose Deaths—United States, 2013-2017*, 67 CDC MORBIDITY AND MORTALITY WEEKLY REPORT 1419 (2019).

325. McCoy, *supra* note 136, at 56.

326. Ashley Duckworth, Note, *Fighting America's Best-Selling Product: An Analysis of the Solution to the Opioid Crisis*, 26 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 237, 246 (2019).

estimated that the annual economic cost of opioid abuse is $500 billion.[327]

The opioid addiction epidemic can be traced to the introduction of OxyContin by Purdue Pharma.[328] OxyContin is a narcotic prescription pain reliever whose active ingredient is oxycodone hydrochloride.[329] It was developed by Purdue Pharma and first marketed in 1996.[330] Although OxyContin was twice as powerful as morphine, it was touted as superior to other opioids because of a time-release mechanism which allowed a higher dose to be released over a twelve-hour period of time, instead of the more common four- to six-hour period.[331] In order to persuade doctors to prescribe OxyContin for the treatment of chronic pain, Purdue embarked on a comprehensive and sophisticated marketing campaign.[332]

At one time, the accepted practice among the medical profession was to avoid using opioids to treat chronic pain and limit it to the treatment of short-term acute pain.[333] However, in the 1980s, a growing number of pain specialists claimed that chronic pain was undertreated.[334] Relying on this surge in interest in pain treatment, Purdue sought to greatly increase the market for OxyContin by persuading doctors to prescribe it for the treatment of non-malignant chronic pain.[335] In order to change existing prescribing practices, Purdue and other opioid manufacturers assured doctors that opioids were effective for treating moderate chronic pain and that the risk of addiction was not significant.[336]

Purdue communicated these assurances to healthcare providers by direct advertising and during office visits by their sales representatives.[337] The company also engaged in unbranded advertising by fund-

327. Council Econ. Advisors, The Underestimated Cost of the Opioid Crisis 1, 1 (2017).

328. Engstrom & Rabin, *supra* note 323, at 307–08.

329. Frederickson, *supra* note 257, at 132.

330. Quinones, *supra* note 128, at 134.

331. Joseph B. Prater, Comment, *West Virginia's Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 N.W. U. L. Rev. 1409, 1413 (2006).

332. Engstrom & Rabin, *supra* note 323, at 307–08.

333. Quinones, *supra* note 128, at 80.

334. Sarpatwari et al., *supra* note 145, at 465.

335. Nino C. Monea, *Cities v. Big Pharma: Municipal Affirmative Litigation in Response to the Opioid Crisis*, 50 Urb. Law. 87, 103–04 (2019).

336. Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 Utah L. Rev. 757, 766 (2019).

337. Elizabeth Weeks & Paula Sanford, *Financial Impact of the Opioid Crisis on Local Government: Quantifying Costs for Litigation and Policymaking*, 67 U. Kan. L. Rev. 1061, 1065 (2019).

ing seemingly independent key opinion leaders and organizations who echoed these assurances in medical and scientific journals and at continuing medical education programs.[338]

The company also encouraged physicians to prescribe OxyContin for the treatment of chronic pain by treating them to all-expense-paid conferences at exotic resorts and provided them with pain-related educational programs.[339] In addition, Purdue mailed thousands of promotional materials to physicians and paid substantial bonuses to its sales staff.[340] Furthermore, the company also provided doctors with OxyContin starter vouchers and coupons to give to their patients and also gave them logo-branded fishing hats, tote bags, clocks, stuffed toys, and compact discs as additional incentives to prescribe OxyContin.[341]

Additionally, opioid manufacturers told doctors that symptoms of addiction that they might have observed were not evidence of actual addiction but rather were symptoms of "pseudoaddiction," a condition that was caused by undertreated pain that required higher doses of opioids.[342] In addition, Purdue and others falsely claimed that opioids could be safely prescribed for patients who were susceptible to addiction because screening, counseling, and drug testing would enable doctors to detect addiction before it became a serious problem.[343] Furthermore, drug companies claimed that their products were safer than non-opioid pain relievers, such as non-steroidal anti-inflammatory drugs.[344] Finally, opioid manufacturers targeted primary care physicians who were unlikely to be familiar with the addiction risk of opioids for the treatment of chronic pain.[345]

This marketing campaign was very successful.[346] Within a few years of its introduction into the market, OxyContin became the nation's most highly prescribed Schedule II prescription drug.[347] Between 1996

338. Monea, *supra* note 335, at 103–04; Taylor Giancarlo, Note, *Pharmaceutical Advertising Disclosures: Is Less Really More?*, 22 QUINNIPIAC HEALTH L.J. 449, 467–68 (2019).

339. Duckworth, *supra* note 326, at 257.

340. *Id.* at 257–58.

341. *Id.* at 258.

342. Christine Minhee & Steve Calandrillo, *The Cure for America's Opioid Crisis? End the War on Drugs*, 42 HARV. J.L. & PUB. POL'Y 547, 560–61 (2019).

343. Paul L. Keenan, *Death by 1000 Lawsuits: The Public Litigation in Response to the Opioid Crisis Will Mirror the Global Tobacco Settlement of the 1990s*, 52 NEW ENG. L. REV. 69, 72 (2017).

344. City of Chicago v. Purdue Pharma L.P., 211 F. Supp. 3d 1058, 1063–73 (N.D. Ill. 2016).

345. ERIC EYRE, DEATH IN MUD LICK 13 (2020).

346. Sarpatwari et al., *supra* note 145, at 467.

347. Dianne E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231, 273 (2008).

and 2019, Purdue made an estimated $35 billion from the sale of OxyContin.[348]

As the addiction crisis grew at the beginning of the twenty-first century, injured parties brought numerous lawsuits against Purdue and other opioid manufacturers.[349] In general, these lawsuits were unsuccessful, although the cost of defending against them was significant.[350] Eventually, Purdue and its top executives were charged with criminal violations by the Department of Justice.[351] The company and its officers pled guilty to these charges and paid more than $600 million in fines and civil penalties.[352]

On the civil side, the tide began to turn against Purdue and other drug companies in 2014 when a number of cities, counties, and states filed lawsuits against them, based on public nuisance and other liability theories.[353] Most of these cases were transferred to federal courts, although state plaintiffs were able to keep their cases in state courts.[354] Recently, one such case was tried in a bench trial in an Oklahoma trial court.[355] This resulted in a damages award against Johnson & Johnson and its subsidiary, Janssen, for $572 million.[356] However, the lower court's judgment was reversed on November 9, 2021.[357]

By late 2017, thousands of such cases had been brought into federal court, prompting the Judicial Panel on Multidistrict Litigation (MDL) to transfer all of the pending federal cases to Judge Dan Polster in the

348. Benjamin Soskis, *Why Haven't Major Institutions Cut Ties with the Sackler Family?* WASH. POST (Mar. 15, 2019), https://www.washingtonpost.com/outlook/why-havent-major-institutions-cut-ties-with-the-sackler-family/2019/03/15/6b06d2ec-4102-11e9-a0d3-1210e58a94cf_story.html.

349. *See generally* Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1122–38 (2014).

350. By the end of 2004, Purdue had spent $250 million defending against lawsuits by injured consumers. Frederickson, *supra* note 257, at 134.

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

352. Andrew E. Lelling, *Corporate Accountability for the Opioid Epidemic*, 66 U.S. ATTY. BULL. 159, 166 (July 2018).

353. Richard C. Ausness, *The Current State of Opioid Litigation*, 70 S.C. L. REV. 565, 566 (2019).

354. Attorneys General in forty-nine states have brought suits against opioid manufacturers and others in state courts. Lance Gable, *Preemption and Privatization in the Opioid Litigation*, 13 NE. U. L. REV. 297, 312 (2012).

355. Oklahoma *ex rel.* Hunter v. Purdue Pharma, L.P., No. C1-2017-816, 2019 Okla. Dist. LEXIS 3486, at *1 (Aug. 26, 2019).

356. Duckworth, *supra* note 326, at 261–62. This was later reduced to $465 million to correct a mathematical error. Justin Kaufman, Oklahoma v. Purdue Pharma: *Public Nuisance in Your Medicine Cabinet,* 42 CARDOZO L. REV. 429, 429 n.5 (2020).

357. *See* State *ex rel.* Hunter v. Johnson & Johnson, No. 118,474, 2021 WL 5191372, at *11 (Okla. Nov. 9, 2021).

Northern District of Ohio.[358] In addition, other lawsuits brought by hospitals, Indian tribes, healthcare plans, and neonatal abstinence syndrome babies are also pending at the time of this writing.[359] Meanwhile, Purdue, one of the most significant contributors to the opioid crisis, filed for bankruptcy in September 2019 and, most likely, will no longer participate in the MDL process.[360]

IV. Factors that Influence Corporate Behavior

The foregoing examples suggest that corporate misconduct has become the business model of choice for many pharmaceutical companies.[361] The conditions that encourage or facilitate improper behavior include: (1) weak or ineffective regulation by the FDA and other government agencies; (2) an excessive focus on short-term profits fueled by external market conditions, the nature of the corporate structure, and internal compensation practices; and (3) the existence of a toxic culture within many pharmaceutical companies that tolerates unethical conduct.[362]

A. Weak Governmental Regulation

Virtually all pharmaceutical products, including prescription drugs, medical devices, and over-the-counter drugs, are regulated by the FDA under the provisions of the Food, Drug and Cosmetic Act.[363] FDA regulations cover the entire lifecycle of a drug from the beginning stages of development to its use after approval.[364] Unfortunately, the FDA's regulatory regime is not always as effective as it could be. Weaknesses are present throughout the entire regulatory process, including clinical testing, marketing to physicians, direct-to-consumer advertising, control over the promotion of off-label uses, and the monitoring of post-approval adverse events.[365]

One concern is the process by which new drugs are tested prior to FDA approval. Drug companies typically hire for-profit institutions to conduct clinical studies of prescription drugs and often try to influence

358. *In re* Nat'l Prescription Opiate Litig., 290 F. Supp. 3d 1375, 1378–79 (J.P.M.L. 2017).

359. Erich Eiselt, *The Opioid Wars—Notes from the Front*, 60 Municipal Law. Sept.-Oct. 2019, at 24, 25.

360. Samantha T. Pannier, *Litigating an Epidemic: California Plaintiffs in the National Opioid Litigation,* 54 Loy. L.A. L. Rev. 275, 295–96 (2020).

361. McCoy, *supra* note 136, at 65.

362. *See supra* Part III.

363. 21 U.S.C. §§ 300–99 (2021).

364. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 Ind. L.J. 845, 858–59 (2017).

365. *See supra* Part II.A.

the design of these studies in order to ensure a favorable outcome.[366] Moreover, in the past, pharmaceutical companies have been accused of manipulating test data or providing ghostwritten reports of these studies to scientific journals in order to encourage doctors to prescribe their products.[367]

The FDA's drug approval process is also not without its problems. The FDA has been accused of setting too low a bar for drug approvals.[368] For example, the FDA authorized Eli Lilly, the product's manufacturer, to market its antidepressant, Prozac, in a "one size fits all" high-dosage formulation even though company scientists recommended a lower dose regimen because of concerns about the increased risk of harmful side effects from the higher dosage pills.[369] In addition, the FDA has sometimes approved new drugs even though safety issues had arisen in connection with similar drugs.[370] For example, the FDA continued to approve oxycodone-based opioids long after the experience with OxyContin showed these opioids were extremely addictive.[371] Labeling can also be a problem. In one instance, the FDA allowed Purdue to claim that OxyContin was less likely than other opioids to be misused by patients because of its timed-release formula when this was untrue.[372] To make matters worse, FDA-approved labeling unintentionally told users how to defeat the timed-release mechanism by telling them not to crush the tablets.[373]

The FDA also oversees advertising, marketing, and promotional materials in order to ensure that drug companies provide accurate and truthful information about their products.[374] However, the FDA rarely sanctions drug companies for serious marketing violations.[375] Moreover, because the FDA only regulates marketing materials that promote a branded product, drug companies can circumvent oversight regulation by disseminating materials that relate to a class of drugs

366. McCarthy, *supra* note 101, at 46–49.

367. Cohan, *supra* note 107, at 161.

368. Melissa Marie Bean, Comment & Note, *Fatal Flaws in the Food and Drug Administration Drug-Approval Formula*, 2003 UTAH L. REV. 881, 891–92 (2003).

369. *Id.* at 122.

370. Noah, *supra* note 336, at 760–62.

371. Duckworth, *supra* note 326, at 270.

372. QUINONES, *supra* note 128, at 126.

373. *Id.*

374. Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 102 (2002).

375. Anna Stapleton, Comment, *In Defense of the Hare: Primary Jurisdiction Doctrine and Scientific Uncertainty in State Court Opioid Litigation*, 86 U. CHI. L. REV. 1697, 1701 (2019).

rather than a particular branded product.[376] Drug companies engaged in this practice extensively when they promoted opioids for the treatment of chronic pain without advertising their own products by name.[377]

Another area of concern is direct-to-consumer (DTC) advertising. Drug companies now spend $5 billion annually to promote their products directly to consumers.[378] The relaxed restrictions on DTC advertising encourage drug companies to develop and promote products which are aimed at large numbers of potential consumers who suffer from chronic (but not life-threatening) conditions such as erectile dysfunction, asthma, indigestion, or insomnia.[379] Not only does the prospect of capturing a share of a large and profitable market induce drug companies to focus on producing incremental improvements to existing lifestyle drugs instead of developing more useful products, in some cases, as the Vioxx case illustrates, but it also causes them to ignore evidence of potential adverse reactions.[380]

The FDA's efforts to prevent drug companies from promoting off-label uses of prescription drugs also need to be improved. Off-label uses are uses that have not been subjected to clinical trials and, therefore, are not approved by the FDA.[381] Generally speaking, doctors may legally prescribe drugs for off-label uses, and medical professionals may encourage others to do so as well.[382] However, drug companies are not allowed to promote or advocate off-label uses for their products.[383] That being said, the market for off-label uses in some cases is sometimes greater than the market for approved uses,[384] so drug companies may be tempted to ignore the FDA's prohibition of such uses.[385] This problem is exacerbated by the fact that the penalties

376. *Id.*

377. Monea, *supra* note 335, at 103–04.

378. McCoy, *supra* note 136, at 82.

379. Green, *supra* note 118, at 751.

380. *Id.* at 751.

381. Steven R. Salbu, *Off-Label Prescription and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 187–88 (1999).

382. Ralph F. Hall & Elizabeth S. Sobotka, *Inconsistent Government Policies: Why FDA Off-Label Regulation Cannot Survive First Amendment Review Under Greater New Orleans*, 62 FOOD & DRUG L.J. 1, 9 (2007).

383. John N. Joseph et al., *Enforcement Related to Off-Label Marketing and Use of Drugs and devices: Where Have We Been and Where Are We Going?*, 2 J. HEALTH & LIFE SCI. L. 73, 78 (2009).

384. Michael I. Krauss, Essay, *Loosening the FDA's Drug Certification Monopoly: Implications for Tort Law and Consumer Welfare*, 4 GEO. MASON L. REV. 457, 472 (1996) (estimating that between 20% and 60% of all prescriptions are for off-label uses).

385. Kaspar J. Stoffelmayr, Comment, *Products Liability and "Off-Label" Uses of Prescription Drugs,* 63 U. CHI. L. REV. 775, 777–79 (1996).

imposed for violating the prohibition against promotion of off-label prescribing are not always sufficient to deter this practice.[386]

The FDA also needs to strengthen its post-marketing oversight. Premarket tests cannot detect many of the risks that may surface when a new drug is approved.[387] To be sure, drug manufacturers are required to gather information about adverse events and report them to the FDA.[388] In addition, under some circumstances, the FDA can ask or require a drug company to conduct post-market tests on approved drugs.[389] However, this power is limited. In the case of a drug that has already been approved for marketing, the FDA can only order additional testing based on new safety information.[390] Furthermore, the FDA can only order the drug company to conduct a new clinical study if it concludes that other existing studies are insufficient.[391] Thus, the agency is often slow to recognize and react to evidence of serious side effects caused by some of the drugs that it has approved.[392]

B. Economic Factors

Various economic factors promote misconduct by pharmaceutical companies. These can be attributed to the corporate structure, external market forces, or a corporation's internal promotion and compensation practices.[393]

1. Corporate Structure

To some analysts, corporate misconduct is a product, at least in part, of the legal structure of corporate entities.[394] A fundamental aspect of the corporate structure is the separation of ownership and manage-

386. Hannah Smoot Combs, Note, *Striking a Balance: Ensuring the Safety and Efficacy of a Drug's Use, While Recognizing the First Amendment Protection of Truthful, Non-Misleading Off-Label Drug Communications*, 14 FIRST AMEND. L. REV. 424, 433 (2016). For a list of cases involving off-label promotion and other violations *see* Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN ST. L. REV. 41, 42 n.9 (2005).

387. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L.& ETHICS 587, 598–99 (2005).

388. Mary J. Davis, *Time for a Fresh Look at Strict Liability for Pharmaceuticals*, CORNELL J. L. & PUB. POL'Y 399, 405 (2019) (citing 21 U.S.C.A. § 355(o)(3) (West 2013)).

389. Cahoy, *supra* note 105, at 633–34.

390. Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941, 960–61 (2007).

391. *Id.* at 961.

392. Jillian Clare Cohen-Kohler & Laura Esmail, *Scientific Misconduct, the Pharmaceutical Industry, and the Tragedy of Institutions*, 26 MED. & L. 431, 435 (2007) (discussing the FDA's failure to respond to concerns about Vioxx).

393. *See infra* Part IV.B.

394. Douglas Litowitz, *Are Corporations Evil?*, 58 U. MIAMI L. REV. 811, 813 (2004).

ment.[395] Shareholders are the owners of the corporation, the board of directors makes major decisions, and corporate officers run the day-to-day operations of the business.[396] However, this aspect of the corporate structure weakens responsibility for decision-making. Shareholders exercise control through their power to elect the board of directors and to approve matters such as mergers and charter amendments.[397] In theory, shareholders can discipline corporate officers through derivative lawsuits; however, these are expensive and burdensome.[398]

Likewise, directors can exercise control over corporate officers by removing those who engage in wrongdoing.[399] However, in reality, directors delegate most managerial responsibilities to corporate officers, and they often lack either the incentive or capacity to monitor their officers.[400] In addition, for-profit corporations are formed for the purpose of making money for shareholders, and the interests of other stakeholders are generally marginalized.[401] Instead, corporate managers are often pressured by investors and market forces to think in terms of short-term gains at the expense of longer-term interests.[402]

2. External Market Forces

According to most commentators, the primary function of corporate management is to maximize profit for the benefit of shareholders.[403] However, this objective may also encourage management to focus on increasing short-term profits even if that means engaging in risky or unethical conduct.[404] This demand for short-term results comes from a wide variety of shareholders, including day traders, mutual funds, insurance companies, private pension funds, foundations, and university endowments.[405] Shareholders, such as pension plans, which depend upon capital markets to enable them to maintain ex-

395. Megan Wischmeier Shaner, *Officer Accountability*, 32 GA. ST. U. L. REV. 357, 359 (2016).

396. Larry E. Ribstein, *Accountability and Responsibility in Corporate Governance*, 81 NOTRE DAME L. REV. 1431, 1439–40 (2006).

397. *Id.* at 1440.

398. Shaner, *supra* note 395, at 383.

399. Corporate officers serve at the pleasure of the board of directors. *Id.* at 404.

400. *Id.* at 383.

401. Acevedo, *supra* note 38, at 655.

402. Lynne Dallas, *Short-Termism, the Financial Crisis, and Corporate Governance*, 37 J. CORP. L. 265, 295–96 (2012).

403. D. Gordon Smith, *The Shareholder Primacy Norm*, 23 J. CORP. L. 277, 278 (1998).

404. David Million, *Shareholder Social Responsibility*, 36 SEATTLE U. L. REV. 911, 915–16 (2013).

405. *Id.* at 913.

isting benefit levels, often exert pressure to keep profits and stock prices high.[406] In addition, because patent protection for drugs is relatively short, pharmaceutical companies often feel the pressure to introduce drugs to the market quickly and promote them aggressively before patent protection runs out and they face competition from cheaper generic equivalents.[407] Competition from similar pharmaceutical products sometimes induces companies to engage in unethical or illegal sales practices.[408]

3. Financial Incentives and Cultural Norms within the Company

In most companies, senior management determines the nature of corporate culture, and this in turn influences the behavior of lower-level employees.[409] Thus, if senior officers and managers call for profits at any price or engage in shady or reckless practices, this conduct will undoubtedly affect the conduct of lower-level employees, including sales personnel.[410]

In addition, lower-level employees are often subjected to "stretch" goals or other policies that are aggressive or unethical.[411] For example, pharmaceutical companies created an incentive structure that encouraged sales representatives to encourage doctors to prescribe drugs inappropriately.[412]

Another phenomenon that sometimes occurs is an excessive sense of loyalty to the company. In such an environment, being a "team player" and one who is loyal to the company is highly valued in many organizations.[413] As the Vioxx experience demonstrates, this cultural norm can sometimes cause employees to go along with policies or decisions that they know are wrong.[414]

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406. Bernard S. Sharfman, *Shareholder Wealth Maximization and Its Implementation Under Corporate Law*, 66 FLA. L. REV. 389, 394 (2014).

407. Ho, *supra* note 144, at 795.

408. *See, e.g.*, Zalesky, *supra* note 258, at 255 (discussing how competition between the makers of Lupron and Zoladex caused them both to violate the Anti-Kickback Act).

409. Kimberly D. Krawiec, *Organizational Misconduct: Beyond the Principal-Agent Model*, 32 FLA. ST. U. L. REV. 571, 599–600 (2005).

410. *Id*.

411. Donald Langevoort, *Chasing the Greased Pig Down Wall Street: A Gatekeeper's Guide to the Psychology, Culture, and the Ethics of Financial Risk Taking*, 96 CORNELL L. REV. 1209, 1230 (2011).

412. For example, some of Purdue's sales representatives received bonuses of up to $240,000 for encouraging doctors to write more prescriptions for OxyContin. Roseann B. Termini, *50 Years Post-Controlled Substances Act: The War on Drugs Rages on with Opioids at the Forefront*, 46 OHIO N.U. L. REV. 1, 13 (2020).

413. Culp & Berry, *supra* note 117, at 31.

414. *Id.*

V. SOLUTIONS

Unfortunately, corporate misconduct is a longstanding and pervasive practice among pharmaceutical companies.[415] For this reason, I do not propose any sort of "magic bullet" but instead suggest a number of responses which, taken together, may have a beneficial effect. These proposals are for the FDA to: (1) develop more effective regulation over prescription drugs; (2) create economic incentives to discourage unethical behavior within the pharmaceutical industry; and (3) implement policies to change the current culture within the industry.

Part IV identified a number of areas where government regulation of pharmaceutical products could be strengthened.[416] For example, the FDA needs to exercise more oversight and control over the preapproval clinical testing process so that harmful or ineffective drugs are not approved. In addition, the FDA should be given more power to respond promptly to adverse reaction reports and, if necessary, suspend the sale of drugs when safety concerns are raised. Furthermore, the FDA should ensure that approved warnings and other labeling are scientifically accurate and that they fully disclose all of a drug's serious risks.

The FDA also needs to regulate promotion and marketing activities by pharmaceutical companies more strictly. This includes prohibiting, or at least discouraging, the publication of ghostwritten articles regarding their products in medical and scientific journals. The FDA should also monitor branded advertising, particularly DTC advertising, to ensure that safety issues are fully disclosed.

Furthermore, the FDA should exercise more control over unbranded advertising. In particular, the agency should intervene when a drug company places misleading or fraudulent statements on its website, supports front groups for the purpose of touting its products, or pays speakers to act on its behalf without disclosure at professional conferences and events. The FDA should also aggressively search for and punish companies that unlawfully promote off-label uses of their products. Finally, the FDA should monitor the practices of sales representatives to ensure that they provide physicians with full and accurate information about the risks associated with their products.

Of course, there is no assurance that any of these proposals will actually be implemented. The pharmaceutical industry has a powerful lobby, and no doubt has sufficient political power to oppose any seri-

415. *See supra* Part II, notes 289–338.
416. *See supra* Part IV, notes 365–90.

ous attempt by Congress to increase the FDA's regulatory authority.[417]

As described earlier, corporations, including pharmaceutical companies, are motivated by profits and other economic incentives which sometimes encourage them to act irresponsibly.[418] Therefore, any response to this problem must include a range of financial measures to deter unwanted conduct.

One option is to increase the criminal and civil penalties imposed on companies that violate laws and regulations.[419] Although pharmaceutical companies have paid millions of dollars in fines, civil penalties, and settlements, apparently these sanctions are not always sufficient to deter them from engaging in further misconduct.[420]

For example, Eli Lilly paid the federal government $1.415 billion in 2009 for promoting off-label uses of its antipsychotic drug, Zyprexa.[421] In comparison, for several years, annual sales of the drug amounted to $4.2 billion.[422] Similarly, Pfizer paid a whopping $2.3 billion fine for illegally marketing its painkiller, Bextra, but that amount allegedly amounted to less than three weeks of sales revenue from the drug.[423] GSK paid a $3 billion fine in connection with its promotion of Paxil but reputedly made $12 billion from sales of the drug.[424] Although Warner-Lambert paid the federal government a $240 million criminal fine and $190 million in civil penalties for promoting off-label uses of Neurontin,[425] sales of that drug during the previous year were approximately $2.7 billion.[426] Finally, Purdue paid more than $600 million in fines and civil penalties to settle a case against it for "misbranding" OxyContin.[427] However, OxyContin sales generated an estimated $30 billion in revenue for the company between 1996 and 2019.[428]

Corporate compliance agreements are another tool that could be strengthened by making them longer in duration, more comprehen-

417. W. John Thomas, *The Vioxx Story: Would It Have Ended Differently in the European Union?,* 32 AM. J.L. & MED. 365, 376 (2006).

418. *See supra* Part I, notes 6-88.

419. McCoy, *supra* note 136, at 69–70.

420. Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation*, 15 J.L. & POL'Y 1051, 1054 (2007).

421. David G. Owen, *Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate*, 42 CONN. L. REV. 733, 737 (2010).

422. Curtin & Relkin, *supra* note 141, at 1784.

423. Ho, *supra* note 144, at 795.

424. McCarthy, *supra* note 5, at 454.

425. *In re* Neurontin Mtg. & Sales Practices Litig., 712 F.3d 21, 25 (1st Cir. 2013); *see also* Scheineson & Klinger, *supra* note 252, at 9.

426. Greene, *supra* note 238, at 653.

427. Frederickson, *supra* note 257, at 138.

428. Duckworth, *supra* note 326, at 260.

sive in scope, and more closely supervised by the regulatory agency. Some commentators have suggested that corporate officers should be held civilly, and even criminally, liable for allowing their companies to engage in illegal conduct.[429]

Arguably, corporate misconduct may also be deterred by the threat of civil litigation.[430] In general, personal injury actions by private individuals are problematic.[431] For example, of the hundreds of lawsuits that were brought against the manufacturers of SSRI drugs, most were either settled or dismissed.[432] Only one such case, *Estates of Tobin v. SmithKline Beecham Pharmaceuticals*, resulted in a verdict for the plaintiff.[433] However, it should be noted that the possibility of recovering punitive damages would appear to give plaintiffs more bargaining power in settlement negotiations.[434]

Consolidated actions, such as class actions and multidistrict litigation, are another matter. Although courts are sometimes reluctant to certify a class when personal injuries are involved,[435] over the years, there have been a number of successful consolidated class actions brought against pharmaceutical companies.[436]

The final—and more controversial—economic incentive is civil litigation by governmental entities. During the past forty years or so, state and local governments have sued various product manufacturers, including pharmaceutical companies.[437] The most significant example of this is the litigation currently being brought by state and local governments against the manufacturers, distributors, and retail sellers of opioid products.[438] Some of these cases have been brought in state courts by state attorneys general under the state's *parens patriae*

429. *See generally* McCarthy, *supra* note 5.

430. Jill E. Fisch, *The Overstated Promise of Corporate Governance*, 77 U. CHI. L. REV. 923, 938–39 (2010).

431. Jonathan T. Molot, *Litigation Finance: A Market Solution to a Procedural Problem*, 99 GEO. L.J. 65, 85–86 (2010).

432. Andrew E. Falsetti, *Fluoxetine-Induced Suicidal Ideation: An Examination of the Medical Literature, Case Law, and the Legal Liability of Drug Manufacturers*, 57 FOOD & DRUG L.J. 273, 283 (2002).

433. Estates of Tobin v. SmithKline Beecham Pharmaceuticals, 164 F. Supp. 2d 1278, 1290 (D. Wyo. 2001).

434. Thomas Koenig, *The Shadow Effect of Punitive Damages on Settlements*, 1998 WIS. L. REV. 169, 172 (1998).

435. Richard A. Epstein, *Class Actions: Aggregation, Amplification, and Distortion*, 2003 U. CHI. LEGAL F. 475, 475 (2003).

436. *E.g.*, *In re* Vioxx Prods. Liab. Litig., 239 F.D.R. 450 (E.D. La. 2006); *In re* Lupron Marketing & Sales Practices Litig. MDL No. 1430, 2005 WL 2005 WL 1140553 (D. Mass. 2005).

437. *See supra* Part II, notes 72-78 (Exxon Valdez oil spill); 322-360 (opioids).

438. Ausness, *supra* note 353, at 566.

power.[439] Another group of cases, currently numbering more than 2,500, has been transferred to a federal district court in Cleveland under the Multidistrict Litigation Act.[440] So far, although a few cases have been settled, most of them have not yet been resolved.[441] However, it is fair to say that any settlement that is reached will cost the defendants billions of dollars.

Factors such as regulatory sanctions and social pressure can sometimes lead to a change in corporate culture.[442] For example, government sanctions, reinforced by pressure from women's groups and civil rights organizations, have had a salutary effect on corporate culture in the entertainment industry.[443] Government regulations against "redlining" have caused financial institutions to abandon the practice.[444] The Occupational Safety and Health Administration regulations have led workers and employers to adopt practices that make the workplace safer.[445]

One regulatory device that has been used to change company practices, though not necessarily the underlying corporate culture, is a compliance agreement which is typically part of a plea agreement or settlement in a criminal or civil case, and which obligates the defendant to implement certain practices or to discontinue others in order to comply with government laws or regulations.[446] Both Purdue Pharma and a number of other opioid companies have entered into such an agreement after being charged with violating federal regulations involving the labeling or distribution of opioid products.[447]

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439. Gable, *supra* note 354, at 312.

440. Catherine M. Sharkey, *The Opioid Litigation: The FDA is MIA*, 124 DICK. L. REV. 669, 670 (2020).

441. Engstrom & Rabin, *supra* note 323, at 319. One case, *Oklahoma* ex rel. *Hunter*, resulted in a decision for the state of Oklahoma. No. C1-2017-816, 2019 Okla. Dist. LEXIS 3486, at *11 (Aug. 26, 2019). In addition, several other trials are currently underway or scheduled for trial in various courts. Pannier, *supra* note 360, at 290.

442. David Hess & Christie L. Ford, *Corporate Corruption and Reform Undertakings: A New Approach to an Old Problem*, 41 CORNELL INT'L L.J. 307, 311 (2008).

443. Sara Khorasani, *Harvey of Hollywood: The Face That Launched a Thousand Stories*, 41 HASTINGS COMMS. & ENT. L.J. 103, 123–24 (2019).

444. Steven Pitt & Daniel Maldonado, *Prohibiting de Facto Insurance Redlining: Will Hurricane Katrina Draw a Discriminatory Redline in the Gulf Coast Sands?*, 14 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 199, 209–18 (2008).

445. Wayne B. Gray & John T. Scholtz, *Does Regulatory Enforcement Work? A Panel Analysis of OSHA Enforcement*, 21 L. & SOC. REV. 177, 199 (1993).

446. *See generally* F. Joseph Warin & Jason C. Schwartz, *Corporate Compliance Programs as a Component of Plea Agreements and Civil and Administrative Settlements*, 24 J. CORP. L. 71 (1993).

447. *E.g.*, Andrew F. Letting, *Corporate Accounting for the Opioid Epidemic*, 66 DOJ J. Fed. L. & Prac. 159, 165, 168–70 (2018) (discussing agreements with Purdue, Mallinckrodt, McKesson Corp. and Cardinal Health, Inc.).

While these agreements have some value, their effectiveness may be reduced by the fact that they are sometimes limited in duration.[448]

Corporations also respond to changes in social mores and attitudes. Thus, for example, many companies are taking measures to reduce their carbon footprint now that public concern about climate change has increased.[449] In addition, increasing diversity in the workplace has led to the enactment of statutes prohibiting sexual harassment and gender discrimination in employment.[450]

Corporate behavior may also be influenced by the threat of a negative market reaction to the disclosure of unethical practices.[451] Most pharmaceutical companies want to be regarded by the public as honest and socially responsible. Therefore, one would hope that past and present scandals will eventually cause them to adopt a corporate culture that corresponds more closely to the benign public image that they wish to cultivate.

Conclusion

Fraud and other forms of misconduct are pervasive and deeply ingrained in the operations and practices of the pharmaceutical industry.[452] Among other things, drug companies have been accused of manipulating the results of clinical trials, concealing damaging information revealed by failed trials, falsely assuring doctors that their products are safe and effective, promoting off-label uses of their products, bribing doctors to overprescribe their drugs, and encouraging healthcare providers to file false claims to Medicare and Medicaid.[453]

There are a number of factors that encourage such misconduct, including weak regulation, pressure from investors to maximize profits, and internal compensation practices that encourage employees to increase sales at any cost. This Article has made a number of suggestions to encourage pharmaceutical companies to behave more responsibly.[454] First, the FDA must be given sufficient authority and resources to tighten up the drug approval process and provide better oversight over the marketing and promotion of prescription drugs and

448. Warin & Schwartz, *supra* note 446, at 86.

449. Emma M. Lloyd, *"Greening" the Supply Chain: Why Corporate Leaders Make It Matter*, 27 J. Land Use & Envtl. L. 31, 55–64 (2011).

450. Erika C. Collins, *Global Diversity Initiatives*, 46 Int'l Law. 987, 989–96 (2012) (discussing gender-based anti-discrimination measures in various countries).

451. Margaret Ryznar & Karen E. Woody, *A Framework on Mandating Versus Incentivizing Corporate Social Responsibility*, 98 Marq. L. Rev. 1667, 1674 (2015).

452. McCarthy, *supra* note 5, at 443.

453. *See supra* Part III.

454. *See supra* Part V.

medical devices. Second, penalties should be increased to the point where the consequences of criminal convictions can no longer be treated as a cost of doing business. Third, civil litigation may also act as a deterrent, particularly when individual cases are consolidated in class actions or multidistrict litigation. Fourth, in rare cases, state and local governments might be allowed to sue drug companies when their products create a public nuisance. Finally, public opinion and pressure from shareholders, along with corporate compliance agreements, might encourage a more socially responsible corporate culture.