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## The Pharma Barons: Corporate Law's Dangerous New Race to the Bottom in the Pharmaceutical Industry

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# THE PHARMA BARONS: CORPORATE LAW’S DANGEROUS NEW RACE TO THE BOTTOM IN THE PHARMACEUTICAL INDUSTRY

*Eugene McCarthy* \*

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## INTRODUCTION

Martin Skhreli, the “Pharma Bro” and former CEO of Turing Pharmaceuticals, outraged the American public when he raised the price of Daraprim—an HIV drug with no alternative treatment—from \$13 to \$750 per pill.<sup>1</sup> Lost in the outrage over Skhreli’s conduct is the fact that he was a small-time operator in an industry that exhibits far more egregious examples of dangerous and socially irresponsible behavior. The pharmaceutical industry is the most profitable in the world because drug company executives persuade Americans to consume huge quantities of prescription drugs that they do not need.<sup>2</sup> The average American

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1. Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sep. 20, 2015), <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

2. See Liyan Chen, *The Most Profitable Industries in 2016*, FORBES (Dec. 21, 2015, 4:19 PM), <https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#6e3fc99c5716>; see also Rolando Y. Wee, *Biggest Pharmaceutical Markets in the World by Country*, WORLDATLAS, <https://www.worldatlas.com/articles/countries-with-the-biggest-global->

takes 13 distinct prescription drugs a year;<sup>3</sup> yet, since the 1970s, American life expectancies have fallen well behind those in other developed nations.<sup>4</sup> Our use, overuse, and misuse of prescription drugs contribute to this alarming trend. Prescription drug overdoses are the leading cause of accidental death in the United States.<sup>5</sup> Adverse reactions to pharmaceutical drugs are the fourth leading cause of American hospital deaths.<sup>6</sup> The prescription opioid crisis kills 50 Americans *every day* while producing \$55 billion in annual social costs.<sup>7</sup> It is revealing that prescription drugs designed to treat the adverse side effects of other *prescription drugs* are among the fastest growing pharmaceutical markets.<sup>8</sup> Indeed, many of the drugs that doctors prescribe do little if anything to improve public health and are both dangerous and ineffective.<sup>9</sup> Prescription drugs exist to generate corporate revenue. As a leading industry observer puts it, “we are quite literally taking pills to save the lives of companies who have a greater interest in the vitality of the diseases they market than in our well-being.”<sup>10</sup> Paradoxically, our prescription medicines are making us sick.

In this Article, I argue that drug companies have created a highly profitable but dangerous business model by employing the same legal tactics as the nineteenth-century “robber barons,” the group of financiers who orchestrated corporate law’s infamous race to the bottom. Like these historical financiers, drug company executives have captured the legal apparatus and regulatory bodies that oversee them. In so doing, they have transformed the law from a system of governance into a set of enabling doctrines. The pharmaceutical industry has turned legislation intended to protect the public into a legal justification for marketing ineffective and unsafe prescription drugs. Like the nineteenth-century robber barons who transformed American corporate law into a tool for maximizing wealth and limiting liability, modern-day “pharma barons” have corrupted

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pharmaceutical-markets-in-the-world.html (stating that the pharmaceutical industry is a major sector in the world economy) (last updated Apr. 25, 2017).

3. JOSEPH DUMIT, *DRUGS FOR LIFE: HOW PHARMACEUTICAL COMPANIES DEFINE OUR HEALTH* 2 (2012).

4. DAVID HEALY, *PHARMAGEDDON* 6 (2012).

5. Robert Parker Tricarico, *A Nation in the Throes of Addiction: Why a National Prescription Drug Monitoring Program is Needed Before it is Too Late*, 37 WHITTIER L. REV. 117, 123 (2015).

6. Donald W. Light et al., *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*, 41 J.L., MED. & ETHICS 590, 593 (2013).

7. Howard G. Birnbaum, et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 PAIN MED. 657, 657 (2011); Corey S. Davis & Derek H. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 IND. HEALTH L. REV. 1, 9 (2017).

8. DUMIT, *supra* note 3, at 85.

9. Paul Jorgensen, *Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda*, 14 J.L. MED. & ETHICS 561, 562 (2013).

10. HEALY, *supra* note 4, at 10.

the laws that govern the pharmaceutical industry. The law now operates in the service of the pharma barons and allows them to profit at the public's expense.

This Article has three key components. First, it examines corporate law's notorious nineteenth-century race to the bottom. The race to the bottom is the phenomenon through which financiers like Jay Gould, Andrew Carnegie, and J.P. Morgan encouraged states to offer increasingly lax corporate laws in exchange for new revenue streams. In this race, many states (*e.g.*, New Jersey and Delaware) revised their corporate codes in order to *enable* corporations rather than *police* them. These legal changes produced great corporate wealth but little, if any, liability for corporate malfeasance.

Second, the Article turns to the pharmaceutical industry and demonstrates that several factors have produced a contemporary race to the bottom in the prescription drug industry. Drug companies have transformed government-mandated clinical trials meant to prove a drug's safety and efficacy into a system of "evidence-based medicine" aimed at deceiving both doctors and the public. The drug companies employ biased clinical trials and ghostwritten medical journal articles to create a dangerous illusion of safe and effective pharmaceutical drugs. These rigged clinical trials—coupled with the recent deregulation of prescription drug advertising—enable drug companies to market misleading "evidence" about their prescription drugs. Companies market these drugs through controversial (and singular to the United States) direct-to-consumer advertising campaigns to drum up awareness of previously unrecognized symptoms and diseases. Legal deregulation also permits drug companies to engage in private, in-person "detailing" of doctors in an effort to persuade them to prescribe drugs to patients for untested and unapproved uses that often prove detrimental—and deadly. The pharmaceutical industry lobby, the nation's most powerful over the last two decades, ensures that this new race to the bottom proceeds unimpeded.

Finally, the argument concludes with an examination of the pharma barons who developed and marketed the prescription drugs Vioxx, Paxil, and OxyContin. Collectively, the adverse side effects of these three drugs have resulted in the *hundreds of thousands* of American deaths.<sup>11</sup> The drug company executives who fraudulently marketed these deadly drugs have faced little, if any, criminal liability for their actions. Indeed, they have become extremely wealthy just as Gould, Carnegie, and Morgan did a century before them. While corporate law's original race to the bottom had beneficial outcomes that included innovative financial instruments and new and efficient economies of scale, the same cannot be said for the contemporary race to the bottom.<sup>12</sup> Legal changes in the pharmaceutical industry have stunted scientific research and innovation while endangering American public health.

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11. Davis & Carr, *supra* note 7, at 9.

12. See generally ALFRED D. CHANDLER, JR., *THE VISIBLE HAND: THE MANAGERIAL REVOLUTION IN AMERICAN BUSINESS* (1977).

## I. THE RACE TO THE BOTTOM AND THE RISE OF THE ROBBER BARONS

The late nineteenth century saw the rise of larger-than-life financiers who aggregated then-unheard-of levels of wealth, often at the expense of the general public. This era, defined in part by its opulence and disparity in wealth between the social elite and the rest of the population, spawned a new kind of business person. Jay Gould, the crafty railroad and telegraph tycoon, accumulated the equivalent of \$58.2 billion in today's currency.<sup>13</sup> Andrew Carnegie, the steel magnate, amassed the equivalent of \$281 billion.<sup>14</sup> J.P. Morgan, the first modern investment banker, earned a relatively modest \$1.2 billion, but did so by manipulating the entire United States economy for the sake of his powerful clients.<sup>15</sup> These ruthless financiers, whom historians dub the "robber barons," achieved this level of wealth (and, we will see, legal impunity for their actions) in large part due to corporate law's so-called race to the bottom.

This section maps corporate law's race to the bottom, whereby the law shifted from constraining corporate actors to enabling their pursuit of wealth by easing and sometimes even erasing corporate regulations. These enabling laws fall into two categories: (1) affirmative legislation that paved the way for greater corporate freedoms and (2) regulations that appeared to constrain corporate actions but ultimately came to serve corporate interests. The race to the bottom is the byproduct of several U.S. states competing with one another and "racing" to attract corporate revenue by offering attractive corporate laws within their jurisdictions. The robber barons and industry leaders catalyzed the race to the bottom and blurred the lines between government and industry, or through what J. Willard Hurst calls the phenomenon of legal "default and drift"—that is, the purposeful imbrication of government and industry concentrated unprecedented public policy decision making in private hands.<sup>16</sup> As a result, public policy came to serve private interests.

A. *Revising the Corporate Codes*

In its earliest days, American corporate law looked like its conservative English ancestor: incorporation was a rare and special privilege that the legislature granted, and the corporation was a "creature of the state," bound by strin-

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13. *The All-Time Richest Americans*, FORBES (Sept. 14, 2007, 3:00PM), [https://www.forbes.com/2007/09/14/richest-americans-alltime-biz\\_cx\\_pw\\_as\\_0914ialltime\\_slide/#afac02139846](https://www.forbes.com/2007/09/14/richest-americans-alltime-biz_cx_pw_as_0914ialltime_slide/#afac02139846).

14. *Id.*

15. Chase Peterson-Withorn, *From Rockefeller to Ford, See Forbes' 1918 Ranking of The Richest People In America*, FORBES (Sept. 28, 2017, 8:03 AM), <https://www.forbes.com/sites/chasewithorn/2017/09/19/the-first-forbes-list-see-who-the-richest-americans-were-in-1918/#5f9de1ab4c0d>.

16. JAMES WILLARD HURST, LAW AND THE CONDITIONS OF FREEDOM IN THE NINETEENTH-CENTURY UNITED STATES 78 (1956).

gent legal requirements enunciated in its corporate charter.<sup>17</sup> These initial corporate charters (the legal documents that bring a corporation into existence and define its capacities) established a number of mandatory rules for the corporation and drastically restricted corporate powers.<sup>18</sup> For instance, most pre-Civil War corporate charters limited the type of business in which a corporation could engage.<sup>19</sup> Any *ultra vires* corporate actions (those exceeding the powers granted in the charter) would be void.<sup>20</sup> The *ultra vires* doctrine not only limited what a corporation could do, but also dictated what kind (and what amount) of property it could own in conducting its business.<sup>21</sup> These charters likewise restricted the corporation's size, life span, financial resources, territorial boundaries, and held shareholders to "double liability," meaning they had to pay twice their investment amount upon corporate liquidation or dissolution.<sup>22</sup> Early American corporate law also expressly denied one corporation the right to own shares in another corporation, preventing the creation of corporate subsidiaries and holding companies.<sup>23</sup> In short, corporations were relatively small business operations subject to strict government regulation.

This would all change when corporate law initiated its infamous race to the bottom and began to enable rather than regulate corporate action. The historical starting line for the race to the bottom is debatable, but a reasonable hypothesis marks its beginning at the Civil War and the subsequent ascendance of the Republican Party's pro-industrial political platform.<sup>24</sup> Civil War financing generated the first investment bankers and a public market for securities (the trading of government war bonds), two of the driving forces behind corporate law's early evolution.<sup>25</sup> After the war, the nation continued to expand westward at a rap-

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17. See P.M. Vasudev, *Corporate Law and its Efficiency: A Review of History*, 50 AM. J. LEGAL HIST. 237, 246–47 (2010).

18. *Id.*

19. STEPHEN A. BAINBRIDGE, *CORPORATION LAW* 30 (2d ed. 2015).

20. Clyde L. Colson, *The Doctrine of Ultra Vires in United States Supreme Court Decisions*, 42 W. VA. L.Q. 179, 184–89 (1936).

21. 1889 N.J. Laws 414. These changes in New Jersey corporate law indicate that the type of property that a corporation could own and use was very much at the core of delineated corporate capacities in the late nineteenth century.

22. Vasudev, *supra* note 17, at 246.

23. JAMES WILLARD HURST, *THE LEGITIMACY OF THE BUSINESS CORPORATION IN THE LAW OF THE UNITED STATES: 1780–1970* 69 (1970).

24. See 2 CHARLES A. & MARY R. BEARD, *THE RISE OF AMERICAN CIVILIZATION* 52 (1927) (describing the Civil War as the "Second American Revolution," that ended in the capitalist co-opting of the political system); see also HURST, *supra* note 23, at 140; MATTHEW JOSEPHSON, *THE ROBBER BARONS* 51 (1932) (noting that Lincoln, whether he realized it or not, "hastened miraculously a transfer of power to the emergent groups of large-scale capitalism"); CHARLES R. MORRIS, *THE TYCOONS: HOW ANDREW CARNEGIE, JOHN D. ROCKEFELLER, JAY GOULD, AND J.P. MORGAN INVENTED THE AMERICAN SUPERECONOMY* 10 (2005) (noting that "[o]nce in office, and freed from Southern obstructionism after the attack on Fort Sumter, Lincoln and his Republican majority unleashed a blitz of predevelopment legislation without parallel in American History.").

25. RICHARD WHITE, *RAILROADED: THE TRANSCONTINENTALS AND THE MAKING OF MODERN AMERICA* 11 (2011).

id rate, and the corporation emerged as the primary “instrument for mustering and disciplining large amounts of capital and allowing dependable continuity for its use.”<sup>26</sup> The corporation’s ability to accumulate private capital through shareholder investment and then to use that capital to perform quasi-public functions (*e.g.*, build a transcontinental railroad, provide a city with water, etc.) enticed the government to sweeten the deal for incorporators from both a legal and financial perspective.<sup>27</sup> Federal and state governments granted corporations great leeway because they were doing the government’s job for it.<sup>28</sup> The government evaluated corporate utility so highly that it warranted the use of law to give “businessmen a free hand in adapting the corporate instrument to their own will” and determined that the function of corporate law was to “enable businessmen to act, not police their action.”<sup>29</sup> In the blink of an eye, the race to the bottom was off and running.

States subsequently began to eliminate restrictions on corporations in their respective corporate codes.<sup>30</sup> These states sought revenue from in-state corporations while business promoters sought jurisdictions with less stringent corporate restrictions.<sup>31</sup> This alignment of interests produced symbiotic combinations of state legislatures and corporate lawyers who worked together to re-draft more lenient and attractive corporate laws.<sup>32</sup> The next big surge in the race to the bottom occurred when New Jersey—the “Mother of Corporations” or, alternatively, the “Traitor State”—decided to openly court corporations in order to maximize this newfound revenue-generating potential.<sup>33</sup> In 1875, New Jersey amended its constitution to abolish legislatively granted special corporate charters, ushering in an era of so-called “general incorporation.”<sup>34</sup> Under the special charter system, state legislatures issued a sparing number of charters to incorporators based on a system of political patronage.<sup>35</sup> In order to generate a larger stream of corporate revenue, New Jersey’s law of general incorporation allowed anybody to incorporate in the state of New Jersey so long as they filed an incorporation fee, obeyed simple corporate formalities, and—most importantly—paid

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26. HURST, *supra* note 23, at 34.

27. *See id.* at 62.

28. *See* HURST, *supra* note 16, at 65.

29. *Id.* at 13, 71.

30. *See* BAINBRIDGE, *supra* note 19, at 30.

31. *See* William L. Cary, *Federalism and Corporate Law: Reflections upon Delaware*, 83 YALE L.J. 663, 664 (1974).

32. Morton J. Horwitz, *Santa Clara Revisited: The Development of Corporate Theory*, 88 W. VA. L. REV. 173, 194 (1985).

33. Charles M. Yablon, *The Historical Race Competition for Corporate Charters and the Rise and Decline of New Jersey: 1880–1910*, 32 IOWA J. CORP. L. 323, 337 (2007).

34. *Id.* at 331.

35. *Id.* at 332.

an annual franchise tax to the state.<sup>36</sup> Businesses flocked to New Jersey, and the state quickly became the most popular venue for legal incorporation.<sup>37</sup>

New Jersey emerged as the most attractive state for corporations because a small group of corporate lawyers effectively wrote the state's corporate statutes to serve the needs of their clients.<sup>38</sup> The goal was to create as much legal protection and economic opportunity as possible for corporate executives and directors. Corporate lawyers from the industry subject to proposed regulation drafted the legislative bills ostensibly aimed at curbing their corporate powers.<sup>39</sup> After the 1875 move to general incorporation, New Jersey continued its methodical program of loosening corporate law restrictions. In 1889, the legislature passed a statute that allowed one corporation to purchase and own stock in another corporation, even if that corporation was incorporated in a state other than New Jersey.<sup>40</sup> This law allowed one corporation to act as a massive holding company with a corporate structure that included various subsidiary corporations on a nationwide scale. It also allowed a corporation to purchase another corporation's assets and to use its own stock, to which it could assign any value, as consideration for the asset purchase.<sup>41</sup> This wrinkle enabled "cash-strapped promoters" to purchase another corporation's valuable assets with what might ultimately amount to worthless stock (the risk was on the seller of the assets, who believed—with good reason and from practical experience—that the stock would one day be as valuable as advertised when the holding company was finally reorganized and began oligarchical price fixing within its industry).<sup>42</sup>

New Jersey again revised its laws in 1896 to eliminate the *ultra vires* doctrine and to remove limitations on a corporation's size, lifespan, and business activities.<sup>43</sup> Single corporate entities like Standard Oil could now grow to dominate an entire industry, which only increased their wealth and political clout. The 1896 Act also allowed New Jersey corporations to issue different classes of stock with varying powers and shareholder voting rights.<sup>44</sup> This new power enabled corporations to issue non-voting stock, whose primary purpose was to function as an asset to be traded on a capital exchange market, thus encouraging investment for purely speculative purposes. Shareholders became speculators; as speculators, these shareholding "owners" of the corporation became geographically scattered and largely disinterested in the corporation's day-to-day

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36. *Id.* at 330.

37. *Id.* at 327.

38. *Id.* at 336; *see also* Horwitz, *supra* note 32, at 194.

39. GABRIEL KOLKO, RAILROADS AND REGULATION: 1877–1916 95 (1965).

40. 1889 N.J. Laws 414.

41. Yablon, *supra* note 33, at 341.

42. *Id.* at 343.

43. 1896 N.J. Laws 279–80.

44. Yablon, *supra* note 33, at 352.



business operations.<sup>45</sup> If the stock price rose (no matter the reason), they were content. This left those in control of the corporation—corporate managers and directors—in a position to use the corporation for self-dealing and self-enrichment so long as they could inflate the stock price, whether through legitimate or artificial means.<sup>46</sup>

Because corporate managers decided where to incorporate, New Jersey and other states that participated in the race to the bottom (in particular, Wyoming, Maine, West Virginia, and Delaware) tailored laws to suit management interests rather than shareholder interests.<sup>47</sup> In the event that shareholders sought to discipline or punish the corporation or its officers and directors, they found it difficult to pierce the corporate veil to reach key investors, individual directors, or the financiers acting through the corporate body. In 1891, the Supreme Court reinforced these increasingly permissive state corporate laws when it validated the doctrine known as the business judgment rule.<sup>48</sup> According to the business judgment rule, directors (at that time, usually composed of the promoting financiers and their intimates) were not liable for mistakes of judgment with regard to corporate actions, even if they were “so gross as to appear to us absurd and ridiculous.”<sup>49</sup> As a result, directors and executives could justify all sorts of self-serving decisions by couching them as mere mistakes in “business judgment.”

These deregulations allowed corporate agents to be the buyer and seller in the same corporate transaction, fleecing both corporations while personally enriching themselves as a third-party beneficiary.<sup>50</sup> Likewise, late-nineteenth century corporate law did not prohibit insider trading (trading in securities while in possession of material nonpublic information).<sup>51</sup> Financiers used “bear” tactics such as rumors of new competition or decreased dividends to drive stock prices down in order to purchase large blocks of stock. They would follow with “bull” tactics (rumors of large dividends or new acquisitions) to quickly elevate the stock price so that they might sell to the public at enormous personal profit.<sup>52</sup> This cycle of buying and selling stock at prices that the financier manipulated was potentially endless. The corporate laws permitted other low-risk and high-reward financial maneuvers, as well. Financiers and their corporations could issue corporate bonds to the public to finance some large enterprise (*e.g.*, build-

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45. ADOLF A. BERLE & GARDINER C. MEANS, *THE MODERN CORPORATION AND PRIVATE PROPERTY* 251 (1932).

46. *Id.* Berle and Means were, famously, among the first to identify this “agency problem” with regard to the emerging separation of corporate ownership and control.

47. *See generally*, Lucian Bebchuk, *Federalism and the Corporation: The Desirable Limits on State Competition in Corporate Law*, 105 HARV. L. REV. 1443 (1992).

48. *Briggs v. Spaulding*, 141 U.S. 132, 165–66 (1891).

49. *Spring’s Appeal*, 71 Pa. 11, 24 (1872).

50. WHITE, *supra* note 25, at 199.

51. The federal prohibition arose in *Strong v. Repide* 213 U.S. 419 (1909); *see also* STEPHEN A. BAINBRIDGE, *CORPORATION LAW AND ECONOMICS* 519–24 (2002).

52. *See* MAURY KLEIN, *THE LIFE AND LEGEND OF JAY GOULD* 96 (1986).

ing a bridge, a railroad, etc.).<sup>53</sup> They would then loot the capital raised through these bonds by using a construction or service corporation that they also controlled.<sup>54</sup> Indeed, in many cases the primary corporate enterprise was created simply so financiers could plunder that corporation's publicly raised capital via subsidiary service and construction corporations.<sup>55</sup>

The race to bottom even turned legislation that was meant to curtail corporations into tools that increased corporate power. Take, for instance, the *Sherman Antitrust Act of 1890*.<sup>56</sup> The Sherman Act was designed to prevent monopolistic business trusts by making illegal "every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States or with foreign nations."<sup>57</sup> Federal judges unabashedly turned this piece of antimonopoly legislation against the very organizations it was designed to protect—labor unions. In the first seven years of the *Sherman Act*, federal courts found thirteen antitrust violations, *twelve* of which involved labor union "conspiracies" in restraint of trade.<sup>58</sup> In other words, when labor organizations rose up against corporate monopolies, the government turned antimonopoly legislation against the labor unions to help reinforce the very corporate monopolies the *Sherman Act* was meant to eliminate. The race to the bottom subverted all meaningful attempts to regulate nineteenth-century corporations and transformed corporate law into a tool that aided and abetted corporate actors.

#### B. *The Emergence of Nineteenth-Century Lobbying*

This race to the bottom was made possible by a blurring of the line between industry and government. This occurred in two forms: through lobbying of state and federal legislatures and the emergence of a revolving door between the public and private sectors. James Willard Hurst observes that one of the most impactful legal changes to occur in the nineteenth century was the emergent power of special interest groups—or lobbies.<sup>59</sup> Indeed, legal historians have noted that the emergence of lobbying in nineteenth-century America transformed politics into "a realm of economic competition between corporations," whereby lobbyists who were often "ex-politicians, helped to move legislation and thus avoid gridlock, but at a price."<sup>60</sup> In one such instance of lobbying for favorable legislation, Oakes Ames—a member of Congress *and* an officer of the Union Pacific

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53. MORRIS, *supra* note 24, at 92–93.

54. *Id.*

55. *Id.* at 92.

56. Sherman Act, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1–7 (2004)).

57. *Id.* at § 1.

58. Herbert Hovenkamp, *Labor Conspiracies in American Law, 1880–1930*, 66 TEX. L. REV. 919, 950 (1988).

59. See HURST, *supra* note 16, at 101.

60. WHITE, *supra* note 25, at 103.

Railroad—distributed stock related to his railroad interests to other members of Congress. The result was congressmen receiving stock in “a corporation they had chartered, one they had to supervise, and which repeatedly came before them for legislation.”<sup>61</sup> It is no wonder recipients of the stock payments routinely favored railroad interests in their legislative efforts. Collis Huntington of the Central Pacific Railroad once lamented that he would have to pay \$200,000 to get a particular bill passed through Congress—a price he felt was too steep given his previous payouts.<sup>62</sup> And this was a small sum, all things considered. A railway commission investigation regarding \$5 million of unaccounted-for money on the books of the Central Pacific Railroad determined “there is no room for doubt that a large portion of this money was used for the purposes of influencing legislation and of preventing the passage of measures deemed to be hostile to the interests of the company, and for the purpose of influencing elections.”<sup>63</sup> Lobbying—or outright bribery—played a large part in securing legislation (and legislatures) that contributed to corporate law’s race to the bottom.

A revolving door between the government and private industry also facilitated corporate law’s deregulatory decline. During the race to the bottom, an individual could have a job in private industry while also holding public office. The muckraker David Graham Phillips demonstrates this fact through the example of U.S. Senator Chauncey Depew.<sup>64</sup> During his tenure as a senator, Depew, in addition to serving as a director on over 70 corporate boards, represented the New York Central Railroad corporation as its general counsel.<sup>65</sup> Such conflicts of interest were commonplace throughout the government. While serving as U.S. Attorney General, Richard Olney also worked as counsel for the Burlington railroad and repeatedly used his political position to secure government injunctions to prevent railroad strikes that were adverse to his private interests.<sup>66</sup> On the advice of railroad corporation attorneys, Attorney General Olney persuaded President Cleveland to send federal troops—over the governor of Illinois’ loud objections—to break the Pullman Strike, which was endangering corporate railroad revenues.<sup>67</sup> Senator John Spooner of Wisconsin wrote and passed legislation on March 12, 1886, that granted major land interests to the Chicago, St. Paul, Minneapolis and Omaha Railroad corporation in his home state.<sup>68</sup> On March 16, 1886, he represented the same railroad as its lawyer before the Supreme Court and successfully defended the railroad’s land acquisition, which he had just orchestrated as Senator.<sup>69</sup> Historian Gabriel Kolko notes

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61. *Id.* at 65.

62. *See* JOSEPHSON, *supra* note 24, at 84.

63. WHITE, *supra* note 25, at 129–30.

64. DAVID GRAHAM PHILLIPS, *THE TREASON OF THE SENATE* 64–75 (1964).

65. *Id.* at 63.

66. WHITE, *supra* note 25, at 385.

67. *Id.* at 442.

68. PHILLIPS, *supra* note 64, at 119.

69. *Id.*

that “more likely than not, the average railroad president in the 1870s had a background in politics—over half held some political job before or during their careers as railroad presidents.”<sup>70</sup> These blurred boundaries between the public and private sectors negated the government’s regulatory capacity to curtail the power and interests of wealthy financiers and their corporate interests.

### C. *The Robber Barons*

Three financier “robber barons” help shed light on the type of corporate transactions that the race to the bottom made possible: Jay Gould, Andrew Carnegie, and J.P. Morgan. These three businessmen used corporate law as both a sword and a shield in amassing great fortune. They exploited intercorporate stock ownership—looting corporations via self-dealing service contracts—and industry-side collusion through interlocking directorates that the race to the bottom made possible. They each engaged in illegal and antisocial behavior that harmed the public but faced no criminal liability for their actions.

Jay Gould used the stealth and guile that New Jersey’s corporate code revisions made possible in amassing his fortune. A contemporary of Gould described him as “the worst man on earth since the beginning of the Christian era. He is treacherous, false, cowardly, and a despicable worm incapable of a generous nature.”<sup>71</sup> Recent biographies suggest that Gould, also known as the Mephistopheles of Wall Street, probably was not *quite* as bad as his contemporaries suggested, but he was certainly a crafty man. Gould mastered the financial world by cultivating “the art of controlling huge enterprises with minimal holdings, utilizing not only equity control but funded debt, the proxy market, floating debt, contractual flaws, receiverships, and especially *legal technicalities*.”<sup>72</sup> In his earliest ventures as a surveyor and tannery manager, he sought to explore opportunities and engage in behavior that quickly taught his business partners that he had no intention of conforming to traditional business norms. In one instance, Gould armed his employees and had them take over a tannery from which one of his business partners attempted to exclude him.<sup>73</sup> In other instances, he openly bribed legislators, bought judges, betrayed business partners, and in the case of the Erie Wars, actually “stole” the Erie Railway Company (well, its stocks and ledgers) and rushed it across the state border from New York to New Jersey to evade arrest.<sup>74</sup> His escape to New Jersey was successful, and all criminal charges were eventually dismissed after Gould reincorporated in the “Traitor State” and made the proper “political contributions” back in Albany.<sup>75</sup> When faced with the threat of state or financial discipline, Gould’s response

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70. KOLKO, *supra* note 39, at 15.

71. KLEIN, *supra* note 52, at 3.

72. *Id.* at 66 (emphasis added).

73. *Id.* at 59.

74. *Id.* at 83 (describing the situation as “the novel spectacle of a corporation in exile”).

75. *Id.* at 84.

was inevitably “ingenious, strikingly original, unexpected, technically legal, and ethically dubious.”<sup>76</sup> One might well apply these same five descriptors to the race to the bottom more generally.

Two of Gould’s related financial transactions demonstrate his business ingenuity. In 1874, Gould controlled the Union Pacific Railroad corporation.<sup>77</sup> Due to his insider position, he knew that the corporation would soon have to redeem government bonds at great expense to the corporate treasury, which would depress the stock price.<sup>78</sup> As such, he quietly sold most of his interest in the corporation and used the profits to buy into other railroad companies.<sup>79</sup> He secretly began buying smaller, regional railroad corporations such as the Kansas Pacific, Missouri Pacific, and the Wabash.<sup>80</sup> He scattered his stock ownership across a wide field to veil his intentions.<sup>81</sup> His holdings “were too diverse and sprawling for anyone to know where the heart of his system lay.”<sup>82</sup> At the same time, using several newspapers he owned, Gould attacked out of nowhere Western Union’s monopoly over the telegraph industry.<sup>83</sup> As public sentiment against Western Union grew, its stock price fell.<sup>84</sup> Gould began purchasing Western Union stock as he facilitated a bear market for its shares.<sup>85</sup> He also took control of a defunct telegraph corporation, the Atlantic & Pacific, and reincorporated it as the American Union.<sup>86</sup> He then illegally interfered with Western Union’s contracts to arrange contracts between his new regional railroads and the recently acquired American Union telegraph corporation—and got away with it.<sup>87</sup>

Gould subsequently stepped down from the Union Pacific board of directors and threatened to combine his regional railroads into a national system to compete directly with Union Pacific.<sup>88</sup> Facing “ruinous competition” from Gould’s new railroad network, Union Pacific was compelled to buy Gould’s railroad system for \$6.7 million.<sup>89</sup> Meanwhile, Western Union faced “ruinous” competition from Gould’s American Union telegraph corporation.<sup>90</sup> Western Union proposed a merger with American Union, and upon the merger Gould became

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76. *Id.* at 330.

77. MORRIS, *supra* note 24, at 136.

78. *Id.* at 138.

79. *Id.* at 144.

80. *Id.* at 142–44.

81. *Id.* at 143.

82. KLEIN, *supra* note 52, at 249.

83. MORRIS, *supra* note 24, at 146.

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. KLEIN, *supra* note 52, at 245.

89. *Id.*

90. MORRIS, *supra* note 24, at 146.

the majority shareholder of the Western Union corporation. He immediately entered into a lucrative contract on behalf of Western Union with Union Pacific to provide telegraph services. Essentially, Gould shifted from ownership and control of Union Pacific to ownership and control of Western Union, using different corporate bodies and underhanded tactics to make the shift possible and to extract huge sums of capital from both entities along the way. His secretive tactics “enabled him to roam freely, a dealer in the unexpected. It was impossible for others to know what he actually controlled, let alone discover his intentions. He was the consummate one-eyed jack, an enigma, a phantasmagoria.”<sup>91</sup> All the while he illegally invalidated contracts, used corporate attorneys to issue and cancel injunctions, and orchestrated judicial rulings that perfectly met his needs. For these reasons, to his rivals, “Gould would remain an image spread to infinity across a hall of mirrors.”<sup>92</sup> These enigmatic business powers arose from the deregulation of business and the new corporate laws that encouraged such financial gambits. The stock-for-asset purchases and the new corporate structures that the race to the bottom produced enabled Gould to “spread himself to infinity” through various industries.

Andrew Carnegie used fewer moving pieces than Gould in amassing his fortune. Instead, he operated as an obstinate, self-interested, and monolithic figure in a single field: the steel industry. He succeeded by hedging his investments and ensuring that his enterprise took on as little risk as possible through legally sanctioned corporate looting and self-dealing. Carnegie was always looking for a way to climb the corporate ladder, starting as a telegraph operator at the Pennsylvania Railroad corporation and ending as the owner of the monolithic Carnegie Steel Company, which he sold in 1901 for nearly \$500 million.<sup>93</sup> He entered into countless enterprises with a small financial stake, “bouncing from flower to flower,” until he saw a “good opportunity to scale up—reorganizing, reenergizing, and recapitalizing—almost always emerging as the lead shareholder.”<sup>94</sup> One of his earlier deals, the St. Louis Bridge project, is illustrative of his financial self-dealing and business acumen. He financed the operation by issuing bonds through the St. Louis Bridge Company (which he owned) and selling those bonds to the public.<sup>95</sup> The Keystone Bridge Company, which Carnegie also owned, carried out the construction on behalf of the St. Louis Bridge Company.<sup>96</sup> The St. Louis Bridge Company paid Keystone with the funds it generated from selling its bonds to the public.<sup>97</sup> The Keystone Bridge Company purchased its supplies from the Union Iron Mills, which Car-

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91. *Id.* at 254.

92. *Id.* at 421.

93. RON CHERNOW, *THE HOUSE OF MORGAN: AN AMERICAN BANKING DYNASTY AND THE RISE OF MODERN FINANCE* 84 (1990).

94. MORRIS, *supra* note 24, at 91–92.

95. *Id.* at 92.

96. *Id.* at 93.

97. *Id.*

negie, likewise, owned.<sup>98</sup> For good measure, the St. Louis Bridge Company employed the one and only Andrew Carnegie, at a huge fee, as its investment banker to place its bonds and sell them to investors.<sup>99</sup> The bridge opened in 1874 and the St. Louis Bridge Company quickly settled its accounts with Keystone (*i.e.*, Carnegie), Union Iron Mills (*i.e.*, Carnegie), and with Carnegie as investment banker.<sup>100</sup> The bridge company went bankrupt within the year, leaving the bondholders high and dry, but leaving Carnegie with a small fortune from the various construction and financial services he supplied (Jay Gould, incidentally, purchased the bridge for a song and used it as leverage in his Union Pacific transactions).<sup>101</sup>

Carnegie justified his dubious business dealings, quite simply, by “lying—egregiously, consistently, and continually.”<sup>102</sup> Indeed, his biographers suggest that he was one of the most prolific liars in American history. This same immoral mendacity accompanied Carnegie’s war profiteering, where he escaped legal punishment for Carnegie Steel’s supplying faulty steel plates to the U.S. Navy. A government investigation substantiated one of his disgruntled employee’s claims that Carnegie knowingly supplied faulty steel armor and falsified the results of ballistic tests to the government, but the investigation could not determine precisely *who* within the corporation had lied or plugged holes in the armor plates.<sup>103</sup> The government imposed a fine on the *corporation* (not Carnegie individually), in the amount of \$150,000—or ten percent of the transaction cost.<sup>104</sup> Carnegie retained his lucrative government contracts to supply steel to the navy after the investigation, notwithstanding the scandal.

J.P. Morgan did not have to hustle as much as either Gould or Carnegie to attain the status of robber baron. Morgan’s father, Junius Spencer Morgan, was one of the nation’s leading bankers and established Morgan in the family business. Morgan acted as banker and fiscal agent for the leading corporations in most major American industries, and he held large blocks of stock in the corporations he represented.<sup>105</sup> He exercised “direct, secret authority” over these corporations by strategically influencing each of the companies’ boards of directors.<sup>106</sup> A congressional investigation later revealed that Morgan’s infamous system of “interlocking directorates” held 341 directorships in 112 separate corporations.<sup>107</sup> These interlocking directorates allowed Morgan to engage in

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98. *Id.*

99. *Id.* at 93.

100. *Id.* at 93–94.

101. *Id.* at 94.

102. *Id.* at 16.

103. *See* JOSEPHSON, *supra* note 24, at 391–92.

104. *Id.*

105. *Id.* at 313.

106. *Id.*

107. DAVID A. ZIMMERMAN, PANIC! MARKETS, CRISES, & CROWDS IN AMERICAN FICTION 154 (2006).

unprecedented self-dealing between corporations and to exert undue influence over the economy more generally. Louis Brandeis described Morgan's vast economic influence in the following terms:

J.P. Morgan (or a partner), a director of the New York, New Haven, and Hartford Railroad, causes the company to sell to J.P. Morgan & Co. an issue of bonds. J.P. Morgan & Co. borrow the money with which to pay the bonds from the Guaranty Trust Co., of which Mr. Morgan (or a partner) is a director. J.P. Morgan & Co. sell the bonds to the Penn Mutual Life Insurance Company of which Mr. Morgan (or a partner) is a director. The New Haven spends the proceeds of the bonds in purchasing steel rails from the United States Steel Corporation, of which Mr. Morgan (or a partner) is a director. The United States Steel Company spends the proceeds of the rails in purchasing electrical supplies from the General Electric Company, of which Mr. Morgan (or a partner) is a director[.]<sup>108</sup>

Morgan controlled the markets to ensure that he and his clients came out ahead in each transaction. At one point, Morgan controlled a third of the nation's railroads and over two thirds of the steel industry through the U.S. Steel corporation (the largest portion of which, incidentally, he purchased from Andrew Carnegie).<sup>109</sup> In addition to an incident of war profiteering in which he knowingly financed the sale of defective weapons to American troops, Morgan remained committed to influencing legislation (via bribery) to amend state corporate laws to serve his own interests.<sup>110</sup>

Morgan's primary and oft-repeated goal was to end "ruinous competition" by creating large corporate trusts to engage in price fixing and market control within each major industry.<sup>111</sup> The sheer size of his interlocking directorates made it difficult to know which directors were serving Morgan's interests and which were serving the corporation's interests. This industry-wide (or even nationwide) control was on display during the Panic of 1907, a three-week banking crisis that resulted in the collapse of several banking and trust companies in New York. In the aftermath, credible accusations arose that Morgan helped orchestrate the Panic, enabling him to weed out his bank's competitors and to overcome legal barriers against profitable, but forbidden, corporate mergers.<sup>112</sup> This story probably sounds all-too familiar to students of the 2007 banking crisis. Morgan agreed to help end the Panic on the condition that President Roosevelt promise to refrain from applying the *Sherman Antitrust Act* to Morgan's acquisition of the Tennessee Coal and Iron Company, which he long coveted but which would result in a monopolistic restraint on trade when joined with his U.S. Steel Corporation.<sup>113</sup> Roosevelt agreed to allow the corporate merger and

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108. MORRIS, *supra* note 24, at 269.

109. ZIMMERMAN, *supra* note 107, at 154.

110. See CHERNOW, *supra* note 93, at 370. Morgan's "preferred list" or bribe recipients (in the form of stock sales on a when-issued basis) shows the level of corruption the banker attained and how little he thought of the laws that governed his actions.

111. KOLKO, *supra* note 39, at 65.

112. 42 CONG. REC. 3795-96 (1908).

113. See CHERNOW, *supra* note 93, at 128.



the Panic ended soon thereafter.<sup>114</sup> Morgan purchased Tennessee Coal and Iron during the Panic for \$45 million; financial analysts at the time valued the company at close to \$1 billion.<sup>115</sup>

As this section demonstrates, corporate law's nineteenth-century race to the bottom enabled these robber barons to engage in complex, antisocial, and very profitable behavior free from meaningful regulation and personal liability. New Deal corporate and securities regulations would ultimately slow this race to the bottom in the 1930s but, as the next section demonstrates, a new deregulatory race is currently underway in the contemporary pharmaceutical industry.<sup>116</sup>

## II. THE PHARMACEUTICAL INDUSTRY AND THE NEW RACE TO THE BOTTOM

In 2011, the U.S. government accused Merck Pharmaceutical of intentionally misbranding its pain-relieving drug Vioxx, which had adverse side effects that killed somewhere between 60,000 and 500,000 people via heart attack and stroke.<sup>117</sup> Merck executives were aware of these deadly side effects and concealed them from the FDA.<sup>118</sup> Merck settled the charges by paying a criminal fine and no corporate executives faced criminal charges for their actions.<sup>119</sup> In fact, the CEO who presided over Merck's Vioxx decisions received a final corporate compensation package of \$37.8 million in 2005.<sup>120</sup>

The U.S. government accused Purdue Pharmaceutical of fraud and intentionally misbranding its highly addictive opioid pain reliever OxyContin, which is the primary catalyst of the opioid epidemic and contributes to approximately 50 prescription opioid overdose deaths in the U.S. *every day*.<sup>121</sup> Purdue settled

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114. *Id.*

115. *Id.*

116. GERALD PAUL MCALLIN ET AL., AN INTRODUCTION TO AMERICAN LAW 333–34 (2d ed. 2010).

117. *See* Press Release, U.S. Dep't of Justice, U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx® (Nov. 22, 2011), <https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion> [hereinafter Vioxx Press Release]; Alexander Cockburn, *When Half a Million Americans Died and Nobody Noticed*, THE WEEK (Apr. 27, 2012), <http://www.theweek.co.uk/us/46535/when-half-million-americans-died-and-nobody-noticed>; Matthew Herper, *David Graham On The Vioxx Verdict*, FORBES (Aug. 19, 2005, 6:31 PM), [https://www.forbes.com/2005/08/19/merck-vioxx-graham\\_cx\\_mh\\_0819graham.html#2b3ed9175698](https://www.forbes.com/2005/08/19/merck-vioxx-graham_cx_mh_0819graham.html#2b3ed9175698).

118. Herper, *supra* note 117.

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

120. TOM NESI, POISON PILLS: THE UNTOLD STORY OF THE VIOXX DRUG SCANDAL 255 (2008); *see also* *Executive Pay*, FORBES, <https://www.forbes.com/static/pvp2005/LIRE1B2.html> (last visited Nov. 29, 2018).

121. Davis & Carr, *supra* note 7, at 9.

the criminal charges by paying a series of criminal fines.<sup>122</sup> The family who owns and controls the closely held corporation faced no legal repercussions for the corporation's crimes and continues to reap annual profits of \$700 million from the sale of OxyContin and possesses a familial net worth of \$13 billion.<sup>123</sup>

GlaxoSmithKline paid a \$3 billion criminal fine relating to government charges that it engaged in kickbacks and fraudulently marketed its drug Paxil.<sup>124</sup> This fraud related to the company's effort to convince doctors to prescribe Paxil to treat adolescent depression despite the fact that executives knew Paxil triggered suicides in teenagers.<sup>125</sup> In the same year that GlaxoSmithKline settled these charges with the government, the company paid its CEO the equivalent of \$14 million in executive compensation.<sup>126</sup> As these fact patterns suggest, drug company executives represent the next generation of robber barons akin to Jay Gould, Andrew Carnegie, and J.P. Morgan. The pharma barons reap profits from engaging in socially irresponsible and illegal behavior and face no real liability for their actions.

In this section, I demonstrate that the pharmaceutical industry is in the midst of a new legal race to bottom reminiscent of corporate law's nineteenth-century race toward deregulation. Pharmaceutical executives have coordinated a deregulatory push that has enabled them to increase industry profits at the expense of public safety while avoiding personal criminal liability. This legal race to the bottom has three driving forces. First, the *Kefauver-Harris Amendments of 1962* instituted the modern regime of "evidence based medicine," which requires drug companies to conduct clinical trials to prove a new drug's safety and efficacy.<sup>127</sup> Loopholes in these laws allow drug companies to use biased research and publication methods to create the illusion of safety and efficacy that hides

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122. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 223 (2009). The government did fine three company executives \$5,000 a piece for perpetuating this deadly fraud, but Purdue indemnified them for these and other costs related to criminal charges (*Friedman v. Sebelius*, 755 F. Supp. 2d 98, 102 n.7 (D.D.C. 2010)).

123. Chase Peterson-Withorn, *Fortune of Family Behind OxyContin Drops Amid Declining Prescriptions*, FORBES (June 29, 2016, 9:00 AM), <https://www.forbes.com/sites/chasewithorn/2016/06/29/fortune-of-family-behind-oxycontin-drops-amid-declining-prescriptions/#21ac2ea46341>.

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

125. Timothy J. Hixson, *Anti-Depressants and Children: Suicidality, Off-Label Use, and Trial Publication*, 3 IND. HEALTH L. REV. 201, 207 (2006); see also Scott Tillett, *Off-Label Prescribing of SSRIs to Children: Should Pediatric Testing be Required, or are there Other Means to a Safer End for Children?*, 19 S. CAL. REV. L. & SOC. JUST. 447, 477 (2010); see also David Dobbs, *The Human Cost of a Misleading Drug-Safety Study*, ATLANTIC (Sept. 18, 2015), <https://www.theatlantic.com/health/archive/2015/09/paxil-safety-bmj-depression-suicide/406105/>.

126. Jill Treanor, *GlaxoSmithKline Chief's Pay Package More Than Doubles to £6.7m*, GUARDIAN (Mar. 12, 2012, 3:13 PM), <https://www.theguardian.com/business/2012/mar/12/glaxosmithkline-chief-pay-andrew-witty>.

127. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(a), 76 Stat. 780-81.

the fact that many new drugs are only minimally effective and have extremely dangerous side effects. Second, the drug companies have produced and exploited the deregulation of prescription drug advertising. Through direct-to-consumer advertising and in-person “detailing” (or persuasion) of doctors, drug companies now channel their time and resources into marketing prescription drugs as opposed to scientific research and innovation. Many prescription drugs now exist to capture pre-existing markets through sophisticated advertising campaigns in order to generate corporate profit, not to cure sick patients. Finally, the pharmaceutical industry utilizes the nation’s most extensive lobbying campaign (for twenty years running) and dangles lucrative job offers in front of federal officials to erode the boundaries between government and industry. As a result, the government agency tasked with regulating the pharmaceutical industry—the Food and Drug Administration—now serves the industry rather than polices it.

#### A. *Clinical Trials and the Rise of “Evidence-Based Medicine”*

The government began regulating the pharmaceutical industry in 1906 with the Pure Food and Drug Act, which required drug manufacturers to provide labels disclosing the drug’s therapeutic ingredients and prohibited the sale of misbranded drugs.<sup>128</sup> Then, in response to a scandal where the drug sulfanilamide killed 106 people, Congress passed the Food, Drug, and Cosmetic Act in 1938 (“FDCA”).<sup>129</sup> FDCA, in turn, created the Food and Drug Administration (“FDA”) and required drug companies to seek FDA permission to market drugs in interstate commerce.<sup>130</sup> In 1962, Congress responded to the tragic birth defects caused by the anti-anxiety drug Thalidomide by passing the *Kefauver-Harris Amendments* to the FDCA.<sup>131</sup> The *Kefauver-Harris Amendments* required drug companies to conduct clinical trials to prove a new drug’s efficacy and safety and to disclose the drug’s adverse side effects.<sup>132</sup> Drug companies assert that conducting the required research and clinical trials to secure FDA approval costs an average of \$800 million for each new drug they develop.<sup>133</sup>

As this subsection demonstrates, the *Kefauver-Harris Amendments* and the high costs of research and development tempt drug companies to cheat in their clinical trials in order to gain approval for their new prescription drugs. First, drug companies engage in “clinical bias,” which is the process through which

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128. See Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, 770.

129. Marc A. Rodwin, *Independent Clinical Trials to Test Drugs: The Neglected Reform*, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 113, 122 (2012).

130. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938).

131. Rodwin, *supra* note 129, at 123.

132. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(a), 76 Stat. 780 (1962).

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

they rig the design of the trial to ensure that the new drug will appear both safe and effective.<sup>134</sup> Then, to ensure that all the evidence points toward a safe and effective drug, the drug companies ghostwrite journal articles and pay leading specialists and doctors to sign their names as co-authors to lend credibility to the studies.<sup>135</sup> If, despite these tactics, a drug company still cannot achieve a successful clinical trial to gain FDA approval, they petition the FDA to conduct a trial with “enriched enrollment protocols.”<sup>136</sup> Enriched enrollment protocols allow the company to run a clinical trial with only patients who have, in an earlier trial, responded well to the new drug and to exclude patients who had adverse reactions to the drug in earlier tests.<sup>137</sup> (In other words, the FDA allows companies to run clinical trials that are *guaranteed* to be successful.)

The *Kefauver-Harris Amendments* established a system through which a drug company can only gain FDA approval to sell a new drug if it demonstrates that the drug is both safe and effective.<sup>138</sup> To prove this, drug companies engage in a long and arduous process of testing their new drugs. They must first identify a potential therapeutic use for the drug, and then begin testing the drug on animals to identify therapeutic or toxic effects.<sup>139</sup> If the drug proves nontoxic, the drug company begins three phases of human testing.<sup>140</sup> The first phase involves toxicity and efficacy tests on a small group of human subjects, usually ranging between 20 and 80 patients.<sup>141</sup> If the drug still appears safe and effective, drug companies begin phase two of their investigation, in which they expand the testing to a larger group of several hundred human subjects.<sup>142</sup> Again, if the results are positive the company begins phase three testing, which includes controlled clinical trials that test the drug on thousands of human subjects who suffer from the disease or ailment the drug is designed to treat.<sup>143</sup> These clinical trials compare human subjects taking the experimental drug with a control group, who are taking either a placebo (a sugar pill) or an alternative therapy that has already received FDA approval to treat the disease in question.<sup>144</sup> These trials are typically “double blind” studies, in which neither the

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134. *See id.* at 1008–11.

135. JEROME P. KASSIRER, *ON THE TAKE: HOW AMERICA’S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH* 31 (2005).

136. Martha Rosenberg, *What Big Pharma Doesn’t Want You to Know About the Opioid Epidemic*, SALON (Jun. 3, 2016, 8:15 AM), [https://www.salon.com/2016/06/03/what\\_big\\_pharma\\_doesnt\\_want\\_you\\_to\\_know\\_about\\_the\\_opioid\\_epidemic\\_partner/](https://www.salon.com/2016/06/03/what_big_pharma_doesnt_want_you_to_know_about_the_opioid_epidemic_partner/).

137. ANNA LEMBKE, *DRUG DEALER, M.D.: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT’S SO HARD TO STOP* 69 (2016).

138. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(a), 76 Stat. 780 (1962).

139. FDA Investigational New Drug Application, 21 C.F.R. § 312.23 (2002).

140. 21 C.F.R. § 312.21 (2018).

141. 21 C.F.R. § 312.21(a) (2018).

142. 21 C.F.R. § 312.21(b) (2018).

143. 21 C.F.R. § 312.21(c) (2018).

144. Rodwin, *supra* note 129, at 125.

patients nor the doctors know which person is taking the new drug or the placebo—this safety mechanism is in place to prevent bias on the part of the party conducting the trial.<sup>145</sup> If the drug company believes it has conducted two successful phase three trials that demonstrate “statistically significant” positive results over placebo or standard treatment, they may seek FDA approval to sell the drug.<sup>146</sup> After the FDA approves the drug, the drug company can begin marketing and selling its treatment.

These theoretically strong safety precautions have proven to be anemic (or worse, *dangerous*) in actual practice. This paradoxical result arises because drug companies have complete control over the design and execution of their clinical trials. As such, they only report the “evidence” from the clinical trials that have favorable outcomes. This results in a phenomenon called “clinical bias.” Marc Rodwin identifies clinical bias as the corruption that “lies at the root” of the FDA approval process.<sup>147</sup> He has noted that an “ample record reveals that drug firms can design clinical trials in ways that bias the conclusions” in their favor and then compound the problem because they routinely “misinterpret or misreport their trial data, or engage in fraud.”<sup>148</sup> Adding to the potential for clinical bias is the fact that the FDA officially ignores failed clinical trials.<sup>149</sup> A drug company might conduct as many as 100 clinical trials, where 98 *trials* show that the new drug is less safe and effective than a placebo or standard treatment while *only two trials* yielded positive results in favor of the new drug. The overwhelming bulk of the evidence in this scenario points to the new drug being more dangerous and less effective than a placebo or pre-existing treatments, yet these two “successful” trials are sufficient to gain FDA approval for the drug.<sup>150</sup> In other words, it is possible to gain FDA approval for a drug that clinical trials have proven to be ineffective or dangerous 98% of the time.

Drug companies likewise “hobble” the standard treatment against which they are testing their new drug. In order to obtain the results the drug company is seeking, the researcher running the trial administers the standard treatment “in the wrong dose by the wrong route.”<sup>151</sup> That is, they administer the standard treatment against which they are testing at a dosage that they already know will be less effective or perhaps entirely ineffective. Under these rigged conditions, the new drug appears to outperform the standard treatment in the clinical trial. The doctors who engage in clinical bias do so, it is alleged, because drug companies pour an estimated \$24 billion a year into the clinical trial industry, which

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145. See U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: E9 STATISTICAL PRINCIPLES FOR CLINICAL TRIALS 11 (1998).

146. HEALY, *supra* note 4, at 77.

147. Rodwin, *supra* note 129, at 116.

148. *Id.*

149. DUMIT, *supra* note 3, at 100.

150. HEALY, *supra* note 4, at 77.

151. Rennie, *supra* note 133, at 998.

accounts for the bulk of the annual funding these researchers receive.<sup>152</sup> Critics of the clinical trial system describe it as “profoundly corrupting,” concluding that “it makes no sense for the pharmaceutical companies to be the only one developing the evidence. At present, those who have the most to gain by finding positive results in clinical trials are often the only source of information about their drugs.”<sup>153</sup> Without independent third parties conducting the trials, it is impossible to know whether or not a researcher has strategically designed a clinical trial to produce biased results in favor of the new drug’s safety and efficacy.

If simple clinical bias proves an insufficient tool for securing FDA approval, drug companies have obtained an additional deregulatory shortcut with regard to conducting clinical trials: so-called “enriched enrollment” protocols. Clinical trials that allow for an enriched enrollment protocol flip the FDA approval process on its head. Drug companies lobbied the FDA for enriched enrollment procedures because they could not conduct successful clinical trials in which opioid painkillers outperformed a placebo or standard treatments like Aspirin and Tylenol.<sup>154</sup> Enriched enrollment allows a company to start a clinical trial without a control group, instead giving all the patients the new drug—in this case, the opioid painkillers. Patients who respond poorly to the opioids (typically half of the clinical trial participants) drop out of the study and the only subjects that remain in the study are the ones who respond well to opioids.<sup>155</sup>

At this point, the researchers assign a control group and give them a placebo, while the other half of the participants—who the researchers already know respond well to the opioids—continue to receive the opioid treatment.<sup>156</sup> The subjects who receive the placebo, of course, undergo withdrawal from the highly addictive opioids, and drop out of the study or report negative side effects (*i.e.*, agonizing withdrawal symptoms) while those who already responded well to the opioid continue to do so. The result is a clinical trial that appears to demonstrate the efficacy of opioid painkillers in comparison to placebo, which in turn leads to FDA approval.<sup>157</sup> Dr. Anna Lembke of Stanford Medical School concludes that “the enriched enrollment protocol does appear to be a way for drug companies to cheat, getting approval for opioid painkillers that don’t really work.”<sup>158</sup> Industry observers have expressed deep concern over the “unsettling circularity” of clinical trials that utilize enriched enrollment protocols, but such protocols nonetheless persist.<sup>159</sup>

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152. Rodwin, *supra* note 129, at 126.

153. Rennie, *supra* note 133, at 1010.

154. LEMBKE, *supra* note 137, at 69.

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.* at 68.

159. Jonah Campbell & Nicholas B. King, “Unsettling Circularity”: *Clinical Trial Enrichment and the Evidentiary Politics of Chronic Pain*, 12 *BIO SOC’YS* 191, 205 (2017).

Drug companies also engage in “publication bias” to create the appearance of scientific evidence that a new drug is safe and effective despite, in many cases, clear evidence to the contrary. Most people are shocked to discover that there is a large (and entirely legitimate) “ghostwriting” industry in the field of scientific writing. Drug companies pay third-party professional authors to draft articles that portray their new drugs in a positive light—regardless of the findings from the clinical trials—and then place those articles in prestigious medical journals.<sup>160</sup> After the drug company and the ghostwriter produce a final draft of the article, they offer “thought leaders” and respected doctors tens of thousands of dollars to attach their names to the articles to give the “evidence” more credibility.<sup>161</sup> This practice is so scandalous that it sounds like a conspiracy theory, but the editors of top medical journals have been trying to alert the public about this commonplace practice for years.<sup>162</sup> Drummond Rennie, editor at the highly respected JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (“JAMA”), laments that he and his colleagues have published

manuscripts that we editors received in good faith, only to discover, sometimes years later, that the “authors” had been anointed as such when everything but the final draft of the manuscript had been completed by the company, their sole function being to lend the scientific and institutional prestige to the trials, and make them credible to the profession.<sup>163</sup>

Indeed, a former drug company ghostwriter who participated in these schemes described her scientific writing on behalf of the pharmaceutical industry as “marketing masquerading as science.”<sup>164</sup>

Sergio Sismondo explains that drug companies control every step of the publication process through a phenomenon he calls “ghost management.”<sup>165</sup> Sismondo observes that “in extreme cases, drug companies pay for trials by contract research organizations (“CROs”), analyze the data in-house, have professionals write manuscripts, ask academics to serve as authors of those manuscripts, and pay communication companies to shepherd them through publication in the best journals.”<sup>166</sup> Publication bias works in the inverse, as well. Drug companies prevent researchers from publishing articles (sometimes through

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160. See, e.g., HEALY, *supra* note 4, at 83–84.

161. Rennie, *supra* note 133, at 998.

162. E.g., *id.* at 991–92 (“In various ways I and my fellow medical editors are seen as representing the establishment. So consider this. Indirectly, the issue of money’s influence on researchers and physicians has over the past two decades eased the departure of several of the editors in chief of our major medical journals. My colleagues, Jerome Kassirer and Marcia Angell, both of the NEJM, and Richard Smith, editor of the British Medical Journal, have all, the moment that they left their posts, written books bemoaning the appalling influence of pharmaceutical company money on the morals and practices of their profession.”).

163. *Id.* at 998.

164. KASSIRER, *supra* note 135, at 33.

165. Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 PLOS MED. 1429, 1429 (2007).

166. *Id.*

overt threats and intimidation) about failed clinical trials that have proven a new drug to be ineffective or unsafe.<sup>167</sup> This collective publication bias and ghost management creates a false appearance of drug safety and efficacy that deceives regulators, doctors, and patients alike. *The Kefauver-Harris Amendments* and the clinical trials they require have produced a paradoxical outcome: the proof that a drug works is based on evidence that the drug does not, in fact, work. Instead of protecting the public health, clinical trials function as a tool through which drug companies produce misleading evidence about the safety and efficacy of their new drugs. Clinical trials and the scientific publications they produce, we will see, amount to little more than deceptive marketing tactics.

B. *Contagious Advertising: The Primacy of Marketing over Research*

The systematic legal deregulation of prescription drug advertising has caused drug companies to turn away from pharmaceutical innovation and to focus instead on marketing derivative “lifestyle” drugs. Lifestyle drugs target chronic, lifelong conditions that ensure patients will take the drug on a routine or daily basis for the rest of their lives.<sup>168</sup> Drug companies focus on treatments for chronic conditions because cures are not profitable; once a patient is *cured*, she no longer has to purchase the prescription medicine.<sup>169</sup> Chronic treatments, on the other hand, are very profitable: in 2010 the global market for pharmaceutical drugs approached \$1 trillion, most of which stemmed from “chronic disease management” in the U.S.<sup>170</sup>

As this subsection demonstrates, the drug company focus on producing blockbuster treatments for chronic conditions has caused pharmaceutical research and innovation to grind to a halt. It has also endangered public health by unnecessarily exposing patients to potentially unsafe medications. The grim fact that drug companies now spend more than twice as much money on advertising than they do on developing new drugs speaks to the primacy of marketing over

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167. Rodwin, *supra* note 129, at 129; *see also* David R. Culp & Isobel Berry, *Merck and the Vioxx Debacle: Deadly Loyalty*, 22 ST. JOHN’S J. C.R. & ECON. DEV. 1, 27 (2007) (citing the example of Gurkirpal Singh, a professor at Stanford University’s medical school, who “said that a Merck senior executive had contacted his superiors to warn that if Singh continued to express his concerns about Vioxx he would have career problems in the future.”).

168. *See generally* DUMIT, *supra* note 3 (examining the industry tactic of getting Americans hooked on prescription drugs for life out of fear of high blood pressure, high cholesterol, or other asymptomatic “risk factors”).

169. *See, e.g.*, HEALY, *supra* note 4, at 50 (“Marshall made overtures to Glaxo but found they had no interest in a cure for ulcers. The beauty of H-2 blockers was that once they began taking them, many patients remained on them indefinitely. Actually eliminating ulcers, the treatment of which had just become the cash cow of the pharmaceutical industry, was not what Glaxo had in mind. The decade between the contrasting scientific experiments of James Black and Barry Marshall had propelled medicine into a new world, one in which it could not be assumed that science and business were on the same side, as they had appeared to have been over the previous three decades.”).

170. *Id.* at 10.



research in the pharmaceutical industry.<sup>171</sup> The Food and Drug Administration Modernization Act of 1997 (“FDAMA”) provided the deregulatory legal change that enabled the pharmaceutical industry to shift its focus from research to marketing.<sup>172</sup> After FDAMA, drug companies abandoned the quest for cures to instead market the threat of disease and pre-disease “risk factors” to the public.<sup>173</sup> First, FDAMA removed the ban on televised direct-to-consumer prescription drug advertising.<sup>174</sup> As a result, drug companies are now able to “educate” consumers and increase “public awareness” about a host of chronic diseases. Many of these “diseases” did not even exist until companies created drugs to treat them (e.g., restless leg syndrome, fibromyalgia, mitochondrial disorder).<sup>175</sup> Second, FDAMA and subsequent litigation eased restrictions on direct in-person advertising to doctors, or “detailing.”<sup>176</sup> Detailing is when a drug company representative meets with a doctor to inform her about off-label (non-FDA approved) treatments for which she might conceivably prescribe the drug.<sup>177</sup> Doctors maintain the legal right to prescribe any drug they choose, even if the FDA has not approved a drug to treat a particular condition.<sup>178</sup> Persuading a doctor to write off-label prescriptions bypasses the time-consuming and expensive FDA approval process and helps the drug company to create substantially larger markets for the sale of prescription drugs. It also makes patients unwitting subjects of untested experimental treatments that often have dire consequences.

The quasi-legal standard to maximize shareholder value has enabled drug companies to seek out larger markets and to develop “blockbuster drugs”—drugs that achieve annual sales in excess of \$1 billion.<sup>179</sup> Ironically, research

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171. Stephanie M. Greene, *After Caronia: First Amendment Concerns in Off-Label Promotion*, 51 SAN DIEGO L. REV. 645, 696 (2014).

172. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997).

173. DUMIT, *supra* note 3, at 206.

174. Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 FED. REG. 43171, 43172 (Aug. 12, 1997); *see also* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997).

175. KASSIRER, *supra* note 135, at 34.

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

177. *Id.* *See also* Washington Legal Found. v. Henney, 56 F. Supp. 2d 81, 87 (D.D.C. 1999) (discussing the FDMA’s provisions regarding information dissemination).

178. *See* Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*, 41 J.L. MED. & ETHICS 654, 654–56 (2013).

179. DUMIT, *supra* note 3, at 90. For the quasi-legal standard to maximize shareholder value, *see* Eugene McCarthy, *Ralph Clare, Fictions Inc.: The Corporation in Postmodern Fiction, Film, and Popular Culture*, 13 LAW, CULTURE, & HUMAN. 173, 175 (2017). In challenging this quasi-legal standard, McCarthy observes that “[t]he book repeatedly claims that corporations are legally bound to maximize profit (or, as corporate apologists say, to ‘maximize shareholder value’). This catchphrase is a myth that corporate actors perpetuate to rationalize unpopular executive decisions, like downsizing and outsourcing. The business judgment rule, which gives management tremendous leeway in directing the corporation, makes clear that maximizing corporate profit is not an enforce-

and development is not the key to producing a blockbuster drug. Drug companies instead copy pre-existing blockbuster drugs as closely as they can without infringing upon the patent. They then attempt to acquire the preexisting market through a sophisticated advertising campaign of their new “me-too” drug (*i.e.*, our company makes an even better drug for that condition) that closely resembles their competitor’s product.<sup>180</sup> In his book-length study of the pharmaceutical industry, Joseph Dumit describes this new industry logic in the following terms:

Once you take the perspective that what matters is not return to health but the growth of prescription sales, it is obvious that patients are valuable only to the extent they can afford to purchase treatments (or have treatments purchased for them). Often, research is directed . . . at me-too drugs, tiny variations on existing drugs with very little difference in efficacy that can nonetheless be patented and used to take over existing markets.<sup>181</sup>

In some instances, a company produces a “me-too” drug that copies its *own* successful drug when its patent is set to expire. This trick, called “patent evergreening” or “product hopping,” is precisely what the drug company AstraZeneca pulled off with its acid reflux drug Prilosec, or the “Purple Pill.”<sup>182</sup> As Prilosec’s patent expiration date approached, AstraZeneca did not seek to develop a better treatment, but instead patented a drug—called Nexium, or the “new purple pill”—that was in effect chemically identical to Prilosec.<sup>183</sup> AstraZeneca proved Nexium’s efficacy, not without controversy, by conducting a clinical trial against Prilosec in which they “hobbled” the soon-to-be off patent Prilosec’s dosage.<sup>184</sup> The result of the product hopping: an extended 20-year patent period for what amounts to an identical drug produced by the same company.<sup>185</sup> Patented drugs, of course, cost much more money than generic, off-patent drugs.<sup>186</sup>

The manipulation of clinical guidelines is another deregulatory tactic the pharmaceutical industry employs to prioritize market growth over innovation. Clinical guidelines determine whether a person is “at risk” for a disease and should receive treatment, even if they exhibit no symptoms or negative health effects associated with the medical condition in question.<sup>187</sup> Experts in a given

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able legal dictate. There is no ‘legal corporate directive’ to engage in antisocial corporate conduct.” (citing *Shlensky v. Wrigley*, 237 N.E. 2d 776 (Ill. App. 1st Dist. 1968)).

180. See DUMIT, *supra* note 3, at 95.

181. *Id.* at 94–95.

182. See Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. TECH. L. REV. 1, 27–28 (2015).

183. *Id.* at 29.

184. *Id.* at 28.

185. *Id.* at 29.

186. See HEALTHSMART, *Generic Versus Brand Medications*, <http://www.healthsmart.com/PDFs/Generic-vs-Brand-Name-Drugs.pdf> (last visited Oct. 18, 2018) (finding the average price of a brand name drug was \$137.90, while the average generic prescription cost \$35.22).

187. See HEALY, *supra* note 4, at 14.

field establish a set of clinical guidelines that tell a doctor at what point she should prescribe treatment to a patient based on certain test results.<sup>188</sup> Drug companies exert tremendous influence over the establishment and revision of these guidelines.<sup>189</sup> As the guidelines for treatment are lowered, patients receive earlier and increased pharmaceutical intervention. In 2003, for instance, the National Blood Pressure Committee changed the hypertension (*i.e.*, high blood pressure) clinical guidelines to include a new category called “prehypertension,” which required earlier treatment at lower blood pressure levels.<sup>190</sup> This change created—in an instant—45 million new patients to whom doctors should be prescribing once-a-day for-life statin drugs like Lipitor and Crestor.<sup>191</sup> Nobody’s health or blood pressure readings changed—the pharmaceutical industry simply helped redefine which blood pressure levels require treatment.

The American Heart Association revised the guidelines for high blood pressure again in 2017, which determined that an additional 14% of Americans now had high blood pressure and should be receiving treatment.<sup>192</sup> Redefining health is as simple as saying that while once 140/90 was a normal blood pressure reading, now 120/80 is the *new normal* reading.<sup>193</sup> Unsurprisingly, revised clinical guidelines “almost always recommend more treatment for more people.”<sup>194</sup> As one doctor describes it, drug companies are engaged in a process of “pathologizing huge swathes of daily life” in an effort to “coerce us into treatment for conditions we never knew we had, with treatments that in some instances are more likely to injure or kill us than improve our well-being.”<sup>195</sup>

Changes in the laws that govern prescription drug advertising have enabled drug companies to persuade people to become patients and to seek out their lifestyle drugs. Recall, FDAMA lifted the ban on televised direct-to-consumer (“DTC”) prescription drug advertising.<sup>196</sup> DTC advertising for prescription drugs is an extremely effective strategy for generating customer interest in a product. Each dollar the pharmaceutical industry spends on DTC advertising results in an additional \$4.20 in sales.<sup>197</sup> This exceptional return on investment results from the fact that when a patient requests a specific drug from her doc-

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188. *See id.* at 136–37.

189. *See id.* at 129–58.

190. *See* DUMIT, *supra* note 3, at 164.

191. *Id.*

192. Robert M. Carey, et al., *High Blood Pressure Redefined for First Time in 14 Years: 130 Is the New High*, AM. HEART ASS’N (Nov. 13, 2007), <https://newsroom.heart.org/news/high-blood-pressure-redefined-for-first-time-in-14-years-130-is-the-new-high>.

193. Monique Tello, *New High Blood Pressure Guidelines: Think Your Blood Pressure Is Fine? Think Again...*, HAR. HEALTH PUBL’G (Nov. 17, 2017, 6:30 AM), <https://www.health.harvard.edu/blog/new-high-blood-pressure-guidelines-2017111712756>.

194. DUMIT, *supra* note 3, at 14.

195. HEALY, *supra* note 4, at 4, 14.

196. 21 U.S.C.A. § 331 (Westlaw through Pub. L. No. 115-231); *see also* Draft Guidance for Consumer-Directed Broadcast Advertisements, 62 Fed. Reg. 43171, 43172 (Aug. 12, 1997).

197. Brennan, *supra* note 182, at 27.

tor, the doctor prescribes that drug at least 75% of the time.<sup>198</sup> This, of course, sheds new light on the familiar DTC advertising phrase, “ask your doctor about . . . .” And since the average American views 16 hours of televised prescription drug advertisements each year (which is more time than they spend annually with their doctor), a patient knows precisely which prescription drugs to request.<sup>199</sup> Prior to FDAMA, the presumption was that it was too dangerous to advertise prescription drugs and commodify sickness, which is why *every* other nation in the world prohibits DTC prescription drug advertising (except New Zealand, but there by oversight, not design).<sup>200</sup>

Drug companies justify these ubiquitous DTC advertising campaigns by claiming that they only seek to educate consumers about health, not to persuade them that they are sick and need to buy medicine.<sup>201</sup> Indeed, some of the FDA-approved DTC advertisements are authorized for “educational purposes” only. The FDA authorizes drug companies to air three types of advertisements: product claim ads (these inform about a drug’s benefits and risks), reminder ads (these name the drug but not the benefits or risks of the drug), and help-seeking ads (these “educate” the consumer about disease symptoms and name the drug maker, but not the specific drug).<sup>202</sup> Of course, such educational claims are difficult to take seriously, and most medical experts recognize that DTC advertisements seek to “drive consumer demand for . . . drugs far beyond the bulk of those patients who really benefit from them.”<sup>203</sup> David Vladeck explains the reality of DTC advertising in the following terms:

DTC advertising imperils the health of the American public by offering exaggerated, incomplete, and deceptive information about drugs. DTC ads are inevitably misleading because it is impossible to present accurate and balanced information about the benefits and risks of a drug in a commercial that is typically thirty to sixty seconds long. Moreover, the proponents would argue, the primary purpose of DTC advertising is not to educate consumers, but instead is to encourage them to actively seek out medication that their physician would not otherwise prescribe. The empirical evidence supports that claim.<sup>204</sup>

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198. David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 270 (2007).

199. *Id.*

200. Amanda L. Connors, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 ALB. L. REV. 243, 267 (2009); Susanna Every-Palmer et al., *Direct-to-Consumer Advertising of Prescription Medication in New Zealand*, 127 N.Z. Med. J. 102, 103 (2014) (for New Zealand oversight).

201. Connors, *supra* note 200, at 269.

202. *Id.* at 268.

203. Barry Meier, *Med. Fueled by Marketing Intensified Trouble for Pain Pills*, N.Y. TIMES, (Dec. 19, 2004), <http://www.nytimes.com/2004/12/19/business/medicine-fueled-by-marketing-intensified-trouble-for-pain-pills.html>.

204. Vladeck, *supra* note 198, at 276.

DTC advertising, like all commercial advertising, is aimed at persuading the public to buy a product—in this case, that product happens to be a prescription drug.

Upon closer examination, the pharmaceutical industry's claim to be using advertising to educate consumers takes on frightening dimensions. It turns out that drug companies actually sponsor educational and so-called "awareness" campaigns to drum up business for their diseases (and, subsequently, treatments) in a marketing tactic called "astroturfing"—the creation of an artificial "grassroots" buzz about an issue.<sup>205</sup> The American Obesity Association ("AOA") serves as a prime example of drug company astroturfing. Dr. Richard Atkinson, an AOA spokesperson, has been quoted saying that it is "time to stop thinking of obesity as a problem of willpower, and start thinking of it as a chronic disease that requires long-term treatment," before concluding that "diet, exercise, and behavior modification don't work long term . . . *the time has come to start thinking about drugs.*"<sup>206</sup> The AOA would later reveal that it received the bulk of its funding from the major drug companies that manufacture and sell diet pills.<sup>207</sup> When confronted about his role in this astroturfing scheme, Atkinson nonchalantly responded that "I think I've been pretty honest and uncorrupted by the money. But who knows, maybe it's so insidious that I don't notice it."<sup>208</sup> While advertisers politely call this tactic astroturfing, more pointed critics of the pharmaceutical industry refer to this behavior as "disease mongering."<sup>209</sup> These critics attribute disease mongering to the rise in "awareness" of dubious medical conditions such as osteopenia, fibromyalgia, attention deficit hyperactivity disorder, and restless leg syndrome.<sup>210</sup> And awareness of these diseases is no laughing matter: experts believe the drug company GlaxoSmithKline will surpass \$1.2 billion in revenue selling a drug approved to treat restless leg syndrome, a disease that may not even exist.<sup>211</sup>

FDAMA also loosened restrictions on off-label "detailing"—the in-person advertising that drug companies engage in behind closed doors with doctors.<sup>212</sup> Before these regulatory changes, the FDA strictly prohibited drug companies

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205. DUMIT, *supra* note 3, at 44.

206. KASSIRER, *supra* note 135, at 34 (emphasis added).

207. *Id.*

208. *Id.* at 35.

209. HEALY, *supra* note 4, at 38.

210. *Id.*

211. Jim Edwards, *Can Glaxo Make \$1.2B Treating a Disease That Doesn't Exist?*, CBS MONEY WATCH (Apr. 12, 2011, 12:54 PM), <https://www.cbsnews.com/news/can-glaxo-make-12b-treating-a-disease-that-doesnt-exist>.

212. U.S. FOOD & DRUG ADMIN., FDA-2008-D-0053, GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES: DRAFT GUIDANCE FOR INDUSTRY (2008), <https://www.regulations.gov/document?D=FDA-2008-D-0053-0002>.

from advertising a prescription drug for a non-FDA approved use.<sup>213</sup> This long-standing prohibition was in place for obvious reasons: if a drug company could advertise a drug that has not been approved, why have an FDA approval process in the first place? Nonetheless, a drug company may now disseminate peer-reviewed journal articles about an off-label (unapproved) use of its drug to a doctor in an effort to persuade her to prescribe the drug to her patients on an experimental basis.<sup>214</sup> Of course, as the previous section demonstrates, the drug companies themselves write the peer-reviewed journal articles that they then disseminate as “evidence” to convince the doctors to prescribe the drug off-label. An industry observer describes the pharmaceutical industry’s approach to detailing, noting that:

[The drug companies] sponsor studies to produce evidence supporting off-label uses, oversee the publication of study results, purchase reprints of the articles, and distribute them to physicians. Typically, these studies produce data that falls woefully short of what the FDA would require to approve the drug for the new use. Nevertheless, the articles describing the studies often convince physicians to prescribe the drugs off-label.<sup>215</sup>

Detailing doctors to prescribe drugs for off-label uses pays off: at least 20% of all prescriptions that doctors write are for off-label uses.<sup>216</sup> For some patient populations, off-label prescriptions make up the bulk of treatment, as 50–75% of cancer drugs are prescribed off-label, 80% of drugs prescribed to pediatric patients are off-label, and 80–90% of prescriptions for rare diseases are off-label.<sup>217</sup> It is estimated that drug companies earn hundreds of billions of dollars each year from off-label prescription drug sales.<sup>218</sup>

The high frequency of off-label prescription writing endangers public health because at least 70% of these off-label uses lack significant scientific support for the drug’s safety and efficacy.<sup>219</sup> Parke-Davis’s off-label detailing campaign of the drug Neurontin—which one company employee referred to as the “snake oil” of the twentieth century—provides a good example of the dangers detailing poses to consumers.<sup>220</sup> Neurontin was approved to treat epilepsy, but Parke-

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213. U.S. FOOD & DRUG ADMIN., BACKGROUNDER ON FDAMA, (Nov. 21, 1997), <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCA/FDAMA/ucm089179.htm>.

214. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, § 401 (codified as amended at 21 U.S.C. § 552 (2012)).

215. Rodwin, *supra* note 178, at 658–59.

216. Greene & Noah, *supra* note 176, at 241.

217. Rodwin, *supra* note 178, at 656.

218. *Id.* at 658. This calculation is based on estimated 2017 global pharmaceutical sales (\$1.2 trillion) multiplied by the percentage of off-label prescription sales (20%). Greene & Noah, *supra* note 176, at 241 (detailing the percentage of off-label prescription sales at 20%); Craig W. Lindsley, *New 2016 Data and Statistics for Global Pharmaceutical Products and Projections through 2017*, 8 ACS CHEM. NEUROSCI. 1635, 1635 (2017).

219. Rodwin, *supra* note 178, at 656.

220. Greene, *supra* note 171, at 652.

Davis detailed doctors to prescribe the drug to treat bipolar disorder, “pain,” and migraines, despite the fact that Nuerontin was known to increase the risk of suicide in patients taking the drug.<sup>221</sup> The company actively suppressed evidence that Nuerontin was not an effective treatment for these off-label uses.<sup>222</sup> In just one of many off-label detailing campaigns that included 2,700 patients receiving Nuerontin via off-label prescription, 11 patients died and 73 others suffered “severe adverse reactions.”<sup>223</sup> Ninety percent of all Nuerontin sales were from off-label prescriptions and Parke-Davis made \$2.7 billion from Nuerontin sales in 2003 alone.<sup>224</sup>

The federal courts have repeatedly upheld the right to detail as authorized commercial speech against FDA attempts to more closely regulate the practice.<sup>225</sup> First, in *Washington Legal Foundation v. Henney*, the court found that the FDA could not restrict truthful off-label detailing to doctors, as the off-label speech was protected commercial speech under the First Amendment.<sup>226</sup> Again, in *United States v. Caronia*, the court determined that the FDA could not prevent truthful and non-misleading off-label drug promotion of any kind to doctors, as off-label promotion is no different than other forms of protected commercial speech.<sup>227</sup> The court reached this holding despite the fact that the drug company representative—and defendant—in *Caronia* told doctors that the drug Xyrem was “very safe” with no contraindications despite the fact that it carried the FDA’s most serious safety warnings due to its dangerous side effects.<sup>228</sup>

FDAMA has produced a legal environment that enables drug companies to focus on profit through advertising at the expense of safety and innovation. Instead of researching new treatments, drug companies seek to create new patients. Consumers are inundated with DTC advertisements on the internet, on television, and in magazines. Meanwhile, doctors prescribe untested drugs to patients who are unaware that they are the experimental subjects of off-label detailing campaigns. The legal race to the bottom in the pharmaceutical industry allows drug companies to invent diseases, raise awareness for these corporate constructions, adjust treatment guidelines, and then sell expensive prescription drugs that are of little to no medical value to many patients. In other words, the “industry has corrupted the system so that, in several ways, the system now subverts the public good. Pharmaceutical firms have learned how to make huge profits with drugs that do not much improve public health and that sometimes

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221. *Id.*

222. *Id.*

223. Carl Elliot, *Useless Studies, Real Harm*, N.Y. TIMES (Jul. 28, 2011), <http://www.nytimes.com/2011/07/29/opinion/useless-pharmaceutical-studies-real-harm.html>.

224. Greene, *supra* note 171, at 675.

225. *See, e.g.*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557 (1980) (affirming that commercial speech is entitled to First Amendment protection).

226. *See Wash. Legal Found. v. Henney*, 56 F. Supp. 2d 81, 87 (D.D.C. 1999).

227. *See, e.g.*, *United States v. Caronia*, 703 F.3d 149, 168–69 (2d Cir. 2012).

228. Greene, *supra* note 171, at 675.

are unsafe or are prescribed without need.”<sup>229</sup> And, akin to corporate law’s nineteenth-century race to the bottom, this atmosphere of deregulation appears to be the product of an intentional blurring of the boundaries between the private and the public sectors.

### C. *Lobbying, the Revolving Door, and Limited Liability*

In his canonical analysis of nineteenth-century government regulation, Gabriel Kolko observes that federal regulators often cease to function as industry policemen and instead come to *serve* the industry they are supposed to regulate.<sup>230</sup> The robber barons that spearheaded the race to the bottom “realized that they needed the protection of the federal government, and they became the leading advocates of federal regulation *on their own terms*.”<sup>231</sup> This phenomenon of government regulation that serves and enables a particular industry is known as “regulatory capture”—the system through which an industry infiltrates and directs the regulatory body that is supposed to control it. Industry leaders were able to capture these regulatory bodies because they “thoroughly insinuated themselves into the modern state. Through their lobbies and friendships, they could be found in Congress, the legislatures, bureaucracies, and courts.”<sup>232</sup> Industry insiders blurred the line between the public and private sector by erecting a revolving door through which members of the industry routinely joined the government and, subsequently, members of the government seamlessly rejoined the industry.

This final subsection demonstrates that contemporary pharmaceutical executives have infiltrated the modern American government and captured the FDA. To achieve this outcome, the pharmaceutical industry has spent more on government lobbying than any other industry for nearly twenty years in a row.<sup>233</sup> In addition, they have established a revolving door between the pharmaceutical industry and both the FDA and Congress, such that in any given year more than half of the pharmaceutical industry lobbyists are former federal officials.<sup>234</sup> This political clout has resulted in an industry largely insulated from liability for its individual criminal actions. The government routinely avoids holding individual pharmaceutical executives accountable for illegal acts of misbranding, fraud, and bribery. The government instead enters into non-prosecution agreements (or deferred prosecution agreements) with corporate subsidiaries, which result in

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229. Jorgensen, *supra* note 9, at 562.

230. KOLKO, *supra* note 39, at 168–69.

231. *Id.* at 231 (emphasis added).

232. WHITE, *supra* note 25, at 511.

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

234. *Id.* at 903.



inconsequential criminal fines that drug companies write off as just another “cost of doing business.”<sup>235</sup>

From 1998 to 2017 drug companies have spent \$3.7 billion on lobbying government officials to support industry initiatives.<sup>236</sup> This staggering amount of money is \$1 billion more than the insurance industry, which ranks a distant second in special interest spending over the same time period.<sup>237</sup> Indeed, the pharmaceutical industry has ranked first in lobbying expenditures every year since 1999.<sup>238</sup> In 2009 alone, drug companies spent \$272 million on government lobbying, a sum that still stands “as the greatest amount ever spent on lobbying efforts by a single industry for one year.”<sup>239</sup> It should come as little surprise that Congress enacted FDAMA (discussed at length above), which legalized DTC advertising, off-label detailing, and provided for streamlined FDA approval, “following intense lobbying” by the pharmaceutical industry.<sup>240</sup>

FDAMA—itself the product of special interest influence—produced additional levels of industry influence through its reauthorization of the Prescription Drug User Fee Act of 1992 (“PDUFA”).<sup>241</sup> PDUFA requires drug companies to pay a fee to the FDA to review and approve the drug company’s new drug application; these “user fees” pay for about 65% of the costs that the FDA incurs during the review and approval process.<sup>242</sup> Although superficially these fees appear to penalize the drug companies, in actual practice the user fees have:

changed the entire culture at the FDA as well as its relationships with the pharmaceutical companies and the American people. The FDA used to have one client: the American people. The fact that the companies it regulates pay user-fees for the service has meant that the only clients on the FDA’s case are drug company representatives. This is so even though the speeded up process results in profits that vastly exceed the fees, and even though the actual contribution of industry to the finances of the FDA is a fraction of that provided by public monies. The FDA now behaves as if the manufacturers are the only clients worth serving.<sup>243</sup>

In essence, drug companies lobbied the government to enact a law that not only permits but also *legally requires* drug companies to finance the one agency that

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235. See Greene, *supra* note 171, at 653.

236. OPENSECRETS.ORG: CTR. FOR RESPONSIVE POL., <https://www.opensecrets.org/lobby/top.php?indexType=i> (last visited Oct. 30, 2018).

237. *Id.*

238. *Id.*

239. Taschner, *supra* note 233, at 902–03.

240. Vera Hassner Sharav, *The Impact of the FDA Modernization Act on the Recruitment of Children for Research*, 5 ETHICAL HUMAN SCI. AND SERVS. 83, 85 (2003).

241. The Prescription Drug User Fee Act, Pub. L. No. 102-571 (1992).

242. Gail Dutton, *2011 Budget Outlook: Trim, Cut, Then Slash*, GEN: GENETIC ENG’G & BIOTECH. NEWS (Feb. 7, 2011), <https://www.genengnews.com/gen-exclusives/2011-budget-outlook-trim-cut-then-slash/77899360>.

243. Rennie, *supra* note 133, at 1004.

regulates them. This, to put it mildly, creates a host of potential conflicts of interest.<sup>244</sup>

In addition to their lobbying efforts, drug companies have facilitated a revolving door between the federal government and the pharmaceutical industry. Industry observers have identified an uptick in the speed of the revolving door beginning in 2001, when President George W. Bush appointed Daniel Troy as the FDA's Chief Counsel.<sup>245</sup> Incidentally, this revolving door arose contemporaneously with the pharmaceutical industry's rise to the top of the list of government lobbyists.<sup>246</sup> Before his appointment as Chief Counsel, Troy was a partner at Wiley, Rein & Fielding (and later at Sidley Austin LLP), where he "represented pharmaceutical companies and trade associations relating to US FDA and government regulations."<sup>247</sup> In fact, Troy represented the Washington Legal Foundation on behalf of the pharmaceutical industry in the aforementioned *Washington Legal Foundation v. Heeney*, the controversial case that established drug company off-label detailing as protected commercial speech.<sup>248</sup> In a very real sense, Troy went from representing the pharmaceutical industry *against* the FDA to regulating his former clients from *within* the FDA. Shortly after Troy's appointment as Chief Counsel, the number of FDA warning letters censuring drug companies dropped by half and the time it took to issue a warning letter jumped from two weeks to four months.<sup>249</sup> It was Troy's job to review and issue FDA warning letters.<sup>250</sup> After resigning as Chief Counsel of the FDA, Troy joined the drug company GlaxoSmithKline where he served for nearly a decade as General Counsel and Senior Vice President.<sup>251</sup>

The current FDA Commissioner is Scott Gottlieb.<sup>252</sup> In addition to having served on the advisory board or board of directors of six drug companies, Gottlieb has "received some \$413,700 from drug companies for consulting, speaking or other services. In 2015 alone, he collected \$199,951 from eight drug companies, including GlaxoSmithKline, Squibb, Pfizer, and Valeant. All are likely to have regulatory business with the FDA in coming years."<sup>253</sup> Gottlieb's predecessor as FDA Commissioner, a President Obama appointee,

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244. FRAN HAWTHORNE, *INSIDE THE FDA: THE BUSINESS OF POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT* 153 (2005).

245. *Id.* at 145.

246. *Id.* at 143–45.

247. Daniel Troy, LINKEDIN, <https://www.linkedin.com/in/dan-troy-701868b> (last visited Nov. 29, 2018).

248. HAWTHORNE, *supra* note 244, at 145.

249. Vladeck, *supra* note 198, at 273–74.

250. *See id.* at 273.

251. Daniel Troy, *supra* note 247.

252. U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/CommissionersPage/> (last visited Nov. 29, 2018).

253. Michael Hiltzik, *Farewell to Drug Regulation? Trump Nominates a 'Bona-Fide Pharma Shill' to Head the FDA*, L.A. TIMES (Mar. 6, 2017, 9:05 AM), <http://beta.latimes.com/business/hiltzik/la-fi-hiltzik-gottlieb-fda-20170315-story.html>.

was Robert Califf.<sup>254</sup> Prior to joining the FDA, Califf disclosed that the drug companies Merck, Novartis, and Eli Lilly supported his salary at Duke University.<sup>255</sup> Harvard professor Daniel Carpenter called Califf “the ultimate industry insider.”<sup>256</sup> After resigning as FDA Commissioner, Califf joined the scientific board at Verily Life Sciences,<sup>257</sup> a company that has close partnerships with GlaxoSmithKline, Sanofi Pharmaceutical, Biogen Pharmaceutical, and Johnson & Johnson.<sup>258</sup> Compounding this revolving door problem at the FDA’s highest levels is a recent study finding that, at a minimum, 27% of FDA employees leave the agency to work with or consult for the pharmaceutical industry.<sup>259</sup> The primary issue with these sorts of revolving door relationships is that “if you know in the back of your mind that a major career opportunity after the FDA is going to work on the other side of the table,” it can make these regulators “less likely to put [their] foot down.”<sup>260</sup> Indeed, recent history has shown ample evidence confirming the frequency of this flight from the FDA to industry. As Fran Hawthorne notes:

With the FDA’s relatively low salaries and generous retirement incentives, many reviewers leave after 20 years, and the obvious move is to work at or consult to a big drug company. This is what Tom Garvey did in setting up his own consulting firm, and Susan Alpert did in going to Medtronic. So did Steve Koepke and Stuart Portnoy, who joined the contract research organization PharmaNet. Jay Siegel now runs research and development at Centocor, after leaving the Center for Biologics. Michael Friedman, the acting commissioner during the tumult of the late 1990s, became a senior-level executive at G.D. Searle & Company, then at Pharmacia Corporation when the latter bought Searle’s parent Monsanto Company in 2000. He also did special work on preparedness at PhRMA, the industry trade group.<sup>261</sup>

The additional fact that 66% (926 of 1403) of pharmaceutical industry lobbyists were once federal officials highlights just how blurred the lines between government and industry have become.<sup>262</sup>

As lobbying reinforces the pharmaceutical industry’s political clout and the revolving door blurs the line between government and industry, drug company

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254. U.S. FOOD & DRUG ADMIN., FDA STATEMENT ON SENATE CONFIRMATION OF DR. ROBERT M. CALIFF (Feb. 24, 2016), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm487455.htm>.

255. Sabrina Tavernise, *F.D.A. Nominee Califf’s Ties to Drug Makers Worry Some*, N.Y. TIMES (Sept. 19, 2015), [https://www.nytimes.com/2015/09/20/health/fda-nominee-califfs-ties-to-drug-industry-raise-questions.html?\\_r=1](https://www.nytimes.com/2015/09/20/health/fda-nominee-califfs-ties-to-drug-industry-raise-questions.html?_r=1).

256. *Id.*

257. *Leadership*, VERILY, <https://verily.com/leadership/> (last visited Nov. 29, 2018).

258. *Partners*, VERILY, <https://verily.com/partners/> (last visited Nov. 29, 2018).

259. Alexandra Sifferlin, *Is the FDA Too Cozy With Drug Companies?*, TIME (Sept. 28, 2016), <http://time.com/4510025/fda-drug-companies-pharmaceutical-industry-medical-reviewers/>.

260. *Id.* (quoting Dr. Vinay Prasad).

261. HAWTHORNE, *supra* note 244, at 150.

262. *Pharm/Health Prod, 2017*, CTR. FOR RESPONSIVE POL., [https://www.opensecrets.org/lobby/indusclient\\_lob.php?id=h04&year=2017](https://www.opensecrets.org/lobby/indusclient_lob.php?id=h04&year=2017) (last visited Oct. 28, 2018).

executives appear to be escaping liability for their criminal conduct. The primary legal devices that enable corporate executives to avoid criminal liability are the deferred prosecution agreement (“DPA”) and the non-prosecution agreement (“NPA”).<sup>263</sup> Under a DPA, the “prosecutor and the corporation agree that although the prosecutor will charge the corporation in federal court, the prosecutor will defer the continued prosecution of the charges until the end of a certain period of time agreed upon by both parties. If, at the end of the term of the agreement, the corporation has followed through on its obligations, the prosecutor will dismiss the charges.”<sup>264</sup> NPAs work in a similar fashion, with the exception that under an NPA the government never even files criminal charges in federal court; they only threaten to do so if the corporation does not comply with the terms of the agreement.<sup>265</sup> Normally, the corporation pays a large criminal fine to the government and must agree to a number of compliance reforms that are aimed at preventing similar incidents of criminal behavior in the future.<sup>266</sup> According to Brandon Garrett, the government relies on DPAs and NPAs in prosecuting corporate malfeasance because prosecutors lack certainty that they can secure convictions of individuals as a result of the “organization complexity” of corporate decision making.<sup>267</sup> Another theory is that the government conducts a simple cost-benefit analysis: the government achieves the same results (corporate cooperation, fines, admissions, and reform) at a fraction of the cost of going to trial.<sup>268</sup>

Legal scholars have also raised more cynical explanations for the government’s use of DPAs and NPAs to address corporate crime: corruption resulting from lobbying and the revolving door between the public and private sector.<sup>269</sup> The use of DPAs to settle corporate criminal trials emerged as the government’s primary tactic in 2001 during the Bush administration, which some view as “the predictable response of a business-friendly administration to increased corporate crime.”<sup>270</sup> Indeed, the government entered only 9 DPAs with corporations in the decade before 2001, while they entered into 39 DPAs in the subsequent

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263. See generally CINDY R. ALEXANDER & MARK A. COHEN, TRENDS IN THE USE OF NON-PROSECUTION, DEFERRED PROSECUTION, AND PLEA AGREEMENTS IN THE SETTLEMENT OF ALLEGED CORPORATE CRIMINAL WRONGDOING (2015) (for a detailed study of the differences between non-prosecution agreements and deferred prosecution agreements).

264. *Id.* at 8.

265. *Id.*

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

267. BRANDON L. GARRETT, TOO BIG TO JAIL: HOW PROSECUTORS COMPROMISE WITH CORPORATIONS 18 (2014).

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

269. *Id.* at 1320.

270. *Id.*

five years.<sup>271</sup> The government entered into 17 DPAs to settle corporate crimes in 2017 alone.<sup>272</sup> The empirical evidence supports the finding that the government tends to enter DPAs with large, publicly traded corporations that have high annual earnings (and, presumably, greater lobbying capacity).<sup>273</sup> Whatever the underlying intent, DPAs certainly create the appearance that “large companies can buy their way out of criminal prosecution.”<sup>274</sup> As the next section explains, this erosion of corporate liability has contributed to the ascendance of the pharma barons.

### III. THE RISE OF THE PHARMA BARONS

Just as corporate law’s nineteenth-century race to the bottom enabled the rise of the robber barons, the current legal and regulatory race to the bottom in the pharmaceutical industry has elevated some drug company executives to the status of what I call the “pharma barons.” As this section argues, executives and controlling stockholders at Merck, GlaxoSmithKline, and Purdue Pharmaceuticals steered their respective companies through the development and marketing of drugs that have collectively killed hundreds of thousands of people. Executives and researchers from these three companies exploited clinical trials, evidence-based medicine, clinical guidelines, DTC advertising, and off-label detailing in the development and marketing of drugs that they knew had efficacy issues and deadly side effects. No executives from these companies have gone to prison or faced meaningful liability for their actions. Instead, Merck, GlaxoSmithKline, and Purdue have entered into DPAs and NPAs with the government and paid hefty fines to settle criminal charges of fraud, misbranding, and bribery. Where once there was a Gilded Age, America is now in the throes of the Prescription Age. The pharma barons, unfortunately, are proving far more dangerous to the American public than the robber barons ever were.

The FDA approved Merck’s COX-2 inhibiting painkiller Vioxx in 1999.<sup>275</sup> Merck voluntarily withdrew Vioxx from the market in 2004 due to fatal side effects relating to heart attack and stroke.<sup>276</sup> The FDA concluded that in the five years Vioxx was on the market, it was responsible for at least 60,000 deaths.<sup>277</sup> The entire Vietnam War, for the sake of comparison, resulted in 58,200 U.S.

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271. *Id.* at 1308.

272. See *Corporate Prosecution Registry*, UNIV. OF VA. SCH. OF L. LIBR., <http://lib.law.virginia.edu/Garrett/corporate-prosecution-registry/browse/browse.html> (last visited Oct. 28, 2018). DPAs and NPAs are used interchangeably for this statistic.

273. Brandon L. Garrett, *Globalized Corporate Prosecutions*, 97 VA. L. REV. 1775, 1870 (2011).

274. Uhlmann, *supra* note 268, at 1301.

275. U.S. FOOD & DRUG ADMIN., *Vioxx (rofecoxib) Questions and Answers*, <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106290.htm> (last updated Sept. 30, 2004).

276. *Id.*

277. Herper, *supra* note 117.

causalities.<sup>278</sup> Other estimates suggest that Vioxx's adverse side effects may have killed as many as 500,000 people.<sup>279</sup> To provide additional scale, World War II caused 418,500 U.S. causalities.<sup>280</sup>

The story of Vioxx serves as a microcosm of the pharmaceutical industry's legal race to the bottom. First, Merck conducted clinical trials to test Vioxx under the regime of "evidence based medicine" that the *Kefauver-Harris Amendments* initiated.<sup>281</sup> Merck's researchers and executives became aware of the deadly cardiovascular risks associated with Vioxx during a phase 2 trial in 1996.<sup>282</sup> In 1998, the clinical trial "Study 090" determined that serious cardiovascular side effects "occurred almost six times more often in patients taking Vioxx than in patients taking another arthritis drug or placebo."<sup>283</sup> Despite this evidence (or, perhaps, *because* of this evidence) Merck proceeded to engage in both clinical and publication bias to create deceptive evidentiary support for Vioxx's efficacy and safety. The company ghostwrote articles that appeared in leading medical journals and quickly it "became clear that in every case the authors [of the journal articles] either could not take full responsibility for their trials, or there were distortions of the evidence that seriously weakened the conclusions of the trials that such drugs did not cause cardiovascular disease."<sup>284</sup> In other words, Merck doctored the clinical trial outcomes.

After securing FDA approval based on the biased evidence from these clinical trials, Merck began an aggressive advertising campaign for Vioxx, spending \$161 million in DTC advertising in 2000 alone.<sup>285</sup> Merck's successful DTC ad campaign starring figure skater Dorothy Hamill has since been pilloried for turning "hope into hype" and pushing the use of Vioxx "well beyond what could be justified medically."<sup>286</sup> Merck representatives also conducted in-person detailing of doctors armed with the "Cardiovascular Card"—a piece of promotional material Merck prepared to reassure doctors that Vioxx was *protecting* the heart, not harming it.<sup>287</sup> For obvious liability reasons, Merck instructed its sales representatives to never leave the Cardiovascular Card behind with physi-

278. *Vietnam War U.S. Military Fatal Casualty Statistics*, NAT'L ARCHIVES (Apr. 29, 2008), <https://www.archives.gov/research/military/vietnam-war/casualty-statistics>.

279. Ron Unz, *Chinese Melamine and American Vioxx: A Comparison*, AM. CONSERVATIVE (Apr. 17, 2012), <http://www.theamericanconservative.com/articles/chinese-melamine-and-american-vioxx-a-comparison>.

280. *Research Starters: Worldwide Deaths in World War II*, NAT'L WWII MUSEUM, <https://www.nationalww2museum.org/students-teachers/student-resources/research-starters/research-starters-worldwide-deaths-world-war> (last visited Nov. 29, 2018).

281. *See supra* Part III.A.

282. Culp & Berry, *supra* note 167, at 18; *see also* NESI, *supra* note 120, at 107.

283. Culp & Berry, *supra* note 167, at 19.

284. Rennie, *supra* note 133, at 1000–01.

285. Ronald M. Green, *Direct-to-Consumer Advertising and Pharmaceutical Ethics: The Case of Vioxx*, 35 HOFSTRA L. REV. 749, 752 (2006).

286. *See* Vladeck, *supra* note 198, at 276.

287. Culp & Berry, *supra* note 167, at 25.

cians after detailing them.<sup>288</sup> In 2000, Merck conducted another Vioxx clinical trial in the hopes of gaining more far-reaching FDA approvals to grow the drug's market size. The now infamous "VIGOR Study (Vioxx Gastrointestinal Outcomes Research)" returned similarly damning results with regard to cardiovascular risk.<sup>289</sup> CEO Raymond Gilmartin was present at the board meeting when company officials reported these results to top executives.<sup>290</sup>

Merck feared that public knowledge of the Vioxx cardiovascular risks would reduce sales by at least 50%.<sup>291</sup> To allay growing concerns about Vioxx's safety profile, Merck issued a press release titled "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx."<sup>292</sup> In response, the FDA issued a warning letter calling Merck's misleading claims "simply incomprehensible."<sup>293</sup> Contemporaneously, President Bush was attempting to appoint Merck executive Eve Slater as the new FDA Commissioner; however, Congress rejected the appointment due to concerns about Slater's status as a pharmaceutical industry insider (concerns, it seems, that no longer appear to trouble Congress).<sup>294</sup> Instead, President Bush appointed Slater as the Assistant Secretary of Health at the Department of Health and Human Services, which conveniently oversees the FDA.<sup>295</sup> Merck never received another FDA warning letter related to Vioxx.<sup>296</sup>

After Merck *voluntarily* withdrew Vioxx from the market, the Department of Justice charged Merck with the crimes of introducing a misbranded drug into interstate commerce, conducting illegal off-label promotion, and making false statements about "Vioxx's cardiovascular safety in order to increase sales of the drug."<sup>297</sup> Merck entered into an NPA with the government and one of its subsidiaries agreed to plead guilty to one misdemeanor charge of illegal promotional activity and to pay a fine of \$950 million.<sup>298</sup> Importantly, it was Merck's subsidiary that entered the agreement—not Merck. If Merck had been convicted of this crime, it could no longer participate in the highly lucrative state and federal Medicare and Medicaid programs through which drug companies earn vast revenue streams.<sup>299</sup> All told, Merck made \$11 billion from sales of Vioxx, a sum

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288. Connors, *supra* note 200, at 262.

289. Green, *supra* note 285, at 753.

290. *Id.* at 754.

291. *See* Culp & Berry, *supra* note 167, at 23.

292. Snigdha Prakash, *Merck Rests Its Defense in Federal Vioxx Trial*, NAT'L PUB. RADIO (Dec. 7, 2005, 12:00 AM), <https://www.npr.org/templates/story/story.php?storyId=5043658>.

293. Culp & Berry, *supra* note 167, at 26.

294. *See* NESI, *supra* note 120, at 236.

295. *Id.* at 237.

296. *Id.*

297. *See* Vioxx Press Release, *supra* note 117.

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

299. *Id.*

which greatly exceeds the criminal and civil fines it paid in connection with illegally marketing the drug.<sup>300</sup> The government did not charge any Merck executives or employees with a crime.<sup>301</sup> After receiving his nearly \$40 million compensation package, Merck CEO Raymond Gilmartin moved on to a teaching position at Harvard Business School.<sup>302</sup> While at Harvard, Gilmartin wrote a piece encouraging CEOs to prioritize social responsibility over profit as he claimed he had done as Merck's CEO—Gilmartin, notably, makes no mention of Vioxx in his article.<sup>303</sup>

GlaxoSmithKline ("GSK") engaged in nearly identical behavior in its development and marketing of Paxil, a selective serotonin reuptake inhibiting ("SSRI") antidepressant drug. The FDA had approved Paxil for treatment of adults with social anxiety disorder, major panic disorder, obsessive compulsive disorder, and post-traumatic stress disorder.<sup>304</sup> In securing these approvals, GSK engaged in both clinical bias and publication bias. GSK had to conduct 16 clinical trials before it secured the 2 positive results it needed for FDA approval.<sup>305</sup> An independent review of GSK's clinical trial data "suggested that at least 75% of the benefit supposedly due to the antidepressants was also seen in the placebo group."<sup>306</sup> In addition to hiding these failed clinical trials from the FDA, GSK concealed information that Paxil greatly increased the frequency of suicidal behavior in adolescents.<sup>307</sup> During clinical trials, GSK went so far as to move human subjects who committed suicidal acts into the placebo group in an attempt to skew the evidence in its favor.<sup>308</sup> Indeed, the clinical trial data revealed that an adolescent taking Paxil was nearly 3 times more likely to become suicidal than an adolescent taking a placebo.<sup>309</sup> Despite this knowledge, GSK actively engaged in an off-label detailing campaign to encourage doctors to prescribe Paxil to children suffering from depression.<sup>310</sup> GSK even engaged in a scheme

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300. Tracy Staton, *Merck-Vioxx*, FIERCEPHARMA (2011), <https://www.fiercepharma.com/special-report/merck-vioxx>.

301. Duff Wilson, *Merck to Pay \$950 Million Over Vioxx*, N.Y. TIMES (Nov. 22, 2011), <http://www.nytimes.com/2011/11/23/business/merck-agrees-to-pay-950-million-in-vioxx-case.html>.

302. Ben White & Carrie Johnson, *Executives Cash In, Regardless of Performance*, WASH. POST (Mar. 22, 2005), <http://www.washingtonpost.com/wp-dyn/articles/A55305-2005Mar21.html>.

303. Raymond Gilmartin, *CEOs Need a New Set of Beliefs*, HARV. BUS. REV. (Sep. 26, 2011), <https://hbr.org/2011/09/ceos-need-a-new-set-of-beliefs.html>.

304. DRUG DEV. TECH., *Paxil—SSRI for the Treatment of Major Depressive Disorders*, <https://www.drugdevelopment-technology.com/projects/paxil/> (last visited Nov. 29, 2018).

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

306. *Id.*

307. Hixson, *supra* note 125, at 222.

308. HEALY, *supra* note 4, at 214.

309. Hixson, *supra* note 125, at 209 (citing *Medicine and Health: FDA Backs Child Antidepressant Warnings: Other Developments*, FACTS OF FILE WORLD NEWS DIG., Sept. 30, 2004, at 756C3).

310. Glaxo Press Release, *supra* note 124.



of bribery and kickbacks to entice doctors to write off-label prescriptions of the drug specifically to treat children.<sup>311</sup> Executives sent a memo to sales representatives informing them that “Paxil demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression,” and encouraged them to convey this information to doctors.<sup>312</sup> Thousands of children and teens ultimately committed suicide while on Paxil.<sup>313</sup>

In connection with its deadly fraud related to Paxil and other drugs, GSK settled criminal charges with the government and paid a \$3 billion fine for introducing a misbranded drug into interstate commerce.<sup>314</sup> GSK has earned an estimated \$11.6 billion in Paxil sales.<sup>315</sup> GSK and the government also entered into an NPA that protected the drug company from additional criminal liability related to its illegal conduct.<sup>316</sup> No GSK executives were charged with a crime.<sup>317</sup> J.P. Garnier, CEO of GSK at the time of the Paxil criminal investigation, likened government probes into GSK’s misrepresentations as “extortion” and a legal system “out of control.”<sup>318</sup> In 2007, he earned \$9.4 million in his final year as CEO of GSK.<sup>319</sup> In the same year that GSK settled criminal charges with the government, it paid its new CEO Andrew Witty the equivalent of \$14 million in executive compensation.<sup>320</sup> Despite the fact that these criminal settlements related to the company’s profiteering via adolescent suicide, the British government knighted GSK’s CEO for his “services to the economy and the UK pharmaceutical industry.”<sup>321</sup> If not a pharma baron, Witty has—quite literally—attained the status of a “pharma knight.”

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311. *Id.*

312. Brooke A. Masters, *N.Y. Sues Paxil Maker Over Studies on Children*, WASH. POST (June 3, 2004), <http://www.washingtonpost.com/wp-dyn/articles/A10979-2004Jun2.html>.

313. David Dobbs, *The Human Cost of a Misleading Drug-Safety Study*, ATLANTIC (Sept. 8, 2015), <https://www.theatlantic.com/health/archive/2015/09/paxil-safety-bmj-depression-suicide/406105/>.

314. U.S. DEP’T OF JUST., Side-Letter Agreement, (June 27, 2012), <https://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/side-letter.pdf>.

315. Darrow, *supra* note 305, at 2104.

316. U.S. DEP’T OF JUST., *supra* note 314.

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

318. ALISON BASS, SIDE EFFECTS: A PROSECUTOR, A WHISTLEBLOWER, AND A BESTSELLING ANTIDEPRESSANT ON TRIAL 181 (2008).

319. Tracy Staton, *GlaxoSmithKline’s Jean-Pierre Garnier—CEO Pay*, FIERCEPHARMA, <https://www.fiercepharma.com/special-report/glaxosmithkline-s-jean-pierre-garnier-ceo-pay> (last visited Oct. 26, 2018) (total compensation includes \$4.5 million in salary and bonus plus an options bonus of \$4.9 million that was payable in 2010).

320. Treanor, *supra* note 126.

321. Louisa Peacock, *Glaxo’s Andrew Witty Gets New Year Knighthood*, TELEGRAPH (Dec. 31, 2011, 6:00 AM), <http://www.telegraph.co.uk/finance/newsbysector/pharmaceuticals/andchemicals/8985213/Glaxos-Andrew-Witty-gets-New-Year-knighthood.html>.

Purdue Pharmaceutical is the drug company that develops and markets the opioid painkiller OxyContin.<sup>322</sup> OxyContin, due to its patented time-release formula, contains a larger dose of the highly addictive oxycodone (a semisynthetic opioid) than other opioid painkillers.<sup>323</sup> Purdue began marketing OxyContin in 1996, and by 2009 doctors were writing 6 million OxyContin prescriptions a year.<sup>324</sup> This is a staggering number of prescriptions considering that Purdue and other opioid manufacturers have yet to conduct “high-quality, long-term clinical trials demonstrating the safety and efficacy for [opioids] for chronic non-cancer pain.”<sup>325</sup> Indeed, even for short-term pain the evidence for establishing the efficacy for opioids is “weak and of generally low-quality, particularly compared with other therapies.”<sup>326</sup> Instead, drug companies that manufacture opioid painkillers rely on clinical trials that use enriched enrollment protocols to secure FDA approval.<sup>327</sup> They are forced to rely on enriched enrollment protocols because opioids simply do not work for the long-term treatment of chronic pain.<sup>328</sup> In fact, in a tragic irony, one of the primary risks of opioid use to manage chronic pain is *increased pain* stemming from a phenomenon called “opioid induced hyperalgesia.”<sup>329</sup> In securing FDA approval, Purdue has recognized the pivotal role industry lobbying played in bringing about the enriched enrollment protocols.<sup>330</sup> Like Merck and GSK, Purdue also employed a ghostwriting campaign to produce false and misleading evidence of OxyContin’s safety and efficacy.<sup>331</sup>

Purdue’s most successful exploitation of the pharmaceutical industry’s reach to the bottom was the company’s manipulation of clinical guidelines and its nationwide astroturfing campaign to raise “pain awareness” in the service of OxyContin sales. In the early 1990s, Purdue began an aggressive pain awareness initiative whereby:

Purdue provided financial support to the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the Joint Commission, pain patient groups, and other organizations. In turn, these groups all

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322. Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1118 (2014).

323. *Id.*

324. *Id.* at 1119.

325. Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 562–63 (2015), <https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957>.

326. Davis & Carr, *supra* note 7, at 7.

327. LEMBKE, *supra* note 137, at 68.

328. *Id.*

329. *Id.* at 59.

330. Martha Rosenberg, *What Big Pharma Doesn’t Want You to Know About the Opioid Epidemic*, SALON (June 3, 2016, 8:15 AM), [https://www.salon.com/2016/06/03/what\\_big\\_pharma\\_doesnt\\_want\\_you\\_to\\_know\\_about\\_the\\_opioid\\_epidemic\\_partner/](https://www.salon.com/2016/06/03/what_big_pharma_doesnt_want_you_to_know_about_the_opioid_epidemic_partner/).

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

advocated for more aggressive identification and treatment of pain, especially use of [opioid pain relievers]. For example, in 1995, the president of the American Pain Society introduced a campaign entitled “Pain is the Fifth Vital Sign” at the society’s annual meeting. This campaign encouraged health care professionals to assess pain with the “same zeal” as they do with vital signs and urged more aggressive use of opioids for chronic non-cancer pain.<sup>332</sup>

Doctors cannot objectively measure “pain” like the four other vital signs (*i.e.*, body temperature, pulse rate, respiration rate, and blood pressure). As such, doctors must rely on the patient’s assessment of pain levels in determining whether or not to provide opioid treatment.<sup>333</sup> Patients can sue doctors for not properly addressing their pain—this new vital sign.<sup>334</sup> Given that up to 12% of patients who receive chronic opioid treatments become addicted to opioids, allowing patients to subjectively measure the “fifth vital sign” poses obvious dangers regarding drug dependency outcomes.<sup>335</sup> The sobering fact that four out of five new heroin users became addicted from using prescription opioids demonstrates the reality of this danger.<sup>336</sup> Nevertheless, in raising awareness of pain as the fifth vital sign, Purdue sponsored 40 pain management conferences in a five-year period where “more than 5,000 physicians, pharmacists, and nurses attended these all-expense-paid symposia.”<sup>337</sup> Purdue also used a “patient starter coupon program,” through which they provided patients with a free 30-day supply of the highly addictive OxyContin.<sup>338</sup>

Purdue’s awareness campaign was successful from a business perspective, as doctors wrote ten times as many OxyContin prescriptions in 2001 than they did in 1997.<sup>339</sup> Purdue has generated an estimated \$35 billion in sales since the release of OxyContin.<sup>340</sup> In 2007, Purdue Frederick Company Inc., an affiliate of Purdue (not Purdue itself—for the same reasons that Merck settled through a subsidiary), pled guilty to “misbranding OxyContin by claiming that it was less addictive and less subject to abuse and diversion than other opioids” and agreed to pay \$634 million in criminal and civil fines.<sup>341</sup> Purdue entered into an NPA with the government, forestalling any additional criminal charges in connection

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332. Kolodny et al., *supra* note 325, at 562 (quoting James N. Campbell, *APS 1995 Presidential Address*, 5 J. PAIN 85, 86 (1996)).

333. See LEMBKE, *supra* note 137, at 66.

334. *Id.* at 64.

335. Davis & Carr, *supra* note 7, at 8–9.

336. Anita Harper Poe, *Prescription Drug Abuse: What Does America’s Painkiller Abuse Epidemic Mean for Attorneys—And What Can Be Done?*, MONT. LAW., Oct. 2016, at 26, 27.

337. Van Zee, *supra* note 122, at 221.

338. *Id.* at 222.

339. Tricarico, *supra* note 5, at 121.

340. Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, FORBES (Jul. 1, 2015, 10:17 AM), <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#2daaeb1a75e0>.

341. Van Zee, *supra* note 122, at 223.

with its criminal conduct at issue in the case.<sup>342</sup> Three company executives were also charged with crimes, but all three settled the charges by paying criminal fines of \$5,000, respectively.<sup>343</sup> Pursuant to an indemnification agreement, Purdue paid the fines on behalf of its executives.<sup>344</sup> Not mentioned in the criminal charges or plea agreement are members of the Sackler family who own and control Purdue<sup>345</sup> and who have an estimated cumulative net worth of \$13 billion, the bulk of which has been derived through OxyContin sales.<sup>346</sup> Experts have attributed the “lion’s share” of the prescription opioid crisis to Purdue’s marketing of OxyContin.<sup>347</sup> Purdue has recently suggested that they will cease advertising OxyContin directly to doctors, but industry observers suggest that this public-relations gesture will do little, if anything, to curb the prescription opioid crisis.<sup>348</sup> The ongoing prescription opioid crisis has killed hundreds of thousands of people, with nearly 20,000 Americans dying from prescription opioid overdoses each year.<sup>349</sup> As of 2016, the Sacklers were ranked as the nineteenth richest family in America.<sup>350</sup>

#### CONCLUSION

A group of respected legal scholars have rebranded corporate law’s race to the bottom as a “race to the top,” whereby the competition between states for corporate charters tended toward “optimal legal systems regulating the market for capital.”<sup>351</sup> That is, state competition for corporate charters culled away outdated and unnecessary regulations and paved the way for an era of unrivaled economic growth and efficiency. Indeed, financiers like Gould, Carnegie, and Morgan produced the steel, laid the tracks for, and helped finance the transcontinental railroad that ushered in the era of American economic dominance on a

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342. Plea Agreement at 9, *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (No. 1:07-CR-00029), available at <http://lib.law.virginia.edu/Garrett/corporate-prosecution-registry/agreements/purduefrederick.pdf>.

343. Frederickson, *supra* note 331, at 115.

344. *Friedman v. Sebelius*, 755 F. Supp. 2d 98, 102 n.7 (D.D.C. 2010).

345. #19 *Sackler Family*, FORBES, <https://www.forbes.com/profile/sackler/> (last updated June 29, 2016).

346. Peterson-Withorn, *supra* note 123.

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

348. See Ben Poston, *Capping Years of Criticism, Purdue Pharma Will Stop Promoting Its Opioid Drugs to Doctors*, *L.A. TIMES* (Feb. 10, 2018, 7:00 PM), <http://www.latimes.com/local/lanow/la-me-ln-purdue-marketing-20180210-story.html>.

349. Davis & Carr, *supra* note 7, at 9–10.

350. Peterson-Withorn, *supra* note 123.

351. See Ralph K. Winter, Jr., *State Law, Shareholder Protection, and the Theory of the Corporation*, 6 *J. LEGAL STUD.* 251, 290–91 (1977).

global scale.<sup>352</sup> Regardless of one's ideological viewpoint concerning modern corporate capitalism, it is undeniable that the race to the bottom made possible vertically integrated consolidation companies and new economies of scale that have benefited the nation in one form or another.<sup>353</sup> That is to say, it is not unreasonable to make the argument that the nineteenth-century race to the bottom was (at least in part) a race to the top, in that it produced efficiency, innovation, and new luxuries available in mass markets.

The same cannot be said for the pharmaceutical industry's contemporary race to the bottom.<sup>354</sup> In addition to the widespread and deadly side effects described in detail throughout this Article, there is a growing scholarly consensus that drug companies have ceased to innovate and now only imitate.<sup>355</sup> The perverse result of corporate law's contemporary race to the bottom is that drug companies are now incentivized to produce "the most minimally effective, the most ineffective effective drug."<sup>356</sup> If a drug company can eke out two clinical trials that "prove" that a "new" allergy medicine (a "me-too" molecular knockoff of an existing treatment) out-performs the current treatment (through hobbled and biased trials), they now have a patented drug to advertise to a pre-existing, mass market of individuals who they hope will take their drug every day for the rest of their lives. As patients, we have to hope that the drug company has not buried a host of failed trials that reveal adverse side effects relating to heart attacks, suicidal thoughts, or a high possibility of subsequent heroin addiction. If nothing else, awareness of the pharma barons might cause some patients to think twice the next time a doctor prescribes them a once-a-day drug for the rest of their lives to treat "risk factors" for a "disease" that appears to have no symptoms.

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352. See generally MORRIS, *supra* note 24 (devoting a book-length study to explain how these financiers invented, as his title suggests, America's "supereconomy." The race to the bottom established the framework for modern corporate capitalism, for better or worse).

353. See generally CHANDLER, *supra* note 12. (In his landmark study, Chandler demonstrates how the "visible hand" of corporate managers in the nineteenth century supplanted the "invisible hand" of the free market in producing the vertically integrated consolidation company. The first wave of these consolidation companies grew so innovative, efficient, and powerful that many still exercise control over their respective industries today).

354. See generally MICHEL FOUCAULT, *THE HISTORY OF SEXUALITY* (1978) (discussing Foucault's notion of "biopower"). Foucault famously discusses the power of institutions to discipline and control human bodies and populations to make them more productive. Drug companies are using their prescription medicines to shape our bodies and the population; however, the end result is not efficiency or productivity but rather sickness and a less useful population. See generally *id.*

355. See generally DUMIT, *supra* note 3; HEALY, *supra* note 4. (Both Dumit and Healy discuss in great detail how the pharmaceutical industry now prioritizes "lifestyle" and "blockbuster" drugs that treat chronic ailments as opposed to seeking cures for dangerous diseases. If one major pharmaceutical company produces a successful blockbuster treatment, each of the other major companies quickly produce a "me-too" drug and attempt to access this new market by advertising a similar drug instead of seeking a more innovative treatment).

356. DUMIT, *supra* note 3, at 206–07.